

2019
Annual Report
of Curetis N.V.
(In Liquidation)



### Statement of the Board

In accordance with article 5:25c, paragraph 2 sub c of the Financial Supervision Act, the Liquidators of Curetis N.V. in Liquidation confirm that, to the best of their knowledge, (i) the financial statements in this Annual Report 2019 give a true and fair view of the Company's assets and liabilities, the Group's financial position as of 31<sup>st</sup> December 2019, and the results of its consolidated operations for the financial year 2019; and (ii) the Report of the Management Board includes a fair review of the position as of 31<sup>st</sup> December 2019, and the development and performance during the financial year 2019 of Curetis and the undertakings included in the consolidation taken as a whole and describes the principal risks that Curetis is exposed to. The names and positions of the Liquidators can be found below (current composition of the Management Board).

Amsterdam, the Netherlands and Holzgerlingen, Germany

30<sup>th</sup> June 2020

The Liquidators
Oliver Schacht, PhD
Johannes Bacher

Dr. Achim Plum

### Forward looking statement (disclaimer)

This annual report does not, and is not intended to, constitute or form part of, and should not be construed as, an offer to sell, or a solicitation of an offer to purchase, subscribe for or otherwise acquire, any securities of the Company, nor shall it or any part of it form the basis of or be relied upon in connection with or act as any inducement to enter into any contract or commitment or investment decision whatsoever. This annual report is not an offer of securities for sale in the United States. The securities of the Company have not been registered under the U.S. Securities Act of 1933, as amended (the "securities act") or with any securities regulatory authority of any state or other jurisdiction of the United States and may not be offered or sold in the United States unless registered under the Securities Act or pursuant to an exemption from such registration.

This annual report is made available on the expressed understanding that it does not contain all information that may be required to evaluate and will not be used by the recipients in connection with the purchase of or investment in any securities of the Company. This annual report is accordingly not intended to form the basis of any investment decision and does not constitute or contain (express or implied) any recommendation by the Company or any of its directors, officers, employees, agents, affiliates or advisers.

Certain information in this annual report is based on management estimates. By their nature, estimates may not be correct or complete. Accordingly, no representation or warranty (express or implied) is given that such estimates are correct or complete.

This annual report may include statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including but not limited to the terms "believes", "estimates", "anticipates", "expects", "intends", "may", "will", or "should", and include statements the Company makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. The Company's actual results may differ materially from those predicted by the forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.

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# I. MANAGEMENT REVIEW

### INTRODUCTION

Curetis N.V. in liquidation (hereinafter "Curetis" or "Curetis N.V.") was a publicly listed company, which owned 100% of Curetis GmbH which in turn owns 100% of all international subsidiaries (together "Curetis Group"). The Curetis Group develops, manufactures and commercializes innovative solutions for molecular microbiology.

As an important note when reading our 2019 annual report, as highlighted throughout as well, Curetis N.V. has filed for liquidation since the business combination between OpGen Inc. and Curetis GmbH. As such, there is no longer a management board which has formally been replaced by the liquidators of Curetis N.V. and therefore any references to the 'Management Board' should be read as 'former Management Board'. Similarly, Curetis N.V. is in liquidation and therefore any references to 'Curetis N.V." should be read as "Curetis N.V. in liquidation" or "Curetis N.V. i.l.".

Curetis' business model is based on two complementary business pillars:

The Unyvero A50 high-plex PCR platform for molecular microbiology

for comprehensive and rapid diagnosis of severe infectious diseases in hospitalized patients. The platform is based on proven, yet intelligently integrated technologies, allowing for the testing of very broad panels of pathogens and antibiotic resistance markers and the processing of a large variety of native patient samples with an intuitive workflow. Unyvero's advantage is the timely access to comprehensive, actionable and reliable data. Curetis' molecular tests for different indications are commercially available in the U.S., EMEA, certain Asian and Latin American markets. With the Unyvero A30 RQ Analyzer in advanced stages of development, Curetis intends to develop a platform extension with low- to medium-plex capabilities that is intended to be commercially leveraged in licensing deals and partnerships with one or more diagnostics industry partners.

The ARES AMR Database (ARESdb),

which permits Curetis to increasingly utilize the proprietary biomarker content in its own assay and cartridge development, as well as to build an independent business in next-generation sequencing (NGS) based offers for AMR research and diagnostics in collaboration with partners in the life science, pharma and diagnostics industries. To further advance ARESdb, the underlying ARES Technology Platform, and NGS-based services and products, Curetis has founded Ares Genetics GmbH, an operationally autonomous yet wholly-owned subsidiary, based in Vienna, Austria. Offerings such as ARESupa and an NGS service lab in Vienna, Austria were made available to a growing list of partners and customers in 2019.

On  $4^{th}$  September 2019 Curetis and OpGen Inc. (NASDAQ ticker OPGN) announced their intention to combine their businesses by way of a sale of the Curetis Business (essentially Curetis GmbH including its wholly owned subsidiaries in the USA and Ares Genetics in Austria). The transaction was subject to debt holder and shareholder approvals on both sides and closed 1st April 2020.

Curetis' headquarters are based in Holzgerlingen, near Stuttgart in Southern Germany. In addition, and as of 31<sup>st</sup> December 2019, Curetis wholly owns two subsidiaries, which are located in San Diego, CA (U.S.) and Vienna (Austria).

### CURETIS - KEY FACTS AT 31 DECEMBER 2019

- Public commercial stage molecular diagnostics company
- Founded: August 2007
- Fully Integrated: R&D, manufacturing, commercialization
- Publicly Listed on Euronext Amsterdam and Euronext Brussels since November 2015 ("CURE")
- Market Segment: molecular microbiology
- Proprietary platforms:
  - Unyvero sample-to-answer any-plex PCR platform
  - ARES AMR Database (ARESdb)and ARES Technology Platform for antibiotic resistance data intelligence
- Unique IVD Product Portfolio: Unyvero applications
  - U.S. FDA cleared: Lower Respiratory Tract Infections (LRT and LRT BAL)
  - CE-IVD: Hospitalized Pneumonia (HPN), Implant and Tissue Infections (ITI), Bloodstream Infections (BCU), Intra-Abdominal Infections (IAI) and Urinary Tract Infections (UTI)
  - Singapore, Thailand, Malaysia: HPN and / or BCU
- Installed Base: 173 Unyvero Analyzers by the end of 2019
- Global Commercial Presence:
  - Headquarters and cartridge production facility in Germany
  - Wholly-owned subsidiaries in the USA and in Austria with other subsidiaries now closed down
  - Growing network of 18 distribution partners covering 43 countries in Europe (including Pan-European distribution to 11 countries via Menarini Diagnostics), Middle East, Africa, Latin America and Asia
- Partner Network in the Diagnostics and Pharmaceutical Industries: Siemens (GEAR Database as basis for ARES AMR Database, ARESdb), Qiagen, Sandoz and undisclosed IVD corporation (Ares Genetics partnerships), MGI/BGI (NGS-based molecular microbiology)
- Lean and effective organization of 79 employees by 31<sup>st</sup> December 2019

### 2019 AND YTD IN BRIEF

### **KEY EVENTS IN 2020 YTD**

- May 7<sup>th</sup>, Curetis N.V. completes distribution in advance of OpGen consideration shares to Curetis N.V. shareholders after having sold 20% of the consideration shares in line with EGM resolution in order to generate cash required for orderly dissolution
- May 6<sup>th</sup>, Curetis N.V. delists from Euronext Amsterdam and Brussels
- April 20<sup>th</sup>, Curetis N.V. in liquidatie announced liquidation distribution in advance and last trading day
- April 1<sup>st</sup> Curetis N.V. and OpGen close business combination transaction successfully and OpGen Inc. becomes new parent company and now wholly owns Curetis GmbH including its subsidiaries Curetis USA Inc. and Ares Genetics GmbH; Supervisory Board members Rhodes, Crovetto and Fernandes resign from the SB of Curetis N.V. to join the Board of Directors of OpGen Inc. and Management Board members act as Liquidators of Curetis N.V. in Liquidation going forward
- March 30<sup>th</sup> OpGen shareholders vote in favor of the business combination with Curetis
- March 16<sup>th</sup> Curetis Begins Offering BGI's CE-IVD Rapid Test Kit for Coronavirus in Europe
- March 10<sup>th</sup> Curetis N.V. Updates on OpGen, Inc. Special Shareholders' Meeting Held on 10<sup>th</sup> March 2020 which was adjourned to 30<sup>th</sup> March 2020 as the required quorum had not been achieved
- March 10<sup>th</sup> Curetis N.V. Reports Results of the Extraordinary General Meeting Held on 10<sup>th</sup> March 2020 with shareholders approving all proposed resolutions including the business combination with OpGen and the subsequent distribution of OpGen consideration shares to Curetis N.V. shareholders and dissolution as well as de-listing of Curetis N.V.
- Feb 20<sup>th</sup> Curetis Announces Preliminary, Unaudited 2019 Condensed Combined Key Financials and provides Business Update
- Feb o6<sup>th</sup> Curetis and Quaphaco Enter into Unyvero Distribution Partnership for Vietnam
- Invitation to EGM to be held on 10<sup>th</sup> March 2020 for shareholders to resolve on the business combination with OpGen.
- SEC clearance of S-4 filing by OpGen on 23<sup>rd</sup> January 2020
- In January 2020, Curetis announced the launch of the Unyvero LRT Panel for BAL specimens in the U.S.

### KEY EVENTS IN Q4-2019

- On 20<sup>th</sup> December 2019 Curetis received FDA clearance on Unyvero LRT Application Cartridges for BAL specimens
- Ares Genetics was selected for NVIDIA and AWS programs to accelerate commercialization of its Alpowered universal pathogenome assay – ARESupa
- Ares Genetics awarded MERCUR innovation prize by the Vienna Economic Chamber to the most innovative companies
- Curetis Group Company Ares Genetics launched AI-powered molecular antibiotic susceptibility test

### KEY EVENTS IN Q3-2019

- Curetis Group Subsidiary Ares Genetics signed R&D and option agreement with leading global IVD corporation
- On 4<sup>th</sup> September 2019 Curetis and OpGen entered into a definitive agreement to combine their businesses
- Curetis retained H.C. Wainwright & Co. as strategic advisor

- Curetis Group Company Ares Genetics launched service laboratory for NGS-based molecular drug resistance testing
- Curetis elected share settlement for excess entitlement under first tranche of Yorkville convertible notes
- Curetis and AKO MED inked distribution agreement covering four countries in CEE region
- On 22<sup>nd</sup> July 2019 Curetis filed for U.S. FDA 510(k) clearance of Unyvero LRT for BAL specimens
- Curetis Group Company Ares Genetics granted key European patent on genetic resistance testing

### KEY EVENTS IN Q2-2019

- Curetis reported results of the Annual General Meeting held on 27<sup>th</sup> June 2019
- New data on Curetis' Unyvero LRT Panel for pneumonia presented at ASM Microbe 2019
- Curetis reported positive results from clinical validation study for U.S. FDA 510(k) submission of Unyvero LRT for BAL samples
- Curetis received additional EUR 6.5 million financing from EIB (EUR 5 million) and Yorkville (EUR 1.5 million gross)
- Curetis' Subsidiary Ares Genetics introduced NGS services for pharma and public health sector at ECCMID 2019
- Curetis presented study data at ECCMID 2019 that confirmed clinical benefits of Unyvero platform
- Curetis introduced the Unyvero AMR Atlas to support adoption of rapid DNA testing for antibiotic resistance

#### KEY EVENTS IN Q1-2019

- Curetis' partner Beijing Clear Biotech submitted filing for Unyvero approval in China
- Curetis' Subsidiary Ares Genetics and Qiagen entered strategic bioinformatics partnership
- Curetis and Menarini Diagnostics signed strategic pan European distribution agreement for the Unyvero A50 platform and application cartridges
- Unyvero application cartridges received regulatory approvals in Malaysia (Unyvero HPN) and Thailand (Unyvero HPN and BCU)
- Ares Genetics received additional non-dilutive grant co-funding for the EUR 1.3 million Triple-A project

# MESSAGE FROM THE CEO

### Dear Shareholders,

Undoubtedly 2019 has been a very challenging year for Curetis. Following the strategic decision to reorganize and close down all direct sales activities in Europe, partner with pan European distributor Menarini, and a reduction in organizational size that has helped to significantly reduce cash burn, the focus has been on evaluating all available strategic and tactical options. To that end we retained H.C. Wainwright as strategic advisors to Curetis' Management and Supervisory Boards. After many options had been pursued throughout 2018 and 2019, on 4<sup>th</sup> September we announced the signing of a definitive agreement to combine our entire Curetis business with NASDAQ listed and US headquartered OpGen Inc. in Gaithersburg, Maryland. You will find a lot of the background information and context in the shareholder circular that was distributed to all of you on 27<sup>th</sup> January 2020. Therefore, these financial statements and reports have been prepared not on a going concern basis for Curetis N.V. and the consolidated Curetis Group, but rather with the subject to the implementation agreement being disclosed as held for sale to OpGen as a discontinued operation under IFRS 5.

This proposed business combination has enabled us to access up to US\$ 5 million in additional funding under an Interim Financing Facility from OpGen who successfully raised gross \$ 9.4 million in an equity financing transaction at the end of October 2019 and another more than \$ 15 million in 2020 year to date as disclosed in the OpGen earnings call on 24<sup>th</sup> March 2020 as well as in OpGen's most recent 10-Q filing and current June 2020 OpGen corporate presentation. During the course of 2019 we also raised an additional EUR 1.5 million via the Yorkville convertible notes facility and a further EUR 5.0 million non-dilutive EIB debt financing tranche. However, it was also very clear that absent any alternative transaction and financing we had come to the conclusion that the only viable path forward at this stage is the completion of the business combination with OpGen and hence strongly recommended that all shareholders approve this deal which the EGM did on 10<sup>th</sup> March 2020.

Ares Genetics, our Austrian subsidiary working on NGS-based and Al-powered solutions for AMR prediction models, has achieved outstanding results and made great progress throughout 2019. From multi-million projects co-funded by grants such as e.g. the Triple-A project, via the opening of our NGS service lab, to strategic partnerships successfully executed with Sandoz, the signing of Qiagen as bioinformatics partner for research use only of ARESdb, and most recently a global leading IVD corporation, which not only includes a sizeable fully pre-funded R&D program but also an option for an exclusive three-month negotiation period for certain licensing scope, which we would anticipate for 2020.

Throughout 2019, we have continued to drive forward our Unyvero Platform and Lower Respiratory Tract Infection Cartridge for BAL specimens (LRT BAL) towards FDA clearance in late 2019 and commercial launch in the U.S. in Q1-2020. Significant regulatory milestones have also been reached in China with the submission to the NMPA of the Unyvero System and pneumonia cartridge in February 2019, as well as Q1-2019 approvals in Thailand and Malaysia. On the commercial side we have signed Menarini Diagnostics as exclusive pan European distribution partner for 11 countries. We did expect significant revenue growth throughout 2020 as Menarini continues to optimize the installed base of Unyvero Analyzers across these European markets. Several studies and clinical evaluations across multiple sites in several countries and indications have already been planned, some in collaboration with Menarini Pharma also. However, with the ongoing Covid19 pandemic it is simply not possible to provide any reliable guidance on revenue at this stage.

The Unyvero A30 RQ Analyzer has seen significant progress in development and using a number of fully integrated and functional prototype instruments, we have generated a strong data package including various real time PCR assays from third parties transferred onto the A30 RQ cartridges to share with potential future licensing and development partners. Design-freeze for the A30 RQ has been mostly finalized and all injection molds and cartridge parts obtained with final molds have been obtained from our supply chain partners. Our strategy in 2019 has been shifted from a direct-to-market strategy towards a partnering driven model in 2020 with certain options for using the Unyvero A30 RQ platform in the context

of some of the OpGen assay menu in the future.

In light of the very limited cash reach and financing needs of the combined OpGen Inc. and Curetis business following a completion of the transaction and business combination with OpGen, all platforms, products and projects' further development remain subject to the future availability of additional funding. Given the closing of the business combination and Curetis N.V. having sold 100% of its ownership in Curetis GmbH and the adopted resolutions of the EGM on 10<sup>th</sup> March 2020 Curetis N.V. distributed the OpGen consideration shares to the Curetis N.V. shareholders and then de-listed from Euronext and will dissolve Curetis N.V. in Liquidation which will thereby cease to exist once completed.

Yours sincerely,
Oliver Schacht, PhD
CEO Curetis N.V. (until 31<sup>st</sup> March 2020)
Liquidator (from 1<sup>st</sup> April 2020)

### LETTER FROM THE CHAIRMAN OF THE SUPERVISORY BOARD

Dear Curetis Shareholders,

After four years as Chairman of the Supervisory Board, I am pleased to update you on Curetis' major strategic initiatives and more specifically address the business combination with OpGen.

All of our Supervisory Board members have fully evaluated and support Curetis' overall plans and the strategic business combination with OpGen. We are always keeping in mind the best interests of shareholders, as well as customers and other stakeholder groups, which include physicians, patients, global partners and, very importantly, our employees. Throughout 2019 we have done this in the context of a very challenging financing situation and volatile capital markets. This focus on ensuring shareholder and stakeholder value, while at the same time optimizing opportunities for the success of Curetis, led us to complete the corporate re-organization, assess all available strategic alternatives and options available, retain H.C. Wainwright as advisors to the Supervisory Board and Curetis management, and ultimately conclude that the best path forward indeed is the business combination with OpGen.

We continue to work very closely with the Management Board to ensure the effective execution of Curetis' business plans and the strategic transaction before us. We held regular face-to-face meetings and telephone conference calls between the entire Supervisory Board and the Management Board, ensuring continuous and timely dialogue. In addition, there were regular calls between the Company's CEO and me, to ensure we have open and timely discussions and the opportunity to proactively address strategic topics as they arise. During critical times the Management Board and Supervisory Board interacted and communicated in real-time on an almost daily basis.

The Supervisory Board was continuously kept informed and updated, and all members are engaged in relevant discussions of all material aspects of the business and corporate development. This was especially true for all aspects of the strategic business combination with OpGen. As a Board we routinely reviewed, among many other things, items such as the progress toward and obtaining FDA clearance, strategic partnering and licensing opportunities, the setting of commercial goals, global organizational structure, marketing and selling approaches, overall company financial and sales performance against budgets and targets and strategic corporate considerations.

2019 was another year of contrasts and challenges successfully met by the organization in several financing transactions and a strategic M&A transaction that is now nearing completion. Our very limited cash position put us in a position where decisive action and implementing significant organizational and strategic changes became key to ensuring the company can move forward into 2020 following the proposed business combination with OpGen.

Curetis' offering has continued to expand beyond the syndromic Unyvero test offerings, with increasing focus on partnering the Ares Genetics AMR database and bioinformatics offerings and advancing the development of the A30 *RQ* platform towards being able to strategically partner and license this asset in the coming years. Together with the Management Board, the Supervisory Board has been actively monitoring the Company's commercial progress in the EMEA markets following the shift to the Menarini distribution partnership. We have also been working closely together to refine and evolve Curetis' organizational structure and commercial tactics in the US.

This included critical analysis and challenging management on various available future financing and other strategic options as well as direct interaction with the Company's strategic advisors at H.C. Wainwright. Being in a position to raise capital for the future development and execution of the strategy continues to be of utmost importance to the Supervisory Board and after thorough analysis and discussion of all alternatives presented to the company over the course of 2018 and 2019, the Supervisory Board and I as its chairman concluded that the proposed business combination with OpGen presented the best available – and in some regards the only viable - course of action.

The Supervisory Board and its Audit Committee also worked very closely with the auditors at PwC during

the business combination process and all required SEC filings, as well as regular public company financial reporting and general shareholder meeting. The Supervisory Board continuously and very closely monitored the corporate risk management and risk reporting, and advised the Management Board on further steps in these critical activities. The Supervisory Board also closely collaborated with the chairpersons of its subcommittees, with whom I was also in regular dialogue.

Curetis continues to face the challenging early phase of commercial roll-out in the U.S., the world's largest diagnostics market. As with all new MDx platforms, there are often lengthy sales cycles to deal with, as customers evaluate and validate Curetis' products. As the Company moves forward in the business combination with OpGen, it will be key to motivate and appropriately incentivize top talent in commercial, corporate and R&D functions globally.

The Supervisory Board and I expect to continue to actively support Curetis and its Management Board in implementing its strategic business combination with OpGen and to ensure that it is vigorously pursued with the best interests of all shareholders and stakeholder groups in mind.

Yours sincerely,

William (Bill) Rhodes, III

Chairman of the Supervisory Board (until 31st March 2020)

# **OPERATIONAL REVIEW 2019**

### FINANCING & STRATEGIC ASSESSMENT

#### **FINANCING**

To further advance its R&D programs as well as product and platform development, Curetis has drawn down a further tranche of EUR 5 million from its EIB debt financing facility in Q2-2019. Following an amendment of the EIB contract, this third tranche, which brought the total debt principal amount outstanding to EUR 18 million as of 31 December 2019, also comes with a 2.1% equity linked participation (i.e. 2.1% of the then current market cap of Curetis N.V. or the fair value of the Curetis Business at such point), which becomes due upon maturity of this third – and expected final – tranche under the EIB facility by mid-2024. The EIB debt financing facility in its entirety has been sold along with Curetis GmbH upon closing of the business combination with OpGen Inc. in 2020 which will replace the downstream guarantee currently in place by Curetis N.V. by a new guarantee from OpGen Inc. to EIB.

In October 2018 Curetis had secured up to EUR 20 million in growth capital through the issuance of convertible notes with share subscription warrants to YA II PN, LTD., an investment fund managed by Yorkville Advisors Global LP, an U.S. based management firm. In 2018, Curetis had drawn down EUR 3.5 million of the first tranche and in Q2-2019 Curetis was able to access another EUR 1.5 million tranche thereunder. Following the decline in Curetis share price and various conversions into equity by Yorkville, which completed the conversion of the entire EUR 3.5 million first tranche plus another EUR 200 thousand from the second tranche, there are no more shares available for Yorkville to convert any of the remaining EUR 1.3 million in unconverted notes into Curetis N.V. shares. It has been agreed that upon completion of the OpGen business combination in 2020, that OpGen Inc. will assume the remaining unconverted notes as well as the Yorkville facility in an amended version that is to be negotiated between OpGen and Yorkville.

Following the public announcement on 4<sup>th</sup> September 2019 that Curetis would combine its business with OpGen Inc. by way of selling the entire Curetis business to OpGen for 2.66 million new OpGen shares, we do not believe that Curetis N.V. is in any way able to raise additional equity capital. This is especially true since the 20% cap under the EU prospectus directive has been reached with the issuance of shares over the past 12 months and therefore any further issuance would be subject to both, preemptive rights of all existing Curetis shareholders as well as an AFM approved prospectus, which Curetis cannot prepare given its exclusive focus on the strategic business combination with OpGen (see below).

#### STRATEGIC ASSESSMENT

In the light of the lower than expected proceeds from financing transactions in 2018 the Company had initiated a reorganization of its global operations. The measures that were implemented in Q1-2019 included, among others, the closing and unwinding of the Company's sales subsidiaries in France, the UK, the Netherlands, and Switzerland and moving its current direct sales model towards an exclusive distribution partnership model with Menarini in key EMEA markets. In total, the Company by the end of 2019 reduced its global headcount across all levels and liquidated and / or dissolved its European sales subsidiaries by year-end 2019. As a result, the Company significantly reduced net cash consumption from operations in 2019.

The Company also continued to assess all strategic options to raise additional capital. Throughout 2018 and 2019 various strategic alternatives were evaluated. These ranged from a potential trade sale, individual asset sales or other asset monetizing business deals, further cost cutting and restructuring, and hibernation mode scenarios. Given that equity and debt financing options were maxed out and facing continued downward pressure on share price, there was no realistic path to raising sufficient amounts of capital in the European capital markets under the Curetis N.V. Euronext listing in Amsterdam and Brussels.

Curetis has assessed a series of alternative financing transactions and M&A deal opportunities but determined that the OpGen business combination was the best course of action.

Given that none of the various aforementioned strategic alternatives yielded any viable scenario in the relevant mid-2019 timeframe, the Management and Supervisory Boards who were advised by H.C.

Wainwright, came to the unanimous conclusion that the proposed business combination with OpGen Inc. is the best – if not the only – available strategic option. Therefore, following more than a year of informal and increasingly formal discussion between Curetis and OpGen, extensive mutual due diligence, a non-binding letter of intent and intense negotiation of a Definitive Implementation Agreement, which was signed and announced on 4<sup>th</sup> September 2019. This was also backed by a fairness opinion furnished to the Curetis Management and Supervisory Boards as of 3<sup>rd</sup> September 2019 by H.C. Wainwright, confirming that the proposed share split and hence consideration of 2.66 million shares (based on then outstanding ca 880 thousand OpGen shares) between Curetis and OpGen were fair.

Following a highly dilutive S-1 filing based capital raise where OpGen successfully raised US\$ 9.4 million in new equity capital by issuing an additional 4.7 million units (shares plus warrants) at US\$ 2 per unit, OpGen and Curetis entered into an Interim Financing Facility Agreement. Under this agreement as amended Curetis has access to up to at least US\$ 5 million in inter-company debt financing and as of 31 December 2019 Curetis had drawn down a total of US\$ 2.5 million.

### **COMMERCIAL OPERATIONS**

#### UNITED STATES

For the commercialization of Unyvero in the U.S., Curetis uses Curetis USA, Inc. as a distribution partner as a wholly-owned subsidiary in San Diego. The U.S. commercial operation comprises all functions crucial for the market development and initial commercial roll-out in the U.S., including sales, marketing, scientific affairs, customer service and support, warehousing and logistics. Following the corporate reorganization and reduction in force, Curetis USA been streamlined and as of 31<sup>st</sup> December 2019 comprised a total of 10 commercial and operations team members.

#### **EMEA**

Curetis' commercial organization in the EMEA region at the end of 2019 has been adjusted to a dedicated commercial partner support and service organization. The four European commercial sales subsidiaries in the UK, France, The Netherlands and Switzerland were all closed and dissolved. Also, the direct Germany sales and customer service team was dissolved.

From distributor trainings, sales support functions, product marketing experts and tactical marketing and business development support a highly experienced eight-person team has been working closely with all global distribution partners. However, special emphasis in 2019 was put on the handover of the Unyvero A50 business in key EMEA markets to Menarini as exclusive pan European distribution partner. Curetis sees good progress with a growing number of the Menarini accounts in various European countries and has trained many country teams from sales, marketing and technical service perspectives across Europe.

By December 31, 2019, Curetis had in total signed 18 distribution partnerships covering 43 countries and is planning to evolve its distribution network and commercial reach through further partnerships with suitably positioned distributors with a particular focus on consolidating its commercial partner network globally.

# **INSTALLED BASE**

The installed base of Unyvero Analyzers of 173 Analyzers as of the end of 2019, compared to 167 Analyzers at year-end 2018. This installed base at year end 2019 included 7 Analyzers installed with potential customer evaluation sites in the USA plus a pool of Analyzers available for various US FDA clinical studies and trials, a demo pool for EMEA of 42 Analyzers now managed by Menarini and being optimized for utilization and commercial impact, as well as 93 Analyzers managed by Menarini and the remaining global distributor network.

### MARKET ACCESS

### U.S.A.

In 2018, the FDA had reached a positive clearance decision on the *De Novo* request for the Unyvero System and the Unyvero LRT Lower Respiratory Tract Infection Cartridge for tracheal aspirate samples. The

Unyvero System and LRT Application Cartridge was launched during 2018 and first systems were installed in fall of 2018 for evaluations.

With the 510(k) clearance of the Unyvero LRT application cartridge for BAL specimens, the Unyvero LTR Application Cartridges are believed to cover more than 90% of infection cases of hospitalized pneumonia patients and provides clinicians with clear directions based on pathogens and genetic antibiotic resistance markers detected. As the first-in-class molecular test for lower respiratory tract infections it addresses a significant unmet medical need that causes over US\$10bn in annual costs for the U.S. healthcare system¹. Unyvero LRT BAL is also the only molecular test for pneumonia for which the U.S. FDA has cleared the atypical microorganism *Pneumocystis jirovecii*.

The potential of the Unyvero System and LRT Application Cartridge to positively impact clinical outcomes, support antibiotic stewardship, and create health economic benefits was substantiated by several key contributions by U.S. key opinion leaders to the scientific program of multiple US conferences throughout 2019.

#### **CHINA**

Working towards a Chinese market clearance in February 2019, BCB filed for regulatory approval of the Unyvero A50 System and Application Cartridge for pneumonia with the Chinese National Medical Products Administration (NMPA; formerly Chinese Food and Drug Administration) in the name and on behalf of Curetis. The submission was based on comprehensive data from Curetis' U.S.-FDA trials as well as from European CE-IVD validation studies with analytical validation data of the Unyvero HPN Application Cartridge and additional testing under the auspices of the Beijing Institute of Medical Technologies in China. In July 2019, the NMPA held an expert panel meeting to discuss the application with local clinical experts and gave Curetis an opportunity to comment on various aspects of the application. As a result, Curetis and BCB are currently clarifying the requests for further clinical studies in China, ancillary data and any required edits to the original application.

Assuming a potential regulatory approval by NMPA in late 2020, Curetis anticipates that it would generate initial revenues from commercial sales through BCB in China starting not before then.

BCB and Curetis had expanded their exclusive distribution agreement from five to eight years post NMPA approval with total minimum purchasing commitments by BCB that would indicate revenues to Curetis of more than EUR 150 million over the entire duration of the contract.

# SINGAPORE AND ASEAN REGION

After filings by Curetis' exclusive distribution partner for Singapore, Malaysia, Indonesia and Thailand, Acumen Research Laboratories Pte. Ltd. (Acumen), several Unyvero Application Cartridges received regulatory approvals by the respective authorities in the Singapore, Thailand, and Malaysia in 2018 and early 2019. The Unyvero HPN and BCU Applications have been approved by the Singapore Health Sciences Authority (HSA) and fully registered as a Class C IVD medical device with the Singapore Medical Device Register. Further, Unyvero HPN was approved by the respective regulatory authorities to market the in Malaysia and Thailand. Thailand also approved the Unyvero BCU Blood Culture Application Cartridge.

# U.S. MEDICAL ADVISORY BOARD AND EU SCIENTIFIC ADVISORY BOARD

Curetis in 2019 continued to maintain both a U.S. MAB and EU SAB. The goal of these advisory boards is to advise Curetis on important trends and issues in clinical microbiology as well as novel product concepts addressing key questions and challenges in the diagnosis of severe infections in hospitalized patients. The advisory boards provide valuable insight and guidance along the entire value chain of innovative molecular

<sup>&</sup>lt;sup>1</sup> CDC (2015) 'New CDC study highlights burden of pneumonia hospitalizations among U.S. adults', available at: https://www.cdc.gov/media/releases/2015/p0714-pneumonia- hospitalizations.html American Thoracic Society (2015) 'Top 20 pneumonia facts – 2015', available at:

https://www.thoracic.org/patients/patient-resources/resources/top-pneumonia-facts.pdf

diagnostic products. OpGen and Curetis intend to integrate and streamline their combined medical, clinical and scientific advisory boards in 2020 following the closing of the business combination transaction.

### SUPERVISORY BOARD

After reelections of four of its members at the AGM on 27<sup>th</sup> June 2019, the Supervisory Board continues to consist of six members.

#### **ANNUAL GENERAL MEETING**

During the Annual General Meeting held in Amsterdam on 27<sup>th</sup> June 2019 the Company's shareholders approved all items on the agenda of the AGM. Johannes Bacher was re-appointed as Managing Director for a three-year term from 1<sup>st</sup> July 2019 until 30<sup>th</sup> June 2022. In addition to this Management Board appointment, Dr. Rudy Dekeyser was re-elected to the Company's Supervisory Board for another one-year term and William E. Rhodes, Mrs. Prabhavati Fernandes, Ph.D. and Mario Crovetto were re-elected for another two-year term each. Moreover, the Supervisory Board was authorized to grant stock options to Managing Directors. Further, the proposed extension of the designation of the Management Board to issue new shares and rights to subscribe for shares with the ability to limit or exclude pre-emptive rights on such newly issued shares or rights to subscribe for shares, and an extension of authorization of the Management Board to repurchase shares as well as to issue new shares or grant rights to subscribe for shares in relation to strategic capital raising(s) without limiting or excluding pre-emptive rights on such, were also approved by the shareholders.

# **FINANCIAL REVIEW 2019**

- Given the presentation of the 2019 financial statements under IFRS 5 discontinued operations a side by side comparison with 2018 financial statements in the form of previous years is not informative and has been left out here. Please refer to the financial statements and notes further down in the annual report.
- FOR CURETIS NV GROUP: The financial statements 2019 have not been prepared on a going concern basis anymore. Curetis N.V. as of 31<sup>st</sup> December 2019 holds Curetis GmbH and all of its subsidiaries solely for the purpose of selling the business to OpGen. Therefore, financial statements have been prepared under IFRS 5 discontinued operations assumptions.

# **OUTLOOK 2020**

Given the fact that Curetis has sold its entire business to OpGen Inc. following the EGM and shareholder vote on 10<sup>th</sup> March 2020 and closing of the business combination transaction on 1<sup>st</sup> April 2020, there is no operational, commercial or financial forecast for Curetis N.V. and the Group as it has been historically reported. The EGM has resolved not only on the transaction but also on the distribution of OpGen consideration shares to Curetis N.V. shareholders, which occurred on 7<sup>th</sup> May 2020, the delisting from Euronext Amsterdam and Brussels, which happened on 6<sup>th</sup> May 2020 and the dissolution of Curetis N.V. as a company which will no longer have any assets nor operations and will cease to exist. We therefore abstain from providing any outlook for 2020 and beyond as it would not be meaningful in this context.

Due to the dissolution of Curetis N.V., the current social and economic circumstances regarding COVID-19, which have no relation to the business operations year to date, will have no impact on the future performance of Curetis N.V.

### BUSINESS AND PRODUCT OVERVIEW

#### **OVERVIEW**

It is important to note that while the Curetis products and business were owned by Curetis N.V. in 2019 and as of 31 December 2019, on 1st April 2020 Curetis N.V. sold all of its business to OpGen Inc. by way of selling 100% of its ownership stake in Curetis GmbH including its subsidiaries Curetis USA Inc. and Ares Genetics GmbH. Therefore, the business and markets are no longer of relevance to Curetis N.V. as it is expected to be dissolved and de-listed from Euronext and cease to exist in 2020. Nevertheless, the below presents an accurate description of the business that was held for sale as of 31 Dec 2019 and is included in the IFRS 5 financial statements.

Curetis is a molecular diagnostics company that focuses on the development and commercialization of reliable, fast and cost-effective products for diagnosing severe infectious diseases in hospitalized patients, an indication with a high unmet medical need and significant prevalence in developed countries. Curetis' unique Unyvero Platform currently comprises the Unyvero System with the Unyvero A50 Analyzer at its core, proprietary software, and single use Application Cartridges. These Application Cartridges contain molecular tests addressing specific severe infectious diseases and detect a broad range of pathogens relevant in a given indication and associated toxin genes and genetic antimicrobial resistance markers. The Unyvero Platform has been CE-IVD-marked since 2012 and is commercialized in Europe and certain other markets that accept CE-IVD-marking or where it has successfully passed the registration process (i.e. Kuwait, Qatar, Belarus, UAE, Israel, Singapore, Malaysia, Thailand), and is in the process of being rolled out commercially in the United States following *De Novo* clearance of the Unyvero System and the LRT Application Cartridge by the FDA in April 2018 and the 510(k) clearance the LRT Application for BAL samples in December 2019.

Today, the diagnosis of infectious diseases in the hospital setting is still largely carried out through traditional culture-based microbiology methods. This process is labor-intensive and time-consuming, typically delivering results only after 24 to 72 hours or, in some cases, weeks. As a result, informed antibiotic therapy decisions may be delayed, which can lead to poor patient outcomes, including higher mortality rates for indications such as pneumonia and sepsis, longer hospital stays, increased hospital costs and overall spread of antibiotic resistance, a significant and increasing problem throughout the world. All of these factors pose clinical and economic challenges to hospitals and a significant threat to public health globally.

Curetis aims to improve on this standard-of-care by offering comprehensive test information in a timely manner that allows for early, efficacious treatment, which Curetis believes results in improved clinical and health economic outcomes. Its Unyvero Platform deliver results within four to five hours and can cover over 100 diagnostic targets. The broad Unyvero test panels also allow the identification of microorganisms that are difficult to culture and hence missed in culture-based test methods, as well as rare but critical pathogens not routinely tested for by standard methods, a conclusion confirmed by a number of clinical studies. The FDA clinical trial for the LRT Application Cartridge concluded that the Unyvero System identified 35 positive atypical pathogen results, as opposed to only four positive atypical pathogen results identified using traditional culture-based diagnostic methods. Curetis believes this allows clinicians to make early adjustments to the specific treatment of the patient, saving significant time and cost, in particular by reducing the duration of the patient's hospital stay.

The Unyvero Platform is intended to complement rather than replace traditional microbiology-based diagnostics testing. Curetis believes, however, that timely diagnosis of the underlying pathogens and their resistances could greatly improve outcomes for patients and is likely to provide net savings to hospitals.

The Unyvero Platform is marketed through a combination of direct sales in the United States and a growing network of distributions partners in Europe, Middle East, the ASEAN Region, Asia and Latin America. As of 8<sup>th</sup> November 2019, the distribution network of 18 distribution partners covers 43 countries in those regions with regulatory clearance for the Unyvero System and the Unyvero Application Cartridges in some of these countries still pending.

There are currently seven commercially available Application Cartridges, which include:

- the HPN Application Cartridge, which addresses severe forms of pneumonia;
- the ITI Application Cartridge, which addresses severe cases of implant and tissue infections;
- the BCU Application Cartridge, which addresses severe blood stream infections;
- the IAI Application Cartridge, which addresses intra-abdominal infections;
- the UTI Application Cartridge, which addresses severe urinary tract infections, all of which are CE-IVD-marked; and
- the LRT Application Cartridge, which is technically similar to the HPN Application Cartridge and also addresses severe forms of pneumonia, which was cleared by the FDA in April 2018 for use with tracheal aspirates and is now being marketed in the United States.
- The LRT BAL Application Cartridge which was cleared on 20 December 2019 by the FDA for use with BAL specimens and has been launched in the Unites States in Q1-2020.

The HPN and BCU Application Cartridges have also been approved by the Singaporean HAS as well as regulatory authorities in Malaysia and Thailand.

In addition to the current Unyvero System, Curetis also develops its Unyvero A30 *RQ* Analyzer module designed to offer a rapid time-to-result (potentially as fast as 45 to 90 minutes), qualitative and, where needed, quantitative real-time PCR testing in a cartridge format that can provide up to 11 parallel multiplex (i.e. simultaneously running multiple assays in one reaction) PCR reactions from one sample, with up to three assays per reaction (for a total of up to 33 assays per cartridge). It is expected to be operated on a stand-alone basis or fully integrated into the Unyvero System suite of products with respect to system architecture, design, software and handling, thereby expanding the Unyvero Platform to include low- and mid-plex capabilities. A further advantage of the Unyvero A30 *RQ* Analyzer is that the costs of the Analyzer and cartridges are expected to be lower than those for the current Unyvero System and Application Cartridges, potentially opening up commercial opportunities in the medium multiplexing infectious disease testing market segment. Initially developed as an expansion of the Unyvero platform complementing the Unyvero A30 high-plex Application Cartridges with low- to mid-plex Unyvero A30 *RQ* Application Cartridges for infectious diseases, Curetis in December 2018 changed its strategy and now also seeks partners in the global IVD industry that want to license the Unyvero A30 *RQ* for commercialization of their own assays on this platform as legal manufacturer under their own branding.

Curetis believes its Unyvero Platform has the potential for menu expansion into other areas such as oncology, companion diagnostics, transplant medicine and veterinary applications, thereby potentially opening up partnering opportunities beyond its core business of Curetis' own core business in infectious disease testing.

Curetis' other core business in Next Generation Sequencing, or NGS and Bioinformatics based solutions for molecular microbiology is operated by Curetis' wholly-owned subsidiary Ares Genetics GmbH, or Ares Genetics, founded in 2017 and based in Vienna, Austria. This business is based on the proprietary ARES Technology Platform and Ares Genetics' proprietary genetic database on AMR, ARESdb. The ARES Technology Platform and ARESdb build and expand upon the GEAR assets acquired from Siemens Technology Accelerator GmbH in 2016. Ares Genetics believes ARESdb is a unique comprehensive database on the genetics of antibiotic resistance. While Curetis expects to increasingly utilize ARESdb for proprietary biomarker content in its own assay and as a knowledgebase supporting the interpretation results obtained with the Unyvero Application Cartridge development, Ares Genetics also pursues an active out-licensing and collaboration strategy with suitable partners in the life science, pharmaceutical, and diagnostic industry to jointly development of solutions for microbiology relying on the database and/or the Ares Technology Platform. Ares Genetics has already entered into its first partnering and strategic collaborations with QIAGEN, Sandoz, and an undisclosed global IVD corporation in 2018 and 2019.

In addition to its out-licensing strategy, Ares Genetics offers next-generation molecular AMR testing

services out of its NGS service lab opened in mid-2019 in Vienna, Austria, with initial focus on infection control, AMR epidemiology and surveillance, clinical research and pharmaceutical anti-infectives R&D.

Ares Genetics has also initiated the development of its ARESupa Universal Pathogenome Assay, which will be based on the ARES Technology Platform and ARESdb. ARESupa is intended to cover nearly any pathogen in a broad array of sample types and to predict antimicrobial drug response to a wide variety of treatment options using a single NGS laboratory workflow. Ares Genetics – depending on the availability of suitable funding - plans to launch the assay as a laboratory developed test first and thereafter seek regulatory approval for its use as an *in vitro diagnostic* test which it will eventually seek to commercialize.

#### **CURETIS' PRODUCTS**

### UNYVERO PLATFORM

Curetis launched its CE-IVD-marked Unyvero Platform with a first disposable Application Cartridge for pneumonia in 2012. In April 2018, the FDA cleared the Unyvero System and LRT Application Cartridge in the United States, and Curetis launched them commercially in the United States in June 2018. The Unyvero Platform is a highly automated sample-to-answer molecular diagnostics platform, based on multiplexed end-point PCR with an array-based detection process. It integrates fully automated sample preparation, analysis and identification of disease relevant pathogens and antibiotic resistance markers to provide timely high-quality information to its end-users. The scalable system is designed to be either placed in laboratory settings or directly in hospital wards or intensive care units. Time-to-result is four to five hours for the different Application Cartridges commercially available today Application Cartridges, including 30 minutes of automated sample preparation (lysis) and total hands-on time of no more than five minutes. The Unyvero Platform's intuitive workflow with only minimal hands-on time enables untrained hospital staff to perform molecular tests at the point of need, such as ICUs.

### UNYVERO PLATFORM, SYSTEM COMPONENTS AND WORKFLOW

The Unyvero System consists of three devices, the Unyvero L4 Lysator, the Unyvero C8 Cockpit and the Unyvero A50 Analyzer. The Unyvero L4 Lysator is used for sample pre-processing and pathogen lysis. The Unyvero C8 Cockpit is the control panel for the Unyvero L4 Lysator and Unyvero A50 Analyzer and displays the results of patient sample analysis. The Unyvero A50 Analyzer consists of mechanical, electronic, pneumatic and optical elements and enables a fully automatic random-access processing of the Application Cartridges. The Application Cartridges are single-use, disposable and disease specific. The Unyvero System, together with proprietary software and the Application Cartridges, comprise the Unyvero Platform.



Figure 1: Unyvero Platform

The Unyvero L4 Lysator. This instrument is used for sample pre-processing and pathogen lysis. It performs proprietary software-controlled lysis of up to four samples, simultaneously within 30 minutes, combining mechanical, thermal, enzymatic and chemical lysis steps and allows the use of a wide range of native sample types due to a proprietary sample processing method (in respect of which several patents have been granted or are currently pending). Biofilm-building pathogens can be detected by the Unyvero Platform. In addition, the Unyvero Platform is CE-IVD-marked for a broad variety of native patient sample types including sputum, (mini) BAL, tracheal aspirates, aspirates and exudates, catheter tips, pus, sonication fluid, synovial fluid, swabs and tissue. The lysis of further sample types such as blood, urine, stool and formalin-fixed paraffin embedded tissues is also possible with the proprietary Unyvero lysis method. Up to two Unyvero L4 Lysators can be attached to a single Unyvero C8 Cockpit to allow processing of up to eight samples simultaneously within 30 minutes.

The Unyvero C8 Cockpit. This device is the control panel for the Unyvero L4 Lysator and Unyvero A50 Analyzer. It has a touchscreen and built-in bar code reader and runs on proprietary in-house developed Unyvero software. Step-by-step instructions guide the user from preparing a test to executing the fully automated process in the Unyvero A50 Analyzer in just a few minutes. The results display, storage of results and data storage, as well as information about the performed tests including the Application Cartridges' shelf-life and lot numbers, are generated automatically. Data can be exported as PDF files via a USB key or to a connected printer. It also features built-in interfaces for possible future connectivity to standard hospital and laboratory information systems.

The Unyvero A50 Analyzer. This instrument consists of mechanical, electronic, pneumatic and optical elements and enables a fully-automatic random-access processing of the Application Cartridges. Once a run is started, the Unyvero A50 Analyzer automatically executes and controls all sample processing and analysis steps (including DNA extraction, DNA purification, PCR set-up, highly multiplexed end-point PCR amplification and a hybridization array-based fluorescence detection) inside the Application Cartridge. For safety and equipment longevity, and to avoid issues of calibration or waste-removal, the Unyvero A50 Analyzer contains neither reagents nor waste. All fluids are handled within the sealed Application Cartridge. Up to four Unyvero A50 Analyzers can be attached to a single Unyvero C8 Cockpit and each Unyvero A50 Analyzer includes the two available slots that provide full random access per Unyvero A50 Analyzer, allowing the processing of up to eight patient samples simultaneously within four to five hours. In the future a further expansion towards up to eight Unyvero A50 Analyzers will also be possible.



Figure 2: Unyvero sample tube, sample tube cap, sample pre-treatment tool and Master\_Mix tube

**Workflow.** The Unyvero Platform is a modular, flexible easy-to-use platform, which substantially reduces turnaround time from up to 24 hours or even weeks for traditional microbiology culture-based tests to around four to five hours. This allows physicians to adjust treatment at a much earlier stage than with the traditional microbiology culture-based test, which is the current clinical standard of care. Curetis believes that the reduced hands-on time of no more than five minutes and the intuitive workflow makes the system operable by non-specially trained laboratory personnel and reduces the risks of errors.

#### UNYVERO A50 APPLICATION CARTRIDGE PORTFOLIO

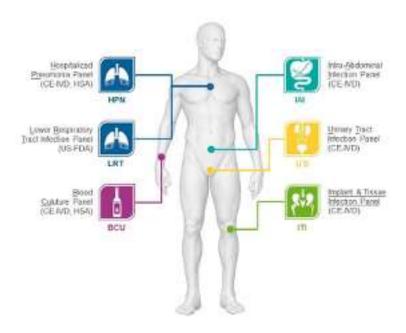


Figure 3: Current available Application Cartridges

The HPN and LRT Application Cartridges. The HPN Application Cartridge was commercially launched in April 2015 and is the second-generation version of the P50 Application Cartridge, the Pneumonia Application Cartridge originally launched in 2012. It is a CE-IVD-marked Application Cartridge for the fully automated performance of currently 21 PCR assays for microorganisms and 19 PCR assays for antibiotic resistance markers combined in a total of eight multiplex PCR reactions on native respiratory samples, such as sputum, tracheal aspirates and BAL fluids with no pre-culturing required. This Application Cartridge combines the necessary detection of bacteria, fungus and resistance markers into a single test to aid diagnosing pneumonia. With the HPN Application Cartridge, Curetis aims to detect the vast majority of pneumonia-causing pathogens and antibiotic resistance markers in hospitalized patients.

The HPN Application Cartridge of microorganisms and resistance gene markers was designed based on feedback of clinical experts and international and national guidelines. It aims to detect at least 90% of healthcare-associated pneumonia-causing pathogens and clinically relevant resistances against antimicrobials. The Application Cartridge is primarily designed to capture patients at risks for:

- microorganisms causing severe, and complicated to treat, forms of pneumonia, e.g. Pseudomonas aeruginosa;
- microorganisms carrying antibiotic resistance and where patients may need isolation (MRSA, Klebsiella);
- infections with multidrug-resistant bacteria that might not be targeted by empiric treatment schemes;
- rare and difficult to detect pathogens like Legionella sp.

The Application Cartridge composition takes pathogen incidences into account. It includes those microorganisms showing an incidence of above 1%. The Application Cartridge is completed by adding pathogens with lower incidence but a high clinical need, such as *Legionella* sp.

The HPN Application Cartridge covers 19 antibiotic resistance markers, including: (i) ß-Lactam resistance, including ESBL; (ii) *kpc* resistance; (iii) macrolide resistance; (iv) quinolone resistance; and (v) multi-drug resistance.

The LRT Application Cartridge was launched in the United States in April 2018. It is an FDA cleared Application Cartridge for the fully automated detection of 46 targets, consisting of 36 microorganisms and 10 antibiotic resistance markers, for lower respiratory tract infections and severe cases of pneumonia with a total of 29 PCR assays combined in eight multiplexed PCR reactions. Although similar in most respects to the HPN Application Cartridge, the LRT differs from the HPN in its pathogen reporting due to FDA reporting requirements. In accordance with a *De Novo* request that was granted by the FDA in April 2018, the initial label claim covers the use of LRT with tracheal aspirate samples only and has cleared 19 pathogens as well as 10 antibiotic resistance marker assays.

The LRT BAL Application Cartridge that was 510(k)-cleared by the U.S. FDA in December 2019 and launched in the United States in January 2020, is a version of the LRT Application Cartridge that is optimized for use with commonly obtained BAL specimen. The Unyvero LRT BAL application is the first and only U.S. FDA-cleared molecular diagnostic pneumonia panel that includes *Pneumocystis jirovecii*.

The ITI Application Cartridge. The ITI Application Cartridge was launched in May 2016 and is the second-generation version of the ITI Application Cartridge originally launched in the second quarter of 2014. Improvements were made to the panel and analytical performance as well as clinical sensitivity and specificity. It is a CE-IVD-marked Application Cartridge for the fully automated detection of currently 102 targets, consisting of 85 microorganisms and 17 antibiotic resistance markers for eight different clinical indications within the areas of prosthetic joint infections, surgical site infections, diabetic foot ulcers, catheter-associated infections, deep skin and tissue infections, cardiology-related infections, burn wounds and other implant infections. CE performance evaluation has demonstrated sensitivity of 86.9% at specificity of 99.2%. A diverse range of sample types such as aspirates and exudates, pus, sonication fluid, swabs, synovial fluid and tissue can be used on this Application Cartridge. Moreover, biofilm-building pathogens can be identified by the Unyvero Platform. The ITI Application Cartridge was jointly developed and co-funded with a worldwide market leader in orthopedic bone cement, which offers comprehensive infection management solutions. Curetis pays a customer referral commission but has retained full control on product commercialization.

The BCU Application Cartridge. The BCU Application Cartridge was launched in Europe in April 2016. It is a CE-IVD-marked and Singapore HSA-cleared Application Cartridge for the fully automated detection of 103 targets, consisting of 87 microorganisms and 16 antibiotic resistance markers relevant in the area of blood stream infections. The CE-IVD performance evaluation has demonstrated a weighted average sensitivity for all pathogens of 96.2%, and a weighted average specificity of 99.4%. Unlike other Unyvero Application Cartridges, BCU uses samples from positive blood cultures rather than native patient samples. Such blood cultures are started in cases of suspected blood stream infections.

The IAI Application Cartridge. The IAI Application Cartridge was launched in April 2017. It is a CE-IVD-marked Application Cartridge for the fully automated detection of 130 targets, consisting of 105 pathogens, three toxins and 22 resistance markers for several different clinical indications within the areas of severe intra-abdominal infections such as symptoms of peritonitis, appendicitis, acute abdomen, acute pancreatitis, and megacolon. Overall weighted average sensitivity for the pathogens specifically targeted by the test panel was 93.8% at an overall weighted average specificity of 99.7% following discrepant result resolution.

The UTI Application Cartridge. The UTI Application Cartridge was launched in April 2018. It is a CE-IVD-marked Application Cartridge for the fully automated detection of up to 103 diagnostic targets, consisting of 88 microorganisms and 15 genetic resistance markers for the areas of severe urinary tract infections in patients with anatomical, structural and functional alterations, renal impairments, impaired immune status, catheter-associated UTI, patients failing to respond to therapy and suffering from severe manifestations, urosepsis. Curetis estimates that the addressable market for the UTI Application Cartridge is 1.6 million cases eligible for testing per year in the EU and the United States

# ARES GENETICS' NGS AND BIOINFORMATICS SERVICES FOR MOLECULAR MICROBIOLOGY

In August 2019, Ares Genetics opened a specialized service laboratory offering next-generation AMR testing services with an initial focus on infection control, AMR epidemiology and surveillance, clinical research and

pharmaceutical anti-infectives R&D. All services are based on NGS and Curetis' proprietary, Al-powered antimicrobial resistance database ARESdb and the ARES Technology Platform for data interpretation.

Initial services launched focused on the molecular identification of bacterial species and the detection of mutations and genes conferring antibiotic resistance with Ares Genetics Universal Pathogenome Assay, ARESupa. A second generation of ARESupa predicting antibiotics susceptibility based on complex genetic signatures was launched in an early access program October 2019. The launch followed the successful completion of a blinded\_feasibility study in which Ares Genetics correctly identified 100% of the pathogen species and successfully predicted antibiotic susceptibility for over 50 drug/pathogen combinations in line with FDA requirements (<1.5% very major error, i.e. misclassification of resistant isolates as susceptible and <3 % major error, i.e. misclassification of susceptible isolates as resistant). As of 31<sup>st</sup> October 2019, Ares Genetics has completed first customer projects with the first generation ARESupa and had contracted an order volume of more than 1,000 ARESupa tests amounting to more than EUR 500,000 in service revenue mostly for the second generation ARESupa test. Together with advanced bioinformatics and Al services leveraging ARESdb for partnering in the diagnostic and pharmaceutical industries, Ares Genetics has received orders and fees amounting to > EUR 2 million in 2019. A broad roll-out of the second generation ARESupa is planned for early 2020.

# INDUSTRY & MARKET

#### **OVERVIEW**

Since the discovery of deoxyribonucleic acid, or DNA, over 60 years ago, followed by the development of PCR and sequencing technologies, there have been many advances in the research of human health and diseases. Insights into the molecular mechanisms underlying normal human physiology and disease have given way to the continuous discovery of variations and dysregulations of genes that can be used as biomarkers to assess disease predisposition, detect disease at its earliest stages, diagnose and classify diseases in tremendous detail, determine the individual patient's prognosis to respond to therapeutic intervention and monitor disease recurrence post intervention. Diagnostic methods and products for detecting nucleic acid-based biomarkers are summarized under the term molecular diagnostics, or MDx, and can also be used to identify microorganisms causing an infection.

The availability of methods to fast and reliably detect and characterize specific nucleic acids in a large variety of sample type materials easily obtained from patients has made MDx a driver of innovation in medicine allowing for a shift to an increasingly personalized and more effective healthcare.

Based on information from the World Health Organization, or WHO, MDx testing of DNA derived from pathogens causing infections are by far the largest segment of the MDx market and infectious diseases are still one of the leading causes of death worldwide. The rapid and precise detection of pathogens as well as biomarkers relating to their resistance to anti-infective agents has become paramount in effectively managing infections in individual patients, controlling outbreaks and pandemics, and the more informed use of scarce antibiotics resources thereby may slow down the spread of antibiotic resistant pathogens – one of the acknowledged global health threats in the 21st century, according to WHO.

Initially, the vast majority of MDx tests targeted single viruses or bacteria and were used to screen larger populations effectively for these pathogens. Due to increasingly personalized healthcare syndromic-based multiplexed MDx tests are becoming increasingly important. These multiplexed tests allow for the simultaneous detection of numerous specific nucleic acids important in clinical syndromes and hence can provide a detailed picture of those microorganisms underlying an individual patient's infection including their genetic predisposition for antibiotic resistance, thus allowing for a personalized approach to treatment with anti-infectious agents at the earliest stage of care.

#### THE MOLECULAR DIAGNOSTICS MARKET

Size of the Molecular Diagnostics Market. Based on market research reports, the global molecular diagnostics market is projected to reach US\$ 11.5 billion by 2023 and presents a significant share of the total IVD market. Other segments in the IVD market include immunoassays, diabetes, clinical chemistry, point of care, hematology, (culture-based) microbiology, or coagulation. According to Marketsandmarkets:

Molecular Diagnostics Market (2018), the MDx market is growing rapidly and it is expected to grow from US\$ 7.7 billion in 2018 with a CAGR of 8.4% globally to US\$ 11.5 billion in 2023, North America represents the largest part of the market with 44% of the total, followed by Europe with 26% and Asia Pacific with 22% of the total.

Molecular Diagnostics Market by Application. According to the same market data source, in 2016, infectious disease testing (in particular viral screening) with a share of 55% was the largest segment of the MDx market, followed by oncology (21%), genetics (10%), and microbiology (8.5%). Curetis products target the infectious disease market, projected to grow at 7.0% p.a. from US\$ 4.2 billion in 2018 to US\$ 6 billion by 2023, as well as the molecular microbiology markets projected to grow with a CAGR of 8.6% from USD 650 million in 2018 to US\$ 1 billion in 2023. Curetis believes that there is a crucial need for multiplex MDx assay panels for severe symptomatic infections in particular in hospitalized patients, including but not limited to respiratory tract infections, gastrointestinal tract infections, bloodstream infections and sepsis urinary tract infections, intra-abdominal infections, implant and tissue infections and CNS/Meningitis.

Curetis has focused the development of new Application Cartridges in the areas that it believes have most potential for the development of an MDx offering. Curetis defines its total addressable market by the incidence of infections that it targets through its offering. This represents over 9.73 million addressable cases across United States and Europe spread across applications:

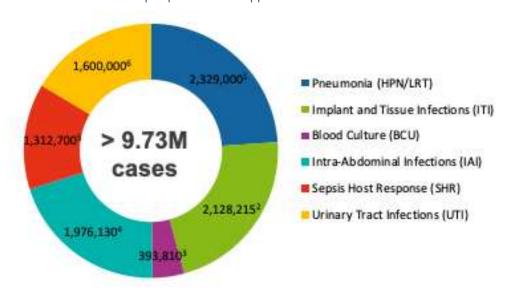


Figure 4: Total addressable market (United States and Europe) by Unyvero Products on the market or in the R&D pipeline

Sources: <sup>1</sup> CDC (2010); ECDC (2008); Chalmers, J.D. *et al.* (2014) <sup>2</sup> Margolis *et al.* (2011); American Diabetes Association (2014); Diabetes Deutschland (2012); Richard *et al.* (2011); Livesley and Chow (2002); Dorner *et al.* (2009); Deutsche Gesellschaft für Verbrennungsmedizin (2014); Mayhall (2003); Klevens *et al.* (2007) in Jhung (2009); Geffers (2001); Brun-Buisson (2010); Michelotti *et al.* (2012); Sunderlin (2006) <sup>3</sup> Martin (2012); Statista (2015a); Dellinger *et al.* (2013) <sup>4</sup>Lucado et al. (2013); CDC (2010) <sup>5</sup> Martin (2012); Statista (2015b) <sup>6</sup> ECDC (2013); Klevens *et al.* (2002).

However, Curetis believes that microbial pathogen identification is still underserved by MDx methods and vastly relies on traditional microbiology culture-based tests despite an increasing need for faster and more comprehensive diagnostics. Thus, even though modern medicine and medical research are evolving and have achieved remarkable advances, infectious diseases are still one of the leading causes of death worldwide and are expected to have a significant impact on health in the future. In addition, conditions like climate change, increasing international trade and travelling in a globalized world facilitate the spread of pathogens, disease and antibiotic resistance. Therefore, Curetis focuses on assays in severe infectious diseases in hospitalized patients capturing relevant microorganisms and antibiotic resistance markers.

The Molecular Diagnostics Market by Customer. Molecular testing — which has traditionally been performed mostly by large specialized and complex laboratories with highly trained staff — has now also entered facilities with less skilled and trained staff as widely automated and integrated MDx systems simplify the laboratory workflow and require less training and no special laboratory infrastructure. Major end-users of MDx tests are currently hospital laboratories and in the United States so-called reference laboratories, accounting for a combined 90% share of the global MDx market in 2013. Of these, hospital laboratories account for 54.4% of the total market and are the largest end-user customer group. Placing systems in hospital departments depends on the individual hospital infrastructure and if they consider that molecular testing should be exclusively performed within laboratories or not. Despite the opportunity for decentralized MDx systems placements outside traditional laboratory settings (e.g. in intensive care units), Curetis expects that molecular testing for severe infectious disease will still mostly be performed in microbiology laboratories. However, point-of-need placements or near patient MDx system installation are also expected to gain market share.

The Molecular Diagnostics Market by Technology. Molecular testing can be performed through the use of various technologies. PCR has remained the most widely used technology, well ahead of other technologies such as isothermal nucleic acid amplification, or INAAT, and fluorescence in situ hybridization, or FISH, technologies for anatomical pathology and cytogenetics.

PCR is a well-established method, which allows detection of few copies of nucleic acid (e.g. DNA/RNA) in a sample (e.g. blood) for diagnostic purposes. PCR makes use of specific starter molecules (primers), DNA replication enzymes and a cyclic temperature profile. Within each cycle a specific segment of the target DNA defined by the primers is copied doubling the copy number of this nucleic acid fragment in the reaction. Hence, the amplification is exponential. Therefore, billions of copies are generated, which can be detected by means of fluorescent dyes within a short period of time. As a limitation, the targeted nucleic acid sequence has to be known beforehand to design the specific primers for the test. The broad adoption and acceptance of PCR is owed to its high specificity and sensitivity. Curetis' Unyvero Platform relies on a combination of PCR and microarray-based PCR product detection, combining the advantages of PCR in terms of sensitivity and specificity with the multiplexing capabilities of microarrays.

NGS comprises highly parallelized sequencing methods that permit to sequence the human (or bacterial) genome(s) rapidly at low costs. While detailed information of the DNA sequences can be obtained at high resolution, interpreting this information requires significant computational resources and bioinformatics skills. NGS workflows are often very complex, require time, many manual steps and skilled staff as well as well-equipped laboratories and sophisticated data handling. NGS technology has received major capital investments but further advances in technology are likely to result in lower prices. However, despite several companies working on highly automated and integrated NGS solutions for potential use in the IVD market for considerable time already, none of these have yet reached the routine diagnostics market in infectious disease at the point of need. Thus, Curetis believes that NGS based technologies at present do not yet constitute direct competition to Unyvero, but may hold great potential for the future that can potentially be leveraged through Ares Genetics.

# COMPETITION

Unyvero System. The Unyvero Platform is a sample-to-answer MDx solution. There are several other companies who develop and commercialize similar systems. In terms of devices and assays, Curetis believes its key competitors include bioMérieux (BioFire with its FilmArray® platform) and GenMark with its ePlex® platform as well as Accelerate Diagnostics with its Pheno™. Taking into consideration the broader market, devices of other key competitors can be extended to include Cepheid (GeneXpert®), T₂ Biosystems (T₂DX®), Luminex Corporation (formerly known as Nanoshphere) (Verigene System® and Aries®), Atlas Genetics (with io™ System), Roche (Cobas® with the Liat® and GeneWEAVE platform), Qiagen (QIAstat-Dx™) and Biocartis N.V (Idylla™), Bosch with the Vivalytic platform and the Meridian Bioscience (formerly GenePOC) Revogene® system. Disease-related assay competitors including those providing reagent kits only (e.g. Seegene, Fast-Track Diagnostics/Siemens Healthineers, Genetic Signatures) and LDT developers have to be separately assessed by each application. Curetis believes that its Unyvero Platform has certain key characteristics that clearly differentiate it from other sample-to-answer systems:

- Based on its corporate market analysis, Curetis believes that due to the proprietary lysis technology its Unyvero Platform is able to process a broader variety of sample types than competing platforms. In most cases, no labor or time intensive manual sample preparation is necessary and even difficult and blood-contaminated native samples can be processed. Furthermore, the Unyvero Platform is CE-IVD-marked for a variety of samples including sputum, bronchoalveolar lavage, tracheal aspirate, exudate, catheter tip, pus, sonication fluid, synovial fluid, swab and tissue. Further samples such as blood, urine, stool and formalin-fixed paraffin embedded tissues present further options for extending the variety of samples for future applications. Fresh or frozen samples and also samples that have been stored in different media can be processed easily on the Unyvero Platform. As the lysis is integrated into the workflow, hands-on time and potential handling errors are significantly reduced.
- What also sets apart Curetis' Unyvero Platform is its high multiplexing capability based on end-point PCR, which allows for the execution of eight independent multiplex PCR reactions simultaneously. Therefore, Curetis can identify a broad range of microorganisms and in addition a large variety of antibiotic resistance markers in a single run.
- Focusing on severe infectious diseases and having developed a HPN Application Cartridge, an ITI Application Cartridge, a BCU Application Cartridge, an IAI Application Cartridge and a UTI Application Cartridge and planning to develop further Application Cartridges in the severe infectious disease area, Curetis has a highly differentiated positioning in the market.
- Although several direct competitors have in the past three years started to develop and / or commercialize their own infectious disease tests, Curetis believes that the variety and breadth of its menu of cartridges targeting different infection areas positions it favorably to answer patient and customer needs.
- With the acquisition of the GEAR database from Siemens and its further development into ARESdb, Curetis also believes that it can increasingly differentiate its test panels through proprietary biomarkers for antibiotic resistance.

**Unyvero Application Cartridges.** Considering its panel design, Curetis believes that there are currently no assays directly comparable to the Company's HPN / LRT / LRT BAL, ITI, IAI, and UTI Unyvero Application Cartridges that are commercially available to date. With its BCU Unyvero Application Cartridge, Curetis has entered a competitive indication area for which the Company believes it can offer a more comprehensive panel compared to its competitors. Various competitors offer testing in some, but not all, of the infections targeted by Curetis' Application Cartridges. For example, for the HPN and LRT Application Cartridges, currently only two companies (Curetis and bioMérieux/BioFire) offer an FDA-cleared IVD automated molecular panel for lower respiratory tract infections / pneumonia. According to publicly available sources, Accelerate Diagnostics has a CE-IVD pneumonia assay and it is believed to be in clinical trials for future U.S. FDA submission of this application. Other companies, such as, Luminex (formerly Nanosphere), GenMark, Seegene, Genomica, Miacom, PathoFinder, Fast-Track Diagnostics (recently acquired by Siemens Healthineers), Randox, ArcDia, Qiagen, and iCubate are primarily targeting the upper respiratory tract with their panels. Their panels mainly cover viruses and a few bacteria, and in some occasions a limited number of antibiotic resistance markers only. Diatherix offers a manual test claiming to cover both upper and lower respiratory infections. Curetis believes that it offers the most comprehensive panel for severe bacterial pneumonia for critically ill patients that require hospitalization, as the panel includes unique and differentiated bacterial targets and the broadest coverage of carbapenem resistance markers, while BioFire's panel has a limited range of resistance markers and viral targets.

Ares Genetics. Ares Genetics' peers and competitors include companies providing conventional microbiology, PCR- and NGS based molecular diagnostics, as well as AMR databases and bioinformatics solutions. In general, the vast majority of peers and competitors are also considered potential ARESdb licensing partners due to the unique content and positioning of ARES' artificial intelligence curated reference database, ARESdb.

Conventional Microbiology

The conventional microbiology market consists of culture and MALDI-TOF based testing and is

largely shared by well-established players including BD, bioMérieux, Bio-Rad Laboratories, Danaher (Cepheid, Beckman Coulter), Thermo Fisher Scientific. Culture-based testing is usually performed in the central laboratory at TATs of 48 to 72 h and it is yet to be seen whether it can robustly be accelerated by miniaturization, an approach pursued by the company Accelerate Diagnostics. While TATs for MALDI-TOF based testing is much faster, overall TATs from sample to report are still greater than 24 hours as MALDI-TOF generally depends on an initial culturing step for pathogen isolation and cannot be performed from native patient samples. Generally, providers of conventional microbiology solutions are focusing on reducing TAT, use of labor and lab space, as well as overall costs by automatic specimen processing and pathogen identification.

### Molecular Diagnostics – PCR

Key competitors in the PCR-based molecular diagnostics market include bioMérieux, BD, Danaher, Roche, Qiagen, Abbott, Hologic, OpGen and, amongst others, Ares Genetics' parent company, Curetis. PCR-based microbiology testing is usually performed at the point of need or in the central laboratory at rapidly reduced TAT compared to conventional microbiology. Generally, providers of PCR-based molecular diagnostics are focusing on further reducing TAT to less than 30 minutes to one hour and/or increasing multi-plexing degree as well as reducing use of labor, lab space, and overall costs. Ares Genetics believes that its ability to quantitatively predict antibiotic susceptibility based on the pathogen's genetic profile complements PCR-based approaches detecting panels of genes and mutations as indicators of resistance.

# Molecular Diagnostics – NGS

The emerging NGS-based molecular diagnostics market is shared by start-up-like companies such as IDbyDNA, Karius, CosmosID, Noscendo, Day Zero Diagnostics, or ArcBio aiming at disrupting the molecular microbiology by pathogen detection via direct sequencing from patient samples, as well as established players such as bioMérieux focusing on isolate sequencing to monitor outbreaks in hospitals (in partnership with Illumina). NGS-based testing is currently performed as a service and companies mostly focus on reducing TAT as well as increasing the NGS market share in molecular microbiology. NGS-based molecular diagnostics companies are considered as Ares Genetics' closest competitors, while Ares Genetics believes to have a competitive advantage by its ability to predict antibiotic susceptibility based on the pathogen's genetic profile with a performance meeting FDA requirements for functional testing of AST by culture.

#### AMR Databases & Bioinformatics Solutions

Up-to-date several AMR databases exist (e.g. CARD, PATRIC, etc.) but they are purely designed for academic research applications as they neither represent IVD-grade reference databases, nor systematically cover high-resolution resistance profiles including confidence levels and diagnostic performance parameters for associated AMR markers. The commercial microbial bioinformatics solution market on the other hand, is largely covered by QIAGEN, a strategic licensing partner of ARES for co-marketing bioinformatics research solutions based on ARESdb.

# **CURETIS' PARTNERING AND COLLABORATION AGREEMENTS**

Acumen (Curetis GmbH). On 5<sup>th</sup> October 2015, Curetis and Acumen Research Laboratories Pte Ltd., Singapore, or Acumen, entered into two separate collaboration agreements. First, a non-exclusive patent license and research collaboration agreement, under which Curetis has obtained a limited, royalty-bearing, non-exclusive, non-transferrable, non-sublicensable license to Acumen's proprietary sepsis biomarker panel for detection of sepsis host response in blood samples. Under this agreement the parties further agree to a research and development collaboration, in which Acumen is expected to further develop its technology underlying the license and Curetis is expected to develop products based on such technology and develop a novel sepsis host response Application Cartridge that the parties will jointly validate in a series of clinical studies in Singapore, Germany and possibly the UK. It is envisaged that Curetis becomes the manufacturer of the sepsis host response Application Cartridge, subject to an up-front one-time payment of several hundred thousand euros by Curetis to Acumen and a single-digit royalty percentage on net sales to be paid

to Acumen for all such sepsis host response sales except for the territories where Acumen is the exclusive distributor of Unyvero products (see below under *Indirect Sales*). The agreement is set to expire upon the expiration of the last claim of any of the relevant patents, provided that it is not terminated by one of the parties.

Second, a distribution agreement under which Acumen has become the exclusive distributor of Unyvero Systems and HPN, BCU and ITI Application Cartridges and possibly future Application Cartridges in Singapore, Malaysia, Thailand and Indonesia. Both parties at a later point may mutually agree to amend the agreement to include additional territories of the ASEAN region. Under the terms of the agreement, Acumen is subject to certain minimum purchase commitments for the Unyvero Systems and the Application Cartridges per year. The agreement provides an initial three-year term, which shall be automatically extended for one year, provided that it is not terminated by one of the parties. During that period, Acumen has exclusive rights to market, sell and distribute all Unyvero products in the respective territories. In return, Acumen needs to commit to annual minimum purchases of Unyvero systems as well as Application Cartridges at agreed upon transfer prices for the Unyvero Systems and Application Cartridges. In case Acumen fails to meet its annual minimum commitments fixed in the contract, Curetis has the right to either terminate the agreement in its entirety, or to terminate Acumen's territorial exclusivity.

Beijing Clear Biotech (Curetis GmbH). On 25<sup>th</sup> September 2015, Curetis and Beijing Clear Biotech, or BCB, entered into an exclusive international distributor agreement for initially five years following NMPA approval of the Unyvero System and a first Application Cartridge. On 11<sup>th</sup> October 2018, the agreement with BCB was amended, extending the initial term of the agreement from five to eight years following NMPA approval of the Unyvero System and a first Application Cartridge, which eight-year term shall be automatically extended for an additional five years, provided that it is not terminated by one of the parties. The agreement appoints BCB as the exclusive distributor of Unyvero Systems and HPN and ITI Application Cartridges in greater China.

Under the agreement with Curetis, BCB is responsible for conducting and implementing, as well as fully funding, comprehensive NMPA clinical trials of the Unyvero System and the HPN and ITI Application Cartridges according to NMPA guidelines. Beijing Clear Biotech shall act as direct contact for the Beijing NMPA and is obligated to file the Unyvero Platform NMPA registration as Curetis' Chinese representative. Curetis is obligated to fully support Beijing Clear Biotech in obtaining NMPA clearance by providing its expert knowledge. Curetis shall be responsible for the labelling of instruments and consumables according to the requirements of the NMPA during the clinical trial and after the approval.

BCB will become the exclusive distributor for Unyvero Systems and HPN and ITI Application Cartridges in greater China. BCB is responsible for the local marketing, which is to correspond with Curetis' global marketing strategy. The marketing activities of Beijing Clear Biotech shall include marketing with hospitals as well as with physicians and microbiology laboratories and/or core laboratory marketing. Curetis shall, upon BCB's request, provide support services, including technical and scientific training for the promotion, marketing and distribution of the products as well as the provision of second-level technical support. BCB has committed to annual minimum purchases of Unyvero Systems as well as Application Cartridges. Transfer prices for the Unyvero Systems and Application Cartridges are defined and reflect typical MDx industry distributor margins with certain further volume discounts on the consumable sales. The agreement may be terminated upon written notice by either party in the event of a breach by the other party under the terms of the agreement and its failure to remedy that breach within 30 days. If BCB fails to meet its annual minimum commitments fixed in the contract, Curetis has the right to either terminate the agreement in its entirety, or to terminate BCB's territorial exclusivity.

On 30<sup>th</sup> May 2016, Technomed (Hong Kong) Ltd assumed the role of BCB as Curetis' distributor in Hong Kong.

Under the agreement, BCB has committed to a minimum purchase of more than 360 Unyvero A50 Systems as well as over 1.5 million Unyvero Application A50 Cartridges for the duration of the agreement. This commitment would, based on agreed transfer price levels, lead to potential revenues to Curetis of over EUR 30 million annually in years six to eight of commercialization in China in addition to potential cumulative

revenues of more than EUR 60 million for years one to five of commercialization in China, as had been agreed previously.

Further, the parties agreed to waive certain milestone payments otherwise payable by Curetis to BCB, consisting of payments due upon (1) initiation of up to three clinical trial sites as marked by first patient enrolment and (2) regulatory approval by NMPA of the Unyvero System and the HPN and ITI Application Cartridges. These waivers represent a total savings to Curetis of EUR 600 thousand over the next one to three years.

Collaboration Agreements with Pharmaceutical Companies (Curetis GmbH). Curetis has previously entered into collaboration projects in which the partner was a pharmaceutical company that typically used the Unyvero Platform in a clinical trial of a novel antibiotic. Collaboration agreements can range from a simple research and development collaboration and service agreement where Curetis acts as central reference lab for a clinical trial to situations where the pharmaceutical company purchases the Unyvero System and Application Cartridges outright and commissions certain installation, training and support services from Curetis to set up the Unyvero Platform at various clinical trial sites. A single collaboration agreement offers the potential for Curetis to place multiple Unyvero Platforms and sell corresponding Application Cartridges to a single partner over a defined period of up to several years for a given trial.

MGI (Curetis GmbH & Ares Genetics). On 12<sup>th</sup> September 2017, Curetis and MGI Tech Co. Ltd, Shenzhen, China, or MGI, a fully-owned subsidiary of BGI Group, one of the world's leading genome sequencing centers headquartered in Shenzhen, Guangdong, P. R. China, entered into a MoU for a broad collaboration to develop targeted NGS IVD assays for microbial infections. The broad collaboration includes the development of a targeted NGS assay for microbial infections, a workflow for native samples integrating MGI and Curetis instrumentation and the development of assay design and data interpretation by Curetis' subsidiary Ares Genetics.

Under the terms of the MoU MGI will provide hardware and chemistry integration and develop an automated workflow as well as manufacture the targeted NGS assays. MGI will also be in charge of validating the assay and seeking regulatory approval as needed. Curetis and Ares Genetics will provide expertise in sample preparation technologies, panel design and NGS sequencing assay design using its ARES*db*. Ares Genetics will also develop a data interpretation application that automates the bioinformatics analysis of the NGS data and supports the interpretation and visualization of NGS results on pathogens and antibiotic resistance markers detected by the assay to facilitate the deployment of the assay in the clinical routine. Ares Genetics and BGI Group will be supported by Prof. Dr. Andreas Keller from the Center for Bioinformatics at Saarland University, the leading academic partner in the development of GEAR.

On 10<sup>th</sup> January 2018, Curetis entered into a supply and authorization agreement with MGI to advance its strategic alliance in NGS-based infectious disease testing. Curetis and MGI aim to integrate Curetis' patented Unyvero L4 Lysator-based sample preparation technology and MGI's NGS next generation sequencing technology to develop a fully automated workflow that allows the processing of any type of native clinical sample with the subsequent NGS-based detection of microbial pathogens and genetic markers for antibiotic resistances. Under the terms of the agreement and subject to certain conditions, including the first commercial order for the products to be supplied by Curetis, as described above, and specific agreement on pricing and the relevant commercial terms, MGI reimbursed Curetis for supporting the workflow integration and transferring this advanced technology, and pay technology access fees, a transfer price on OEM hardware and consumables, and royalties on product sales.

### **ACQUISITION AGREEMENTS**

The Gyronimo Acquisition (Curetis GmbH). In December 2016, Curetis acquired the real-time qPCR-based Gyronimo platform from joint owners Carpegen GmbH, Muenster, Germany, or Carpegen, and Systec GmbH, Muenster, Germany, or Systec. Integrating Gyronimo into the Unyvero Platform as the Unyvero A30 RQ analyzer module for infectious disease testing allows Curetis to expand its product portfolio as well as partner with companies with appropriate multiplex assay menus in infectious diseases, cancer or other indications that are in need for such platform. Under the terms of the agreement, Curetis acquired all Gyronimo platform assets, including fully functional prototype systems and the entire intellectual property

portfolio comprised of several patent families pending and a key patent granted in the U.S., Canada and China, and allowed in Europe. Curetis obtained exclusive license to Gyronimo know-how and a non-exclusive license to general background know-how of Carpegen and Systec. Curetis was granted exclusive worldwide rights to the platform, including the right to sublicense, partner or sell it, with an exemption for Carpegen and Systec in dental testing as well as in environmental and food safety testing. In exchange for these assets, Curetis made a one-time up-front cash payment of EUR 5 million. In addition, Carpegen and Systec are eligible for two discrete, one-time milestone payments upon platform and first cartridge CE marking and FDA clearance, respectively, totaling up to EUR 2.5 million. There will also be the potential for a royalty-based earn-out at an industry-typical mid-single digit percentage rate, up to a cumulative maximum amount of EUR 9 million.

GEAR Asset Acquisition (Curetis GmbH, Ares Genetics GmbH). On 7<sup>th</sup> September 2016, Curetis GmbH as acquirer entered into an asset acquisition agreement with Siemens Technology Accelerator GmbH, Munich, Germany, or STA, pursuant to which Curetis acquired sole commercial rights from STA to the GEAR platform and database with all its content, numerous GEAR-related patents and patent applications, as well as all corresponding know-how. Curetis received sole worldwide product development and commercial rights, including the right to sublicense in the fields of human and animal diagnostics as well as food safety testing. As a result of this transaction, Curetis secured the sole rights to leverage the GEAR assets in collaboration with pharmaceutical companies for the development of novel antimicrobial drugs for human and animal health. As consideration for these assets, STA has received a certain upfront payment from Curetis, and Curetis shall make milestone payments for products including GEAR biomarkers upon first CE-IVD-marking and first FDA approval (or similar regulatory clearance), respectively as well as royalty payments to STA in industry-typical percentage ranges on future products based on use of the GEAR platform or GEAR biomarkers. Following the acquisition of GEAR from STA, Curetis in 2017 transferred all assets to Ares Genetics. Ares Genetics since then has integrated GEAR into ARESdb, Ares Genetics' proprietary database on the genetics of AMR with significantly increased pathogen and drug coverage and significantly expanded functionality compared to the original GEAR platform and database.

# ARES GENETICS MATERIAL CONTRACTS

**Sandoz.** Ares Genetics GmbH signed a collaboration agreement on 18 December 2018 with Sandoz to leverage Ares Genetics' database on the genetics of antibiotic resistance, ARESdb, and the ARES Technology Platform for Sandoz' anti-infective portfolio.

Under the R&D collaboration agreement, which has an initial term of 36 months until 13 Dec 2021, the companies intend to develop a digital anti-infectives platform combining established microbiology laboratory methods with advanced bioinformatics and artificial intelligence methods to support drug development and life cycle management. The collaboration in the short- to mid-term aims at rapidly and cost-effectively re-purposing existing antibiotics and designing value-added medicines with the objective of expanding indication areas and overcoming antibiotic resistance, in particular in infections with bacteria that already developed resistance against multiple treatment options. Longer-term, the platform is expected to inform the development of novel anti-infectives that are less prone to encounter resistance and thereby preserve antibiotics as an effective treatment option.

The collaboration agreement covers the first phases of the collaboration with Sandoz providing certain moderate R&D funding to Ares Genetics. No milestones or royalties have been agreed as part of this first phase of the R&D collaboration agreement. The agreement may be terminated by Sandoz effective immediately at any time with written notice.

**Qiagen.** On 18<sup>th</sup> February 2019 Ares Genetics and Qiagen have entered into a strategic licensing agreement for ARES db and ARES tools in the area of antimicrobial resistance (AMR) research. The agreement has a term of 20 years and may be terminated by Qiagen for convenience with 180 days written notice.

Under the terms of the agreement, Qiagen against a moderate up-front licensing payment has received an exclusive license to develop and commercialize general bioinformatics offerings and services for AMR research based on Ares Genetics' database on the genetics of antimicrobial resistance, ARESdb, as well as on the ARES bioinformatics AMR toolbox, AREStools. There is a further milestone upon certain product

launches and a mid-single digit percentage royalty rate on Qiagen net sales payable to Ares Genetics.

Ares Genetics retains the rights to use ARESdb and AREStools for AMR research, customized bioinformatics services, and the development of specific AMR assays and applications for the Curetis Group (incl. Ares Genetics) as well as third parties, e.g. other diagnostics companies or partners in the pharmaceutical industry. As the Qiagen research offering is expected to also enable advanced molecular diagnostic services and products, Qiagen's customers may obtain a diagnostic use license from Ares Genetics.

**Global leading IVD corporation.** On 16<sup>th</sup> September 2019 Ares Genetics GmbH has entered into a multiphase partnership with an undisclosed leading global in vitro diagnostics corporation (the "**Partner**") to jointly develop diagnostic solutions for infectious disease testing based on next-generation sequencing ("**NGS**") technology. The companies signed an R&D and option agreement for the first phase of the partnership. The initial term of the R&D collaboration is 10 months until 13<sup>th</sup> July 2020. The IVD partner may terminate with 30 days' written notice.

In a first phase of the collaboration expected to take about 10 months, the parties will further enrich ARESdb with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication. Additional clinical isolates of such pathogens will be sequenced by Ares Genetics at its recently established NGS laboratory in Vienna, Austria. Based on this enlarged and enriched dataset, Ares Genetics will further optimize the algorithms for predictive antibiotic resistance testing for drug/pathogen combinations particularly relevant in the targeted indication to enable NGS-based infectious disease diagnostics.

Under the initial agreement signed 16<sup>th</sup> September 2019, the Partner will fully fund Ares Genetics' research and development activities for the genotypic and phenotypic characterization of additional bacterial strains to augment ARESdb and the development of optimized algorithms for predicting antibiotic resistance. Furthermore, in return for an undisclosed up-front option fee, the Partner obtains a right of first negotiation for 3 months for an exclusive human clinical diagnostic use license to ARESdb and the ARES Technology Platform. The option can be exercised during the term of the agreement plus three months.

#### MARKETING AND SALES

Customers. Curetis' commercial teams have identified several stakeholder groups: treating clinicians, doctors of pharmacy (PharmDs), antibiotic stewardship programs, microbiologists, molecular biologists and laboratory managers as well as hospital administration, all of whom will be actively involved in the purchase decision at varying levels and stages. In terms of product benefits, Curetis believes that clinicians / physicians seek timely diagnostic results that can be used to better inform or confirm a treatment decision and improve patient outcomes, while microbiology laboratory managers, who have to contend with the steadily decreasing availability of trained lab technicians and the need to perform testing during off-shifts, need simple-to-use, robust technologies. Ultimately, however, the decision whether a proposed new testing solution is cost effective and affordable on a routine basis must be made by the payer, which in the case of hospitalized in-patients under the DRG-reimbursement system is typically the hospital purchasing and finance departments. Curetis' key account management ensures that all stakeholders are targeted early in the sales process.

Sales Process. The typical sales process starts with an introductory visit to the microbiology laboratory director and senior microbiology staff. The goal is to introduce Unyvero and assess general interest in evaluating the Unyvero Platform during a demonstration phase. However, the goal is also to initiate contact to any new hospital customer via the gatekeeping microbiology laboratory function. The primary objective apart from getting a demo phase agreed upon is to seek joint introductory meetings with the senior microbiology staff and the various intensive care units, or ICUs, and clinicians in any relevant ICU. Since the latter can be multiple ICUs (sometimes over a dozen in major university hospitals) with multiple 24/7 rotating shift operations each, it is paramount to identify one or a few key ICUs as internal product champions. The clinicians are ultimately the end-customers of Application Cartridge results for use in treatment assessment and optimizing medical care for their patients. They will also be the ones routinely requesting a Unyvero test to be done. At this stage a discussion about the ideal placement of the Unyvero System during a demonstration usually takes place. In the United States, the Unyvero System is placed in

the core laboratory, In the EU and the rest of world, or RoW, central location in the microbiology laboratory is the preferred option, or alternatively near patient ICU placement.

Curetis expects that the entire sales process, from the introductory visit to the point in time when the hospital begins routinely purchasing Application Cartridges, known as the push-pull triangle model, which includes the lab, the clinicians and the finance entity, will take around nine to twelve months, based on the experience of competitors and peer companies, in the United States and about the same time from start to finish in the EU. Depending on the time of year and budget cycle, however, a contractual arrangement can take significantly longer. An integral part of the sales process is the placement of demo Unyvero Systems without payment for demo evaluation purpose.

Curetis' marketing provides sales and sales support tools adapted to the specifics of each stakeholder and stimulates demand by setting up awareness campaigns for lab personnel, clinicians and general hospital stakeholders.

In the more developed markets of the EU and the RoW, additional customer segmentation reflects the business opportunity per customer / institution and is linked to size of the hospital reflected in the number of beds available at the institution. Therefore, the sales strategy is based on a key account management approach, initially only targeting large hospitals with clear focus on departments like pneumology, large ICUs or orthopedics wards depending on the particular Application Cartridge being promoted.

The focus is on high-volume consumable orders (Application Cartridges and other consumables) instead of driving revenues and profits through hardware placements (Unyvero System installations). Consequently, Curetis and its distribution partners aim to optimize the utilization of each placed hardware unit rather than solely maximizing the installed base of instruments. Therefore, Curetis, with its tests primarily targeting inpatients (hospitalized) with severe infections, is focusing its sales and commercialization efforts on laboratories in hospitals and independent laboratories serving larger hospitals.

Curetis and its distribution partners will also face certain market entry barriers mostly related to upfront investments for the implementation of its new technology, as most laboratories and microbiology centers are cost centers, which do not directly benefit from the current DRG reimbursement scheme. Additionally, the Unyvero Platform will be an add-on test not replacing traditional testing – in this case cultures, which are perceived as comparatively cheap. Therefore, Curetis pursues a sales strategy whereby it offers customers a number of different financial options for its products and services, from a straight cash purchase of the Unyvero Platform, to reagent lease/rental agreements (pursuant to which Curetis would provide the Unyvero Platform on the basis that the customer commits to buying a certain number of Application Cartridges from Curetis over a set period of time, with the cost of such Application Cartridges incorporating a reagent rental charge for the use of the Unyvero Platform). Similar concepts are employed by Curetis' distribution partners at their discretion.

**Investment in brand awareness.** As Curetis is marketing its innovative Unyvero Platform to a diverse and demanding customer base implementing a solution that offers the potential to improve upon the current standard of care, Curetis' management believes it will need to continue making additional investments in clinical validation, scientific publications, brand awareness and market education worldwide, but with a focus in the EU and United States. Some of Curetis' tests will require market access activities to prove their value and to obtain sufficient reimbursement by relevant payers for certain countries.

Curetis has developed a full suite of marketing communications tools using print and online channels. Curetis also supplies supporting evidence for the various individual stakeholders, for instance approaching microbiologists and clinicians with first-in-class scientific marketing. This not only includes the classical marketing mix (i.e. a set of marketing tools regarding product, price, place and promotion), but also compiles information on health economics and clinical outcomes research.

In addition, Curetis' marketing focuses on medical education of physicians through its team of clinical application specialists, participation in scientific conferences, organizing scientific sessions and symposia, and by publications in peer-reviewed journals.

In order to receive valuable input during research and development, stimulate market awareness and the

demand for its products, Curetis has made a significant investment in establishing scientific advisory boards in Europe and the United States Both advisory boards are comprised of key opinion leaders. In addition, follow-on research and clinical studies are conducted at key opinion leader, or KOL, sites, which assist in increasing market awareness. The KOL selection by Curetis is based on the following criteria:

- The KOL has a strong reputation in the area of infectious diseases and/or in molecular diagnostics;
- The KOL is a key opinion leader in the clinical and/or laboratory space with strong influence on peers;
- The KOL is an 'early innovator', a member of clinical society, an editor of scientific journals or a member of a guideline-setting agency and could therefore act as a promoter of the product.

**Distribution Channels.** To distribute the Unyvero System and the Application Cartridges, Curetis, following its revised strategy as of December 2018, has adopted a dual approach combining direct sales in the United States with indirect sales through specialized distributors in European countries such as Germany, Austria, Switzerland, UK, France, BeNeLux, Spain, Italy, Russia, Bulgaria, Romania, Greece, Israel, the Middle East, including Qatar, Kuwait and the UAE and Asian countries such as Indonesia, Malaysia, Singapore, Thailand, China, Taiwan and Hong Kong and other markets outside the United States.

The choice between direct sales and indirect sales distribution is based on available funding for Curetis' commercial operations, the attractiveness of the market in terms of size, pricing, and reimbursement, the ease of market access in terms of regulations, structure and complexity of the healthcare system, and payer situation. Markets are also selected based on the availability of suitable distributors with appropriate size, portfolio, sales channels, experience, networks, and reputation to introduce an innovative product like Unyvero in their respective market. It is also not uncommon for MDx companies to start with a distributor model before going direct once economics permit establishing a direct sales infrastructure.

Curetis going forward will regularly evaluate on a case-by-case basis whether the chosen distribution channel is adequate to also cater for the new target disease segments, or whether a new structure should be put in place.

# **Direct Sales Markets**

Direct Sales ex-U.S. (until March 2019)

Unyvero was initially launched in 2012 in the home market of German speaking countries, i.e. Germany, Austria and Switzerland by Curetis' own sales force combining expertise in microbiology with expertise in hospital IVD sales, instrument business, and consumable sales. Since its IPO in 2015, Curetis had been addressing key Western European markets directly and in 2016 started establishing regional sales teams and wholly owned subsidiaries in key markets such as France, the Netherlands (for BeNeLux region), the UK and Switzerland. As of 31st October 2018, a team of seven clinical application specialists and scientific affairs as well as field engineering support experts were engaged in the scientific and clinical aspects of the sales process, taking responsibility for customer training and supporting the sales team. Additional team members for commercial partner support, marketing and product management and internal sales support round out the EMEA commercial team. However, in December 2018, Curetis revised its sales channel strategy for ex-U.S. markets and switched to an indirect distributor driven sales model. The commercial team at Curetis GmbH was streamlined accordingly to provide optimal support for distribution partners and as of today consist of six experts for marketing, customer service and support, and business development. Following this revised strategy, A. Menarini Diagnostics in March 2019 took over markets previously served directly, i.e. Germany, France, Benelux, UK, Switzerland, as well as additional European markets, i.e. Italy, Spain, Portugal, and Sweden.

# Direct Sales U.S. Market

Curetis USA completed trial enrolment for the LRT Application Cartridge in June 2016. Top line data was reported in October 2016 and the FDA *De Novo* request was submitted on 5<sup>th</sup> January 2017. This was followed by a submissions issue meeting with the FDA in April 2017 as well as interactive review

ongoing with the FDA, culminating with FDA clearance on 3<sup>rd</sup> April 2018. Curetis launched the Unyvero System and the LRT Application Cartridge at the ASM Microbe 2018 Congress in the United States in June 2018. In December 2019, Curetis furthermore received 510(k) clearance for the LRT Application for BAL samples, follow by its commercial launch in Q1 2020.

Curetis markets and sells the Unyvero Platform and will market any future cleared Application Cartridges directly in the United States through its own U.S.-based commercial organization including sales, marketing and after-sales support. This takes the form of a wholly owned subsidiary Curetis USA, which was established in July 2016 in San Diego, USA, shortly after trial enrolment was completed. A core leadership team of five were hired over the next six months. The original full commercial teams consisting of sales, marketing, clinical and customer support, operations and general administration were hired over the course of the third quarter of 2017 and the first quarter of 2018, bringing the total number of U.S. employees to 25 by October 2018.

Despite the revised strategy communicated in December 2018 and the re-organization Curetis USA Inc. in January 2019, which has reduced the size of the team in the United States to 10 full time staff as of December 31, 2019, with the majority being based in the field, Curetis USA Inc. has built a funnel of target accounts and opportunities As of December 31, 2019, Curetis USA Inc. had an installed base of 17 Unyvero Analyzers across the United States and in different types of hospitals and labs Clinical and commercial evaluations are ongoing at multiple of these accounts with first evaluations scheduled to conclude in late 2019.

Indirect Sales Markets. Curetis uses its standard distribution agreement template for most of its Unyvero distributors, which specifies the particular Unyvero product and the respective distribution territory. The distribution agreements typically contain provisions for exclusive distribution within a particular territory and provide for a three to five-year term. During that period, the distributor has exclusive rights to market, sell and distribute all Unyvero products under this agreement. In return, each distributor needs to commit to annual minimum purchases of Unyvero Systems as well as Application Cartridges. Transfer prices for the Unyvero Systems and Application Cartridges are defined and reflect typical MDx industry distributor margins on consumable sales. If a distributor fails to meet its annual minimum commitments fixed in the contract Curetis has the right to either terminate such agreement in its entirety, or to terminate said distributor's territory exclusivity in such country. Each of these agreements can be extended by mutual agreement between the parties. Furthermore, the agreements also contain typical change of control provisions, which comprise a merger of the company, the sale of all assets or the liquidation of the company. None of these change of control provisions are expected to have any impact whatsoever post business combination with OpGen as these contracts are expected to continue unchanged.

Curetis has entered into distribution agreements with 18 distributors covering 43 countries. There are several distribution agreements in place for the following European countries:

- Belgium, France, Germany, Greece, Italy, Luxemburg, Netherlands, Portugal, Spain, Switzerland, United Kingdom: A. Menarini Diagnostics;
- Austria, Czech Republic, Slovakia, Slovenia and Croatia: Axon Lab;
- Romania: Synttergy Consult LTD;
- Bulgaria: SGP Bio Dynamics Ltd;
- Ireland: Cruinn Diagnostics;
- Russia, Ukraine, Kazakhstan: BioLine LLC;
- Belarus: BioLine BS LLC; and
- Bosnia and Hercegovina, Montenegro, Serbia, North Macedonia: Ako Med d.o.o.,

In the RoW markets, Curetis currently plans to commercialize Unyvero through distributors.

As for the ongoing distribution agreements in some European countries mentioned above, Curetis expects its current and future distributors at their expense to:

- cater for local product registrations as required;
- perform local clinical studies as required;
- take responsibility for local marketing based on guidelines and materials provided by Curetis' global marketing team;
- maintain a local inventory; and
- install the Unyvero System, train customers, and provide first-level service.

Distribution agreements usually feature minimal sales commitments and purchase commitments of the Unyvero Systems and Application Cartridges commensurate with the size and structure of the respective market.

Currently further distribution agreements are in place for the following countries:

- Qatar & UAE: Al Zahrawi Medical LLC;
- Kuwait: ATC;
- Singapore, Malaysia, Indonesia and Thailand: Acumen Research Laboratories; and
- China, Taiwan and Hong Kong: Beijing Clear Biotech/ Technomed (Hong Kong) Ltd.
- Vietnam: Quaphaco
- Israel: Rhenium Ltd
- Egypt: Future Horizons Scientific
- Mexico: Quimica Valaner
- Uruguay: Biko S.A.

The total contractual minimum purchase requirements of all distributors amounts to 453 Unyvero Systems of which about 360 are part of BCB's commitment, which applies over an eight year period following NMPA approval and 1,533,264 Application Cartridges (HPN, ITI, BCU, IAI, UTI) of which approximately 1,500,000 are part of BCB's commitment) in the period between 2018 and 2027, subject to extension in certain events (for example, regulatory delays in the case of China). Failure of distributors to reach minimum purchase quantities has not led to any "forced" purchase of the minimum quantities in the past, but can lead to a termination of the distribution agreements or termination of exclusivity in territories for such distributor at the sole discretion of Curetis. The above minimum purchase requirements do not guarantee any certain minimum future levels of revenues.

After-sales support and maintenance. For after-sales support and maintenance, Curetis has established a concept of system replacement instead of onsite repair. Thus, in the event of system failure or required maintenance, systems are rapidly replaced (within one or a few days), minimizing downtime for the customer as well as reducing the need for a costly service organization. In certain instances, e.g. if export / import restrictions make a simple replacement cumbersome and time consuming e.g. in Russia or the Middle East Curetis, uses its own small field service engineering team to provide ad hoc on-site repair and service. In the future Curetis expects to establish a service maintenance arrangement where customers pay for support and repair based on what service package they have purchased.

### REIMBURSEMENT

In the IVD market, sales volumes and prices of innovative products will depend in large part on the availability of coverage and reimbursement from third-party payers, which includes depending on public funding through governmental programs, private insurance plans and workers' compensation plans. In most healthcare settings, reimbursement schemes are complex, processes to achieve reimbursement for new technologies is tedious and time consuming and payers may deny coverage or reimbursement. As a result, even though a new product may have been cleared for commercial distribution, it may find limited demand for the product until reimbursement approval has been obtained from governmental and private

third-party payers. However, specific reimbursement codes for laboratory tests are in most countries only applicable for out-patient's healthcare. In addition, some public funding is already available in most countries for certain established tests and is often technology specific, thus code stacking or cross-walking and using corresponding codes is quite usual to overcome challenging reimbursement situations.

Curetis has analyzed existing reimbursement schemes in Germany, Austria and Switzerland, as well as other European countries and the United States, where hospitalized in-patients with severe infections are typically covered under the DRG system. With DRG, hospitals receive a lump-sum payment, e.g. up to EUR 22 thousand in Germany for a life-threatening case of VAP treated in intensive care. Therefore, Curetis has taken the strategic direction to target hospitalized patients first as in most countries DRG systems as hospitals' general financing are in place covering diagnostics as part of a lump sum payment per patient without specific reimbursement codes for a laboratory test required.

In addition, the current list prices and future anticipated application prices for Curetis' Application Cartridges, amount to a small fraction of this overall DRG payment. It is also favorable in some countries, such as the United States, that pathogen identification by a lab test may even warrant coding to higher DRG rates. For example, Curetis USA has been working with outside consultants to correctly position the LRT Application Cartridge in the context of relevant DRG codes so that, based on the pathogens identified by the LRT Application Cartridge, it can offer hospitals more favorable DRG coding and higher reimbursement on a per patient case overall.

Curetis' management believes that existing DRG reimbursement scheme codes and optimization potential based on a Unyvero diagnostic within those applicable DRGs and their national equivalents can be used in most major markets and therefore an adoption of the Unyvero technology seems feasible.

### SCIENTIFIC ADVISORY BOARDS

Curetis has established an EU Scientific Advisory Board consisting of four persons and a U.S. Scientific Advisory Board consisting of five persons, or the SABs. The goal of the SABs is to advise Curetis on important trends and issues in clinical microbiology as well as novel product concepts addressing key questions and challenges in the diagnosis of severe infections in hospitalized patients. The SABs provide valuable insight and guidance along the entire value chain of innovative molecular diagnostic products.

#### **MANUFACTURING**

For instrument manufacturing, Curetis has decided to co-develop and subsequently outsource all of its instrument manufacturing to Zollner. With regard to Application Cartridges, they are developed and manufactured entirely in-house, using equipment provided by Contexo and certain components provided by Scholz. Curetis has established a sophisticated manufacturing site for its cartridges where it has full control over the entire production process ensuring that Application Cartridges meet stringent quality requirements.

**Unyvero System.** Curetis' EMS (Electronic Manufacturing Services) provider Zollner is an established and experienced medical device manufacturer for large companies and has flexible production processes ensuring it can meet demands with different volume requests. Zollner has established a Curetis dedicated manufacturing island and Unyvero team where in a single eight-hour shift for five days a week, up to four systems (Unyvero L4 Lysator, Unyvero C8 Cockpit and Unyvero A50 Analyzer) can be assembled and tested per week. Zollner has an established 24/7 manufacturing operation, providing significant capacities and capabilities for major scale-up of Unyvero manufacturing operations. Curetis' management believes that manufacturing capacity will not become a bottleneck in the foreseeable future. Zollner also has all required certifications under all applicable ISO standards for IVD instrument manufacture and is also setting up the Unyvero System manufacturing in order to be compliant with future U.S. FDA inspections and manufacturing standards However, to the knowledge of Curetis, no such U.S. FDA inspection with regard to Unyvero system manufacturing has taken place as of today.

So far, no decision has been made on the selection of the OEM provider for the series production of the Unyvero A<sub>3</sub>o *RQ* systems.

Application Cartridges. As part of its operational strategy, Curetis decided to build and operate its own manufacturing facility inside premises leased to it for the manufacturing of the Application Cartridges. The Application Cartridge manufacturing facility based in Bodelshausen, Germany, has been operational since October 2011. Curetis is able to manufacture sufficient product to meet current and forecasted demand. Curetis expects future Application Cartridges to be used with the Unyvero A30 RQ Analyzer for own R&D purposes, potential own products of OpGen and/or potential products by Unyvero A30 RQ licensees will also be manufactured in Bodelshausen, in a dedicated manufacturing line module to be developed and built by Contexo and using plastic parts build by Scholz.

Curetis' headquarters in Holzgerlingen, Germany, as well as Curetis' manufacturing facility in Bodelshausen, Germany have been subject to an FDA inspection in February 2019 successfully completed with several recommendations but no FDA Form 483 observations.

### MANUFACTURING AGREEMENTS (CURETIS GMBH)

**Zollner.** On 27<sup>th</sup> May 2009, Curetis and Zollner Elektronik AG, Zandt, Germany, or Zollner, entered into a framework agreement, pursuant to which Zollner performs certain development and manufacturing services for the Unyvero System. Under the terms of the agreement, each party retains rights to its respective intellectual property. The agreement specifies that manufacturing intellectual property created jointly or solely by Zollner while performing work and services for Curetis shall be solely with Zollner. For any manufacturing intellectual property owned by Zollner, Curetis receives a non-exclusive, non-transferable, world-wide, royalty free, irrevocable perpetual license (without a right to sublicense) to use, provided that such manufacturing intellectual property is embodied in a product provided to Curetis. As of today, there is no such manufacturing intellectual property. The agreement is for an indefinite period of term and may be terminated with 12 months' prior written notice.

The framework agreement has been expanded by a development agreement in 2010 and related project agreements for various development projects as well as by a strategic supply agreement signed in June 2013 under which Zollner became the OEM contract manufacturer for all Unyvero instrument systems for Curetis.

**Scholz.** On 1<sup>st</sup> February 2013, Curetis and Scholz entered into a framework agreement, pursuant to which Scholz is requested to perform certain services in the area of tool development and tool making (injection molding tools to make plastic parts) and manufacturing product components (i.e. all plastic parts for the Application Cartridges) for Curetis. The parts for the Unyvero A50 products comprise inter alia the base plates, valve plate, PCR chamber parts, spin column holder, waste chamber, reagent container, plungers and housing body parts. All rights, title, interest and ownership in the injection molding tools and plastic products specified in this agreement, including the respective intellectual property rights shall be transferred and assigned to and solely belong to Curetis. Under this agreement, Scholz guarantees that all such rights solely belong to Curetis. The framework agreement constitutes the legal basis for all legal relations between the parties after February 2013, in particular for the supply agreement. On 2<sup>nd</sup> January 2013, Curetis and Scholz entered into a supply agreement pursuant to which Scholz shall manufacture and supply products, such as base plates, valve plates, PCR chamber parts, spin column holders, waste chambers, reagent containers, plungers or housing body parts exclusively for and to Curetis. Both agreements are for indefinite period of term and may be terminated with 12 months' prior written notice. All molds owned by Curetis before collaborating with Scholz were transferred from a previous supplier to Scholz to ensure an immediate production start in January 2013.

In addition to volume production with these pre-existing molds, Curetis subsequently commissioned a series of multi-cavity injection molds (owned by Curetis yet stored and used on site at Scholz) under a strategic lease agreement with Scholz for all injection molded plastics parts entered into on 28<sup>th</sup> July 2015. The agreement is for an indefinite period of term and may be terminated with 12 months' prior written notice or may be terminated earlier by Curetis once the last order for related plastic parts has been fulfilled.

Under the framework agreement with Scholz, Curetis in 2018 also commissioned several single- and multicavity injection models for parts of the Unyvero A30 RQ cartridge, namely molds for 'Frame bottom', 'Frame top', 'PCR Disc', 'Drive Ring', 'Switching Wheel bottom', 'Switching Wheel top', 'Sealing Ring switching wheel' und 'Sealing Ring PCR disc'. These injection molds were developed, manufactured and put into

service by Scholz over the course of 2018 and 2019 under the same terms as described above for the injection molds for the Unyvero A50 cartridges.

## SUPPLY AGREEMENTS (CURETIS GMBH)

PCR Master Mix Supply Agreement. Effective as of 19<sup>th</sup> October 2017, Curetis entered into a supply agreement, updating the previous supply agreement between the parties dated 1<sup>st</sup> January 2010, with a large single-source supplier for purchase of PCR Master Mix reagent and other product components, which are used as integral parts of Curetis' Application Cartridges. Pursuant to the agreement, Curetis has the right to resell such product components supplied under the agreement, except for the PCR Master Mix, in conjunction and jointly repackaged with Curetis' products worldwide. Further, the agreement provides that Curetis has the right to resell the PCR Master Mix repackaged and refilled for use only in conjunction with Curetis' products worldwide. Pursuant to the PCR Master Mix supply agreement, Curetis' distribution right is limited to the sale to end-users and Curetis' distributors and does not include sales to users who re-sell Curetis products in modified form (e.g. using their own brand) or sales, which would violate any sanctions, embargos or foreign trade restrictions issued by the EU or the U.S. Further, Curetis, or any of its affiliates or distributors, are not permitted to resell any of the product components, including the PCR Master Mix, to third parties as stand-alone items for use other than in conjunction with Curetis' products. Under the agreement, Curetis is subject to certain minimum annual purchase requirements.

### SUPPLY AGREEMENTS (ARES GENETICS GMBH)

Qiagen GmbH (Qiagen) – Laboratory Devices and Reagents. Effective as of 1st August 2019, Ares Genetics entered into a multi-year supply agreement with Qiagen that encompasses a free of charge rental of laboratory devices as well as maintenance services. The agreement also includes supply of reagents for DNA extraction and NGS library preparation that guarantees Ares Genetics favorable fixed costs per sample for DNA extraction and fixed costs per library preparation in the first year with some further discounts with scaling in the following years.

MGI Tech Co. Ltd. (MGI) – Laboratory Devices and Reagents. Effective as of 24<sup>th</sup> April 2019, Ares Genetics entered into a supply agreement with MGI that encompasses a free of charge rental of a MGISEQ-200 sequencer as well as favorable terms for services and reagents. Further the title of the MGISEQ-200 sequencer will transfer to Ares Genetics if Ares Genetics cumulative purchase of consumables reaches certain thresholds before termination or expiry of this Agreement by 31<sup>st</sup> March 2021 (if not extended).

### CURETIS' PRODUCT DEVELOPMENT & R&D PIPELINE

#### Unyvero Product Development Phases



Figure 5: Curetis product development process

Curetis' Unyvero product development follows a systematic stage-gated process, as shown in the figure below, of five phases under its ISO 13485:2016 certified Quality Management System (Figure 5). The time to develop and market a molecular diagnostics product varies and depends on many factors such as the multiplexing level, amount of different sample types, the targeted clinical indication and expected performance in terms of clinical sensitivity, as well as clinical specificity. On average, the development of a new Application Cartridge through to market launch as CE-IVD-marked Application Cartridge in the EU takes 12 months or longer. Development costs are to some degree dependent on the Application Cartridge complexity and regulatory pathway. Once the new IVD Regulation repealing the IVD Directive and the Commission Decision 2010/227/EU will have become applicable in 2022, such processes are expected to take

even longer, e.g. from 12 to 18 months.

For all of its current Application Cartridges, as well as new products, Curetis typically sets up sponsor-initiated and investigator driven studies depending on the product life cycle of the test. In the initial phase, observational studies focus on product performance comparing the Unyvero test to the standard of care. These are often followed by trials evaluating clinical validity, as well as proving clinical utility.

#### APPLICATION CARTRIDGES FOR THE UNYVERO A50 ANALYZER

The Unyvero LRT BAL Application Cartridge. With the current Unyvero LRT Application Cartridge for lower respiratory tract (LRT) infections being cleared for the use with tracheal aspirates as a sample type, on 23<sup>rd</sup> July 2019, Curetis filed for 510(k) clearance of an LRT application cartridge optimized for use with BAL as an additional sample type. BAL is another common sample type for the diagnosis of lower respiratory tract infections. It is estimated that half of the samples obtained for the diagnosis of lower respiratory tract infections are BALs, and Curetis believes that a clearance of an Unyvero LRT Application Cartridge for this additional sample type would increase the total addressable market for Unyvero in the United States accordingly. The FDA submission for clearance of the LRT BAL Application Cartridge builds on data from 1,400 patient samples in total obtained from prospective and retrospective cohorts demonstrating an overall weighted average sensitivity of 90.1% and 94.7% and an overall average weighted specificity of 98.4% and 97.9% across all pathogens in the prospective and retrospective cohorts, respectively. The study was complemented by an additional set of 240 contrived samples, which successfully confirmed performance of LRT BAL with negative patient samples that were spiked with rare pathogens and resistance markers at known concentrations. Overall, more than 5,500 LRT BAL cartridges were run as part of the comprehensive analytical and clinical performance evaluation. On 20 December 2019 the FDA cleared the LRT BAL Application Cartridge including all analytes filed i.e. also including Pneumocystis jirovecii.

The Unyvero IJI Application Cartridge. As a follow-on product to the Unyvero LRT application cartridge, Curetis has pre-developed the Unyvero IJI Invasive Joint Infection Application Cartridge, a derivative of the CE-IVD-marked Unyvero ITI Application cartridge with a focus on joint infections and prosthetic joint infection with synovial fluid as a sample type. In preparation of a U.S. FDA submission, Curetis has initiated testing of clinical samples at three participating hospitals in the United States in December 2018 and subsequently took the strategic decision to only fully develop the product in collaboration with and with cofunding by suitable partners in the orthopedics field or sufficient funds being available to Curetis. Curetis, however, has continued the collection of retrospective samples for its U.S. trial for the Unyvero IJI Invasive Joint Infection product to augment the future prospective arm of such clinical trial. An initiation of the prospective arm of the trial will depend on Curetis partnering for the further development as well as the commercialization or otherwise raising the capital needed to fund such a trial of this unique Application Cartridge.

The SHR Application Cartridge. Curetis has entered into a licensing and research and development agreement with Acumen (Singapore), that developed a proprietary panel of mRNA biomarkers and an interpretative algorithm for the analysis of peripheral blood lymphocytes (AcuSept). The panel allows (a) the detection of an infection and (b) the early detection of sepsis based on altered gene regulation in the patient's immune cells. The biomarkers constituting the panel were discovered by microarray technologies and validated by manual real-time PCR. However, for an effective adoption of the test in the clinical routine, a sample-to-answer solution that can be implemented in a near-patient setting is required. Accordingly, Curetis and Acumen have been working on the transfer of the panel to the Unyvero Platform and anticipate a joint further clinical validation of this SHR Application Cartridge.

Curetis' management expects that an Application Cartridge for the early diagnosis of sepsis will make a difference in a significant proportion of cases and, as it can be performed within the first hours of hospital admission, may also help to save significant costs. Curetis estimates the sepsis host response market to be larger than the microorganism ID in blood cultures addressed by its BCU Application Cartridge. Based on CDC and ECDC data from 2018 regarding market potential, around 2.3 million patients would be eligible for a SHR test representing a total available market in the United States and EU of several hundred million Euros

depending on price points. As Sepsis Host Response testing is a complementary application, major cannibalization of the BCU Application Cartridge is not anticipated at the outset.

### THE UNYVERO A30 RQ ANALYZER





Figure 6: latest design concept of Unyvero A<sub>3</sub>o *RQ* Analyzer and its Application Cartridge; final product may differ

Curetis acquired a prototype version of the Unyvero A30 RQ Analyzer module from Carpegen and Systec in December 2016 (then called Gyronimo). Currently in the development stage, Curetis intends to fully and seamlessly integrate the Unyvero A30 RQ Analyzer into its Unyvero System suite of products with respect to system architecture, design, software and handling. In doing so, Curetis is expanding its Unyvero Solution to include 'any-plex' capabilities, addressing new market segments and diversifying its application pipeline.

The Unyvero A30 *RQ* Analyzer is expected to offer a rapid time-to-result (potentially as fast as 45 to 90 minutes), qualitative and, where needed, quantitative real-time PCR testing in a cartridge format that can provide up to 11 parallel multiplex qPCR reactions from one sample. As such, it lends itself to medium- and low-plexing applications with the potential for up to about 30 diagnostic targets with some additional controls as well as the possibility of screening and triage tests to screen patients upon their admission to hospital or triage patients through simple panels into two groups who get different follow-up treatment and testing. Importantly, the new Unyvero A30 *RQ* Analyzer module will use the same Unyvero sample tube as the Unyvero A50 Analyzer module, leveraging the capabilities of the Lysator for seamless workflow integration and flexible handling of diverse native patient samples. It is expected to be easy to use, have a small footprint and be point-of-care capable. In addition, to be a module for integration into the Unyvero Platform, a future stand-alone version is envisaged for certain applications, particularly in near-patient settings. The cost of the stand-alone Unyvero A30 *RQ* Analyzer and its consumables is expected to be considerably lower than for the current Unyvero System and the current Application Cartridges.

As of  $31^{st}$  October 2019, the first multiplex real-time PCR were successfully run on fully functional prototypes and all aspects of cartridge manufacturing were fully specified and in development or implementation phase.

With its unique features, the Unyvero A<sub>3</sub>o *RQ* will lend itself to numerous applications in infectious disease testing but also in numerous indications that are beyond the commercial focus of Curetis, including cancer, genetic testing and companion diagnostics, as well as veterinary or food and environmental testing. Following its strategic shift to a more partnering-based strategy in December 2018, Curetis hence is seeking diagnostics industry partners to collaborate in the late stage development and commercialization of Unyvero A<sub>3</sub>o *RQ* and expects the platform to ready for partnering in 2020, funding permitting.

#### ARES GENETICS - ARESUPA - UNIVERSAL PATHOGENOME ASSAY

In September 2019, Ares Genetics initiated the development of its AI-powered ARESupa - Universal Pathogenome Assay. The assay for the diagnosis of microbial infections and antimicrobial drug response is based on the Ares Genetics' proprietary ARES Technology Platform and genetic antimicrobial resistance database ARESdb.

ARESupa is intended to cover nearly any pathogen in a broad array of sample types and to predict antimicrobial drug response to a wide variety of treatment options using a single, uniform laboratory workflow. In August 2019, Ares Genetics opened an NGS service laboratory that – among other services – started offering a first generation of ARESupa for clinical isolates enabling accurate pathogen identification and detailed assessment of the presence of AMR genes or mutations that are likely to render a pathogen resistant to antibiotics. In October 2019, Ares Genetics launched an early access program for an advanced version of ARESupa an artificial intelligence (AI) powered, next-generation sequencing (NGS) based molecular antibiotic susceptibility test (AST). The second generation of ARESupa is capable of also accurately predicting antibiotic susceptibility via AI-powered interpretation of high-throughput DNA sequencing data. ARESupa is initially offered for non-human diagnostic uses by AMR researchers, hospitals, public health institutions, and pharmaceutical companies. With ARESupa, Ares Genetics aims at supporting the cost-effective analysis and management of outbreaks of multidrug-resistant bacterial pathogens in hospitals and care facilities as well as facilitating molecular epidemiology by public health institutions and hospitals and antimicrobial drug development and AMR research.

Funding permitting, Ares Genetics further aims at developing and launching am ARESupa laboratory-developed test, or LDT, on native patient samples for human diagnostic use in indications in which current culture-based diagnostic practice is inherently challenging. The test would be offered through Ares Genetics own laboratories in in Vienna and potentially the United States and potentially partner laboratories in other geographies. Eventually, the development of an ARESupa IVD solution is envisaged. To this end, Ares Genetics in September 2019 entered into a multi-phase partnership with an undisclosed leading global in vitro diagnostics corporation to jointly develop diagnostic solutions for infectious disease testing based on next-generation sequencing technology. The companies signed an R&D and option agreement for the first phase of the partnership. In this phase, expected to take about 10 months, the partner will fully fund Ares Genetics' research and development activities for the genotypic and phenotypic characterization of additional bacterial strains to augment ARESdb and the development of optimized algorithms for predicting antibiotic resistance. Furthermore, in return for an undisclosed up-front option fee, the partner obtained a right of first negotiation for an exclusive human clinical diagnostic use license to ARESdb and the ARES Technology Platform for the term of the agreement plus three months.

Ares Genetics' R&D programs for the development of ARESupa are co-funded by non-dilutive public grants provided by the Vienna Business Agency, the Austrian Research Promotion Agency (FFG), and other.

#### **STRENGTHS**

Curetis believes that the following strengths will enable it to execute its strategy:

- Business combination with OpGen to create a leading company in the molecular AMR detection space with proprietary platforms, premier Bio IT offerings and broad databases.
- Commercial stage: 173 installed Unyvero A50 Analyzers as at 31 December 2019 in Europe, the Middle East, and in the U.S. and the ASEAN region, with direct sales in the U.S. and an increasing network of commercial partners covering 43 countries as at 31 December 2019.
- Targeting Large Market Opportunity: Curetis estimates that the addressable market for its current and nearer-term Unyvero Application Cartridges is about 10 million cases eligible for testing per year in the EU and the U.S.
- Comprehensive platform: processing numerous sample types and covering more microorganisms and resistance markers than competing platforms.
- Validated Unyvero Platform: extensive clinical studies (including U.S. FDA trial for the LRT and LRT BAL Application Cartridges) and endorsements from key opinion leaders and a top-tier investigator base.
- Expanding target market: planning to enter low- and medium-plex market segments through partnering of the Unyvero A<sub>3</sub>o RQ Analyzer for infectious disease testing and potentially further indications with suitable partners in the diagnostics industry.
- Set to become a broad solution provider in molecular microbiology with versatile and proprietary Unyvero platform and proprietary AMR content through ARESdb for Unyvero and third-party platforms, for example in the NGS space.
- Attractive health economics: Curetis believes that the Unyvero Platform supports improvements of hospital economics by allowing effective treatment to be administered more quickly.
- Seasoned management team: combining decades of technological, operational and commercial experience.
- Fully integrated company controlling all key aspects of its value chain such as development, manufacturing, and commercialization.
- Significant upside through partnering opportunities through the ARES Technology Platform and ARESdb as well as the Unyvero Platform.

# II. CORPORATE GOVERNANCE

## RISK MANAGEMENT PROCEDURES

Before making a decision on whether to invest or not, prospective investors should carefully consider the major risks and uncertainties, which may translate into either upside or downside potential – up to and including a complete loss of any investment - which may or may not occur. Since the delisting on 6<sup>th</sup> May 2020, shares in Curetis N.V. are no longer traded on Euronext and an investment into or sale of such shares is no longer possible.

Curetis is facing a number of the material risk factors described below, and one or more of these risks might be interdependent. The order in which these risks are presented below is not meant as any indication as to the likelihood of such risks actually occurring, nor of the potential significance or materiality of the risks or of the level of any potential harm to Curetis' business, results of operations, financial position and future outlook.

These risk factors are all based on a series of assumptions and are subject to management judgement that may turn out to be incorrect. Also, despite the fact that Curetis' management believes that the risks and uncertainties described below represent the major and material risks and uncertainties as they pertain to Curetis, additional or alternative risk factors, facts or circumstances not currently known to Curetis, or which it currently assesses to be less critical could, individually or cumulatively, prove to become critically important and might have material adverse effects on Curetis' business, results of operations, financial position and future outlook. The value of Curetis' shares may decline as a result of the occurrence of any or some of these risks, facts or circumstances or as a result of the events or circumstances described in these risk factors, and shareholders may stand to lose some or all of their investment's value.

The risk factors outlined below present an overview of material risk factors that Curetis' management believes to be of critical importance and are therefore brought to the specific attention of all prospective investors. Furthermore, before making an investment decision with respect to any shares, prospective investors should consult their own stockbrokers, bank managers, lawyers, auditors or other financial, legal and tax advisors and carefully review all of the risks associated with an investment in Curetis' shares and consider such an investment decision in light of their personal circumstances and ability to assume the risk / reward profile.

Given its financing needs, various R&D programs, operations and business activities, Curetis faces a number of significant risks and uncertainties. Curetis' management considers a risk to be an event, which can result from any management decision (strategic), an action (operational) or an external circumstance and, in case it was to occur, might cause negative deviations from the planned result (e.g. revenues, earnings or cash flow). In order to capitalize on opportunities, certain risks need to be consciously entered into at appropriate levels. Possible risk mitigating measures include prevention of losses or reduction measures, the creation of adequate reserves or the transfer of individual risks to third parties (e.g. insurance companies).

Deviations from key performance indicators should be identified as early as possible. To that end, Curetis uses a detailed, structured, and timely risk reporting in the accounting and financial controlling system, which includes all relevant information with regard to the assessment of Curetis' position.

Making use of business opportunities is the primary task of each company. The timely and regular identification and assessment of opportunities and associated risks is therefore a core responsibility of all members of staff, but, in particular, a managerial duty. Curetis' planning and forecasting process, regularly held Management Board and Supervisory Board meetings, and the regular communication with all managers responsible for the various projects and cost centers are all essential elements of such risk management.

Throughout 2019, Curetis has continuously used its corporate risk management policy and regular quarterly or ad hoc corporate risk reporting and updates. This system has continued to evolve and will be further finetuned on an ongoing basis, but without any fundamental changes scheduled.

This system of risk management at Curetis is of very high importance and top priority for the Management and Supervisory Boards, respectively. Material risk factors are identified and assessed, as well as the risk mitigation strategies and implementation of specific measures, to reduce the potential impact from these principal risk factors. As in 2018, in 2019 no major failing of the internal risk management and control system was actually identified nor perceived.

The table below not only outlines the key risk factors and uncertainties that the Management Board believes relevant to Curetis' continuity for the period of at least the next twelve months after the preparation of the report, but also provides the risk management approach and a sensitivity analysis of Curetis' financial and operational results to various risk factors. Curetis' internal control systems routinely identify such important risks and their management, which forms the basis for discussion with the Audit Committee, the Supervisory Board and the external auditors. Most of these risk factors have the potential, either individually or in any combination, to significantly impact timelines, costs, and the ability to reach specific business goals in the following areas: operational, commercial, financial, strategic, compliance and reliability of financial reporting. If one or more of these material risk factors were to occur it is quite likely that there would be a potential material adverse effect on Curetis' revenue generating potential, cost structure, ability to ever achieve profitability or to eventually remain consistently profitable. A more detailed and complex sensitivity analysis (e.g. Monte Carlo simulations) across all risk factors and all scenarios is clearly beyond the resources, capabilities and scope of a small company and is therefore not being undertaken. For a summary of financial risk (such as market risk, foreign exchange risk, other market risk, credit risk and liquidity risk) please also refer to the section on "Financial Risk Management" within the consolidated financial statements.

Please note that with the completion of the business combination with OpGen Inc. on 1<sup>st</sup> April 2020 the risks outlined below that pertain to the business of Curetis are no longer of any relevance to Curetis N.V. which has distributed the OpGen consideration shares to its shareholders and has been de-listed on 6<sup>th</sup> May 2020. Thus, these risks while applicable as of 31 December 2019 to the business held for sale are no longer applicable as of the date of this annual report. The only risk that is now material and relevant to Curetis N.V. is any risk to its orderly dissolution. Amongst other things the cash reach from the proceeds generated by the sale of 20% of the received OpGen shares, and any potential shareholder lawsuits or other action taken that might hinder, delay or otherwise make more onerous the dissolution of Curetis N.V.

#### POTENTIAL IMPACT OF COVID-19

The novel coronavirus outbreak could adversely impact our business, financial condition and results of operations. In December 2019, a strain of novel coronavirus surfaced in Wuhan, China. In January 2020, the World Health Organization declared the novel coronavirus outbreak a "Public Health Emergency of International Concern" and the U.S. Department of State instructed travelers to avoid all nonessential travel to China and on 11th March 2020 President Trump banned all travel from the EU into the US for an indefinite period of time. The coronavirus has significantly impacted the global economy, capital markets, and may also significantly impact our business and operations, including the potential delay or reduction in commercial adoption by our direct customers as well as distributors as countries and healthcare systems focus on Covid-19 rather than other indications and do not have the resources required to evaluate and clinically test our diagnostic platforms and solutions. Also, impact could include the interruption of our clinical trial activities, regulatory submissions and our supply chain. As a result of the outbreak, certain of our distributors, suppliers, collaboration partners and CMOs may be affected and could experience closures and labor shortages, which could disrupt their activities. We could therefore face difficulty sourcing key components necessary to produce our product candidates, which may negatively affect our commercial and clinical product development activities. Even if we are able to find alternate sources for some of these components, they may cost more, which could affect our results of operations and financial position. In addition, the coronavirus outbreak could delay enrollment in our commercial evaluations of Unyvero LRT as well as other CE IVD marked Unyvero cartridges, clinical studies, and clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services.

At this point in time, there is significant uncertainty relating to the potential effect of the

novel coronavirus on our business. Infections may become more widespread or re-occur at a later date, including in countries where we are commercializing products directly or via distributors, conducting clinical trials, and manufacturing closures and travel restrictions may remain or worsen, all of which would have a negative impact on our business, financial condition and results of operations.

Corporate Risk Area	Risk Description and Cause	Potential Impact if Risk Materializes	Mitigation Measures			
Product Development Relat	Product Development Related Risks					
Platform Development Risks	The Unyvero platform may lose its broad & unique panel competitive edge compared against competitors' products with similar or disruptive new technologies, may be considered too slow, too large, too expensive by customers or may not fulfil throughput or other customer needs. Additional effort may be required in the future to remain compliant with upcoming regulations (EU IVDR, UDI labeling, controls etc.). Defocusing / lack of resources due to shift of focus to A30 RQ platform, Ares Genetics, or OpGen products. Insufficient improvements on Unyvero platform.  Reduction and/or loss of skills and experience on Unyvero A50 platform to the point of no longer being able to support/maintain platform (R&D and manufacturing). Dependency on external development / collaboration partners may impact timelines and or quality of their respective contributions.  A30 RQ development may face unexpected technical challenges requiring unplanned resources or resulting in unplanned delays. Booming economy may lead to delays due to limited availability of components and external	Slower and reduced commercial uptake in USA; lower U.S. revenues and inability to achieve or maintain profitability in the future; higher cash burn and financing needs.	Continuous improvement of existing processes (e.g. reduce run-time, COGS further), cartridge performance and add new / updated pipeline products (lifecycle management) - acquired GEAR and Gyronimo; effective and efficient Ares Genetics setup; agile development of A30RO platform with crossfunctional team.  Regular meetings and progress tracking of suppliers, development and collaboration partners.  Planning ahead to limit impact of components on allocation and to ensure timely availability of collaboration partners.  Clear communication with potential platform partners is needed to assess and define the impact (cost, duration, effort and likelihood of success) of any customization efforts.			

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	partners. Requests from partner(s) interested in the platforms may lead to late changes in design specifications in order to accommodate specific needs which may disrupt or delay development activities.		
Regulatory Risks			
NMPA Clearance	Curetis relies on its partner BCB to execute regulatory trials and obtain NMPA clearance for marketing its products in China, the second most important market for Curetis after the US. BCB has limited experience in IVD regulatory approval in China, both posing a significant risk to approval timeline and success. Curetis has no own experience with NMPA and limited resources to support BCB from a regulatory and R&D or Clinical Operations perspective. New regulation in place that may allow submission of foreign clinical trial data for HPN/LRT which may shorten overall time to clearance. Further, BCB wants to propose a clinical study with a not yet defined number of Chinese patients to augment the data package with 'Chinese data'. As the data package with foreign data reflect the US study, NMPA may request such study to be of similar complexity as the US study, which would pose severe challenges to BCB and Curetis and hence may push out the timeline for a first NMPA approval.	Delayed or not at all granted NMPA clearance; limited claim sets; slower and reduced commercial uptake post NMPA clearance in China.	Regular and frequent communication with BCB in English. Discussions with NMPA started. Providing substantial input on analytical validation from Curetis R&D. Very regular contact and communications - increase frequency of on-site visits to China. Increase management board attention on the project. Compiled and provided USFDA data to BCB (submitted in Feb 2019 / NMPA expert panel hearing successfully completed Jul 26, 2019). NMPA has extended submission deadlines to account for COVID-19 related delays due to NMPA closure.

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CE-IVD Regulations Tightening	There is an EU wide agreement to significantly tighten and make the requirements for CE-IVD marking more stringent (IVDR) - depending on risk classification of devices this will have more or less impact; adaption of German law pending.	Loss of ISO13485 certification to develop, manufacture and commercialize CE-IVD products; delays in European commercial roll out; higher resource needs and costs; increased cost base and cash burn with increased financing need.	Regulatory Affairs team has been preparing for this; running trials and Regulatory Affairs on an "as if this had already been in effect" for a while. With the grace period running out bottlenecks with notified bodies become clearly visible.
Other Regulatory	Many international markets require regulatory clearance (e.g. Singapore / ASEAN, Russia etc.); national requirements are various and diverse; limited knowledge on such international regulations and high reliance on distribution partners.	Delayed or not at all granted ASEAN market clearance; limited claim sets; slower and reduced commercial uptake post ASEAN market clearance in ASEAN markets.	Work very closely with distribution partners (e.g. Acumen for Singapore, BioLine for Russia / Belarus etc.); Dedicated in-house RA expert for international filings and support; use outside consultants wherever necessary or useful.
R&D	Triton X supplement in Master Mix may become banned substance in EU in due course, which would make it impossible to continue using it. Would require complete alternative development as it seems to be in many buffers / MDx reagents.	Loss of CE-IVD regulatory clearance to manufacture and commercialize current Curetis Unyvero Master Mix would prevent EU sales and marketing; delayed, reduced or even entirely lost revenue stream in EU; higher cash burn and financing needs.	Support lobbying efforts by all Dx industry associations to ensure an exemption for Triton X is made by EU - work on parallel alternative Master Mix solution in R&D with various possible suppliers.
Operational Risks			
Manufacturing: Staff	Well trained and experienced staff is key for manufacturing Unyvero cartridges in larger volumes with constant high quality. Sickness or employees leaving will lead to significant risks for constant high-quality production.	Sickness or leaves will lead to significant risks for constant high quality production resulting in inability to manufacture and sell / deliver high quality IVD products to customers and partners globally; order back log with negative impact on revenue ramp and thus ability to become or remain profitable and achieve target margins in the future.	Hiring of well-educated staff, thorough training of new employees, rotating jobs (ensure that always more than one worker is trained on each and every manufacturing step and production equipment), keep staff highly motivated by creating an inspiring work environment.

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Manufacturing: Production Infrastructure	Unyvero cartridge production requires a significant amount of fully automated and dedicated equipment and cleanroom environment. Any fault, equipment breakdown or infrastructure breakdown / force majeure (power outage, flooding, building collapse) may lead to an immediate production stop and/or destruction of stock.	Production stoppage could lead to order backlog, lost or reduced revenue, inability to serve customers and partners and could negatively impact the business and financials of the company.	Service agreements with equipment suppliers, stocking of critical replacement parts, at least yearly maintenance and calibration for key equipment, surveillance and alarming systems for freezers, monitoring of all relevant cleanroom parameters, stocking of a minimum amount of finished products for immediate customer shipments. Plan for risk assessment by insurance company (general risks). Plan for additional protection against known risks, e.g. protective cover to prevent water ingress. Modify/enhance infrastructure (e.g. access control improvements)
Manufacturing: Processes	Many production steps use sophisticated processes where already slight deviations from the nominal parameters and/or process deviations due to human error (pipetting, labeling of material, mishandling of material) may lead to faulty products.	Not getting production lots QC released; high scrap rates and resulting negative impact on COGS and margins; order backlog and impact on ability to serve customers and generate revenues.	All implemented processes are validated for repeatability and robustness, key process parameters are monitored, process validations are also implemented at key suppliers, process improvements or changes are only implemented after process validation and training of operators for relevant production SOPs / WIs.
	Outsourced production processes: The production of the "Spin Column Holder complete" was completely outsourced to "Behindertenwerkstatt ZAW gGmbH". We have no direct influence on damages of the plant by e.g. fire, flooding.	Not getting production lots QC released; high scrap rates and resulting negative impact on COGS and margins; order backlog and impact on ability to serve customers and generate revenues.	The stock of finished "Spin Column Holder complete" is designed for approx. 3 months cartridge production. A contract regulating such cases was prepared with Behindertenwerkstatt ZAW gGmbH.

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Manufacturing: Quality	Unyvero cartridges are complex products using many diverse parts and processes in clean room environments during manufacturing. Slight degradation of one component or small process variations may already lead to faulty or deficient products. The same holds true for even the slightest contamination of a component.	Order backlog could lead to lost or reduced revenue, inability to serve customers and partners and could negatively impact the business and financials of the company.	At Curetis we strictly enforce following all of our production, hygiene and quality processes, executing NCMR and CAPA processes, very close collaboration with key suppliers etc. Significant tightening of QC procedures,
Manufacturing: Stock-out of One or More Products	In addition to the risks listed above, Curetis may not be able to ship one or more products due to demand fluctuations not covered in forecasting due to the lead time of cartridge and instrument manufacturing.  Lack of experience with new distributor A. Menarini Diagnostics (AMD) may lead to over-/undershooting of forecasted cartridge demand relative to actual cartridge demand and usage, at least initially.	Any failure of any of our parties that we depend on to deliver on time, to the quality standards and at the prices and conditions agreed may cause significant harm to our business; supplier may become competitor and cease collaboration/ supplying products.	Weekly forecasting, ramp- up planning for new markets, flexible workforce for peak demands; allocation in case of product shortage; work tightly with AMD to obtain sufficiently precise forecasts.
Dependence on Third Parties	As a small company Curetis depends on third parties for many aspects of its value chain: suppliers, OEM, logistics providers, distribution partners, development partners, advisors etc. Thus, a lot of aspects of our value creation are not entirely under our control. Any failure of any of our parties that we depend on to deliver on time, to the quality standards and at the prices and conditions agreed may cause significant harm to our	Further loss of critical staff members; delays to execution of important projects; loss of motivation and commitment of remaining employees could negatively impact the business, revenue generation and financials.	Working very closely in collaborative manner along our entire value chain; having clearly assigned contact persons and responsible managers at the interfaces; regular review, audits of 3rd party service providers and suppliers; regular management reviews; put supply/development/qualit y assurance agreements in place with appropriate change of control clauses to ensure reliable supplies; active dialog with Zollner

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	business; supplier may become competitor and cease collaboration/ supplying products.		
Losing Key Personnel	Risk of losing key employees, key contributors or managers - phase of accelerated growth may create opportunities for some but may also lead to a situation where some no longer feel they can contribute as much or do not feel comfortable anymore as pressure increases. After reorganization especial key employees see also that the future perspective at Curetis is difficult and may start to look for new opportunities	Slower revenue ramp and lower margins that prevents Curetis from reaching or maintaining profitability in the future; higher financing needs.	Identify and develop high potentials; stock option-based retention program; create stimulating work environment and assign key employees to the most challenging and most rewarding projects; succession planning; exit interviews; ESOP grants as retention.
Recruiting Risks	It may take significantly longer than expected to fill new positions with highly qualified staff; some positions may not be filled in time for contribution early enough in any given fiscal year / period; it may take higher recruiting efforts and costs (e.g. headhunter fees) to get the right staff on board and packages may need to be bigger than originally expected with a follow-on risk for skewing the overall comp structure towards the newly hired personnel and disadvantaging those who have been with Curetis for many years. Due to the reorganization it will also be difficult for Curetis to attract candidates from permanent employment contracts. It may also be necessary to fill vacant positions with interim management or to	Higher costs in recruiting; delayed filling of positions; strain on rest of organization which in turn could lead to unwanted attrition.	Focus HR team on recruiting also using search firms and interim staffing solutions.

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	outsource tasks/work, which can lead to higher costs.		
Market Risks			
Customer Uptake	Customer uptake in EU markets, in which A. Menarini Diagnostics has taken over, could be slower than expected as it requires changing medical practice based on limited available evidence for medical and health economic benefit and securing funding for our comparatively pricey IVD products.	Slower adoption, lower revenue ramp, delayed commercial traction, higher cash burn and financing needs.	Focus support term on best possible second level customer support and service as well as product management and marketing support for all commercial partners especially A. Menarini Diagnostics in EMEA.
Price Erosion	With more and more competitors entering the market offering similar applications and increasing cost saving pressure in the healthcare market, a price erosion for multiplexed PCR assay is likely to happen. However, all competitors share similar economics making lobbying for sustainable reimbursement a likely scenario. Average selling price (ASP) is down i.e. EU overall - move to Menarini in EMEA will add further pressure on lower transfer prices to ensure adequate margins for commercial partners.	Price erosion, lower margins, harder to achieve and eventually maintain profitability; negative impact on financials.	Focus on unique applications for high medical need questions; increasingly engage in lobbying for adequate reimbursement. Work closely with A. Menarini Diagnostics and all other strategic distribution partners to ensure optimum pricing strategy across key markets.
Competing Products	More and more competitors with sample-to-answer multiplex PCR systems entering the market that may offer directly competing applications may limit Curetis' market penetration and market share; Unyvero may be considered technically outdated in terms of assay technology, TAT, throughput, and footprint. esp. after bioMérieux	Slower adoption, lower revenue ramp, delayed commercial traction, higher cash burn and financing needs.	Focus on applications that play the strength of Unyvero; continuously update and improve applications in markets where regulatory feasible; create content leadership by increasingly including proprietary content into our panels. Create additional more competitive platform options; strive to bundle Unyvero with additional

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	pneumonia panel has received FDA clearance.		products into workflows. ARESdb provides Curetis with added content leadership and flexibility on menu, multiplexing and pricing.
Reimbursement	Curetis current reimbursement concept relies on tapping the DRG budget (Germany) for patients. However, most DRGs in markets currently addressed by Curetis do not consider multiplex PCR as part of the regular patient care; further, labs cannot easily access the DRGs directly as they are considered cost centers with a fixed budget. These circumstances may pose a significant risk to securing funding for Unyvero by Curetis' customers.	Loss in margins might impact revenue ramp and ability to become profitable or maintain profitability in the future.	Collect data supporting a viable health-economic case for use of Unyvero within the financial constraints for the hospital; work with trade association to secure extra funding for multiplex PCR within relevant DRGs – initial success by securing a specific OPS code in Germany.
Partnering Risk (Technology Out-Licensing)	With slower than expected revenue growth from product sales and a challenging capital market environment for Curetis' equity story, Curetis has to increasingly rely on non-dilutive funding through licensing deals e.g. by outlicensing Unyvero A30 RQ for certain geographies and/or indications, or providing sublicenses to ARESdb for research, pharma, or diagnostic use. Without such deals, Curetis cash position may (a) slow down development of products based on such technologies (A30 RQ/ARESdb) putting a risk to Curetis competitive positioning in its core market or Curetis may even run out of cash.	Delays in partnering would lead to lower revenue and less cash inflow, higher cash burn rate and thus higher financing need or need to slow or cancel whole R&D programs with negative impact on future value creation potential.	With A30 RQ development not yet having reached maturity for out-licensing with the current funding, need to focus on out-licensing deals for Ares Genetics assets; revisit A30 RQ out-licensing once funding is available for further development, e.g. through grants

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USA Commercial & Strategi	c Risks			
Customer Uptake	BioFire FDA clearance of panel similar to Unyvero LRT but including three sample types, semi-quantitative analysis and viruses instrument may impact uptake of Unyvero in the US; sales cycle for evaluation sites is taking 4-6 months longer than initially stated, with the first few evaluation accounts coming on board in Q4-2018. Several commercial conversions now expected for Q1-2020.	Slower U.S. adoption, slower customer conversion and revenue ramp; continued investment needed, higher cash burn and negative impact on financials.	Will leverage new BAL and <i>Pneumocystis</i> clearance to target new accounts and customers who have been waiting for this clearance; deploying new lead generation tools via LinkedIn to expand promotional and demand generating scope; use new data published at ASM Microbe and from U.S. study sites to help with clinical utility story; employ new angle of marketing/positioning.	
Competing Products	BioFire received FDA clearance of their pneumonia panel in November 2018. They can leverage a larger installed base of FilmArray systems already placed in the market as well as a significantly larger sales organization. Further, they could pursue an aggressive pricing strategy. Accelerate Dx looking to launch into pneumonia in early 2020.	Slower U.S. adoption, slower customer conversion and revenue ramp; continued investment needed, higher cash burn and negative impact on financials.	Focus on differentiators (LRT BAL is only pneumonia product which includes <i>Pneumocystis</i> ) and smart tactical marketing; adjust pricing DRG models with new list price to compete on price with BioFire; target non-BioFire accounts based on market intelligence; deploy new marketing agencies tactical collateral to help with refreshed branding and messaging for Unyvero LRT; prepare messaging in case of AccelerateDx launch.	
Reimbursement	In the absence of specific CPT codes, and under a DRG system with increasing cost-awareness of the hospitals, customers may fail to see the health economic benefit without suitable study data.	Customers unable to justify costs reimbursement might in turn lead to slower adoption and negative impact on revenue.	Start generating health economic models and date showing cost-effectiveness on a hospital and/or health system level.	
Legal & Compliance Risks				
Insurance Risks	Significant risks of Curetis that can be insured, e.g. product liability, loss of property, product transports, interruption of business, clinical trials, car insurance, D&O etc. shall	Any uninsured risk materializing would have negative impact on cash burn and reputation with potential negative impact on financials.	Annual review of insurance contracts and discussion with insurance broker with regard to insurance coverage and new products.	

Corporate Risk Area	Risk Description and Cause	Potential Impact if Risk Materializes	Mitigation Measures
	be insured at reasonable levels to protect against major or catastrophic losses. Insurance risk is hence the risk to have inadequate insurance protection for any of the risks, e.g. because a risk is not covered at all or only covered insufficiently.		
D&O Risks / Prospectus Risks	Specific risks pertaining to the directors and officers of a publicly listed company in the context of an ever more complex regulatory environment; specific prospectus liability risks from capital market transactions. US specific risks from Curetis/OpGen Transaction not adequately covered.	Any uninsured risk materializing would have negative impact on cash burn and reputation with potential negative impact on financials.	Code of conduct, insider trading policy, whistleblower policy, clarity of roles and responsibilities for MB and SB; D&O insurance; specific prospectus liability insurance in the context of any potential capital markets transaction; global / US & RoW specific coverage as needed.
Fraud	Any employee, officer or director of the company acting in a fraudulent manner to their own benefit or anyone acting on behalf of the company towards the outside world in a fraudulent manner, misrepresenting and causing major harm to the reputation, financials and causing legal repercussions.	Any case of fraud could have material negative impact on reputation as well as negative impact on financial situation of the company.	Code of conduct, compliance manager, insider trading policy, whistleblower policy; 4-eye principle; signature authorities clearly defined; treasury and cash pooling in combination with regular review of all company group accounts by Director Finance, Accounting, and CEO.
Compliance Risks	Post IPO listing requirements by AFM and FSMA - Dutch corporate governance codex and other compliance rules on the accounting and legal side.	Any case of non-compliance to DCGC could have material negative impact on reputation as well as negative impact on financial situation of the company as well as the timeline for dissolution and de-listing.	In order to avoid non-compliance, we have established a Compliance Management function via our in house legal counsel; on any issue that has the potential for non-compliance we also involve outside counsel (legal, tax etc.) to ensure the highest levels of compliance; regular compliance trainings to all staff with special focus also on sales & marketing teams; active management of insider lists and training of people

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			affected.
Data Protection	Adherence of data security and protection laws; legal basis for storing and transferring personal data to the US.	Lawsuits from anyone wanting to bring a case for breach of EU GDPR or other applicable data protection rules would cause reputation damage and increase cost.	Added clauses in templates for contracts, executed addendums to current contracts, especially employment contracts; access control on Curetis' premises; appointed a DSB and added training; added Data Protection Declaration to homepage; keep a visitor's book.
Insider Trading	Any employee or next of kin or other insider (ab)using such insider info to trade in the stock of Curetis; many members of the Curetis teams will at one point or another be privy to material non-public information and hence insiders.	Any case of insider trading could have material negative impact on reputation as well as negative impact on financial situation of the company.	Insider trading policy; training of all staff on this policy immediately upon IPO, for new employees and at regular intervals; establishing financial calendar with block out periods; administering insider lists for special projects.
IP related risks			
Patents	To lose Curetis' proprietary IP by dilution or unwanted transfer.	Loss of patent protection or FTO.	Surveillance of current and new filings by patent law office ZSP; collision report; conducting coexistence agreements. Protective clauses against unwanted IP-transfer in contracts; ZSP external DD on GEAR and Gyronimo IP portfolios.
	Failure to obtain or maintain IP protection for critical own inventions in relevant geographies.	Loss of patent protection or FTO.	Use of high-quality patent firm (ZSP) for filing. Management decision on countries.
	Patent opposition of 3rd party against Curetis' patents	Loss of patent protection or FTO.	Use of high-quality patent firm (ZSP) for filing to minimize attack points.
	Failure to obtain or maintain IP protection for critical acquired IP in relevant geographies (A30 RQ).	Loss of patent protection or FTO.	IP Due Diligence for acquired IP with high quality patent firm.
	Failure to obtain or maintain IP protection for critical acquired IP in relevant geographies	Loss of patent protection or FTO.	Develop own IP strategy for Ares Genetics, including new filings.

Corporate Risk Area	Risk Description and Cause	Potential Impact if Risk Materializes	Mitigation Measures
	(GEAR).		
	Legal prosecution for patent infringement.	Loss of patent protection or FTO.	Patent exhaustion approach, IP Insurance, change of design to prevent patent infringement - add insurance (see above).
	New innovations are not reported/recognized and not filed.	Loss of patent protection or FTO.	Annual meeting with external patent attorney to review development.
Trade Secrets	Law changed from secrecy presumed to take active appropriate measures by company to safekeep trade secrets.	Loss of patent protection or FTO.	Confidentiality obligations signed by employees, keeping a visitor's book, access control to premises, IT access restrictions, mandatory regulations in the employee handbook, CDAs with service providers where applicable.
	GEAR / ARES AMR Marker IP portfolio based on comprehensive filing of marker candidates is too complex and cannot be maintained long-term at reasonable costs.	Loss of patent protection or FTO.	Ares Genetics IP strategy under development, hired additional personnel to develop and implement ARES IP strategy in interaction with ZSP.
Finance Risks			
Capital Market Regulations	AFM and FSMA regulations apply to us as a listed company on Euronext AMS and BRUS; especially notification on any stock price sensitive information is a critical risk.	Delays in such notifications might result in fines and investigations.	All material info is being kept in tight circle; defined insider lists; processes for ad hoc announcements and reportings to AFM/FSMA have been well established and described; working with internal as well as external providers on legal and corporate communications side to ensure compliance with regulations.

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Financial Reporting Risks	Curetis has the obligation to publish financial statements (audited annual reports and unaudited half year financials) within a given timeframe to meet the requirements of EURONEXT / stock exchange authorities and the capital markets. Additionally, Curetis' Finance department must keep all data up to date continuously to support management decisions, secure liquidity planning and to be able to give data to analysts and investors. Despite decision to close down several salessubsidiaries in 2019 the consolidation scope for now still comprises several companies. It requires a lot of resources at peak times (closing periods) and several adjustments to the ERP-system to keep all these accounting areas up to date to be able to consolidate the numbers quarterly. Given the limited resources any illnesses or other absentee reasons of key employees could lead to delays.	Delays to financial reporting could lead to fines, loss of investor confidence, accounting restatements etc. which could have a material negative impact on Curetis financials and ability to raise capital in the future.	Reduction of complexity by closing subs asap in 2019; hired interim manager / new head of accounting & controlling in March 2020.	
Auditing Risks	The financial statements of Curetis are audited annually and whenever a bigger financing transaction is planned. Curetis has very limited resources at management level that can discuss numbers and the notes disclosures with the auditors. Due to the current liquidity status and due to the new application of 1 big IFRS-standards, the business combination with OpGen, the audit procedures require	Delays to audits or negative audit findings could delay transactions or impair ability to raise capital in the future and hence have material negative impact on company's financial situation.	Interim manager / external support hired	

Corporate Risk Area	Risk Description and Cause	Potential Impact if Risk Materializes	Mitigation Measures	
	tremendous resources from management and discussions about going concern / NV IFRS 5 discontinued operations are lengthy.			
National Reporting, Tax and Disclosure Obligations	With the incorporation of subsidiaries in different countries, Curetis had entered into national reporting-, tax- and disclosure obligations. As Curetis has very limited experience with such possible national regulations there is a risk of non-compliance or not adhering to one of such (unknown) regulations.	Potential negative tax consequences that could negatively impact short term cash flow as well as longer term use of tax loss carryforwards	Curetis works closely together with national advisors and does constantly interact with its service-providers. For very specific matters (like payroll accounting or national GAAP-financial statements) have been outsourced to special service providers.	
ERP System Administration and Development	Curetis uses Microsoft Dynamics Navision (NAV) Version 2009 as its ERP- System for all processes and for all subsidiaries. The System was customized and maintained by Curetis' Senior ERP Engineer, who resigned as of June 2019. A system upgrade is required as Microsoft will discontinue its support for the old version as of o1/o1/2020. Under these circumstances a timely upgrade is critical and could lead to problems in the future. Issues and bugs can occur anytime	Loss of support for current ERP NAV version could lead to systems downtime and need for expensive ad hoc external service support.	Hired NAV Expert - working with additional outside firm	
Equity Capital Raising Risks	Curetis may not be able to raise additional capital in the public capital markets at the time or at the price points and conditions desired; this puts the cash run rate and execution of the revised strategy and adjusted business plans at material risk;	In case the business combination with OpGen does not close there is major uncertainty and there is a significant risk of running out of cash and having to file for insolvency / bankruptcy.	Received 5 Mio European Investment Bank and 1.5 Mio Yorkville tranches in H1-2020 // Received loand from OpGen under the Definitive Implementation Agreement // Resolved EIB and Yorkville obligations as part of the business combination with OpGen	

Corporate Risk Area	Risk Description and Cause	Potential Impact if Risk Materializes	Mitigation Measures	
Debt Financing Risks	So far Curetis has 18-Mio EUR debt received from European Investment Bank on its balance sheet; risk might be debt that cannot be repaid in time	Might require refinancing measures at unfavorable terms in the future; worst case debt may force company into distress situation, fire sale or even bankruptcy.	Maxed-out on European Investment Bank and Yorkville / implemented % PPI structure with European Investment Bank / close communications with Yorkville with regard to new shares being created (EGM needed and > 20% AFM prospectus).	
Stock Price Risks	Curetis N.V. stock has seen considerably improved liquidity – all VCs have been exiting (HBM, Forbion) in 2019, free float now > 93% / Yorkville convertible notes have put additional continued pressure on share price / equity financing need and capital market perception of financing overhang leading to heightened short term pressure / decline in share price.	Curetis may be unable to raise sufficient amounts (or even any) capital in the markets at these stock prices and this could lead to financial distress including potential insolvency or bankruptcy filings	Delivering on fundamentals of revised strategy post-closing of business combination with OpGen (Curetis N.V. no longer a listed stock) and reduced business plan scope is key-need to achieve significant top line revenue growth via Menarini in EMEA and ROW as well as in USA direct; need news flow from A30 RQ / Ares partnering deals and strategic financing	
Equity Story Risk	Equity Story of Curetis has evolved considerably (post Re-Org) / need new equity story for combined entity after closing of business combination with OpGen. Capital markets continue to underappreciate the expansion and De-risking of the Equity Story leading to low company valuation and hence has severely limited Curetis ability to raise the amounts of capital required to execute on our strategy.	Curetis may be unable to raise sufficient amounts (or even any) capital in the markets at these stock prices and this could lead to financial distress including potential insolvency or bankruptcy filings	Closing of business combination with OpGen to access US stock market / US and EU PR & IR advisory help	

Corporate Risk Area	Risk Description and Cause	Potential Impact if Risk Materializes	Mitigation Measures		
Ares Genetics Commercial & Strategic Risks					
Partnering Risks	Ares Genetics' short-term revenue planning partially relies on R&D revenue from co-development activities with bioinformatics solution provider or NGS manufacturers as well as pharma services. These deals are difficult to plan due to the prototype stage of the ARESdb asset. Hence our ability to secure co-development deals and R&D revenue may be limited	Lower revenue, less cash inflow, higher cash-burn rate and negative impact on Ares financials and cash runway	Continue systematic reach out to NGS manufacturer, bioinformatics solutions provider, pharma companies, diagnostic companies and communicate tight timelines for partnering opportunities; dedicated pitches for each potential partner; development of strong pharma service concept including in-vitro resistance development tests, strengthen KOL network. Managed to secure deals with Sandoz, Qiagen and undisclosed IVD partner.		
Grant Co-Funding Risks	Ares short term revenue (other income) planning partially relies on grants. Revenue from grants is difficult to plan and may be limited. Co-funding requirements of grants may limit our ability to accept grants.	Lower other income from grants less cash inflow, higher cash burn rate and negative impact on Ares financials and cash runway.	Implement a grant management process to systematically screen for relevant grants. Continuously monitor and update grant application roadmap and submit to relevant calls. Connect with relevant partners to be included in larger consortia for EU grants; hired external consultants to identify big-ticket grants and support in the submission thereby submitting more grant applications with higher chances of success. Actively manage grants to ensure maximum funding ratio vs. own contribution.		
Growth Risk	Ares Genetics secures co- development deal but lacks personnel resources to timely translate the ARESdb R&D prototype into a joint product offering.	Delays in hiring would possibly lead to delays in execution of partnering deals and loss of revenue or grant income and have negative financial impact.	Continue search for software architects and developer that have experience delivering product grade data analysis software as well as bioinformaticians; consider outsourcing of certain aspects provided that adequate funds are		

Corporate Risk Area	Risk Description and Cause	Potential Impact if Risk Materializes	Mitigation Measures	
			available.	
Hiring/Talent Risk	For the execution of its business plan, Ares Genetics needs highly qualified and ideally experienced experts in bioinformatics, molecular diagnostics, microbiology, software development etc. Such experts are in high demand in the industry and Ares Genetics may not be able to compete with larger companies in attracting these talents.	Delays in hiring would possibly lead to delays in execution of partnering deals and loss of revenue or grant income and have negative financial impact.	Actively promote the mission and vision of Ares Genetics via social media and press; provide an attractive working environment; leverage our network to recruit people; provide attractive compensation packages	
Retention Risk	Ares Genetics team highly driven by ability to pursue the Ares Genetics business plan that is currently underfunded; R&D efforts to leverage full potential of Ares Genetics assets currently not satisfying for team as competition is catching up. The situation may lead to frustration and eventual resignation of key people leading to Ares Genetics' assets potentially becoming impaired.	Loss of key staff would possibly lead to delays in execution of partnering deals and loss of revenue or grant income and have negative financial impact.	Incentivize key people by attractive compensation packages short-term and increasingly make Ares Genetics core to the Curetis equity story.	
ARESdb Sustainability	Antibiotic resistance is continuously evolving and even though the ARESdb database is the most comprehensive resource on genetic antibiotic resistance over the last three decades it needs to be continuously expanded in order to sustain its commercial value.	Less attractive for partners, delays in deal making, slower revenue ramp, negative financial impact.	Actively pursue a partnership-based approach to further enhance ARESdb in bilateral projects with academic key opinion leaders as well as work towards implementing a public-private partnership for continuous enhancement of ARESdb. Additionally, implement an AI-informed ARESdb maintenance process to enhance ARESdb by	

Corporate Risk Area	Risk Description and Cause	Potential Impact if Risk Materializes	Mitigation Measures		
			including publicly available data after stringent quality curation.		
General Funding Risk	Ares Genetics currently relies on funding through grants and discrete partnering deals. This may not provide funding to the extent necessary to fully leverage the ARESdb potential and stay competitive in a very dynamic AMR environment.	Loss of competitiveness towards partners, as an employer and negative impact on future value creation potential.	Seek direct equity investment into Ares Genetics for critical funding of growth on the base of a business plan aiming at fully leveraging the potential of ARESdb and the ARES Technology Platform. Seek non-dilutive funding through licensing and service partnerships; expand service offering; Make Ares core to the Curetis Equity story and provide additional R&D funding by Curetis (if and once available).		
ARESdb Marker Validation	ARESdb contains a vast number of potentially novel antibiotic resistance markers. Those markers need to be further validated (functionally and statistically) as well as validated in terms of clinical utility to facilitate clinical application.	Higher costs and negative impact on financials	Actively pursue a partnership-based approach to further validate ARESdb markers in bilateral projects with academic key opinion leaders as well as work towards implementing a public-private partnership for further validation of the ARESdb. Perform proof-of-concept validation study for a selected subset of ARESdb biomarker candidates.		
Global Commercial & Strategic Risks					
A30 <i>RQ</i> Platform Partnering Risk	A <sub>3</sub> o <i>RQ</i> needs to become a significant revenue source for Curetis (via partnering). Many new competitors in the market, if we get late to distributors will be difficult	No partnering deal / delayed partnering deal / worse than expected deal terms / lower cash inflow, higher cash burn might force Curetis to slow down or abandon A30 RQ	Keep focus on milestones; agile development sprints in close coordination with Biz Dev; secure further funding for A30 RQ development.		

Corporate Risk Area	Risk Description and Cause	Potential Impact if Risk Materializes	Mitigation Measures
	to get market share.	development program.	
Distributor Performance	Curetis' distributors are expected to invest in market development for Unyvero to achieve contractually agreed commitments; Distributors may not be able or willing to take such investments or may not have the expertise and hence may lag behind contractually agreed commitments or do not perform at all.	Lower revenue, less cash inflow, higher cash burn rate and negative impact on financials and cash runway.	Put all Commercial Partners under joint leadership of Commercial Partner Support. Choose distributors based on thorough due diligence (Menarini in EMEA after systematic RFP process); tightly manage and coach them; monitor performance closely; replace when consistently underperforming doing systematic business reviews with all distributors. Marketing activities to support market growth with some selected commercial partners.
Curetis/OpGen Transaction	('Transaction') Risks		
Completion Risk	We may not be successful in consummating the proposed Transaction, which failure could have a material adverse effect on us.	If business combination with OpGen fails and there were no other viable alternative available then Curetis might have to drastically reduce cost, halt operations, unwind and dissolve and possible file for insolvency and bankruptcy.	Work to address all conditions precedent such as debt holder and shareholder approvals and on financing with OpGen Team.
Waiver Risk	Completion of the Transaction is subject to the fulfillment or the waiver, as the case may be, of a number of conditions precedent, which may prevent, delay, hinder or otherwise adversely affect the proposed Transaction.	If business combination with OpGen fails and there were no other viable alternative available then Curetis might have to drastically reduce cost, halt operations, unwind and dissolve and possible file for insolvency and bankruptcy.	Work to address all conditions precedent such as debt holder and shareholder approvals and on financing with OpGen team.
Interim Financing Risk	We have agreed to use a significant portion of the capital raised in the October 2019 Offering to support the operations of Curetis in the period prior	If business combination with OpGen fails and there were no other viable alternative available then Curetis might have to drastically reduce cost, halt	Weekly cash / liquidity forecasts; prudent spending and use budgetary fiscal discipline.

Corporate Risk Area	Risk Description and Cause	Potential Impact if Risk Materializes	Mitigation Measures	
	to the closing. This reduces the proceeds invested in OpGen's operations, which could have a negative impact on us if the proposed Transaction is not consummated, or if the approval process takes longer than anticipated.	operations, unwind and dissolve and possible file for insolvency and bankruptcy.		
Timeline Risk	The date on which the Transaction will close is uncertain.	Delays in transaction closing could put Curetis in cash crunch and might force it to file for insolvency and bankruptcy.	Push S-4 filing aggressively and prepare all required EGM documents in parallel.	
Consequences of Failure to Close the Transaction	If the combination with OpGen does not occur, our financial condition will be materially adversely affected.	If business combination with OpGen fails and there were no other viable alternative available then Curetis might have to drastically reduce cost, halt operations, unwind and dissolve and possible file for insolvency and bankruptcy.	Ensure all commercial partners are met and sufficient financing gets raised.	
Indebtedness Risk	We will incur significant indebtedness as a result of the combination with OpGen which could have a material adverse effect on our financial condition.	Over-indebtedness at any group company level could put such entity in financial distress and force it to declare insolvency or file for bankruptcy.	Interim Financing Facility adds debt to Curetis GmbH balance sheet; draw down in tranches / address intercompany wide post closing.	
Transaction costs	We will incur significant transaction costs as a result of the proposed business combination transaction with OpGen.	these transaction costs have a material adverse effect on our financial condition.	Tight project monitoring and controlling; do as much in house as possible	
Integration Risk	The proposed business combination transaction with OpGen will significantly change the business and operations of Curetis. We may face challenges integrating the businesses.	Delay in integration could lead to unwanted staff attrition, loss of key talent, delays in business execution and thus harm the financial situation of the company.	Establish integration task force across all key functions; weekly task force telephone conferences; bilateral meetings and interaction / take one-company philosophy even preclosing.	
Management Support	Some executive officers and directors of OpGen and Curetis N.V. have interests in the Transaction that are different from ordinary investors and that may	Transaction may not be perceived by some investors as being in their best interest.	Create incentive schemes post transaction closing that aligns shareholder and executive / Board of Director interest.	

Corporate Risk Area	Risk Description and Cause	Potential Impact if Risk Materializes	Mitigation Measures
	influence them to support or approve the Transaction without regard to the interests of ordinary investors.		
Business Strategy Risk	The combination of the OpGen and Curetis and thus harm the final situation of the compact the growth and success of the combined business that we believe will occur.		Integration task force on commercial side to do detailed bottom up planning / focus on launches and commercial execution / reward revenue growth in commercial and executive teams.
Alternative Transaction Offers	If Curetis were to receive a proposal for an alternative transaction, and one of us accepts such proposal, the Transaction will not close.	Might lead to business combination with OpGen not to close; unclear if any alternative would be viable or financially be more beneficial.	Focus on Curetis/OpGen transaction execution.
Relative Valuation Disparity	The fairness opinion of Curetis' financial advisor does not reflect changes in circumstances that may have occurred or that may occur between the signing of the Implementation Agreement and the closing of the Transaction.	Transaction may not be perceived by some investors as being in their best interest.	Focus on IR activities that boost OpGen share price ahead of EGM / focus on benefits of business combination in shareholder circular.
Tax Risk	We expect our ability to utilize our net operating loss carryforwards will be limited as a result of an "ownership change," triggered by consummation of the transaction with OpGen.	Adverse tax consequences with negative impact on future cash flows and financials.	Work with tax advisors and mitigate risk of losing operating NOL by any means available in Germany, Austria, and USA.
Stockholder Interest	Current Curetis N.V. stockholders will have a reduced ownership and voting interest after the business combination and will exercise less influence over management.	Transaction may not be perceived by some investors as being in their best interest.	Proactive IR as NewCo / working with IR firm advisors / NDR / conferences.
Share Price	The market price of Newco common stock after the business combination may be affected by factors different from those affecting the shares of Curetis currently.	Value of shares in OPGN held by former Curetis N.V. shareholders might be less than expected thus negatively impacting individual shareholders financial position.	Make best use of NASDAQ listing and US IR efforts for NewCo with focus on new investor universe.

### STATEMENT OF THE FORMER MANAGEMENT BOARD

In accordance with article 5:25c, paragraph 2 sub c of the Financial Supervision Act, the Management Board of Curetis confirms that, to the best of their knowledge, (i) the financial statements in this Annual Report 2019 give a true and fair view of the Company's assets and liabilities, the Group's financial position as of 31 December 2019, and the results of its consolidated operations for the financial year 2019; and (ii) the Report of the Management Board includes a fair review of the position as of 31 December 2019, and the development and performance during the financial year 2019 of Curetis and the undertakings included in the consolidation taken as a whole and describes the principal risks that Curetis is exposed to. The names and positions of the Management Board members can be found below (current composition of the Management Board).

## FORMER MANAGEMENT STRUCTURE

Curetis has a two-tier board structure consisting of the Management Board (*bestuur*) and the Supervisory Board (*raad van commissarissen*). The Management Board is, among other things, responsible for the day-to-day management, formulating strategies and policies, and setting and achieving Curetis' objectives. The Supervisory Board supervises and advises the Management Board.

Set out below is a summary of certain information concerning the Management Board, the Supervisory Board and corporate governance. It presents a summary of certain provisions of Dutch corporate law as in effect on the date of this Annual Report as well as relevant information of the Articles of Association, the Management Board Rules, the Supervisory Board Rules and the Committee Rules.

This summary does not attempt to give a complete overview and should be read in conjunction with, and is qualified in its entirety by reference to the relevant provisions of Dutch law as in force on the date of this Annual Report and the Articles of Association, the Management Board Rules and the Supervisory Board Rules as in effect as of 31 December 2019. Complete versions of the Articles of Association in the governing Dutch language and in an unofficial English translation thereof, Management Board Rules, the Supervisory Board Rules, Committee Rules and further details on corporate governance are publicly available on the corporate investor website (https://curetis.com/investors/#corporate-governance).

## FORMER MANAGEMENT BOARD

### RESPONSIBILITY, POWERS AND FUNCTIONING

The Management Board is responsible for the management of Curetis' operations, subject to the supervision of the Supervisory Board. The Management Board's responsibilities include, among other things, creating a culture aimed at long-term value creation and, in doing so, defining and attaining Curetis' objectives, determining its long-term strategy and corporate risk management policy, and day-to-day management of Curetis' operations and as well to stimulate openness, accountability and sharing of the values and principles outlined in Curetis' Code of Conduct. The Management Board may perform all acts necessary or useful for achieving Curetis' objectives, with the exception of those acts that are prohibited by law or by the Articles of Association. Pursuant to the Management Board Rules, the Managing Directors will divide their tasks among themselves in mutual consultation, subject to the approval of the Supervisory Board. In performing their duties, the Managing Directors must carefully consider and act in accordance with the interests of Curetis and the businesses connected with it, taking into consideration the long-term strategy of Curetis and the interests of all of the stakeholders in Curetis (which include, but are not limited to, its customers, its employees, the shareholders, business partners and others). Once a year, the Management Board evaluates its own functioning as a whole and that of the individual Management Board members.

The Management Board shall provide the Supervisory Board with all information necessary for the exercise of the duties of the Supervisory Board in a comprehensive and timely manner. The Management Board is required to notify the Supervisory Board in writing of the main features of Curetis' strategies, policies, general and financial risks and management and control systems, at least once per year. The Management

Board must submit certain important decisions to the Supervisory Board and/or the General Meeting for approval, as more fully described below. Subject to certain statutory exceptions, the Management Board as a whole is authorized to represent Curetis. Each Managing Director, acting jointly with another Managing Director, has the authority to represent Curetis. In addition, pursuant to the Articles of Association, the Management Board is authorized to appoint proxy holders (*procuratiehouders*) who are authorized to represent Curetis within the limits of the specific delegated powers provided to them in the proxy.

### FORMER MANAGEMENT BOARD RULES

Pursuant to the Articles of Association, the Management Board may adopt rules of procedure that regulate internal matters concerning its functioning and internal organization (the "Management Board Rules"). The Management Board Rules can be found on Curetis' website under <a href="https://curetis.com/investors/#corporate-governance">https://curetis.com/investors/#corporate-governance</a>.

## COMPOSITION, APPOINTMENT AND REMOVAL

The Articles of Association provide that the Management Board shall consist of two or more members, and that the Supervisory Board determines the exact number of Managing Directors after consultation with the Management Board.

The General Meeting appoints the Managing Directors. The Supervisory Board shall make a non-binding nomination in case a Managing Director is to be appointed. The nomination must be included in the notice of the General Meeting at which the appointment will be considered. If no nomination has been made, which is also considered to be the case if the Supervisory Board's vote on the nomination ties, this must be stated in the notice. However, the General Meeting is not bound by a nomination and may appoint a Managing Director at its discretion, provided a proposal to appoint another person has been put on the agenda of the relevant General Meeting or, failing that, the entire issued capital is represented at the General Meeting and the resolution to appoint the alternative Managing Director has been adopted unanimously. The Supervisory Board may appoint one of the Managing Directors as Chief Executive Officer, or grant any other title to a Managing Director.

A resolution of the General Meeting to appoint a Managing Director in accordance with the nomination of the Supervisory Board shall be adopted by an absolute majority of the votes cast. A resolution of the General Meeting to appoint a Managing Director other than in accordance with a nomination of the Supervisory Board, but in accordance with the agenda for such General Meeting shall require an absolute majority of the votes cast representing at least a third of Curetis' issued share capital.

The General Meeting may at any time and at the proposal of the Supervisory Board suspend or dismiss a Managing Director. Should the General Meeting wish to suspend or dismiss a Managing Director other than in accordance with a proposal of the Supervisory Board, such suspension or dismissal needs to be adopted by an absolute majority of the votes cast, representing at least a third of Curetis' issued capital. The Supervisory Board may at all times suspend but not dismiss a Managing Director. A General Meeting must be held within three months after a suspension of a Managing Director has taken effect, in which meeting a resolution must be adopted to either terminate or extend the suspension, for a maximum period of another three months. The suspended Managing Director must be given the opportunity to account for his or her actions at that meeting. If neither such resolution is adopted nor the General Meeting has resolved to dismiss the Managing Director, the suspension will cease after the period of suspension has expired.

At the 2019 General Meeting on 27<sup>th</sup> June, Johannes Bacher, COO, was re-elected as a member of the Management Board. Therefore, throughout 2019 the Management Board consisted of three Managing Directors.

## TERM OF APPOINTMENT

The Managing Directors will be appointed for a term of up to four years. A Managing Director may be reappointed for a term of up to four years at a time. The Supervisory Board has prepared a resignation schedule for the Managing Directors, which is reflected in the right-hand column labelled 'Term' of the table

under the heading "- Managing Directors" below.

### MEETINGS AND DECISION-MAKING

Pursuant to the Management Board Rules, the Managing Directors shall endeavor to achieve that resolutions are adopted unanimously whenever possible. Where unanimity cannot be reached, and the law and the Articles of Association or the Management Board Rules do not prescribe a larger majority, resolutions of the Management Board are adopted by a majority vote. In the event of a tied vote, the resolution will be decided on by the Supervisory Board.

Pursuant to the Articles of Association, the Management Board shall furthermore require the approval of the Supervisory Board for a number of resolutions, which include inter alia:

- the issue and acquisition of any of Curetis' shares or debt instruments, or of debt instruments issued by a limited partnership or general partnership of which Curetis is a fully liable partner;
- the application or the withdrawal for quotation in the listing on any stock exchange of Curetis' shares or debt instruments, or of debt instruments issued by a limited partnership or general partnership of which Curetis is a fully liable partner;
- the entry into or termination of a long-term cooperation of Curetis or a dependent company with another legal entity or company or as fully liable partner in a limited partnership or general partnership, if such cooperation or termination is of major significance to Curetis;
- the participation for a value of at least one-fourth of the amount of the issued capital with the reserves according to the most recent adopted balance sheet (whether consolidated or not) with explanatory notes of Curetis or by a dependent company in the capital of another company, as well as a significant increase or reduction of such a participation;
- investments involving an amount equal to at least the sum of one-fourth of Curetis' issued capital plus the reserves as shown in its most recent adopted balance sheet (whether consolidated or not);
- a proposal to amend the Articles of Association;
- a proposal to dissolve (ontbinden) Curetis;
- a proposal to conclude a legal merger (juridische fusie) or a demerger (splitsing);
- application for bankruptcy (faillissement) or for suspension of payments (surséance van betaling);
- the termination of the employment of a considerable number of employees of Curetis or of a dependent company at the same time or within a short period of time;
- far-reaching changes in the employment conditions of a significant number of employees of Curetis or of a dependent company; or
- a proposal to reduce the issued share capital.

Dutch law and the Articles of Association provide that decisions of the Management Board involving a significant change in Curetis' identity or character are subject to the approval of the General Meeting.

Such changes include in any event:

- the transfer of all or substantially all of Curetis' business to a third party;
- the entry into or termination of a long-term cooperation with other legal entities or companies, or as a fully liable partner in a limited partnership or a general partnership, if such cooperation or termination thereof is of material significance to Curetis; or
- the acquisition or disposal by the Company or a subsidiary of the Company of a participation in the capital of a company with a value of at least one-third of the sum of the assets of Curetis according to Curetis' consolidated balance sheet including the explanatory notes in its last adopted annual accounts.

In addition, pursuant to the Articles of Association, the Supervisory Board may determine that other

resolutions of the Management Board are subject to its approval, such resolutions must be clearly defined in a resolution adopted by the Supervisory Board and should be notified to the Management Board.

Pursuant to the Articles of Association and the Management Board Rules, resolutions can also be adopted without holding a meeting, provided those resolutions are adopted in writing or in a reproducible manner by electronic means of communication and all Managing Directors entitled to vote have consented to adopting the resolutions outside a meeting.

In each of the abovementioned situations, the lack of approval (whether of the General Meeting or of the Supervisory Board) does not affect the authority of the Management Board or the Managing Directors to represent Curetis.

### **DIVERSITY & MANAGING DIRECTORS**

Curetis strives towards having a diverse set of skills, experiences, backgrounds and gender in its Management Board. While Curetis currently has one of the company's co-founders and engineer, one molecular biologist and a corporate finance professional in its Management Board with rather diverse experiences in large as well as small companies in different geographies, all current Management Board Members are male. The Supervisory Board and Curetis will continue to carefully assess additional diversity in the future if and when an opportunity arises to bring a female candidate onto the Management Board or otherwise enhance its diversity.

At the date of this Annual Report, the Management Board is composed of the following three members:

Name	Nationality	Age	Position	Date of most recent Appointment	Term
Mr. Oliver Schacht, PhD	German	49	Chief Executive Officer	21 June 2018	until 31 December 2021
Mr. Johannes Bacher	German	51	Chief Operating Officer	27 June 2019	until 30 June 2022
Dr. Achim Plum	German	52	Chief Business Officer	21 June 2018	until 31 December 2021

Curetis' registered address, Max-Eyth-Straße 42, 71088 Holzgerlingen, Germany, serves as the business address for the Managing Directors who with the completion of the sale of the Curetis business to OpGen are no longer Management Board members but act as Liquidators of Curetis N.V. in Liquidation.

## Oliver Schacht, Ph.D.

Mr. Oliver Schacht, a corporate finance professional and expert in the molecular diagnostics industry, has been CEO of Curetis since April 2011 and prior to that was a Supervisory Board Member of Curetis AG from mid-2010 to end of the first quarter of 2011. He was a co-founder and the CFO of Epigenomics AG in Berlin and the CEO of the U.S. subsidiary Epigenomics Inc. (Seattle, USA). Mr. Schacht has extensive experience in developing and implementing commercial strategies and financing measures (including two IPOs), as well as in corporate finance, M&A transactions and alliance negotiations. During his time at Epigenomics AG (1999-2011), he headed all central business functions, including corporate finance, investor relations, PR, marketing and business development at the Berlin headquarters. Mr. Schacht also serves on the Board of BIO Deutschland e.V. as its president and previously as treasurer. Mr. Schacht obtained his Diploma in European Business Administration at the European School of Business in Reutlingen and London in 1994 as well as a Master's degree and a Ph.D. at the University of Cambridge (UK). During his time at Mercer Management Consulting (now Oliver Wyman) from 1995 to 1999, he worked on projects in M&A, growth strategies and re-organization in the pharmaceutical, biotechnology and other industries. He has co-founded several start-up companies in biotech, IT and education in Europe and the USA.

#### Johannes Bacher

Mr. Johannes Bacher who co-founded Curetis in 2007 combines over 20 years of R&D and managerial experience with extensive expertise in international project management, finance, human resources and legal affairs. At Curetis Johannes in his role as COO heads all R&D functions in engineering, software, IVD development, innovation & technology, IP, and clinical trial operations of Curetis.

Mr. Bacher has a degree in electrical engineering (Dipl. Ing.) and has previously worked for several international medical technology companies, including Hewlett Packard, Agilent and Philips Medical Systems.

#### Dr. Achim Plum

Dr. Achim Plum joined Curetis in 2015 as Chief Commercial Officer and has held the position of Chief Business Officer since summer 2017. Dr. Plum oversees all corporate business development, portfolio management and company strategy efforts, and is one of the Managing Directors of Ares Genetics GmbH. Dr. Plum also had served as Managing Director in all of Curetis' international commercial subsidiaries. Dr. Plum also directly manages Curetis' corporate communications (PR&IR), legal and HR.

Dr. Plum joined from a senior management position with Siemens, where he was at last heading global Diagnostics and Bioscience Research in the Siemens Healthcare Technology Center. Prior to Siemens, Dr. Plum worked for eight years with the publicly traded German-American molecular diagnostics company Epigenomics AG, most recently as Senior Vice President Business and Strategy. At Epigenomics, he built sales and marketing teams and distribution networks in Europe and the U.S., negotiated strategic commercial agreements with leading diagnostics industry players and led Epigenomics' corporate communications and compliance functions. Dr. Plum since January 2019 also serves as a strategic advisor to TissUse GmbH (Berlin/Germany). Following undergraduate studies at the University of Bonn (Germany) and the University of East Anglia in Norwich (UK), Dr. Plum obtained his doctorate in Molecular Genetics from the University of Bonn in 1999 for developing and studying novel genetic models of human diseases.

## SUPERVISORY BOARD

## RESPONSIBILITY, POWERS AND FUNCTIONING

The Supervisory Board is responsible for supervising the conduct and policies of the Management Board and of the general course of affairs of Curetis and its business enterprise. The Supervisory Board also provides guidance, feedback and advice to the Management Board.

In performing their duties, the Supervisory Directors are required to be guided by the interests of Curetis and its business enterprise, taking into account the interests of Curetis' stakeholders (which include but are not limited to Curetis' employees and shareholders). The Supervisory Board will also observe the corporate social responsibility issues that are relevant to Curetis' business. The Supervisory Board is responsible for the quality of its own performance and therefore will claim any information from the Management Board, the internal audit function and/or the external auditor it deems necessary. The Supervisory Board may, at Curetis' expense, seek the advice of external experts and service providers, which it deems desirable for the correct performance of its duties.

The Supervisory Board has drawn up a profile (*profielschets*) for its size and composition taking into account the nature of Curetis' business, the Supervisory Board's activities and the desired expertise and background of the Supervisory Directors. The Supervisory Board must discuss the profile at the occasion of its adoption and review it annually and each amendment of the profile must be discussed in the General Meeting.

### SUPERVISORY BOARD RULES

Pursuant to the Articles of Association, the Supervisory Board may adopt rules of procedure concerning the division of its duties and its working methods ("Supervisory Board Rules") and that of its committees as described below. The Supervisory Board Rules can be found on Curetis' website at

#### https://curetis.com/investors/#corporate-governance.

### COMPOSITION, APPOINTMENT AND REMOVAL

The Articles of Association provide that the Supervisory Board must consist of a minimum of three members, with the exact number of Supervisory Directors to be determined by the Supervisory Board. As of the date of this Annual Report, the Supervisory Board consists of six members. Only natural persons may be appointed as Supervisory Director. Whilst the current composition of the Supervisory Board is in line with the characteristics outlined in the "Supervisory Board Profile", there is a continued special attention to enhancing the diversity in terms of gender, professional experience and expertise as well as geographic coverage. For an explanation of any deviation from the Dutch Corporate Governance Code with regards to Supervisory Directors, please also see the relevant section below.

The General Meeting appoints the Supervisory Directors upon a non-binding nomination of the Supervisory Board. Any nomination by the Supervisory Board must be drawn up with due observance of the profile (*profielschets*) for the size and the composition of the Supervisory Board. The nomination must specify the reasons for the nomination. If no nomination has been made, which is also considered the case if the Supervisory Board's vote on the nomination ties; this must be stated in the notice. However, the General Meeting is not bound by a nomination and may appoint a Supervisory Director at its discretion, provided a proposal to appoint another person has been put on the agenda of the relevant General Meeting or, failing that, the entire issued capital is represented at the General Meeting and the resolution to appoint the alternative Supervisory Director has been adopted unanimously.

A resolution of the General Meeting to appoint a Supervisory Director in accordance with the nomination of the Supervisory Board shall be adopted by an absolute majority of the votes cast. A resolution of the General Meeting to appoint a Supervisory Director other than in accordance with a nomination of the Supervisory Board, but in accordance with the agenda for such General Meeting shall require an absolute majority of the votes cast representing at least a third of Curetis' issued share capital. The Supervisory Board shall appoint one of its Supervisory Directors as Chairman and shall appoint one of its Supervisory Directors as Vice-Chairman.

The General Meeting may at any time, at the proposal of the Supervisory Board, suspend or dismiss a Supervisory Director. Should the General Meeting wish to suspend or dismiss a Supervisory Director other than in accordance with a proposal of the Supervisory Board, such suspension or dismissal needs to be adopted by an absolute majority of the votes cast representing at least a third of Curetis' issued share capital. A General Meeting must be held within three months after a suspension of a Supervisory Director has taken effect, in which meeting a resolution must be adopted to either terminate or extend the suspension for a maximum period of another three months. The suspended Supervisory Director must be given the opportunity to account for his or her actions at that meeting. If neither such resolution is adopted, nor the General Meeting has resolved to dismiss the Supervisory Director, the suspension will cease after the period of suspension has expired.

#### **TERM OF APPOINTMENT**

Supervisory Directors are appointed for a maximum period of four years, provided that, unless a member of the Supervisory Board resigns at an earlier date, his or her term of office lapses on the day of the first General Meeting to be held in the fourth year after the year of his or her appointment. A Supervisory Director may be reappointed once for a term of up to four years and then reappointed twice for another two years each. In the event of a reappointment after an eight-year period, reasons should be given in the report of the Supervisory Board. The term for each Supervisory Director is shown on the table below under "Supervisory Directors".

## MEETINGS AND DECISION-MAKING

According to the Supervisory Board Rules, resolutions of the Supervisory Board can only be adopted in a meeting at which at least the majority of the Supervisory Directors are present or represented, provided that any member of the Supervisory Board with a direct or indirect personal conflict of interest (as specified

in the Supervisory Board Rules) with Curetis, is not taken into account when establishing this quorum.

The Supervisory Board holds at least four meetings per year, or more often as deemed necessary or desirable by one or more Supervisory or Managing Directors. The Managing Directors shall attend the meetings of the Supervisory Board, if requested, and they shall provide in such meetings all information required by the Supervisory Board.

Pursuant to the Articles of Association, resolutions of the Supervisory Board will be adopted both at and outside a meeting by an absolute majority of the votes cast. In case of a tied vote, the proposal shall have been rejected. The Articles of Association specify that the Supervisory Board Rules may provide that resolutions can only be adopted if one or more Supervisory Directors with a specific function vote in favor of a specific proposal.

Pursuant to the Supervisory Board Rules, the Supervisory Directors shall endeavor to achieve that resolutions are as much as possible adopted unanimously. Where unanimity cannot be reached and if no larger majority is required by law, the Articles of Association or the Supervisory Board Rules, the Supervisory Board may adopt resolutions by an absolute majority of the votes cast at the meeting. In the event of a tie in voting, the proposal shall have been rejected.

### SUPERVISORY BOARD REPORT

In 2019 the Supervisory Board held five meetings (20<sup>th</sup> February, 15<sup>th</sup> May, 27<sup>th</sup> June, 25<sup>th</sup> September and 11<sup>th</sup> December) and in addition two extensive telephone conference calls were held (24<sup>th</sup> January and 26<sup>th</sup> March) and multiple telephone conferences around key financing and strategic corporate topics in April, October and November. The face-to-face Supervisory Board meetings were held at Frankfurt Airport Conference Center with the exception of the Supervisory Board meeting on 27<sup>th</sup> June 2019, which was held immediately following the General Meeting at Schiphol Airport, the Netherlands. All Supervisory Directors and all Management Board members attended all of these meetings as well as on a case-by-case basis individual guests were invited for certain topics. None of the Supervisory Directors have been absent from the Supervisory Board meetings held. The Supervisory Board has been closely involved in all strategy and financing discussions, definition and adaptation of such strategy and transactions and their regular review. During each of the meetings as well as telephone conferences, the Supervisory Board has monitored the respective implementation of Curetis' strategy and financing transactions by asking specific questions to the Management Board as well as reviewing the written Management Board reports on such topics as well as giving particular emphasis to the associated risks and specific risk mitigation measures.

Main points in the January Supervisory Board Telco were the outcomes from the December 2018 restructuring, the future collaboration with Menarini Diagnostics, discussions about an amendment with the European Investment Bank (EIB) and US commercialization efforts.

In February the Supervisory Board met the first time face-to-face in 2019. Nomination and Audit Committee also had meetings beforehand on that same day and the Remuneration Committee had a telco a week before. All three committees reported to the Supervisory Board about their reviews. All decision proposals by the committees were approved by the Supervisory Board. The transfer to the newly signed distribution partner Menarini was discussed. Further discussions around the Yorkville convertible notes facility and potential business combination with OpGen Inc.

In addition to a general update across all areas of business the Supervisory Board telco on 26<sup>th</sup> March 2019 was mainly focused on approving the negotiated Menarini exclusive pan European distribution agreement and the amendment with the EIB. The Supervisory Board also agreed on the re-election terms of the four Supervisory Directors with end of term at the 2019 AGM.

The Supervisory Board meeting in May not only resolved upon the date and agenda of the 2019 AGM and PwC to be proposed again as the auditor for the Company, but was mainly focused on updates to the US commercial activities and ways to raise additional capital into the company other than by commercial actions. The Supervisory Board requested to be updated at least monthly by way of short update telcos.

The June meeting was also the constitutional meeting of the newly re-elected Supervisory Board. William

Rhodes was re-elected as chairman and Dr. Werner Schäfer as vice chair and the committee chairpersons and members were also confirmed. Furthermore, it discussed the U.S. commercial efforts and current status and plan for the A30 *RQ*. Together with H.C. Wainwright the planned business combination of the Curetis Business and OpGen Inc. was discussed extensively.

The Supervisory Board meeting in September was mainly focused on the combination of the businesses of Curetis and OpGen Inc. - the current status of planning, time points and requirements were robustly discussed. First thoughts on future Board of Directors membership of the combined business of Curetis and OpGen were discussed. Business development with regard to Ares Genetics provided some very positive updates regarding a strategic IVD partnering deal and option agreement.

In addition to a general update across all areas of business, focus of the Supervisory Board meeting in December were extensive discussions around the financial situation of Curetis Group and the business combination with OpGen. The later point was thoroughly discussed with phone presence of Dutch legal counsel and banking M&A advisory team members. Finally, the Supervisory Board approved the invitation and agenda for the extraordinary shareholder meeting, which will be necessary in the context of combining Curetis' and OpGen's business, as well as the corresponding shareholder circular. The respective resolutions were unanimously resolved upon by those Supervisory Board members eligible to vote.

#### **AUDIT COMMITTEE REPORT**

The Audit Committee held several meetings and telephone conferences during 2019. On 20<sup>th</sup> February 2019 the audit priorities and key audit matters and areas of focus for the audit of FY 2018 were discussed with PwC. On 7<sup>th</sup> March in another telco, the auditors at PwC reported their findings and discussed the financial statements with special emphasis on Going Concern. An Audit Committee telephone conference was convened for 20<sup>th</sup> March 2019 to discuss completion of the audit field work with emphasis on Going Concern, inventory valuation, impairment testing of intangibles and a reasonable timeline for the furnishing of the Dutch audit opinion. Following the April sign-off on the FY 2018 financials the audit committee continued in an interactive and frequent communication mode for most of 2019 to discuss the various H1-2019 and Q3-2019 financials including Curetis Business carve out financials required for the OpGen business combination and various SEC filings.

During H1-2019 management in consultation with the Audit Committee had also looked into various alternative options for future audit firms but a decision was made to continue with a recommendation to the AGM with PwC as audit firm.

In addition to these aforementioned formal meetings or telephone conferences with the full Audit Committee, there has been and continues to be regular, informal and interactive communication between the CEO, Director Finance, members of the finance team and the Chairman of the Audit Committee. Upon review, the Audit Committee has come to the conclusion and has presented to the Supervisory Board its recommendation to continue with not yet implementing a full internal audit function or department at this time given the small size of the organization and early stage of its corporate development especially following the re-organization and reduction in force with an even smaller team.

#### REMUNERATION COMMITTEE REPORT

The Remuneration Committee reviewed 2018 goal achievements and proposed not to make any bonus payout for the Management Board for 2018 in a telco held on 11<sup>th</sup> February 2019. This was discussed and approved by the entire Supervisory Board in its 20<sup>th</sup> February 2019 meeting. Also, goals for 2019 were discussed, refined and adjusted and approved for Curetis as a whole but also for each member of the Management Board individually in February 2019. A new proposed contract for COO Johannes Bacher was discussed and negotiated between the Management Board member and the Remuneration Committee throughout the first quarter of 2019.

Other topics for the Remuneration Committee in Q1-2018 were the review of compensation of Management Board members and internal benchmarking against e.g. internal pay ratios, share price development or ratio between variable and fixed parts as well as externally against comparable small cap

diagnostics companies in Europe and the U.S. Management Board members were asked their individual view on the amount and structure of their own remuneration during the review of the compensation and this input was used in drafting and getting approval from the AGM for the new COO contract, respectively.

Furthermore, the decision proposal to also grant up to 10,000 additional stock options from the existing ESOP 2016 to all Supervisory Board members of Curetis N.V. as part of the remuneration and compensation plan at the AGM 2019 was discussed extensively in February 2019. These key topics were approved unanimously for inclusion into the agenda of the 2019 General Meeting and the Remuneration Committee as well a Supervisory Board subsequently approved the actual grant of additional stock options to Supervisory Board members effective 1st July 2019. The key terms and conditions for the Curetis ESOP 2016 can be found in a term sheet published on Curetis' website under <a href="https://curetis.com/investors/corporate-governance">https://curetis.com/investors/corporate-governance</a>.

# NOMINATION AND APPOINTMENT COMMITTEE

In early 2019, on 20<sup>th</sup> February 2019 the Nomination Committee held a conference call to evaluate options with regards to the future composition of the Supervisory Board. While several discussions were held with potential candidates for non-executive directors the decision was ultimately made to not propose to the AGM in June 2019 any new external candidates but rather to propose re-election of all four Supervisory Board members up for re-election. The Nomination Committee also discussed in depth on whether to propose the extension and renewal of contract with Johannes Bacher as COO to the Supervisory Board and ultimately the AGM. Throughout H1-2019, several telephone conferences were held between the Nomination Committee and management. At the Supervisory Board meeting on 11 December 2019 the Nomination Committee was tasked with a review of the Management Board and Supervisory Board composition also in light of the business combination with OpGen in 2020. A decision was made with regards to future composition of the Supervisory Board of Curetis N.V: post completion of the OpGen business combination to include only three members: Dr. Werner Schäfer, Dr. Nils Clausnitzer and Dr. Rudy Dekeyser with the other three SB directors expected to resign upon closing of the business combination and join the Board of Directors of OpGen Inc.

An individual review and evaluation of the functioning of the Supervisory Board, its committees as well as each Supervisory Board and Management Board member performance and contribution for 2019 was planned by the Nomination Committee to take place under normal course of business in early Q1-2020. In the light of the sale of Curetis GmbH to OpGen's subsidiary Crystal GmbH it was postponed to take place right after the extraordinary shareholder meeting in March 2020. The evaluation will be based on, including but not limited to, attendance (physical or virtual) of respective meetings, KPIs of the Management Board, review of perceived problems and how they were solved, a check of how communication was handled between the respective board members etc. It will be carried out by way of a closed-door discussion being reported to and discussed with the entire Supervisory Board in the Supervisory Board meeting.

More on the different Committees see below in section "SUPERVISORY BOARD COMMITTEES".

# **DIVERSITY AND LIMITATION OF BOARD POSITIONS**

Although the former requirements of Dutch legislation limiting the number of supervisory positions to be occupied by male Supervisory Directors lapsed, the Dutch Corporate Governance Code provides that the Boards shall aim for a diverse composition of its positions, including in terms of nationality, work background, gender and age. With Prabhavathi Fernandes, Ph.D., the first female Supervisory Director has been serving on the Supervisory Board since 2016. In the recruitment procedure for possible future appointments of Managing and Supervisory Directors, sincere efforts will be made to find Directors suitable according to Curetis' diversity policy and best qualified for the position at that time.

#### SUPERVISORY DIRECTORS

William E. Rhodes, Mr. Mario Crovetto, Mrs. Prabhavathi Fernandes, Ph.D. and Dr. Rudy Dekeyser were all reelected as Supervisory Directors at the General Meeting 2019. Curetis' Supervisory Board therefore as at 31 December 2019 and until 31<sup>st</sup> March 2020 was composed of the following six Supervisory Directors:

Name	Nationality	Age	Position	Date of most recent Appointment <sup>1</sup>	Term
Mr. William E. Rhodes, III	U.S. American	66	Chairman of the Supervisory Board and Chairman of the Remuneration Committee	27 June 2019	End of General Meeting held in 2021
Mr. Mario Crovetto	Italian	66	Member of the Supervisory Board and Chairman of the Audit Committee	27 June 2019	End of General Meeting held in 2021
Dr. Werner Schaefer	German	72	Vice-Chairman of the Supervisory Board and Chairman of the Nomination and Appointment Committee	21 June 2018	End of General Meeting held in 2020
Mrs. Prabhavathi Fernandes, Ph.D.	U.S. American	71	Member of the Supervisory Board	27 June 2019	End of General Meeting held in 2021
Dr. Rudy Dekeyser	Belgian	58	Member of the Supervisory Board	27 June 2019	End of General Meeting held in 2020
Dr. Nils Clausnitzer	German	50	Member of the Supervisory Board	23 June 2017	End of General Meeting held in 2020

Curetis' registered address, Max-Eyth-Straße 42, 71088 Holzgerlingen, Germany, serves as the business address for all Supervisory Directors. Effective 1<sup>st</sup> April 2020 Bill Rhodes, Prabha Fernandes and Mario Crovetto resigned from the Curetis N.V. in Liquidation Supervisory Board to join the OpGen Inc. Board of Directors. Werner Schäfer, Rudy Dekeyser and Nils Clausnitzer are the only 3 Supervisory Board members as of the date of this Annual Report.

#### William E. Rhodes, III

Mr. William E. Rhodes, III, has served as Chairman of the Supervisory Board since the IPO in 2015. Mr. Rhodes is a healthcare executive with more than 30 years of experience in the healthcare industry. During his 14-year career at Becton, Dickinson and Company (BD, 1998-2012), Mr. Rhodes held several senior leadership positions, including roles as Worldwide President of BD Biosciences (2009-2011), a greater than US\$1 billion revenue segment of BD. Mr. Rhodes was also an Executive Officer of BD, and was responsible for corporate strategy and merger and acquisition functions for all of BD's businesses. Furthermore, he founded BD Ventures, the venture capital arm of Becton, Dickinson and Co. Prior to Becton Dickinson, he served in senior business development positions at Johnson & Johnson and Pfizer Inc. Mr. Rhodes also served as President at The William-James Co. and has a track record of over 20 successful acquisitions and divestitures. He was director of Andor Technologies plc (2013-2014), and has served on the boards of Novocell Inc., Conticare Medical, Vitagen Inc., Cellector Inc. and the

California Healthcare Institute, BIO, the San Jose State University Research Foundation and Silicon Valley Leadership Group. He currently serves as Director of Third Day Advisors LLC (since 2013), as Director of Omega Group plc (since 2013), Paramit Corporation LLC (since 2014) and as a member of the Advisory Board of Cayuga Venture Fund (since 2013). Mr. Rhodes has a number of advisory roles with Cornell University, including serving on the Advisory Councils of the McGovern Family Center for Life Sciences (since 2013) and Entrepreneurship at Cornell (since 2015). He also was appointed to the Cornell College of Agriculture and Life Sciences Dean's Council (2016) and served as a venture consultant for Cornell's Blackstone Launchpad (2016). Moreover, he is on the Editorial Board of the journal Clinical and Translational Medicine. Mr. Rhodes holds a Master's degree in International Business from Seton Hall University and a BSc degree from Cornell University. He originated eleven U.S. patents for novel topical drugs and has been a lecturer on entrepreneurship in life sciences, innovation technology and M&A at Cornell University, Seton Hall University and San Jose State University.

#### Mario Crovetto

Mr. Mario Crovetto has been appointed as the Chairman of the Audit Committee upon the IPO. Mr. Crovetto has been working as an independent advisor on M&A and corporate projects, notably integrations, divestments and financings since 2011. From 1999 to 2011, he was the CFO of Eurand NV (Specialty Pharmaceuticals), which he took public on NASDAQ in 2007. From 1990 to 1999, he held various senior business positions at Recordati (Pharmaceuticals), including VP of Corporate Development, Division Manager of Diagnostics and CFO. Prior to that, he held various positions at Montedison (Speciality Chemicals), Digital Equipment Corporation, Mobil and SIAR (Management Consulting). Mr. Crovetto holds a BSc degree in Economics from the Università Cattolica del Sacro Cuore, Milan, and a Master's degree in Business Economics from Harvard University, Cambridge, MA.

#### Dr. Werner Schaefer

Dr. Werner Schaefer has been elected Vice Chairman of the Supervisory Board upon the IPO. He is a specialist in the in-vitro diagnostics industry, and he has nearly 30 years of management experience in this area, having held various international leadership positions throughout his career – including general management, marketing and R&D at major companies such as Behringwerke/Hoechst, Abbott, Boehringer Mannheim and Roche Diagnostics. At Boehringer and Roche, he led the laboratory systems business unit and he served as a member of the Executive Board of Roche Diagnostics GmbH until 2001. Since then, he has worked as a consultant and serves on various executive boards and supervisory boards in highly specialized diagnostics and medical technology companies. He was a member of the Supervisory Board of BRAHMS AG (2002 to 2009, sold to Thermo Fisher) mtm laboratories AG (2003 to 2011, sold to Roche), Vivacta Limited (2006 to 2012, sold to Novartis), Signature AG (2012 to 2013), Genomatix Software GmbH (2011 to 2013) and Cognoptix Inc. (2009 to 2014). He currently serves as a member of the Advisory Board of Human GmbH (since 2005), as the Chairman of the Board of Directors of ProteoMediX AG (since 2012) and as Vice-Chairman of Curetis N.V. (previously Curetis AG - since 2014). Dr. Schaefer holds a Ph.D. in Chemistry from Philipps University Marburg.

# Prabhavathi Fernandes, Ph.D.

Mrs. Prabhavathi Fernandes has been appointed as a member of the Supervisory Board at the General Meeting held in June 2016. Until her retirement in December 2016, she was President and Chief Executive Officer and a member of the Board of Directors of Cempra Inc, a company she has founded. In 2012, she led the initial public offering and listing on Nasdaq for Cempra and has successfully raised over half a billion dollars for the company. During more than four decades, her career has focused on anti-infectives, first on clinical microbiology and infectious diseases and subsequently on pharmaceutical discovery and development. Prior to Cempra, Mrs. Fernandes held executive leadership positions at pharmaceutical corporations including Bristol-Myers Squibb Pharmaceutical Research Institute, Abbott Laboratories and The Squibb Institute for Medical Research. She founded and led three biotechnology and CRO companies. She serves on the Editorial Board of several journals and she has authored over 250 publications and numerous reviews and book chapters and serves as an advisor to three U.S. based biotechnology companies. In 2017, she was appointed to the National Biodefense

Science Board (NBSB) in the Health and Human Services department of the U.S. government and in 2018 she was appointed its Chairperson. In 2018, she was appointed to the Scientific Advisory Board of Global Antibiotic Research & Development Partnership (GARDP), a joint initiative of DNDi and the WHO, which aims to develop and deliver new treatments for bacterial infections, and made Chair of it in November 2019. Finally, Mrs. Fernandes joined the Aelin Therapeutics Board in Leven, Belgium, a company founded on protein aggregation technology that discovers and develops oncology and antibiotic products.

# Dr. Rudy Dekeyser

Dr. Rudy Dekeyser is a non-executive director of Curetis. Dr. Dekeyser joined LSP in 2012 and is Managing Partner of LSP's Health Economics Funds and invests in medical device, diagnostic and digital health companies. Prior to joining LSP, Dr. Dekeyser was a co-founder of VIB in 1995 and Managing Director of the research institute for 17 years. At VIB, he was also responsible for the management of a large patent estate, the licensing activities and the establishment of start-ups such as Devgen (acquired by Syngenta), CropDesign (acquired by BASF), Ablynx (listed on Euronext and Nasdaq and recently acquired by Sanofi), Actogenix (acquired by Intrexon) and Multiplicom (acquired by Agilent). Rudy was a catalyst in the development of a life sciences cluster in Flanders by uniting the actors in the life sciences association FlandersBio, building bio-incubators and triggering the establishment of bio-accelerators. He has been a chairman and non-executive director on many company boards and is currently a board member at Sequana Medical, reMYND, Lumeon and Celyad. He is chairman of EMBLEM (EMBL's business arm) and is a member of the supervisory/advisory board of several not-for-profit foundations, which are funding life sciences research for the benefit of society. Since November 2014, he has been a member of the supervisory board at Curetis. Dr. Dekeyser holds a Ph.D. in Molecular Biology from Ghent University.

#### Dr. Nils Clausnitzer

Dr. Nils Clausnitzer (former EVP Avantor/VWR and Senior Vice President and President EMEA-APAC Lab and Distribution Services of VWR International LLC. / VWR GmbH, Germany) has been appointed a member of the Supervisory Board at the General Meeting held in June 2017. Dr. Clausnitzer has profound knowledge in general management, sales and marketing of diagnostics and medical products serving companies in this space for 19 years now. At VWR Dr. Clausnitzer was responsible for roughly US\$2 billion annual turnover. He was reshaping the EMEA APAC business leading to one of the best results in the following year. Prior to VWR International, he served as President and Head of Commercial Operations, EMEA at Qiagen N.V., joining Qiagen from his position as Managing Director Germany with Abbott Diagnostics. Before, he also held the position of General Manager of Olympus Germany. His emphasis is to enable companies in competitive business environments to succeed with comprehensive customer solutions while driving the necessary changes. Dr. Clausnitzer completed his medical studies at the University of Essen/ University of Hamburg/ University of San Francisco Medical School. He additionally holds an MBA of the Open University, Milton Keynes, UK.

#### SUPERVISORY BOARD COMMITTEES

The Supervisory Board is supported by the Remuneration Committee, the Audit Committee and the Nomination and Appointment Committee. Each of the committees has a preparatory and/or advisory role to the Supervisory Board. In accordance with the Supervisory Board Rules, the Supervisory Board has drawn up respective rules on each Supervisory Board committee's role, responsibilities and functioning, which published online on Curetis' corporate investors https://curetis.com/investors/#corporate-governance. As of the date of this Annual Report, each committee consists of three Supervisory Directors, respectively. Reports of deliberations and findings were presented to the Supervisory Board, which is ultimately responsible for all decision-making at each subsequent Supervisory Board meeting or telephone conference by the Chairman of the respective Committee either under a separate topic or when appropriate in connection with an item already on the Supervisory Board's respective agenda.

#### REMUNERATION COMMITTEE

The Remuneration Committee is a standing committee within the Supervisory Board and advises the Supervisory Board on the exercise of its duties regarding the remuneration policy of the Managing Directors within Curetis', including analyzing developments of the Code, and preparing proposals for the Supervisory Board on these subjects.

#### Members of the Remuneration Committee are:

- Mr. William E. Rhodes (Chairman)
- Prabhavathi Fernandes, Ph.D.
- Dr. Rudy Dekeyser

**Terms of Reference of the Remuneration Committee.** The following presents a summary of the remuneration committee's terms of reference. The complete version is available at Curetis' website. Working within the Supervisory Board, the Remuneration Committee has the following duties:

- Preparation of proposals of the Supervisory Board on the remuneration policy for the Managing Directors to be adopted by the General Meeting;
- Drafting of proposals on the remuneration of the individual Managing Directors to be determined by the Supervisory Board (including the remuneration structure; and the amount of the fixed remuneration, the shares and/or options to be granted and/or other variable remuneration components, pension rights, redundancy pay, and other forms of compensation awarded, as well as the performance criteria and their application);
- Monitoring and analysis of developments of the Dutch Corporate Governance Code;
- Applicable laws and regulations in relation to remuneration policies;
- Preparation of the Remuneration Report;
- Proposals to the Supervisory Board for the remuneration of the individual Supervisory Board Directors to be adopted by the General Meeting;
- Review of the Management Board's proposals on the annual remuneration and bonuses of all employees.

The Remuneration Committee meets at least three times every year. Meetings of the Remuneration Committee are in principle called by the Company Secretary on behalf of the Chairman of the Remuneration Committee, in consultation with the Chairman of the Remuneration Committee.

#### **AUDIT COMMITTEE**

The duties of the Audit Committee include the supervision and monitoring as well as advising the Management Board and each Managing Director regarding the operation of Curetis' internal risk management and control systems.

#### Members of the Audit Committee are:

- Mr. Mario Crovetto (Chairman)
- Dr. Rudy Dekeyser
- Dr. Nils Clausnitzer

**Terms of Reference of the Audit Committee.** Set out below is a summary of the terms of reference of the Audit Committee, which can be obtained in a full version from Curetis' website.

Working within the Supervisory Board, the Audit Committee is charged in particular with the supervision of the Management Board concerning

The operation of the internal risk management and control systems;

- The provision of financial information by Curetis (including the choice of accounting policies, application and assessment of the effects of new rules, information about the treatment of estimated items in the Annual Accounts, forecasts, work of internal and external auditors, etc.);
- Compliance with recommendations and observations of internal and external auditors;
- The role and functioning of the internal audit function;
- The policy of Curetis on tax planning;
- Relations with the External Auditor, including, in particular, his independence, remuneration and any non-audit services for Curetis;
- The financing of Curetis; and
- Application of information and communication technology.

The Audit Committee also provides advice to the Supervisory Board on the nomination of the External Auditor at the General Meeting. Furthermore, the Audit Committee makes proposals to the Supervisory Board on the policy applied to the External Auditor's independence. The preparation of Supervisory Board meetings for discussion of the annual report, the Annual Accounts and half-yearly and quarterly financial figures, the annual budget and major capital expenditures are further duties of the Audit Committee.

Furthermore, the Audit committee has duties towards

- 1. The External Auditor, i.e.
  - a. In acting as the principal contact of the External Auditor if irregularities in the financial reports' content is discovered;
  - b. In providing advice to the Supervisory Board on the External Auditor's remuneration;
  - c. Determining the External Auditor's involvement in content and publication of financial reports except the Annual Accounts;
  - d. Requesting the External Auditor to include all matters that he wishes to bring to the Supervisory Board's attention in his reports;
  - e. Assessment and approval of the External Auditor's functioning and fulfillment of his role at least every four years;
- 2. The Internal Auditor, i.e.
  - a. In being actively involved in drawing up the work schedule;
  - b. In taking cognizance of its findings; and
  - c. In offering access to the Chairman of the Audit Committee.

#### NOMINATION AND APPOINTMENT COMMITTEE

The Nomination and Appointment Committee advises the Supervisory Board on its duties regarding the selection and appointment of Managing Directors and Supervisory Directors. The rules for the Nomination and Appointment Committee are publicly available on Curetis' website.

# Members of the Nomination and Appointment Committee are:

- Dr. Werner Schaefer (Chairman)
- Prabhavathi Fernandes, Ph.D.
- Dr. Nils Clausnitzer

**Terms of Reference of the Nomination and Appointment Committee.** Working within the Supervisory Board, the Nomination and Appointment Committee has the following duties:

- Drafting of selection criteria and appointment procedures for Supervisory Directors and Managing Directors;
- Assessment of the size and composition of the Supervisory Board and the Management Board at least once a year;

- Assessment of the functioning of individual Supervisory Directors and Managing Directors at least once a year;
- Proposals for (re)appointments;
- Supervision of the Management Board's policy on the selection criteria and appointment procedures for Curetis' key employees;
- Preparation of the decision-making process of a Managing Director's membership of the Supervisory Board of a listed company;
- Preparation of the decision-making process concerning any conflicts of interest that may arise in the acceptance by Supervisory Directors of additional positions.

The Nomination and Appointment Committee meets at least once every year.

# REMUNERATION AND EQUITY HOLDINGS

The Supervisory Board establishes the remuneration of the individual Management Board members in accordance with the principles laid down in the Management Board remuneration policy as adopted by the General Meeting of Shareholders on 21<sup>st</sup> June 2018. Details are also published on Curetis' corporate governance website.

This remuneration report is prepared in accordance with the requirements in article 2:135b of the Dutch Civil Code.

After analyzing possible scenarios and outcomes of the variable remuneration components and how they may affect the remuneration, the Supervisory Board presents the Management Board remuneration in the form of shares or options to the General Meeting of Shareholders, for approval. This proposal includes the number of shares and/or options that may be granted to the Management Board and the criteria, which applies to a grant or modification. An equity-based incentive plan has been established at the General Meeting of Shareholders in 2016.

Curetis' current remuneration policy, which can be found on its website under <a href="https://curetis.com/investors/#corporate-governance">https://curetis.com/investors/#corporate-governance</a>, provides for competitive compensation to enable Curetis to recruit and maintain competent management. The Remuneration Policy is designed based on the following remuneration principles:

- The level and structure of the remuneration, which the Managing Directors receive from Curetis for their work shall be in accordance with and benchmarked against industry standards so that qualified and expert Managing Directors can be recruited and retained. The compensation packages of the Curetis N.V.'s Management Board have been benchmarked against a relevant group of international, small-cap, publicly listed molecular diagnostics companies as well as other comparable Germany-based micro-cap biotech companies that are publicly listed. The average Management Board compensation at Curetis is in the lower third of relevant benchmarks and for certain executive positions about a third below the average of benchmarks. This has not changed compared to 2016 as Management Board remuneration remained unchanged.
- When the overall remuneration is fixed, its impact on pay differentials within Curetis shall be taken into account. Typically, the ratio between average Management Board member fixed cash compensation and the senior management (e.g. Director) level should not exceed a ratio of 2:1 for 2019 and not more than 10:1 compared to the lowest average entry level salaries within the Curetis Group. This has not changed compared to 2016 as Management Board remuneration remained unchanged in 2019.
- If the remuneration consists of a fixed component and a variable component, the variable component shall be linked to predetermined, assessable and influenceable targets, which are predominantly of a long-term nature. The variable component of the remuneration must be appropriate in relation to the fixed component.
- The remuneration structure, including severance pay (if any), shall be simple and transparent. It shall

promote the interests of Curetis in the medium and long term, may not encourage Managing Directors to act in their own interests or take risks that are not in keeping with the adopted strategy, and may not reward failing Managing Directors upon termination of their engagement.

- The level and structure of remuneration shall be determined by reference to, among other things, the results, the share price performance and non-financial indicators that are relevant to Curetis' long-term value creation.
- The amount of compensation, which a Managing Director may receive on termination of his engagement may not exceed one year's fixed remuneration component, unless this would be manifestly unreasonable in the circumstances.
- The variable salary may be comprised of two components: (a) an annual cash bonus payment in accordance with industry standards; and/or (b) granting of share options and/or performance share awards in accordance with an employee incentive plan adopted by Curetis.

#### **ADJUSTMENTS TO VARIABLE REMUNERATION**

Pursuant to Dutch law, the remuneration of Managing Directors may be reduced or Managing Directors may be obliged to repay (part of) their variable remuneration to Curetis if certain circumstances apply. The Supervisory Board has the power to adjust the value of variable remuneration (to the extent that it is subject to reaching certain targets and the occurrence of certain events) to an appropriate level if payment of the variable remuneration were to be unacceptable according to requirements of reasonableness and fairness. In addition, the Supervisory Board has the authority under Dutch law to recover the variable remuneration from a Managing Director if such remuneration is awarded on the basis of incorrect information with regard to reaching certain targets and the occurrence of certain events (claw back).

## REMUNERATION OF THE MANAGEMENT BOARD

An overview of the remuneration received by the Management Board for the year ended 31 December, 2019, is shown on the following table. In 2019 there was no variable remuneration for management; thus 100% of the remuneration was fixed.

Name	Base salary/ consultancy fee in kEUR <sup>4</sup>	Employer's pension contri- butions in kEUR	Annual bonus in kEUR	Other benefits in kEUR¹ (car lease, health insurance contribution)	Share based payments and other incentives in kEUR	Total remuneration in kEUR	Total remuneration in kEUR excl. ESOP expenses
Johannes Bacher	200	0	0	3	12 <sup>3</sup>	215	203
Dr. Achim Plum	200	0	0	14²	123	226	214
Oliver Schacht, Ph.D.	240	0	0	11	14 <sup>3</sup>	265	251

 $<sup>^{\</sup>mbox{\tiny 1}}\mbox{Cost}$  reimbursement only, no additional flat catering expenses

<sup>&</sup>lt;sup>2</sup> Company car reimbursement & health insurance

 $<sup>^{\</sup>rm 3}\,\mbox{Expense}$  recognized for granted ESOs

<sup>4</sup> Includes holiday-compensation payouts

#### PROFIT SHARING AND BONUS PAYMENTS ON SHORT TERM

Managing Directors are generally entitled to a bonus that shall be awarded on the basis of the achievement of key performance indicators that are set by the Supervisory Board in advance of each financial year. The key performance indicators will relate to the financial results, and operational progress of Curetis as well as the individual performance of the respective Managing Director.

The bonus entitlement to be awarded is determined by the Supervisory Board upon recommendation by the Remuneration Committee. For 2019, the Supervisory Board established a set of corporate goals (e.g. revenue, cash burn, FDA review and clearance, strategic option evaluation, financings and capital raising etc.), which made up 50% of each Managing Director's potential bonus and for each Managing Director a series of challenging personal goals had been defined, which make up the other 50% of the potential bonus. These individual goals included items such as shareholder value creation, commercial growth and execution post U.S. commercial launch, raising capital and assessing strategic alternatives (CEO), business development and long-term profitable business partnerships for Curetis and Ares Genetics, IR&PR successes, supporting corporate financing and development efforts (CBO), FDA review and clearance, product and platform development objectives, clinical trial execution and FDA inspection outcomes (COO).

Although the individual goals were partially met, no bonus was paid to the Managing Directors due to corporate goals not reaching the 50% threshold.

#### SHARE-BASED PAYMENTS

For detailed information regarding the share-based payment arrangements, refer to note 3.23, note 25 and note 32 of the consolidated financial statements.

# EQUITY-SETTLED OPTION PLAN 2016 (ESOP)

**Grant of options to Managing Directors in 2018.** The Remuneration Policy for the Management Board was adjusted and adopted by the General Meeting on 21<sup>st</sup> June 2018.

Since the initial grant of options to the Managing Directors back in 2016 only one new grant each was made.

Beneficiary	Options granted in 2016	Strike Price in EUR	Options granted in 2019	Strike Price in EUR	Options vested in 2019 (overall)
Johannes Bacher	100,000	6.45	40,000	0.75	100,000
Dr. Achim Plum	100,000	6.45	39,000	0.75	100,000
Oliver Schacht, Ph.D.	100,000	6.45	58,500	0.75	100,000

Beneficiary	Options exercised in 2019	Options forfeited in 2019	Share Based Compensation in 2019 (in kEUR)
Johannes Bacher	0	0	12
Dr. Achim Plum	0	0	12
Oliver Schacht, Ph.D.	0	0	14

The key terms and conditions for the ESOP 2016 can be found in a term sheet, which can be downloaded on the company's website under https://curetis.com/investors/#corporate-governance. There are currently neither plans for buying nor did the company buy back any shares in the past. As part of the sale of Curetis GmbH to OpGen's subsidiary Crystal GmbH, OpGen will assume all duties of the Company with regard to the ESOP 2016 and a defined number of consideration shares (ca. 135 thousand) will be set aside for future possible exercise of these Curetis ESOPs.

#### MANAGEMENT AGREEMENTS AT A GLANCE

The table below shows an overview of the main elements of the current contracts of the Management Board of Curetis for the purposes of Best Practice Provision 3.4.2 of the Dutch Corporate Governance Code.

	JOHANNES BACHER	Dr. ACHIM PLUM	OLIVER SCHACHT, Ph.D.
Position	C00	CBO	CEO
Fixed remuneration (gross per year)	EUR 200,000 (up to EUR 240,000 at the SB discretion)	EUR 200,000 (up to EUR 240,000 at the SB discretion)	EUR 240,000 (up to EUR 300,000 at the SB discretion)
Bonus (gross per year)	Up to EUR 120,000 – to be determined on the basis of the achievement of KPI's related to finance, operations and individual performance, set in advance by the Supervisory Board.	Up to EUR 120,000 – to be determined on the basis of the achievement of KPI's related to finance, operations and individual performance, set in advance by the Supervisory Board.	Up to EUR 150,000 – to be determined on the basis of the achievement of KPI's related to finance, operations and individual performance, set in advance by the Supervisory Board.
Stock options	Initial grant on 1 July 2016 of 100,000 options at a strike price of EUR 6.45; Second grant on 1 July 2019 of 40,000 options at a strike price of EUR 0,75.	Initial grant on 1 July 2016 of 100,000 options at a strike price of EUR 6.45; Second grant on 1 July 2019 of 39,000 options at a strike price of EUR 0,75.	Initial grant on 1 July 2016 of 100,000 options at a strike price of EUR 6.45; Second grant on 1 July 2019 of 58,500 options at a strike price of EUR 0,75.
Severance	N/A	N/A	N/A
End date	30 June 2022	31 December 2021	31 December 2021
Notice period	12 months	12 months	12 months
Insurance	D&O / Accident & injury / Pension (only as part of injury & disability insurance in case of >50% disability); reimbursement of health insurance premiums paid out of pocket up to 12k EUR p.a.	D&O / Accident & injury / Pension (only as part of injury & disability insurance in case of >50% disability); reimbursement of health insurance premiums paid out of pocket up to 12k EUR p.a.	D&O / Accident & injury / Pension (only as part of injury & disability insurance in case of >50% disability); reimbursement of health insurance premiums paid out of pocket up to 12k EUR p.a.
Change of control (i.e. shareholder or shareholders acting in concert acquiring 51% or more of the shares in Curetis)	Within a period of three months after the change of control, the Manager has the one-time right to terminate the agreement with a notice period of three months, being entitled to the management fee for a period of six months after the moment of termination (or maximally the remaining duration of the agreement if shorter than six months).	Within a period of three months after the change of control, the Manager has the one-time right to terminate the agreement with a notice period of three months, being entitled to the management fee for a period of six months after the moment of termination (or maximally the remaining duration of the agreement if shorter than six months).	Within a period of three months after the change of control, the Manager has the one-time right to terminate the agreement with a notice period of three months, being entitled to the management fee for a period of six months after the moment of termination (or maximally the remaining duration of the agreement if shorter than six months).

Curetis does not grant any loans, advanced payments or guarantees to members of the Management and Supervisory Board.

# **EQUITY HOLDINGS**

The number of shares in Curetis N.V. held on 31 Dec 2019 by the Managing Directors (MD) and Supervisory Directors (SD) are as follows:

Name	Shares in Curetis held as of 31 December 2018	Shares in Curetis held as of 31 December 2019
Johannes Bacher (MD)	107,865	5,394
Oliver Schacht (MD)	23,541	0
Dr. Achim Plum (MD)	0	0
Dr. Werner Schäfer (SD)	2,702	0

#### REMUNERATION OF THE SUPERVISORY BOARD

The table below shows the annual remuneration of the Supervisory Board as of 31 December 2019 including additional remuneration for committee chairing roles as well as per meeting and per telephone conference fees earned in 2019.

Name	Base salary/ consultancy fee in kEUR	Employer's pension contributions in kEUR	Annual bonus in kEUR	Other benefits in kEUR (car lease, health insurance contri- bution)	Share based payments and other incentives in kEUR	Total remuneration in kEUR	Total remuneration in kEUR excl. ESOP expenses
William E. Rhodes, III	80	0	0	0	16	96	80
Dr. Werner Schäfer	62	0	0	0	16	78	62
Mario Crovetto	54	0	0	0	16	70	54
Dr. Rudy Dekeyser	0	0	0	0	0	0	0
Prabhavathi Fernandes, Ph.D.	52	0	0	0	16	68	52
Dr. Nils Clausnitzer	32	0	0	0	16	48	32

Curetis does not grant any loans, advanced payments or guarantees to members of the Management and Supervisory Board.

The Remuneration Policy for the Supervisory Board was proposed to and approved by the General Meeting on 16<sup>th</sup> June 2016, and can be found on Curetis' website under:

# https://curetis.com/investors/#corporate-governance.

According to which, each of the Supervisory Directors may also receive a grant of maximum 15,000 Stock Options from the ESOP 2016 per year. The General Meeting on 27<sup>th</sup> June 2019 approved a grant of maximum 10,000 Stock Options from the ESOP 2016 to be granted to each Supervisory Director on 1<sup>st</sup> July 2019. All Supervisory Board members accepted the grant with the exception of Dr. Rudy Dekeyser who waived the grant under LSP fund policies.

Name	Stock Options granted in 2017	Strike Price in EUR	Stock Options granted in 2018	Strike Price in EUR	Stock Options granted in 2019	Strike Price in EUR
William E. Rhodes, III	15,000	4.93	10,000	4.62	10,000	0.75
Dr. Werner Schäfer	15,000	4.93	10,000	4.62	10,000	0.75
Mario Crovetto	15,000	4.93	10,000	4.62	10,000	0.75
Dr. Rudy Dekeyser	waived	n.a.	waived	n.a.	waived	n.a.
Prabhavathi Fernandes, Ph.D.	15,000	4.93	10,000	4.62	10,000	0.75
Dr. Nils Clausnitzer	15,000	4.93	10,000	4.62	10,000	0.75
TOTAL	90,000		50,000		50,000	

Name	Options vested in 2019 (overall)	Options exercised in 2019	Options forfeited in 2019	Stock Option Expense in 2019 in EUR
William E. Rhodes, III	18,333	0	0	13,600
Dr. Werner Schäfer	18,333	0	0	13,600
Mario Crovetto	18,333	0	0	13,600
Dr. Rudy Dekeyser	n.a.	n.a.	n.a.	0
Prabhavathi Fernandes, Ph.D.	18,333	0	0	13,600
Dr. Nils Clausnitzer	18,333	0	0	13,600
TOTAL	91,665	0	0	68,000

The reason why equity stock options have been granted to the Supervisory Board Members are:

- i. Alignment of strategic interest of Supervisory Board Members with the company and its shareholders.
- ii. Ability to recruit, retain and incentivize Supervisory Board Members in line with what is market standard e.g. in the USA.

# COMPARATIVE INFORMATION ON THE CHANGE OF REMUNERATION AND COMPANY PERFORMANCE

		Actual (in kEUR)			
	2016¹	2017	2018	2019	2019
Johannes Bacher	86	-43	20	-20	200
Dr. Achim Plum	104	-2	-	5	205
Oliver Schacht, Ph.D.	63	-22	-	-	240

William E. Rhodes	71	-	-1	-	83
Dr. Werner Schäfer	39	-	-3	-	61
Mario Crovetto	37	-	-2	-	42
Dr. Rudy Dekeyser	-	-	-	-	0
Prabhavathi Fernandes, Ph.D.	19	15	-3	-	31
Dr. Nils Clausnitzer	-	20	9	-	29
Average Amount Other Employees	-20	-26	-4	-3	79
Company Performance - Profit before Tax	-1,127	-4,403	-4,162	414	-23,297

<sup>&</sup>lt;sup>1</sup>Note that the 2015 period has been annualized since the IPO occurred in November 2015

Pay ratio	2018	2019
Average amount other employees vs. management	2.46	2.66

#### SHAREHOLDERS

#### CAPITAL STRUCTURE

Curetis' issued share capital as of 31 December 2019 amounted to EUR 262,823.66 and consisted of 26,282,366 ordinary shares at a nominal value of EUR 0.01 each. The total authorized capital is EUR 550,000.00 at EUR 0.01 per share i.e. 55,000,000 shares. The only class of shares is 'ordinary shares' without any special rights attached to them. Furthermore, there are no special shareholder rights for any of the shareholders of Curetis.

The following major shareholdings fall under the mandatory notice provisions of articles 5:34, 5:35, 5:38 and/or 5:43 of the Financial Supervision Act and have been included in the Dutch AFM's public register in 2019: KfW Bank (3.7%) and Roche Finanz AG (3.6%). No further updates or changes to these have been filed with the AFM until the date of this Annual Report.

#### SHAREHOLDERS' REGISTER

The shares are in registered form (op naam). No share certificates (aandeelbewijzen) are or may be issued. If requested, the Management Board will provide a Shareholder, usufructuary or pledgee of such shares with an extract from the register relating to his or her title to a Share free of charge. If the shares are encumbered with a right of usufruct or a right of pledge, the extract will state to whom such rights will fall to. The shareholders' register is kept by the Management Board.

Curetis' shareholders register records the names and addresses of the Shareholders, the number of shares held, the amount paid on each Share and the date of registration in the shareholders' register. In addition, each transfer or passing of ownership is registered in the shareholders' register. The shareholders register also includes the names and addresses of persons and legal entities with a right of pledge (pandrecht) or a right of usufruct (vruchtgebruik) on those shares. For shares as referred to in the Dutch Securities Giro Transfers Act (Wet giraal effectenverkeer), including the offer shares, which belong to (i) a collective depot as referred to in that Dutch Securities Giro Transfers Act, of which shares form part as being kept by an intermediary, as referred to in the Dutch Securities Giro Transfers Act or (ii) a giro depot as referred to in that Dutch Securities Giro Transfers Act of which shares form part, as being kept by a central institute as referred to in the Dutch Securities Giro Transfers Act, the name and address of the intermediary or the central

institute shall be entered in the shareholders' register, stating the date on which those shares became part of such collective depot or giro depot, the date of acknowledgement by or giving of notice to, as well as the paid-up amount on each share.

#### **ISSUANCE OF SHARES**

The General Meeting may, on a proposal of the Management Board, which is approved by the Supervisory Board, resolve to issue shares or grant rights to subscribe for shares and to restrict and/or exclude statutory preemptive rights in relation to the issuance of shares or the granting of rights to subscribe for shares. The Articles of Association provide that the General Meeting may, upon a proposal of the Management Board, which is approved by the Supervisory Board, designate the Management Board as the body authorized, subject to approval of the Supervisory Board, to resolve to issue shares and to grant rights to subscribe for shares and to restrict or exclude statutory pre-emptive rights in relation to the issue of shares or the granting of rights to subscribe for shares. Pursuant to the Articles of Association and Dutch law, the period of designation may not exceed five years, but the designation may be renewed by a resolution of the General Meeting for periods of up to five years.

Unless provided otherwise in the designation, the designation cannot be cancelled. The resolution designating such authority to the Management Board must specify the number of shares, which may be issued and, if applicable, any conditions to the issuance.

No resolution of the General Meeting or, if designated, the Management Board is required for an issue of shares pursuant to the exercise of a previously granted right to subscribe for shares. Curetis may not subscribe for its own shares on issue.

The General Meeting on 27<sup>th</sup> June 2019, has designated the Management Board for a period that ends 18 months after the date of the annual general meeting 2019, as the corporate body authorized to, subject to approval of the Supervisory Board, issue shares or grant rights to subscribe for shares and to limit or exclude pre-emptive rights in respect thereof. Pursuant to this designation, the Management Board may, subject to approval of the Supervisory Board, resolve to issue shares or grant rights to subscribe for shares (i) up to a maximum of 10% of the total number of shares issued and outstanding on the date of the annual general meeting 2019 plus (ii) an additional 10% of the total number of shares issued and outstanding on the date of the annual general meeting 2019 in connection with or on the occasion of mergers and acquisitions and strategic alliances involving any of more of the Company and its group companies as a party and finally (iii) plus additional shares for implementation of the stock option plan up to a maximum of 2,219,951 shares. Such authorization may from time to time be extended by a resolution of the general meeting subject to the limitations set out above.

Furthermore, the General Meeting on 27<sup>th</sup> June 2019, has designated the Management Board for a period that ends 18 months after the date of the annual general meeting 2019, as the corporate body authorized to, subject to approval of the Supervisory Board, issue shares or grant rights to subscribe for shares without limiting or excluding pre-emptive rights in respect thereof in relation to strategical capital raising(s). Pursuant to this designation, the Management Board may, subject to approval of the Supervisory Board, resolve to issue shares or grant rights to subscribe for up to 50% of the total number of ordinary shares issued on the annual general meeting 2019.

#### **PRE-EMPTIVE RIGHTS**

Each Shareholder shall have a pre-emptive right in proportion to the aggregate nominal amount of his or her shares. Shareholders do not have pre-emptive rights in respect of shares issued against contribution in kind, shares issued to employees of Curetis and any of its group companies or shares issued to persons exercising a previously granted right to subscribe for shares.

Pre-emptive rights may be restricted or excluded by a resolution of the General Meeting at the proposal of the Management Board, which is subject to the approval of the Supervisory Board. Such resolution of the General Meeting requires a majority of at least two-thirds of the votes cast, if less than half of the issued and outstanding share capital of Curetis is present or represented at the General Meeting.

The Management Board is authorized, subject to the approval of the Supervisory Board, to resolve on the restriction or exclusion of the pre-emptive right if and to the extent the Management Board has been designated by the General Meeting to do so. The designation will only be valid for a specific period and may from time to time be extended by the General Meeting, in each case not exceeding five years. Unless provided otherwise in the designation, the designation cannot be cancelled.

The General Meeting on 27<sup>th</sup> June 2019, has designated the Management Board for a period that ends 18 months after the date of the annual general meeting 2018, as the corporate body authorized to, subject to approval of the Supervisory Board, limit and/or exclude statutory pre-emptive rights on newly issued shares or rights to subscribe for shares. Pursuant to this designation, the Management Board may, subject to approval of the Supervisory Board, limit and/or exclude statutory pre-emptive rights in respect of issues of future securities made by making use of the authorization of the Management Board as referred to in agenda item 13 of the agenda of the General Meeting 2019 and illustrated under "Issuance of Shares" above.

#### **ACQUISITION OF SHARES BY CURETIS**

Curetis may acquire fully paid-up shares at any time for no consideration or, subject to the laws of the Netherlands and the Articles of Association if: (i) the distributable part of the Shareholders' equity is at least equal to the total purchase price of the repurchased shares; (ii) the aggregate nominal value of the shares, which Curetis acquires, holds or holds as pledge or which are held by a subsidiary does not exceed 50% of the issued share capital; and (iii) the Management Board has been authorized by the General Meeting to repurchase shares, which authorization can only be granted at the proposal of the Management Board, which proposal is subject to the approval of the Supervisory Board. The General Meeting's authorization is valid for a specific period not exceeding 18 months. As part of the authorization, the General Meeting must specify the number of shares that may be acquired, the manner in which the shares may be acquired and the price range within which the shares may be acquired.

No authorization from the General Meeting is required for the acquisition of fully paid-up shares for the purpose of transferring these shares to Curetis' employees pursuant to any share option plan.

Curetis may not cast votes on, and is not entitled to dividends paid on shares held by it nor will such shares be counted for the purpose of calculating a voting quorum. For the computation of the profit distribution, the shares held by Curetis in its own capital shall not be included. The Management Board is authorized, subject to approval of the Supervisory Board, to dispose of Curetis' own shares held by it.

The General Meeting on 27<sup>th</sup> June 2019, has designated the Management Board for a period that ends 18 months after the date of the annual general meeting 2019, as the corporate body authorized to, subject to approval of the Supervisory Board, cause the Company to acquire its own fully paid-up shares (including shares issued as stock dividend), subject to the approval of the Supervisory Board, up to a maximum of 10% of the total number of shares issued and outstanding on the date of the General Meeting 2019 plus any and all of the roll-over shares, provided the Company will hold no more shares in stock than at maximum 50% of the issued share capital, either through purchase on a stock exchange or otherwise, at a price, excluding expenses, not lower than the nominal value of the shares and not higher than the opening price on Euronext in Amsterdam and Euronext in Brussels on the day of the repurchase plus 10%.

#### CAPITAL REDUCTION

Subject to the provisions of the laws of the Netherlands and the Articles of Association, the General Meeting may resolve to reduce the issued share capital by (i) cancelling shares or (ii) reducing the nominal value of shares through an amendment of the Articles of Association. A resolution to cancel shares may only relate to Shares held by Curetis itself or of which it holds the depositary receipts. A reduction of the nominal value of shares, with or without repayment must be made pro rata on all shares concerned. This pro rata requirement may be waived if all shareholders concerned so agree.

A resolution of the General Meeting upon a proposal of the Management Board, which is subject to the prior approval of the Supervisory Board, to reduce the share capital requires a majority of at least two-thirds of the votes cast, if less than half of the issued and outstanding share capital is present or represented at the

General Meeting. If more than half of the issued and outstanding share capital should be present or represented at the General Meeting, a simple majority is required.

In addition, the laws of the Netherlands contain detailed provisions regarding the reduction of capital. A resolution to reduce the issued share capital shall not take effect as long as creditors have legal recourse against the resolution.

#### **DIVIDENDS AND OTHER DISTRIBUTIONS**

#### **GENERAL**

Distribution of profits only takes place following the adoption of the annual accounts from which it appears that the distribution is allowed. Curetis may only make distributions, whether a distribution of profits or of freely distributable reserves, to its shareholders if its shareholders' equity exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by the laws of the Netherlands or by the Articles of Association. As the requirements were not met, Management Board decided, same as in the last years, not to pay any dividends in 2019 and does not expect to pay any dividends in the foreseeable future.

#### RIGHT TO RESERVE

The Management Board, subject to the prior approval of the Supervisory Board, may resolve to reserve the profits or a part of the profits.

#### DISSOLUTION AND LIQUIDATION

Curetis may only be dissolved by a resolution of the General Meeting upon a proposal of the Management Board, which is subject to the prior approval of the Supervisory Board. If the General Meeting has resolved to dissolve Curetis, the Management Board must carry out the liquidation of Curetis, unless otherwise resolved by the General Meeting. The Supervisory Board shall be charged with the supervision thereof. During liquidation, the provisions of the Articles of Association will remain in force to the extent possible. The balance of Curetis' assets remaining after all liabilities and the costs of liquidation have been deducted shall be distributed among the Shareholders in proportion of their number of shares.

## EXCHANGE CONTROLS AND OTHER PROVISIONS RELATING TO NON-DUTCH SHAREHOLDERS

Under Dutch law, subject to the 1977 Sanction Act (Sanctiewet 1977) or otherwise by international sanctions, there are no exchange control restrictions on investments in, or payments on, shares (except as to cash amounts).

There are no special restrictions in the Articles of Association or the laws of the Netherlands that limit the right of Shareholders who are not citizens or residents of the Netherlands to hold or vote shares.

# GENERAL MEETINGS AND VOTING RIGHTS

#### GENERAL MEETINGS

General Meetings shall be held in the Netherlands in Amsterdam, Haarlemmermeer, The Hague, Rotterdam, Utrecht or Arnhem. The General Meeting must be held at least once a year, no later than in June. Extraordinary General Meetings may be held as often as the Management Board or the Supervisory Board deem desirable. In addition, one or more Shareholders, who solely or jointly represent at least one-tenth of the issued capital, may request that a General Meeting be convened, the request setting out in detail matters to be considered. If no General Meeting has been held within 42 days of the Shareholder(s) making such request, that/those Shareholder(s) will be authorized to request in summary proceedings a Dutch District Court to convene a General Meeting. In any event, a General Meeting will be held to discuss any requisite measures within three months of it becoming apparent to the Management Board that the shareholders' equity of Curetis has decreased to an amount equal to or lower than one-half of the issued and paid-up part of the capital.

The convocation of the General Meeting must be published through an announcement on the website of

Curetis. The notice must state the time and place of the meeting, the record date, the manner in which persons entitled to attend the General Meeting may register and exercise their rights, the time on which registration for the meeting must have occurred ultimately, as well as the place where the meeting documents may be obtained. The notice must be given by at least such number of days prior to the day of the meeting as required by the laws of the Netherlands, which is currently 42 days.

The agenda for the annual General Meeting must contain certain subjects, including, among other things, the adoption of Curetis' annual accounts, the discussion of any substantial change in its corporate governance structure and the allocation of the profit, insofar as this is at the disposal of the General Meeting. In addition, the agenda shall include such items as have been included therein by the Management Board, the Supervisory Board or Shareholders (with due observance of the laws of the Netherlands as described below). If the agenda of the General Meeting contains the item of granting discharge to the Managing Directors and Supervisory Directors concerning the performance of their duties in the financial year in question, the matter of the discharge shall be mentioned on the agenda as separate items for the Management Board and the Supervisory Board respectively. The agenda shall also include such items as one or more Shareholders and others entitled to attend General Meetings, representing, pursuant to the Articles of Association, at least the percentage of the issued and outstanding share capital as required by law (which as of the date of this Annual Report is 3%), have requested the Management Board by a motivated request to include in the agenda, at least 60 days before the day of the General Meeting. No resolutions may be adopted on items other than those, which have been included in the agenda, unless the resolution is adopted unanimously during a meeting where the entire issued capital of Curetis' is present or represented.

Shareholders who, individually or with other Shareholders, hold shares that represent at least 1% of the issued and outstanding share capital or a market value of at least Euro 250,000, may request Curetis to disseminate information that is prepared by them in connection with an agenda item for a General Meeting. Curetis can only refuse disseminating such information, if received less than seven business days prior to the General Meeting, if the information gives or could give an incorrect of misleading signal or if, in light of the nature of the information, Curetis cannot reasonably be required to disseminate it.

The General Meeting is chaired by the Chairman of the Supervisory Board. Managing Directors and Supervisory Directors may attend a General Meeting. In these General Meetings, they have an advisory vote. The Chairman of the General Meeting may decide at his or her discretion to admit other persons to the General Meeting. Each Shareholder may attend the General Meeting, address the General Meeting and exercise voting rights pro rata to his or her shareholding, either in person or by proxy. Shareholders may exercise these rights, if they are the holders of shares on the record date as required by the laws of the Netherlands, which is currently the 28th day before the day of the General Meeting, and they or their proxy have notified Curetis of their intention to attend the General Meeting in writing at the address and by the date specified in the notice of the meeting. The convocation notice shall state the record date and the manner in which the persons entitled to attend the General Meeting may register and exercise their rights.

#### **VOTING RIGHTS**

Each Share confers the right to cast one vote in the General Meeting. Subject to certain exceptions provided by Dutch law or the Articles of Association, resolutions of the General Meeting are passed by an absolute majority of votes cast. Pursuant to Dutch law, no votes may be cast at a General Meeting in respect of shares, which are held by Curetis.

#### AMENDMENT OF THE ARTICLES OF ASSOCIATION

The General Meeting may resolve to amend the Articles of Association upon a proposal of the Management Board, which is subject to the prior approval of the Supervisory Board. A proposal to amend the Articles of Association must be included in the agenda. A copy of the proposal, containing the verbatim text of the proposed amendment, must be lodged with Curetis for the inspection of every Shareholder until the end of the General Meeting.

#### STATUTORY AUDITOR

The fees for services rendered by Curetis' independent auditor PricewaterhouseCoopers Accountants N.V. and its member firms and/or affiliates to Curetis and its subsidiaries were approved by the Audit Committee and/or the Supervisory Board and can be detailed as follows:

	2017 (in EUR)	2018 (in EUR)	2019 (in EUR)
Financial statement audit	161,000	161,000	406,650 (406,650 for 2019; and 250,000 for 2018 and 2017 in connection with the Sale of Curetis GmbH to OpGen's Sub Crystal GmbH)
Audit related services and other audit work	65,000	626,437	1,134,052
Tax consultancy	0	0	0
Total	226,000	787,437	1,540,702

PricewaterhouseCoopers Accountants N.V. and its member firms and/or affiliates did not render any services or charge any fees that were not related to the audit of the financial statements.

# LIABILITY, CONFLICTS OF INTEREST RELATING TO MEMBERS OF THE BOARDS

## LIABILITY OF MANAGING DIRECTORS AND SUPERVISORY DIRECTORS

Under the laws of the Netherlands, the Managing Directors and Supervisory Directors may be liable towards Curetis for damages in the event of improper or negligent performance of their duties. They may be jointly and severally liable for damages towards Curetis for infringement of the Articles of Association or of certain provisions of the Dutch Civil Code. In addition, they may be liable towards third parties for infringement of certain provisions of the Dutch Civil Code. In certain circumstances, they may also incur additional specific civil and criminal liabilities.

The Managing Directors, the Supervisory Directors and certain other employees and all other directors and/or officers of Curetis are insured under an insurance policy taken out by Curetis against damages resulting from their conduct when acting in their capacities as members or officers.

# **OUTLINE OF ANTI-TAKEOVER MEASURES**

There are currently no anti-takeover measures of any form or fashion in place, nor are there any plans by either the Management Board nor the Supervisory Board to implement any such anti-takeover measures at the present point in time. It cannot currently be foreseen any circumstances in which any such anti-takeover measures would be warranted.

#### **CONFLICTS OF INTEREST**

#### MANAGEMENT BOARD

The laws of the Netherlands and the Dutch Corporate Governance Code provide that a Managing Director of a Dutch public company with limited liability (naamloze vennootschap), such as Curetis, may not participate in the adoption of resolutions (including deliberations in respect of these) if he or she has a direct or indirect personal interest conflicting with the interests of Curetis. Such a conflict of interest only exists if in the situation at hand, the Managing Director is deemed to be unable to serve Curetis' interests and its

connected business with the required level of integrity and objectivity. Pursuant to the Management Board Rules, each Managing Director shall immediately report any (potential) personal conflict of interest concerning a Managing Director to the Chairman of the Supervisory Board and to the other Managing Directors and shall provide all information relevant to the conflict.

If no resolution can be adopted by the Management Board as a consequence of such a personal conflict of interest, the resolution concerned will be adopted by the Supervisory Board. All transactions in which there are conflicts of interest with Managing Directors will be agreed on terms that are customary in the sector concerned and disclosed in Curetis' annual report.

The existence of a (potential) personal conflict of interest does not affect the authority to represent Curetis. Each time a resolution is adopted, while one or more of the Managing Directors had a conflict of interest, the Management Board will afterwards inform the General Meeting and the Supervisory Board thereof and will indicate how they have dealt with such a conflict of interest.

#### SUPERVISORY BOARD

Similar to the rules that apply to the Managing Directors as described above, Dutch law and the Dutch Corporate Governance Code also provide that a Supervisory Director of a Dutch public company with limited liability, such as Curetis, may not participate in the adoption of resolutions (including deliberations in respect of these) if he or she has a direct or indirect personal interest conflicting with the interests of the company.

Each Supervisory Director (other than the Chairman of the Supervisory Board) shall immediately report any (potential) personal conflict of interest concerning a Supervisory Director to the Chairman of the Supervisory Board and must provide him with all information relevant to the (potential) conflict. In case the Chairman of the Supervisory Board has a (potential) personal conflict of interest he shall immediately report such potential conflict to the Vice-Chairman of the Supervisory Board and shall provide all information relevant to the (potential) personal conflict of interest. If both the Chairman and the Vice-Chairman of the Supervisory Board have a (potential) personal conflict of interest with respect to the same matter, they will report and provide information to one of the other Supervisory Directors.

If as a result of such a personal conflict of interest either or both the Chairman or Vice-Chairman of the Supervisory Board are not entitled to vote, the resolution of the Supervisory Board will be adopted by the other Supervisory Directors validly present or represented, by unanimous votes. If, as a result of such a personal conflict of interest, all Supervisory Directors are unable to participate in the deliberations and the decision-making process and no resolution of the Supervisory Board can be adopted, the resolution can be adopted by the General Meeting.

All transactions in which there is a conflict of interest with one or more Supervisory Directors shall be agreed on terms that are customary in the sector concerned and disclosed in Curetis' annual report.

#### POTENTIAL CONFLICTS OF INTEREST AND OTHER INFORMATION

The Supervisory Director Dr. Rudy Dekeyser is affiliated with LSP Curetis Pooling B.V. a major shareholder of Curetis. This subjects him to a conflict of interest as a shareholder representative on the one hand and as a Supervisory Director on the other.

In 2017 the Supervisory Director Dr. Werner Schaefer had received 2,702 shares from certain existing Shareholders under a Carve Out Agreement (as disclosed in the IPO Prospectus in 2015). In December 2019, he sold the 2,702 shares in Curetis N.V. This subjected him to a conflict of interest as a Shareholder on the one hand and his duties as a Supervisory Director on the other until the sale of the shares in December 2019.

In addition, the Managing Directors Johannes Bacher and Oliver Schacht held a minority stake in Curetis. All three Managing Directors, including Dr. Achim Plum, were also beneficiaries under Curetis PSOP (Phantom Stock Option Plan) Roll-Over Agreement as well as beneficiaries under the Curetis ESOP 2016 (see notes 3,23, 25 and 32 of the notes of the consolidated financial statement).

With all three Managing Directors of the Company and the Supervisory Directors Mr. William E. Rhodes III, Mr. Mario Crovetto and Mrs. Prabhavathi Fernandes Ph.D. being expected as member of the Board of

Directors of the combined Newco after the sale of Curetis GmbH, the resolutions regarding the transfer with OpGen Inc. and the resolutions regarding the respective extraordinary general meeting of Curetis N.V. were approved by the remaining three members of the Supervisory Board, Dr. Werner Schäfer, Dr. Dekeyser and Dr. Clausnitzer.

Other than these circumstances, Curetis is not aware of any potential conflicts between the personal interests or other duties of Supervisory Directors, Managing Directors and their respective relatives on the one hand and the interests of Curetis on the other hand. There is no family relationship between any Managing Director and any Supervisory Director. Best practice provisions 2.7.3 and 2.7.4 of the Dutch Corporate Governance Code have been complied with.

During the last five years, none of the Managing Directors or Supervisory Directors

- i. has been convicted of fraudulent offenses;
- ii. has served as a director or officer of any entity subject to bankruptcy proceedings, receivership or liquidation; or
- iii. has been subject to any official public incrimination and/or sanctions by statutory or regulatory authorities (including designated professional bodies), or disqualification by a court from acting as a member of the administrative, management or supervisory body of an issuer, or from acting in the management or conduct of the affairs of any issuer.

Other than as disclosed herein, Curetis is not aware of any arrangement or understanding with major Shareholders, suppliers, customers or others pursuant to which any Managing Director or Supervisory Director was selected as a member of such management or supervisory bodies.

There was no transaction in FY 2019 between Curetis and legal or natural persons who hold at least ten percent of the shares in Curetis. Best practice provision 2.7.5 of the Dutch Corporate Governance Code was complied with.

#### MANAGEMENT AND SUPERVISORY BOARD MEMBERS' INDEMNIFICATION

Pursuant to the Articles of Association, and unless the laws of the Netherlands provide otherwise, the following will be reimbursed to inter alia current and former Managing Directors and Supervisory Directors:

- i. The reasonable costs of conducting a defense against claims based on acts or failures to act in the exercise of their duties or any other duties currently or previously performed by them at Curetis' request;
- ii. Any damages or fines payable by them as a result of an act or failure to act as referred to under (i); and
- iii. The reasonable costs of appearing in other legal proceedings or investigations in which they are involved as current or former Managing Directors or Supervisory Directors, with the exception of proceedings primarily aimed at pursuing a claim on their own behalf.

There shall be, however, no entitlement to reimbursement if and to the extent that a Dutch court, or, in the event of arbitration, an arbitrator has established in a final and conclusive decision that the act or failure to act of the person concerned can be characterized as willful (opzettelijk) or grossly negligent (grove schuld) misconduct,

unless the laws of the Netherlands provide otherwise, or this would, in view of the circumstances of the case, be unacceptable according to standards of reasonableness and fairness; or the costs or financial loss of the person concerned are covered by insurance and the insurer has paid out the costs or financial loss.

#### **DUTCH CORPORATE GOVERNANCE CODE**

The Dutch Corporate Governance Code, as amended, became first effective on 1<sup>st</sup> January 2004, and finds its statutory basis in Book 2 of the Dutch Civil Code. The Dutch Corporate Governance Code applies to Curetis as it has its statutory seat in the Netherlands and its shares are listed on the regulated market Euronext in Amsterdam and Euronext in Brussels.

The Dutch Corporate Governance Code is based on the notion that a company is a long-term alliance between the various stakeholders of the company. Stakeholders are groups and individuals who, directly or indirectly, influence – or are influenced by – the attainment of the company's objectives: employees, shareholders and other lenders, suppliers, customers and other stakeholders. The Management Board and the Supervisory Board have responsibility for weighing up these interests, generally with a view to ensuring the continuity of the company and its affiliated enterprises, as the company seeks to create long-term value, maintain a culture of integrity, transparency and trust.

The Dutch Corporate Governance Code is based on a "comply or explain" principle. Accordingly, companies are required to disclose in their annual report filed in the Netherlands whether or not they are complying with the various principles and provisions of the Dutch Corporate Governance Code that are addressed to the Board of Directors or, if any, the Supervisory Board of the company. If a company deviates from a best practice provision in the Dutch Corporate Governance Code, the reason why must be properly explained in its annual report.

#### COMPLIANCE WITH THE DUTCH CORPORATE GOVERNANCE CODE

The current revised Dutch Corporate Governance Code was published on 8 December 2016, and became effective on 1<sup>st</sup> January 2017. The Dutch Corporate Governance Code applies to all Dutch companies listed on a regulated market or a comparable system in a non-EEA member state. The Dutch Corporate Governance Code contains principles and best practice provisions for the Management and Supervisory Board, shareholders and General Meetings of shareholders, financial reporting, auditors, disclosure, compliance and enforcement standards, and is based on a "comply or explain" principle. Accordingly, Curetis is required to disclose in its annual report for which principles and best practices it does not apply the code provisions of the Dutch Corporate Governance Code and, in the event that Curetis does not apply a certain provision, to explain the reason why. The full text of the Dutch Corporate Governance Code can be found on http://www.mccg.nl/?page=4738.

Curetis fully endorses the underlying principles of the Dutch Corporate Governance Code and is committed to adhering to the best practices of the Dutch Corporate Governance Code as much as possible. Curetis complies with the Dutch Corporate Governance Code, however, Curetis does not (yet) fully comply with or deviates from the best practice provisions with the following rationale and explanation provided below:

- Best practice provision 1.3.2 provides that the Management Board should assess the way in which the internal audit function fulfils its responsibility annually, taking into account the audit committee's opinion. As the internal Auditor was part of the Management Board of Curetis GmbH until end of Nevember 2019, the Audit Committee did the assessment. No changes to this are planned.
- Best practice provision 1.3.3 provides that the internal audit function should draw up an audit plan involving the Management Board, the Audit Committee and the external auditor in this process. There is no formal audit plan, but due to the position as Director Finance of Curetis GmbH, the internal auditor had interactions with all three named parties and did his auditing on an ongoing basis in constant consultation with them.
- Whilst Curetis had appointed an internal auditor, due to its size and resource constraints, this function was held by Curetis GmbH's Director Finance. Therefore, no specific audit plan was approved by the Management and Supervisory Boards (best practice provision 1.3.4). However, due to his position as Director Finance, he had full access to all information needed, to the Audit Committee and the external auditors and with the resignation of the Director Finance effective 30<sup>th</sup> November 2019 Curetis no longer had an internal auditor since then. The Audit Committee evaluates the need for an independent

and/or bigger internal audit function on a regular basis and may make a recommendation to the Management and Supervisory Board based on this assessment. Any such recommendation will be included in the Supervisory Board reports.

Best practice provision 2.1.8 provides criteria for the independence of Supervisory Directors. As of year-end 2019, two out of six of the Supervisory Directors, being Dr. Rudy Dekeyser and Mr. William E. Rhodes, III, are not deemed independent according to these criteria. However, due to different criteria being concerned, Curetis still meets the limits for the Supervisory Board as such given in best practice provision 2.1.7 of the Dutch Corporate Governance Code.

Dr. Dekeyser does not meet the requirements of best practice provision 2.1.8 vii. because he is currently affiliated with one of the former largest shareholders, being LSP Curetis Pooling B.V. (held more than 10% of the issued and outstanding share capital of Curetis until year end 2019 before exiting their position in  $\Omega_{1-2020}$ ).

The reappointment of Dr. Dekeyser is based on the aim to secure sufficient continuity within the Supervisory Board. Dr. Dekeyser had been Supervisory Director of Curetis AG prior to the IPO and is expected to be – and still is - well equipped to perform the duties as Supervisory Director. Dr. Dekeyser has been reappointed as Supervisory Director for the term of one year (ending with the General Meeting in 2020).

Mr. Rhodes shall formally not be deemed independent as best practice provision 2.1.8 iii. assumes automatic dependency with Supervisory Directors, which acted as consultants to the company prior to the appointment as Supervisory Director. A few weeks prior to the date of the IPO, Curetis AG and Mr. Rhodes had entered into an agreement relating to his performance of consultancy services for Curetis AG as of 1<sup>st</sup> November 2015, in anticipation of his expected appointment as Supervisory Director. The service agreement has terminated automatically upon his appointment as Supervisory Director on 11<sup>th</sup> November 2015, and with an overall fee of USD 2,000 it no material consultancy fees have been paid. Given his track record in the diagnostics industry and previous executive management roles with Becton Dickinson, Mr. Rhodes was expected to be – and still is - well equipped to perform the duties as Supervisory Director and Chairman of the Supervisory Board. Mr. Rhodes has been reappointed as Supervisory Director for the term of two years (ending with the General Meeting in 2021).

- Best practice provision 2.3.4 provides that more than half of the members of the Audit Committee and the Remuneration Committee should be independent within the meaning of best practice provision 2.1.8. As indicated above, two out of six Supervisory Directors are not deemed to be independent. However, given the wish of the Supervisory Directors to be actively involved within the Supervisory Board and all of its committees, the Remuneration Committee shall not be composed of more than one Supervisory Director, which is not independent: two members of the Remuneration Committee (Mr. Rhodes, and Dr. Dekeyser) are not independent. However, both persons were and still are expected to be equipped best for the role as members of the Remuneration Committee and both more than accomplished those expectations, see the report on the work of committees above.
- Best practice provision 2.3.4 provides that the Remuneration Committee may not be chaired by the Chairman of the Supervisory Board. Mr. Rhodes, however, is Chairman of both the Remuneration Committee and the Supervisory Board. Due to his vast experience, Mr. Rhodes was and still is equipped best for the role as Chairman of the Remuneration Committee and he has fully met those expectations, see the report on the work of committees above.
- Curetis does not yet comply with best practice provision 2.4.5, which requires that the Supervisory Directors will follow an introductory program. Our Supervisory Directors all have extensive relevant experience in the field Curetis operates in, and/or have substantial experience with Curetis itself. Therefore, an introductory program has so far not been deemed relevant or needed. However, in the future whenever new Supervisory Directors will join the Supervisory Board of Curetis, Curetis will reevaluate the necessity and benefit of such an introductory program.
- Best practice provisions 3.1.2 vi. and 3.3.3 provide that any shares awarded to Managing Directors shall be held for at least five years after award and shares held by the Supervisory Directors shall be held as

long-term investment. This basically was the case until December 2019. In December 2019 the PSOP was settled by way of executing the PSOP Roll-Over Agreements. Resulting from this in January 2020 Oliver Schacht was allotted 82,747 and Johannes Bacher and Dr. Achim Plum each 31,236 new shares in Curetis. To pay the German income taxes, among other things, that became due as a result of the roll-up and settlement of the former PSOP Oliver Schacht, Johannes Bacher and Dr. Achim Plum sold their shares in Curetis N.V. in January 2020 as published on the Company's homepage.

- Best practice provision 3.3.2 provides that Supervisory Directors may not be granted any shares or rights to shares by way of remuneration. The General Meeting on 16<sup>th</sup> June 2016 approved a Supervisory Board remuneration policy under which each Supervisory Board Director, subject to approval by the General Meeting, may be granted up to 15,000 Stock Options per year under the ESOP 2016. Curetis believes that being able to grant stock options to Supervisory Directors shall contribute in finding and binding competent Supervisory Directors. The General Meeting on 27<sup>th</sup> June 2019 approved a grant to the Supervisory Directors under which all, except for Dr. Rudy Dekeyser who waived this grant under LSP fund policies, received 10,000 Stock Options under the ESOP 2016 effective 1<sup>st</sup> July 2019.
- Best practice provision 4.2.3 provides that Curetis shall grant all Shareholders access to follow meetings with analysts, presentations to analysts, presentations to investors and institutional investors in real time, by means of webcasting, telephone or by any other means. However, Curetis complies with this rule for major investor conferences only. Curetis believes that, considering its size, enabling Shareholders to follow in real time all of the meetings with analysts, presentations to analysts, and presentations to investors as referred to in this best practice provision would create an excessive burden on Curetis' resources. Curetis will make sure that all presentations shall be posted on the website of the Company as soon practically possible.

# VALUES, CULTURE AND CORPORATE SOCIAL RESPONSIBILITIES

To spread its values into its organization, Curetis' Management Board has established a Code of Conduct, an Insider Trading Policy, a Whistle-blower Policy and a Policy on Bilateral Contacts with Shareholders. Overarching theme is a shared culture of "we do what's right" across all Curetis group entities. Each of these documents can be found under "Corporate Governance" on Curetis' website https://curetis.com/investors/. All employees are trained on these key CSR principles and corporate governance documents as part of their on-boarding with Curetis and as part of general corporate governance update trainings to all staff. Curetis' employees are especially satisfied with the affinity of the rules to day-to-day business. No violation was perceived until now and the Management Board has maintained these high standards of CSR even in the light of required re-organization and corporate restructuring including a significant reduction in force and layoffs at the end of 2018 and in early 2019 as well as throughout the strategic business combination discussions with OpGen.

# III. CONSOLIDATED FINANCIAL STATEMENTS

# CURETIS N.V. - CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the years ended 31 December

in kEUR	2019	2018
Revenue [5]	_	-
Cost of sales [6]	_	-
Gross profit / gross loss	_	-
Distribution costs [8]	-	-
Administrative expenses [9]	(1,090)	(753)
Research & development expenses [10]	_	-
Other income [12]	40	19
Operating loss	(1,050)	(734)
Finance income	1	-
Finance costs	(67)	(2)
Finance result - net [13]	(66)	(2)
Loss before income tax from continuing operations	(1,116)	(736)
Income tax expenses [14]	_	-
Loss for the period from continuing operations	(1,116)	(736)
Loss from discontinued operations [4]	(23,370)	(23,009)
Loss after tax for the year from continued and discontinued operations	(24,486)	(23,745)
Other comprehensive income for the period, net of tax <sup>1</sup>	(14)	(283)
Total comprehensive loss for the period <sup>2</sup>	(24,500)	(24,028)
Loss per share attributable to the ordinary equity holders of the company [15]	2019	2018
Basic	-1.05	-1.40
Diluted	-1.05	-1.40

<sup>[..]</sup> Bracketed numbers refer to the related notes to the financial statements, which form an integral part of these financial statements.

<sup>&</sup>lt;sup>1</sup> Relates to exchange differences on translation of foreign operations, which may be recycled through profit and/or loss in the future

<sup>&</sup>lt;sup>2</sup> Total comprehensive loss is solely attributable to owners of the Company.

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

# **ASSETS**

in kEUR		31 December 2019	31 December 2018
Current Assets		18,281	18,095
	Cash and cash equivalents [16, 30]	852	10,279
	Trade receivables [17, 30]	-	323
	Inventories [18]	-	6,734
	Other current assets [19]	28	759
	Assets classified as held for sale [4]	17,401	-
Non-current A	ssets	-	11,012
	Intangible assets [20]	-	7,425
	Property, plant and equipment [21]	-	3,196
	Right of use assets [22]	-	-
	Other non-current assets [23]	-	162
	Other non-current financial assets [29, 30]	-	158
Deferred tax assets [31]		-	71
Total Assets		18,281	29,107

<sup>[..]</sup> Bracketed numbers refer to the related notes to the financial statements, which form an integral part of these financial statements.

# LIABILITY & EQUITY

in kEUR		31 December 2019	31 December 2018
Current Liabili	ties	29,552	6,064
	Trade and other payables [24, 30]	82	957
	Provisions current [26]		65
	Tax liabilities	_	22
	Other current liabilities [27]	268	1,235
	Other current financial liabilities [28, 30]	61	3,785
	Current lease liabilities	-	-
	Liabilities directly associated with assets classified as held for sale [4]	29,141	-
Non-current L	iabilities	-	13,993
	Provisions non-current [26]	-	44
	Other non-current financial liabilities [23, 30]	_	13,949
	Non-current lease liabilities	-	-
Total Liabilitie	s	29,552	20,057
Equity [32]		(11,271)	9,050
	Share capital	263	209
	Capital reserve	173,201	162,967
	Other reserves	3,064	9,176
	Currency translation differences	(154)	(143)
	Retained earnings	(187,645)	(163,159)
Total Equity a	nd Liabilities	18,281	29,107

<sup>[..]</sup> Bracketed numbers refer to the related notes to the financial statements, which form an integral part of these financial statements.

# **CURETIS N.V. - CONSOLIDATED STATEMENT OF CASH FLOWS**

For the years ended 31 December

in kEUR	2019	2018
Loss after income tay from continuing operations for the period	(1,116)	(726)
Loss after income tax from continuing operations for the period  Loss after income tax from discontinued operation for the period		(736)
Adjustment for:	(23,370)	(23,009)
- Net finance income / costs [13]	67	708
- Depreciation, amortization and impairments [20, 21, 22]	1,728	798
- Gain on disposal of fixed assets		1,256 0
- Changes in provisions [26]	3 96	-60
- Changes in provisions [20] - Changes in equity settled stock options [32]	480	649
- Net exchange differences and other non-cash transactions	2,092	
- Changes in deferred tax assets and liabilities		(375)
- Changes in deferred tax assets and habilities	71	7
Changes in operating assets and liabilities:		
- Inventories [18]	4,869	212
- Trade receivables and other receivables [., 17, 19 ]	(8)	(312)
-Trade payables and other payables [24, 27]	1,843	659
	-7-43	-55
Effects of exchange rate differences not realized from consolidation		89
Income taxes received (+) / paid (-)	(4)	36
	ν.,	3
Interest paid (-)	(527)	(1,173)
Net cash flow used in operating activities	(13,779)	(21,959)
Payments for intangible assets	(43)	(118)
Payments for property, plant and equipment	(1,504)	(669)
Proceeds from sale of property, plant and equipment	-	-
Interest received	-	-
Net cash flow used in investing activities	(1,547)	(787)
Proceeds from other non-current financial liabilities	5,000	3,000
Proceeds from current financial liabilities	3,606	3,109
Proceeds from issue of ordinary shares	-	13,200
Repayment of convertible loan	-	-
Payments for financing costs for issue of ordinary shares	-	(2,972)
Transaction costs for issue of ordinary shares	-	-
Principle elements of leases paid	-424	-
Net cash flow provided by financing activities	8,182	16,337
Net decrease / increase in cash and cash equivalents	(7,144)	(6,409)
Net cash and cash equivalents at the beginning of the year	10,279	16,311
Net decrease in cash and cash equivalents	(7,144)	(6,409)
Effects of exchange rate changes on cash and cash equivalents	(9)	377
Net Cash and cash equivalents at the end of the period	3,126	10,279
Included in cash and cash equivalents per the balance sheet	852	10,279
Included in the assets of the disposal group	2,274	-

<sup>[..]</sup> Bracketed numbers refer to the related notes to the financial statements, which form an integral part of these financial statements.

# **CURETIS N.V. - CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**

For the years ended 31 December

For the years ended 31 Decem	nber					
	Share	Capital	Other	Currency Translation	Retained	TOTAL
in kEUR	Capital	Reserve	Reserve	Difference	Earnings	Equity
Balance at 1 January 2018	155	152,793	8,527	143	(139,414)	22,204
Loss of the period					(23,745)	(23,745)
Other comprehensive income				(283)		(283)
Total comprehensive income	0	o	o	(283)	(23,745)	(24,028)
Capital						
Transactions with owners in their capacity as owners						
Issue of ordinary shares	54	13,146				13,200
Transaction costs for the issue of ordinary shares		(2,972)				(2,972)
Equity stock option program 2016			649			649
Balance as of 31 December 2018	209	162,967	9,176	(140)	(163,159)	9,053
				Currency		
	Share	Capital	Other	Translation	Retained	TOTAL
in kEUR	Capital	Reserve	Reserve	Difference	Earnings	Equity
Balance at 1 January 2019	209	162,967	9,176	(140)	(163,159)	9,053
Loss of the period					(24,486)	(24,486)
Other comprehensive income				(14)		(14)
Total comprehensive income	0	o	o	(14)	(24,486)	(24,500)
Capital						
Transactions with owners in their capacity as owners						
Issue of ordinary shares	54	10,234	(6,592)			3,696
Equity stock option program 2016			480			480
Balance as of 31 December 2019	263	173,201	3,064	(154)	(187,645)	(11,271)

For detailed information please see note 32.

# CURETIS N.V. - NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR 2019

#### GENERAL INFORMATION ABOUT THE COMPANY

#### 1.1. GENERAL INFORMATION ABOUT THE BUSINESS AND THE COMMERCIAL DEVELOPMENT OF THE COMPANY

Curetis N.V. (the Company) is the parent company of a commercial-stage molecular diagnostics (MDx) group focused on rapid infectious disease testing for hospitalized patients with the aim to improve the treatment of hospitalized, critically ill patients with suspected microbial infections.

The Group has developed the innovative Unyvero molecular diagnostic solution for comprehensive infectious disease testing. Curetis' proprietary application portfolio for its Unyvero system currently consists of several CE-marked applications:

- The Unyvero HPN (Hospitalized Pneumonia) cartridge for the detection of pathogens and antibiotic resistances to aid diagnosing pneumonia.
- The Unyvero ITI (Implant and tissue infections) cartridge for the detection of pathogens and antibiotic resistance markers in diagnosis of prosthetic joint infections, surgical site infections, infections associated with implants, infections of the deep skin and soft tissue, burn wounds as well as diabetic foot, cellulitis and others.
- The Unyvero BCU (Blood culture) cartridge for the detection of pathogens (bacteria and fungi) and antibiotic resistance markers in bloodstream infections.
- The Unyvero IAI (Intra-abdominal infections) cartridge for the detection of up to 130 targets, microorganisms (108) and antibiotic resistance markers (22).
- The Unyvero UTI (Urinary tract infections) cartridge for the detection of severe cases of urinary tract infections with up to 103 targets, microorganisms (88) and antibiotic resistance markers (15).

In addition to the existing Unyvero A50 multiplex platform, Curetis has started in 2016 to expand its product portfolio with the development of a low- and midplex analyzer, the new Unyvero A30 RQ for Unyvero integration or as a standalone operation. The Unyvero A30 RQ analyzer will aim at ca. 5 to 30 diagnostic targets with sensitive and quantitative real-time PCR technology within about 45-90 minutes time-to-result and just a few minutes of hands-on-time.

Furthermore, in Q4-2016 Curetis acquired the GEAR database from Siemens, which is a comprehensive database on genetics of antibiotic resistance. In 2017, Curetis established Ares Genetics GmbH, a whollyowned subsidiary of Curetis GmbH in Vienna, Austria. Ares Genetics is dedicated to maximize the R&D and related scientific and business opportunities of the GEAR assets (now called Aresdb) for the entire Curetis Group.

#### 1.2. CORPORATE STRUCTURE

The Company has one subsidiary, Curetis GmbH, Holzgerlingen, Germany where it holds 100% of the shares. As of 31 December 2019 Curetis GmbH holds 100% of the shares of:

- Curetis USA Inc., San Diego, CA, USA
- Ares Genetics GmbH, Vienna, Austria

(together "the Curetis Group" or "the Group" or "Curetis").

During 2019 Curetis completed the execution of the previously announced reorganization of its corporate structure. The planned measures included the closure and liquidation of the following subsidiaries of Curetis GmbH:

- Curetis UK Ltd., London, UK (dissolved 17.12.2019)
- Curetis Schweiz GmbH, Zug, Switzerland (dissolved 11.11.2019)

- Curetis BeNeLux B.V., Amsterdam, the Netherlands (dissolved 25.06.2019)
- Curetis France S.A.R.L., Strasbourg, France (dissolved 24.03.2019)

The measures included the closure and liquidation of the aforementioned subsidiaries of Curetis GmbH, change of strategy from direct to distributor sales and marketing in European markets, reduction in force across all organizational functions of Curetis GmbH and reduction in force at Curetis USA Inc.

The consolidated financial statements of the Group as of and for the year ended 31 December 2019 comprise as such the Company and its wholly owned and controlled subsidiary Curetis GmbH, Holzgerlingen, Germany and the aforementioned subsidiaries of Curetis GmbH.

### 1.3. LOCAL EXEMPTION RULES APPLIED BY SUBSIDIARIES OF THE GROUP

Curetis GmbH makes use of the exemption clause, available under §264 (3) HGB in 2018. The consolidated financial statements of Curetis N.V. as of and for the year ended 31 December 2019 will be filed in Germany as a supplement to the financial statements of Curetis GmbH, in order to meet the requirements of the exemption clause available under §264 (3) HGB in 2019.

#### 1.4. HISTORICAL FINANCING TRANSACTIONS OF THE COMPANIES

Curetis N.V. has been listed on Euronext Amsterdam and Brussels since 11<sup>th</sup> November 2015 under the ticker symbol CURE. The Group does not have an ultimate parent entity nor a controlling party. The statutory seat of Curetis N.V. is in Amsterdam, the Netherlands, the corporate headquarter is at Max-Eyth-Str. 42, 71088 Holzgerlingen, Germany.

The first Group entity was incorporated in 2007 (Curetis AG). From inception through 31 December 2019 the Group's operations have been primarily funded through:

- EUR 63.7 million in equity investments from venture capital and private equity investors
- EUR 44.3 million of gross proceeds from the Group Initial Public Offering completed in November 2015 on Euronext Amsterdam and Brussels.
- EUR 18.0 million of non-dilutive debt financing tranche drawn down under the facility from the European Investment Bank (EIB)
- EUR 4.1 million of gross proceeds from a public investment in private equity (PIPE), executed in April
   2018
- EUR 5.0 million of gross proceeds from a financing facility of up to EUR 20 million through the issuance of convertible notes.
- EUR 8.9 million of gross proceeds from a follow-on offering at Euronext Amsterdam and Brussels completed in November 2018
- US\$ 2.5 million in short term loans under the Interim Financing Facility between Curetis GmbH and OpGen Inc.
- Cash inflows from revenue generating product sales and partnering projects

#### 1.5. Non-Going Concern

Curetis – as is typical in the biotech industry for development stage and early commercial stage companies - has been incurring net losses since its incorporation (except 2015 due to an extraordinary gain). The retained earnings of the Group are still negative and as of 31 December 2019 amounting to EUR 187,645 million.

Curetis N.V. has determined after a systematic process of assessing all potential strategic and tactical financing or other strategic options and on 4<sup>th</sup> September 2019 publicly announced that it has entered into a Definitive Implementation Agreement with OpGen Inc., Gaithersburg, MD, USA (NASDAQ ticker symbol OPGN) to combine its businesses. Following the extraordinary general meeting held post year end with Curetis N.V. Shareholders and other conditions of of the Definitive Implementation Agreement Curetis N.V. sold on 1<sup>st</sup> April 2020 100% of its shares and interest in Curetis GmbH (the Business) including all assets,

liabilities, operations, products, commercial contracts in return for the sole consideration of 2.66 million new OpGen Inc. ('OPGN') shares to be issued to Curetis N.V. shareholders, convertible note holders (500k shares), and ESOP holders (135k shares). Since the transfer of the remaining shares to Curetis N.V. created a beneficial ownership of approximately 13% of OpGen Inc. As per the shareholder approval of Curetis N.V. has distributed the OpGen Inc. shares received to the maximum extent legally permitted under Dutch law.

The cash reach at the level of Curetis NV is expected to be into the third quarter of 2020 provided that Curetis NV is successful in selling up to 20% of the OpGen consideration shares at price levels at or above \$2.00 per share it receives in the capital market to generate additional cash inflow in order to settle its liabilities. Since the distribution of shares of OpGen Inc. to Curetis N.V. shareholders, Curetis N.V. will be delisted from Euronext Amsterdam and Brussels and will be dissolved and liquidated on the shortest possible time frame.

Therefore, there is no viable nor realistic Going Concern Scenario for Curetis N.V. in 2020 and beyond and the FY 2019 financials for Curetis N.V. group thus are created under the non-going concern assumption. Management assessed as part of this evaluation that the IFRS standards as endorsed by the EU are still the appropriate to be used for the preparation of these financial statements. Therefore, the assets and liabilities of the group which are subject to discontinuation have been classified as held for sale whereas the profit and loss is prepared under IFRS 5 discontinued operations. For detailed information please see note 4.

Lastly, as there is no viable or realistic Going Concern Scenario for Curetis N.V. in 2020 and beyond, there is no expected future impact from the COVID-19 outbreak on material uncertainties with regard to Going Concern. For the discontinued operation Curetis NV is not assessing the impact of COVID-19 independently as it is part of the OpGen Inc. Group post transaction closing as of 1st April 2020.

### 2. BASIS OF PREPARATION - CONSOLIDATED FINANCIAL STATEMENTS

#### 2.1. STATEMENT OF COMPLIANCE

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) and the Interpretation (IFRIC) as endorsed by the European Union (EU) and comply with and Title 9 of Book 2 of Dutch Civil Code. The financial year corresponds to the calendar year. The following explanatory notes are an integral part of the consolidated financial statements, which further comprise the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of financial position, the consolidated statement of cash flows and the statement of changes in equity. On 30<sup>th</sup> June 2020 the Management Board authorized the consolidated financial statements for issue and passed it through to the Supervisory Board for review and authorization.

#### 2.2. BASIS OF MEASUREMENT

The financial statements have been prepared under non-going concern (See note 1.5). The statement of profit or loss and other comprehensive income has been prepared in accordance with the function of expense method. These consolidated financial statements are presented in Euro – where appropriate – have been rounded to the nearest thousand (abbreviated kEUR).

## 2.3. CRITICAL ACCOUNTING JUDGEMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY

The preparation of financial statements requires the use of accounting estimates, which, by definition, will seldomly equal the actual results. Management also needs to exercise judgement in applying the group's accounting policies.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

The following areas are areas where key assumptions concerning the future, and other key sources of estimations uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year:

Estimated useful life of intangible assets – note 20

Unyvero A<sub>3</sub>o *RQ* (formerly Gyronimo) has not been amortized since acquisition, since the platform is not yet available to be used and was developed further by the company. The carrying amount of this intangible asset is tested for impairment at each reporting date. Impairment is recognized if the carrying amount of an asset exceeds its estimated recoverable amount.

Estimates of provisions – note 26

When measuring provisions for warranty forward-looking assumptions and estimates are inputs into the calculation. The calculation is based on historical data but as Curetis is in an early commercial stage these assumptions may change in the future.

Estimates of fair values of contingent liabilities and contingent purchase commitments – note 34

Management has certain contingent liabilities and purchase commitments which could, should the budgeted numbers and current assumptions of the future business development not be appropriate, result in provisions for onerous contract to be required.

■ Estimate of inventory obsolescence and inventory valuation – note 18

Inventories are valued at the lower value cost and net realizable value. The net realizable value is determined by the estimated selling price in the ordinary course of business less the incurred plus estimated costs of completion and the estimated costs necessary to sale the end product. The assessment of the obsolescence write-downs on inventories is considered a significant estimate with inherent uncertainty. Given Curetis does not yet have a reliable sales-track-record; the write-downs are based on the best estimate considering technical aging and estimated sales volumes and prices for systems.

Estimates and judgments regarding IFRS 16 – note 3.1

The Company determines the lease term as the non-cancellable term of the lease, together with any periods covered by an option to extend the lease if it is reasonably certain to be exercised, or any periods covered by an option to terminate the lease if it is reasonably certain not to be exercised. When determining the lease term, Curetis considers all relevant facts and circumstances that create an economic incentive to exercise an extension option, or not to exercise a termination option.

In calculating the present value of lease payments, the Company uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable.

Estimate of highly probably transaction certainty und timing concerning the disposal group – note 4

Curetis has assessed the closing conditions of the implementation agreement with OpGen Inc. throughout the period. Following the discussions with major shareholders and debt financing providers with their support on the transaction in addition to approval of management and supervisory board of the merger, it was deemed highly probable on 24 December 2019 that the transaction would close. The business subject to sale is significant and thus was presented as discontinued operation.

Estimates and judgement regarding IFRS 15 – note 3.8

Curetis offers to deliver distinct cartridges or Unyvero Systems against cash considerations to the customer. Apart from the statutory warranty, which represents no separate obligation, no further obligations exist related to cartridges or Unyvero Systems. Furthermore, the company offers licenses to the ARES Database. Outside the licenses offered, there are no further performance obligations. A license may provide the customer (licensee) the right to use the Company's (licensor) intellectual property as it exists at the point in time the license is granted. For such license, revenue is recognized at a point in time when control transfers to the licensee (i.e., the licensee is able to use and benefit from the license) and the license period begins. As opposed to the right to use IP, as described above, a license may provide access to the Company's IP as it exists throughout the license period (right to access IP), such license being a performance obligation satisfied over time which results in revenue recognized over time accordingly, provided that all criteria in IFRS 15.

In the case of cartridges or Unyvero System, there is only one obligation for Curetis (the delivery of the

product) and as such the complete transaction price is allocated to the delivery of the cartridges or Unyvero System. For licenses, the customer product-dependent license formulae, on which the agreement is based, correspond to the respective individual selling prices and that therefore no allocation is necessary.

# 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies set out below have been applied consistently to all periods presented in these consolidated financial statements, unless otherwise stated.

# 3.1. New Standards and Interpretations Applied for the First Time and Their Accounting Policy for the Year

The International Accounting Standards Board (IASB) continues to issue new standards, interpretations and amendments to existing standards. Curetis applies these new standards when their mandatory application is required by the EU. New standards, amendments to standards and new or amended interpretations are effective for annual periods beginning on or after 1<sup>st</sup> January 2019, and have been applied in preparing these financial statements. Curetis has not opted for early adoption for any of these standards.

Standard/Interpretation	Content	Application mandatory from
Amendment to IFRS 9 IFRS 16 IFRIC 23 Amendments to IFRS 3, 11, IAS 12, IAS 23 Amendments to IAS 19	Prepayment Features with Negative Compensation Accounting of Leasing-transactions Uncertainty over Income Tax Treatments Amended by Annual Improvements to IFRS Standards 2015–2017 Cycle. Plan Amendment, Curtailment or Settlement	1 January 2019 1 January 2019 1 January 2019 1 January 2019

Curetis has assessed the accounting standards effective after 1<sup>st</sup> January 2019 and determined that none have a material impact on the financial statements with the exception of IFRS 16, which has been applied in these financial statements and as required, the nature and effect of these changes are disclosed below.

# First time Adoption of IFRS 16 - Leases

## Adopted as of current period

In January 2016, the IASB published the financial reporting standard IFRS 16 *Leases* which replaces IAS 17 *Leases* as well as the associated interpretations. The new standard became effective on 1<sup>st</sup> January 2019 and sets out the principles for the recognition, measurement, presentation and disclosure of leases. Under the new lease standard, assets leased by the Company are being recognized as a right-of-use asset in the statements of financial position with a corresponding lease liability.

Lessor accounting under IFRS 16 is substantially unchanged from IAS 17. Lessors will continue to classify leases as either operating or finance leases using similar principles as in IAS 17. The Group's activities as a lessor are not material; therefore, IFRS 16 did not have an impact for leases where the Company is the lessor

The Company adopted IFRS 16 using the simplified transition approach and did not restate comparative amounts for the year prior to first adoption.

The reclassifications and the adjustments arising from the new leasing rules are therefore recognized in the opening balance sheet on 1<sup>st</sup> January 2019.

Previously, the Company determined at contract inception whether an arrangement was or contained a lease under IFRIC 4 "Determining Whether an Arrangement contains a Lease". Leases entered into before the date of initial application were not reassessed as to whether a contract is, or contains, a lease

at the date of first-time application, but the assessment previously made under IFRIC 4 was retained.

### Transition and impact assessment on IFRS 16

The effect of the adoption of IFRS 16 to the statements of financial position as of 1st January 2019 is as follows:

in kEUR	
Assets	
Right-of-Use assets	1,494
Liabilities	
Lease liabilities	1,494

The adoption of IFRS 16 had no impact on the Company's sales. Lease expense has been replaced by depreciation and interest expense, which had an immaterial impact to the statement of operations for the year ended 31 December 2019.

In addition, the cash flow from operating activities for the year 2019 was positively impacted by approximately kEUR 424 as, under the new standard, cash payments for the principal portion of the lease liabilities are classified in the cash flow from financing activities rather than in the cash flow from operating activities.

The Company foresees no impact of the adoption of IFRS 16 on compliance with debt covenants.

### Leases previously accounted for as operating leases

The Company recognized right-of-use assets and lease liabilities for those leases previously classified as operating leases, with the exception of short-term leases and leases of low-value assets. The right-of-use assets and lease liabilities were recognized based on the present value of the remaining lease payments and discounted using the incremental borrowing rate at the date of initial application. The company applied a discount rate of 1.9% for property and discount rate of 3.9% for all other asset classes. For these two lease categories, the company applied the practical expedient to apply a single discount rate for a portfolio of leases with similar characteristics.

The lease liabilities as of 1<sup>st</sup> January 2019 reconciles to the operating lease commitments as of 31 December 2018 as follows (the amounts in the table below include lease commitments for leases with extension options determined probable to exercise upon adoption):

in kEUR	
Operating lease commitments as of 31 December 2018	1,301
Impact of present value discount	(107)
Short term leases excluded	(94)
Adjustments as a result of a different treatment of extension and termination options	394
IFRS16 opening balance impact on lease liabilities as of 1 January 2019	1,494
Of which are:	
Current lease liabilities	485
Non current lease liabilities	1,009
	1,494

### Right-of-use assets

The Company recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any re-measurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date, less any lease incentives received. Unless the Company is reasonably certain ownership of the leased asset will be obtained at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of-use assets are subject to impairment assessment. Right-of-use assets are tested if events or circumstances indicate that they might be impaired, either individually or at cash-generating unit level. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. Impairments are reversed if and to the extent that the reasons for impairment no longer exist. The recoverable amount is defined as the higher of an asset's fair value less cost to sell and its value in use.

Asset class	Estimated useful life
Real Estate	1-10 years
Other	1-5 years

#### Lease liabilities

At the commencement date of the lease, the Company recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include, insubstance, fixed payments less any lease incentives, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments may also include an exercise price of a purchase option reasonably certain to be exercised by the Company and payments of penalties for terminating a lease, if the lease term reflects the company exercising the termination option.

In calculating the present value of lease payments, the Company uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is reduced for the lease payments made. In addition, the carrying amount of lease liabilities is re-measured if there is a contract modification, change in the lease term, change in the in-substance fixed lease payments, or a change in the assessment to purchase the underlying asset. Lease payments are allocated between principal and finance costs. The finance cost is charged to profit or loss over the lease period so as to produce a

constant periodic rate of interest on the remaining balance of the lease liability for each period. Contracts may contain both lease and non-lease components. The Group allocates the consideration in the contract to the lease and non-lease components based on their relative standalone prices.

## Leasing arrangements

The group leases various cars, buildings and IT equipment. Rental contracts are typically made for fixed periods of three to five years but may have extension options as described below. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants, but leased assets may not be used as security for borrowing purposes.

Extension and termination options are included in a number of property and equipment leases across the group. These terms are used to maximize operational flexibility in terms of managing contracts. All significant leases have extension and termination options which are exercisable only by the group and not by the respective lessor. No variable lease payments nor voluntary prepayments were made in 2019.

In calculating the present value of lease payments, the Company uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable.

The following table shows the maturity analysis of lease liabilities as of 31 December 2019.

		Between One			
<b>Contractual Maturities</b>	Up to	and Five	More than	<b>Total Contractual</b>	Carrying Amount
of Financial Liabilities	One Year	Years	Five Years	Cash Flows	Liabilities
Lease Liabilities	457	670	0	1,127	1,085

# 3.2. STANDARDS, INTERPRETATIONS, AND AMENDMENTS ISSUED, BUT NOT YET APPLIED

The following new standards and interpretations and amendments to existing standards will become effective after 1<sup>st</sup> January 2020.

Standard/Interpretation	Content	Application mandatory from
Amendments to IAS 1 and IAS 8 Amendments to IAS 39, IFRS 9 and IFRS 7	Clarifying the definition of "material" Interest Rate Benchmark Reform	1 January 2020 1 January 2020

# Revision of the framework and changes to cross-references to the framework in various IFRS

On 29<sup>th</sup> March 2018, the IASB published a revised version of the framework. It includes revised definitions of assets and liabilities and new guidance on measurement and derecognition, presentation and disclosures. However, the new framework does not constitute a fundamental revision. Rather, it extends the scope of regulation to those areas which were previously unregulated or which showed discernible deficits. In addition, the IASB has updated various cross-references to the framework in individual IFRSs.

The updates of the cross-references in the individual standards are to be applied from  $1^{st}$  January 2020. Earlier application is permitted. The EU endorsement took place on  $29^{th}$  November 2019. There will be no effects on the consolidated financial statements.

The Group has assessed the accounting standards effective after 1<sup>st</sup> January 2020 and determined that none are likely to have a material impact on the consolidated financial statements.

### 3.3. CONSOLIDATION

## Principles of consolidation

Subsidiaries are all entities (including structured entities), which Curetis N.V. can control directly or indirectly. The group controls an entity when the group is exposed to, or has rights to, variable returns

from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the group. They are deconsolidated from the date that control ceases.

Intercompany transactions, balances and unrealized gains on transactions between group companies are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset.

# 3.4. SEGMENT REPORTING

In accordance with IFRS 8, Curetis is a single-segment entity. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's primary focus is on research and development activities as well as developing sales and distribution channels and relationships to further the commercialization of its offerings. The Management Board is the chief operating decision maker, and regularly reviews the combined operating results to make decisions see about the allocation of the Company's resources.

### 3.5. CURRENT AND NON-CURRENT DISTINCTION

Curetis presents current and non-current assets and current and non-current liabilities as separate classifications in the statement of financial position. Curetis classifies all amounts expected to be recovered or settled within twelve months after the reporting period as 'current' and all other amounts as 'non-current'.

### 3.6. FOREIGN CURRENCY TRANSLATION

## a) Functional and presentation currency

Items included in the financial statements of each of the group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in Euro which is Curetis N.V.'s functional and presentation currency.

## b) Transactions and balances

Transactions in foreign currencies are translated into Euros at exchange rates at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the reporting date are translated into Euros at the exchange rate at the reporting date. Curetis uses the exchange rates of the Deutsche Bundesbank on the reporting date.

Curetis converted amounts in USD to the functional currency with the exchange rate as of 31 December 2019 of 1 Euro = 1.1234 USD (31 December 2018 of 1 Euro = 1.145 USD).

Curetis converted amounts in CHF to the functional currency with the exchange rate as of 31 December 2019 of 1 Euro = 1.0854 CHF (31 December 2018 of 1 Euro = 1.1269 CHF).

Curetis converted amounts in GBP to the functional currency with the exchange rate as of 31 December 2019 of 1 Euro = 0.8508 GBP (31 December 2018 of 1 Euro = 0.89453 GBP).

The foreign currency gains or loss on monetary items is the difference between amortized cost in the functional currency at the beginning of the period, adjusted for effective interest and payments during the period, and the amortized cost in foreign currency translated at the exchange rate at the end of the reporting period.

Non-monetary items that are measured at historical cost in a foreign currency are translated using the historic rate at the date of the transaction.

Foreign exchange gains or losses that relate to borrowings and cash and cash equivalents are presented in the statement of profit or loss and other comprehensive income within finance income or within the finance costs.

# c) Group companies

The results and financial position of foreign operations (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet
- income and expenses for each statement of profit or loss and statement of comprehensive income are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions), and
- all resulting exchange differences are recognized in other comprehensive income.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other financial instruments designated as hedges of such investments, are recognized in other comprehensive income. When a foreign operation is sold or any borrowings forming part of the net investment are repaid, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale.

### 3.7. NOTES TO THE CASH FLOW STATEMENT

The cash flow statement has been prepared using the indirect method. The balance of cash and cash equivalents as at the date of the financial statements disclosed in the cash flow statement is comprised of cash and cash equivalents. Cash comprises cash on hand and demand deposits. Cash equivalents are short-term bank deposits and are not subject to any significant risk of changes in value. Interest paid is included in the cash from operating activities whereas interest received from part of the cash flows from investing activities.

Net Debt Reconciliation				
in kEUR	Other Financial Liabilities	Lease Liabilities		
Balance as of 1 January 2018	10,966	n/a		
Proceeds from borrowings	6,109	n/a		
Decrease	-	n/a		
Exchange rate differences		n/a		
Interest	527	n/a		
Other non cash transactions	132	n/a		
Balance as of 31 December 2018	17,734	n/a		
in kEUR	Other Financial Liabilities	Lease Liabilities		
Balance as of 1 January 2019	17,734	1,494		
Proceeds from borrowings	8,606	15		
Decrease	(502)	(449)		
Exchange rate differences	(36)	-		
Interest	502	25		
Conversion Convertible Bond	(3,696)	-		
Other non cash transactions including accrued interest	2,246	-		
IFRS 5	(24,793)	(1,085)		
Balance as of 31 December 2019	61	-		

### 3.8. REVENUE RECOGNITION

Under IFRS 15, revenue is recognized when a customer obtains control of the goods or services, Determining the timing of the transfer of control – at a point in time or over time – requires judgement.

The Group's revenue consists of the sales of Unyvero Application cartridges and Unyvero Systems and service revenue.

The sale of Unyvero Application cartridges and the sale of Unyvero Systems represent separate performance obligations. Where the contracts include multiple performance obligations, the transaction price will be allocated to each performance obligation based on the stand-alone selling prices. Curetis recognizes revenues at a point in time when the control is transferred to the customer. The control of the product transfers upon shipment to the customer or when the product is made available to the customer, provided that the Group did not retain any significant risks of ownerships or future obligations with respect

to the product shipped.

Furthermore, the Group offers Bio-IT related services via its subsidiary Ares Genetics GmbH. The Group recognizes revenues for such project related services over the period of time in which the services are being provided, in accordance with IFRS 15. The Group applied the input or output method depending on the underlying contractual conditions, separate for the respective performance obligation identified. The main input method utilized by the Group is for technology access fee to the ARES database. The main output method utilized by the Group is the research labor hours. In the case of fixed-price contracts, the customer pays the fixed amount based on a payment schedule. If the services rendered by the Group exceed the payment, a contract asset is recognized. If the payments exceed the services rendered, a contract liability is recognized. As opposed to the right to use IP, a license may provide access to the Company's IP as it exists throughout the license period (right to access IP), such license being a performance obligation satisfied over time which results in revenue recognized over time accordingly, provided that all criteria in IFRS 15 are met.

Service revenues also includes license fees. A license may provide the customer (licensee) the right to use the Company's (licensor) intellectual property as it exists at the point in time the license is granted. For such license, revenue is recognized at a point in time when controls transfer to the licensee (i.e. the licensee is able to use and benefit from the license) and the license period begins.

Revenue is measured based on the consideration expected to be received. The Group also evaluated existing contracts with customers and has determined it currently does not have any contracts or agreements with an enforceable right with regard to minimum purchase obligations.

Payment is generally due at the time of delivery or in line with customary payment terms. Deferred payment terms may be agreed in rare circumstances, however; the deferral never exceeds twelve months. There are no significant financing component.

When contract assets and contract liabilities are recognized, the contract assets are subject to IFRS 9 impairment.

### 3.9. COST OF SALES

Cost of sales includes the costs for products and services sold in terms manufacturing, obsolescence write-downs of inventories, as well as delivery costs for the products or services. Manufacturing costs for products manufactured in-house as well as services rendered include the directly allocable individual material and production costs, the allocable parts of the overhead costs for production including depreciation of production equipment and changes in semi-finished and finished inventories.

### 3.10. RESEARCH AND DEVELOPMENT EXPENSES

Research expenses are defined as costs incurred for investigations undertaken with the prospect of gaining new scientific or technical knowledge and understanding. Development expenses are defined as costs incurred for the application of research findings or other knowledge to a plan or design for the production of new or substantially improved materials, devices, products, processes, systems or services before the start of commercial production or use.

Research costs are expensed when incurred. Development costs have historically been and will continue to be expensed as incurred unless the recognition criteria outlined in IAS 38 are met. The criteria for the recognition of development costs are closely defined: an intangible asset must be recognized if, and only if, there is reasonable certainty that the future economic benefits that are attributable to the asset will flow to the entity; and the cost of the asset can be measured reliably. Since Curetis' development projects are often subject to product development risks, clinical trial risks, regulatory approval procedures and other uncertainties, the conditions for the recognition of costs incurred before receipt of approvals are not satisfied in the ordinary course of business of Curetis.

### 3.11. LEASES

In January 2016, the IASB published the financial reporting standard IFRS 16 Leases which replaces IAS 17 Leases as well as the associated interpretations.

The company elected to adopt the practical expedient related to leases of all asset classes with a lease term of less than 12 months or for which the underlying asset is of low value and leases with a remaining lease term of less than 12 months at the transition date. In these cases, no right-of-use asset and lease liability is recognized. Lease payments on short-term leases and leases of low-value assets are recognized as expense on a straight-line basis over the lease term.

The Group now assesses whether a contract is or contains a lease based on the new definition of a lease. Under IFRS 16, a contract is, or contains, a lease if the contract conveys a right to control the use of an identified asset for a period in exchange for consideration.

Lease terms are negotiated on an individual basis and contain a range of different terms and conditions. Lease contracts are typically negotiated for fixed periods, but may include extension options. These terms offer the Group the greatest possible operational flexibility. For determining the lease terms all facts and circumstances are included which offer an economic incentive to exercise extension options. Extension options are only included in the lease term if the lease is reasonably certain to be extended.

For more details on the adoption of IFRS 16, see note 3.1

### 3.12. FINANCE INCOME AND FINANCE COSTS

Finance income and finance costs are recognized in the income statement in the period as they occur. For non-current loans expenses are recognized using the effective interest method.

### 3.13. EARNINGS PER SHARE

# a) Basic earnings per share

Basic earnings per share (EPS) is calculated by dividing the profit (loss) for the period attributable to equity owners of Curetis by the weighted average number of common shares outstanding during the period.

# b) Diluted earnings per share

Diluted EPS is calculated by adjusting the weighted average number of common shares outstanding for dilutive instruments. The number of shares included with respect to options, warrants and similar instruments is computed using the treasury stock method.

As Curetis is suffering operating losses, options have an anti-dilutive effect. As such there is no difference between basic and diluted earnings/losses per ordinary share.

### 3.14. FAIR VALUE MEASUREMENTS

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place, either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Company. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Quoted prices (unadjusted) in active markets for identical assets or liabilities (Level 1).
- Inputs other than quoted prices included within level 1 that are observable for the asset or liability, either directly (that is, as prices) or indirectly (that is, derived from prices) (Level 2).
- Inputs for the asset or liability that are not based on observable market data (that is, unobservable inputs) (Level 3).

### 3.15. INVENTORIES

Inventories are valued at the lower of cost or net realizable value. The cost of trade goods as well as raw, auxiliary and operating materials is determined by using the specific identification of their individual cost method. The cost of semi-finished and finished goods is determined using the weighted average cost method. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

If the net realizable value of a finished good is lower than its cost, a provision for obsolescence is accounted for and the related expenses are recognized under cost of sales.

#### 3.16. INTANGIBLE ASSETS

### Licenses and Patents

Separately acquired intangible assets are initially measured at cost. Intangible assets not yet available for use are tested for impairment at least annually or more frequently if a potential triggering event is identified. Upon being placed into service, intangible assets are carried at cost less accumulated amortization and impairment losses.

Intangible assets are tested annually for impairment or more frequently if events or changes in circumstances indicate that they might be impaired, either individually or at cash-generating unit level. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. Impairments are reversed if and to the extent that the reasons for impairment no longer exist. The recoverable amount is defined as the higher of an asset's fair value less cost to sell and its value in use.

Licenses for biomarkers are amortized according to the terms of validity of the patent (up to 17.8 years) and amortized according to the straight-line method.

## 3.17. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are valued at cost less depreciation and impairment losses, if any. Cost includes direct costs (e.g. materials, direct labor and work contracted out) and directly attributable overhead costs. Maintenance and repair costs (day-to-day servicing) are expensed as incurred.

Asset retirement obligations are recognized as part of the cost of tangible fixed assets and expensed over the asset's estimated useful life. Land is not depreciated. The estimated useful lives of the principal property, plant and equipment categories are as follows:

Asset class	Depreciation term
Buildings	Max. 10 years
Machines and technical equipment	3-13 years
Office equipment	2-14 years
Buildings	Max. 10 years

Office equipment and Unyvero-Platforms, used for internal demands, are combined into Other tangible assets (refer to note 21).

Property, plant and equipment are depreciated using the straight-line method, based on estimated useful life, taking into account their respective residual value. Property, plant and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the book value of the assets concerned may not be recoverable. An impairment loss is recognized for the amount by which the asset's book value exceeds its recoverable amount. The recoverable amount is defined as the higher of an asset's fair value less cost to sell and its value in use. Impairments are reversed if and to the extent that the reasons for impairment no longer exist.

The assets' residual values and useful lives are reviewed at least annually and adjusted if appropriate.

### 3.18. Noncurrent assets held for sale and discontinued operations

Under IFRS 5, noncurrent assets or groups of assets and liabilities (disposal groups) are classified as held for sale if their carrying amounts will be recovered principally through a sale transaction rather than through continuing use. Such assets and liabilities are carried at the lower of their carrying amount and fair value less costs to sell, and are presented separately in current assets and liabilities in the balance sheet.

Non-current assets (including those that are part of a disposal group) are not depreciated or amortized while they are classified as held for sale. Interest and other expenses attributable to the liabilities of a disposal group classified as held for sale continue to be recognized.

An impairment loss is recognized for any initial or subsequent write-down of the asset (or disposal group) to fair value less costs to sell. A gain is recognized for any subsequent increases in fair valueless costs to sell of an asset (or disposal group), but not in excess of any cumulative impairment loss previously recognized. A gain or loss not previously recognized by the date of the sale of the noncurrent asset (or disposal group) is recognized at the date of derecognition.

Discontinued operations are components of an entity that have either been disposed of or are classified as held for sale. The assets and liabilities of operations that are held for sale represent disposal groups that must be measured and reported using the same principles as noncurrent assets held for sale. These are shown in the balance sheet under Assets held for sale and liabilities held for sale. The income and expenses from discontinued operations are presented in the income statement as profit or loss from discontinued operations below the profit or loss from continuing operations. Corresponding disposal gains or losses are contained in the profit or loss from discontinued operations. The prior-year figures in the income statement are adjusted accordingly. For further details, refer to Note 4.

## 3.19. FINANCIAL INSTRUMENTS

Financial instruments are contracts that give rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

The classification of financial instruments depends on how to characterize a financial instrument into equity instruments, debt instruments or derivatives.

A financial instrument is an equity instrument only if (a) the instrument includes no contractual obligation to deliver cash or another financial asset to another entity and (b) if the instrument will or may be settled in the issuer's own equity instruments. It is either:

- A non-derivative that includes no contractual obligation for the issuer to deliver a variable number of its own equity instrument; or
- A derivative that will be settled only by the issuer exchanging a fixed amount of cash or another financial asset for a fixed number of its own equity instruments.

A financial instrument is a debt instrument which are contractual rights and obligations with defined terms for amount and timing to pay.

A derivative financial instrument is any contract with all three of the following:

- a) its value changes in response to the change in a specified interest rate, financial instrument price, commodity price, foreign exchange rate, index of prices or rates, credit rating or credit index, or other variable, provided in the case of a non-financial variable that the variable is not specific to a party to the contract (sometimes called the 'underlying').
- b) it requires no initial net investment or an initial net investment that is smaller than would be required for other types of contracts that would be expected to have a similar response to changes in market factors.
- c) it is settled at a future date.

Purchases or sales of financial assets that require delivery of assets within a time frame established by regulation or convention in the marketplace (regular way trades) are recognized on the trade date, i.e. the

date that the Group commits to purchase or sell the asset.

### Financial Assets

At initial recognition, the Group measures a financial asset at its fair value plus, in the case of financial asset not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at fair value through profit or loss are expensed in profit or loss. On initial recognition, trade receivables without a significant financing component are measured at their transaction price.

Subsequent measurement of debt instruments depends on the Group's business model for managing the asset and the cash flow characteristics of the asset. The Group classifies its debt instruments into one of the following measurement categories.

Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortized cost. Interest income from these financial assets is included in finance income using the effective interest rate method. Any gain or loss arising on the de-recognition is recorded directly in profit or loss and presented in finance income / cost.

Assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets' cash flows represent solely payments of principal and interest, are measured at fair value through other comprehensive income. Movements in the carrying amount are taken through other comprehensive income, except for the recognition of impairment gains or losses, interest revenue and foreign exchange gains and losses which are recognized in profit or loss. When the financial asset is derecognized, the cumulative gain or loss previously recognized in other comprehensive income is reclassified from equity to profit or loss and presented in finance income / cost. Interest income from the financial assets are presented in other income / cost.

Assets that do not meet the criteria for amortized cost or at fair value through other comprehensive income or for which the fair value option in accordance with IFRS 9 is exercised, are measured at fair value through profit or loss. A gain or loss on a debt investment that is subsequently measured at fair value through profit or loss is recognized in profit or loss and presented net within finance income / expenses in the period in which it arises. Curetis does not use the fair value option.

Curetis has elected to measure all equity instruments at fair value through profit or loss. In the current reporting period, the Group did not hold any equity instruments.

Financial assets with embedded derivatives are considered in their entirety when determining whether their cash flows are solely payment of principal and interest.

Financial assets are derecognized when the rights to receive cash flows from the financial assets have expired or have been transferred and the group has transferred substantially all the risks and rewards of ownership.

# Financial Liabilities

At initial recognition, the Group measures a financial liability at its fair value less, in the case of financial liability not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition of the financial liability. Transaction costs of financial liabilities carried at fair value through profit or loss are expensed in profit or loss.

Financial liabilities are generally classified at amortized cost. There are some exceptions, for example financial liabilities at fair value through profit or loss including derivatives not designated as hedging instruments.

Financial liabilities need to be analyzed to determine whether they contain any embedded derivatives. If the embedded derivative is not closely related to the host contract, such derivatives must be separated and be accounted for separately at Fair Value Through Profit and Loss ("FVTPL").

Financial liabilities (or a part of a financial liability) are derecognized from the statement of financial position when, and only when, it is extinguished, i.e. when the obligation specified in the contract is discharged or

## cancelled or expires.

## **Impairment**

For trade receivables, Curetis applies the simplified approach permitted by IFRS 9, which requires expected lifetime losses to be recognized from initial recognition of the receivables. To measure the expected credit losses, all trade receivables have been grouped together as they share the same credit risk characteristics. A historic corporate default rate specific to the healthcare industry adjusted for forward-looking macroeconomic factors and an appropriate recovery rate were applied to calculate the expected credit losses. During the reporting period, there were no significant changes with regard to the calculation approach or applied assumptions.

Trade receivables are written off when there is no reasonable expectation of recovery. One indicator that there is no reasonable expectation of recovery include, amongst others, when internal or external information indicate that the Group is unlikely to receive the outstanding contractual amount in full. Another indicator that there is no reasonable expectation of recovery is a durable failure of the counterparty to meet its contractual obligations.

From 1<sup>st</sup> January 2018, the Group assesses on a forward-looking basis the expected credit losses associated with its debt instruments carried at amortized cost and at fair value through other comprehensive income. The impairment methodology applied depends on whether there has been a significant increase in credit risk. If, at the reporting date, the credit risk on a financial instrument has not increased significantly since initial recognition, the Group measures the loss allowance for the financial instrument at an amount equal to twelve-month expected losses. In case the credit risk on a financial instrument has increased significantly since initial recognition, the Group measures the loss allowance for that financial instrument at an amount equal to the lifetime expected credit losses. To assess whether there is a significant increase in credit risk Curetis compares the risk of a default occurring on the asset as at the reporting date with the risk of default as at the date of initial recognition. It considers available reasonable and supportive forward -looking information. Especially the following indicators are incorporated:

- external credit rating (as far as available)
- actual or expected significant adverse changes in business, financial or economic conditions that are expected to cause a significant change to the borrower's ability to meet its obligations
- significant increases in credit risk on other financial instruments of the same borrower
- significant changes in the expected performance and behavior of the borrower, including changes in the payment status of borrowers in the group and changes in the operating results of the borrower.

Regardless of the analysis above, a significant increase in credit risk is presumed if a debtor is more than 30 days past due in making a contractual payment.

Deposits with banks and financial institutions are considered to have low credit risk as of the reporting date as the relevant counterparties have investment grade ratings. However, in case of an objective evidence of an impairment, Curetis analyses the respective financial asset on an individual basis and recognizes an impairment in an amount of the lifetime expected credit losses. Impairment losses are incurred if, and only if, there is objective evidence of impairment as a result of one or more events that occurred after the initial recognition of the asset (an incurred "loss event") and that loss event has an impact on the estimated future cash flows of the financial asset that can be reliably estimated. Evidence of impairment may include indication that the debtors or a group of debtors is experiencing significant financial difficulty, default or delinquency in interest or principal payments, the probability that they will enter bankruptcy or other financial reorganization and observable data indicating that there is a measurable decrease in the estimated future cash flows, such as changes in arrears or economic conditions that correlate with defaults. Regardless of the analysis before, a default on a financial asset is presumed to occur when the counterparty fails to make contractual payments within 90 days of when they fall due.

## Offsetting Financial Assets and Financial Liabilities

Curetis currently has not recognized any financial instruments that are offset. The Group did not enter into

any enforceable netting arrangements or other derivative instruments or offsetting arrangements that meet the offsetting criteria in IAS 32.

# Cash and Cash Equivalents

Cash and cash equivalents comprise cash on hand, deposits held at call with banks, and other short-term highly liquid investments with original maturities of three months or less.

### Trade Receivables

Trade receivables are amounts due from customers for merchandise sold or services performed in the ordinary course of business as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due. A specific valuation adjustment is established, when there is objective evidence that Curetis will not be able to collect all amounts due, according to the original terms of the receivables.

## Trade and Other Payables

These amounts represent liabilities for goods and services provided to the group prior to the end of financial year which are unpaid. The amounts are unsecured and are usually paid within 30 days of recognition. Trade and other payables are presented as current liabilities unless payment is not due within 12 months after the reporting period. They are recognized initially at their fair value and subsequently measured at amortized cost using the effective interest method.

### 3.20. Provisions for Other Liabilities and Charges

Provisions are recognized when Curetis has a present legal or factual obligation as a result of past events; and it is more likely than not that an outflow of resources will be required to settle the obligation and the amount can be reliably estimated. Where the effect of the time value of money is material, provisions are discounted using a current pre-tax rate. If discounting is used, the increase in the provision over time is recognized as interest expense. Gains from the reversal of other current liabilities that arose originally in previous years are recognized as other operating income.

### 3.21. CURRENT AND DEFERRED TAX INCOME

The tax expense for the period comprises current and deferred tax. Tax is recognized in the statement of profit or loss and other comprehensive income.

The current income tax charge is calculated on the basis of the tax law enacted or substantively enacted at the balance sheet date where the Company operates and generates taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred income tax is recognized on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements, as well as for tax loss carryforward. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill. In addition, deferred income tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit nor loss. Deferred income tax is determined applying tax rates (and laws) that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized. Deferred tax assets are only considered in the financial statements to offset deferred tax liabilities. The Company does recognize deferred tax assets on unused losses only if it is probable that the related tax benefit will be realized short-term.

Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income taxes assets and liabilities relate to

income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities where there is an intention to settle the balances on a net basis.

In accordance with IAS1 'Presentation of financial statements', the current part of deferred taxes is recognized as non-current assets/ liabilities in the statement of financial position.

### 3.22. *EQUITY*

Share capital is classified as equity. Mandatorily redeemable preference shares as well as common shares had been classified as liabilities until the corporate reorganization. Incremental costs directly attributable to the issuance of shares are recognized net of tax as a deduction from equity.

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recognized at the proceeds received, net of direct issue costs.

### 3.23. SHARE-BASED PAYMENTS

# The Employee Stock Option Plan 2016 ("ESOP")

In July 2016 Curetis has started to grant stock options according to the Employee Stock Option Plan 2016. The terms of this ESOP were adopted by the general meeting on 16<sup>th</sup> June 2016. The stock option plan was designed in order to grant options to ordinary shares in the capital of Curetis N.V. to nominees. The purpose of the plan is the retention of current and the recruiting of new key employees, managing directors and supervisory directors, to spare liquidity, diminish employee turnover, alignment of shareholders' interests with employees' and directors' interests and finally to increase interest of capital markets in the Company by a shareholder value orientated compensation system. The stock options were classified as equity settled.

The fair value of the stock options is measured by using a binomial option pricing model taking into account the terms and conditions upon which the options were granted.

The expense resulting from the share-based payment transactions is recognized during the vesting period with a corresponding increase in equity. Furthermore, the amount recognized is based on the best available estimate of the number of equity instruments expected to vest and is revised, if subsequent information indicates that the number of equity instruments expected to vest differs from previous estimates.

Valuation model, input parameters, recognized expenses and further details are stated in Note 32.

### 3.24. GOVERNMENT GRANTS

Government grants are not recognized until there is reasonable assurance that the Company will comply with the conditions attached to them and that the grants will be received.

The Group receives grants related to research projects from governmental agencies, these are recognized at their fair value when the Group receives the grants from the agency and will comply with the conditions attached to the grants, but in no event prior to the formal grant approval. The grants are accounted for as other income in the statement of operations and other comprehensive loss. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed.

# CURETIS N.V. – NOTES TO THE CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

## 4. DISCONTINUED OPERATIONS

On 4<sup>th</sup> September 2019 Curetis and OpGen Inc. (NASDAQ ticker OPGN, WKN: A2PQ6B) announced their intention to combine their businesses by way of a sale of the Curetis Business (essentially Curetis GmbH including its wholly owned subsidiaries in the USA and Ares Genetics in Austria). The transaction was subject to debt holder and shareholder approvals on both sides, which were obtained post year end and thus the transaction closed on 1<sup>st</sup> April 2020 (see note 39).

At 24<sup>th</sup> December 2019 the Curetis Business and certain liabilities of Curetis N.V. were classified as a disposal group held for sale and as discontinued operation. See note 2.3 for critical accounting judgements.

The liabilities of Curetis N.V., which were classified as held for sale and thus as part of the discontinued operations, mainly refer to the convertible bond (Yorkville). As of 31 December 2019, it was highly probable that the Yorkville convertible bond will transfer to OpGen Inc. in the course of the planned transactions and respective contracts have been set up. Due to this, the respective financial liability as well as the associated effects within profit or loss are deemed to be part of the discontinued operation. Furthermore, an asset of Curetis N.V is classified as part of the discontinued operation. This asset refers to a prepayment of an liability insurance for the issuance of securities of Curetis N.V. According to management this insurance will transfer to the Curetis Business as in the unlikely event of future claims, this insurance can be used so that Curetis Business is the future beneficiary.

In order to present a true and fair view of the result for discontinuing operations adequate allocations were made with respects to the remuneration of management and the supervisory board.

Between the 24<sup>th</sup> December 2019 and 31 December 2019 there were no impairment losses recognized on remeasurement. The results of Curetis Business for the year are presented below:

in kEUR	2019	2018
Revenue	2,271	1,419
Expenses	(23,481)	(23,599)
Operating loss	(21,210)	(22,180)
Finance costs, net	(2,087)	(796)
Loss before income tax	(23,297)	(22,976)
Impairment loss recognized on the remeasurement to fair value less costs to sell	-	-
Loss before tax from discontinued operations	(23,297)	(22,976)
Tax benefit/(expense)	(73)	(36)
Loss for the year from discontinued operations	(23,370)	(23,012)

Curetis N.V. will sell 100% of its shares and interest in Curetis GmbH (the Business) including all assets, liabilities, operations, products, commercial contracts etc. and the non-current financial liabilities of Curetis N.V.

The Transaction is structured as an acquisition by OpGen Inc. Group of all issued and outstanding shares in the capital of Curetis GmbH an entity which owns all of the Curetis' group business and is wholly owned by the Curetis N.V. In consideration for the acquisition of Curetis GmbH by OpGen Inc., the Company will be entitled to receive 2,662,564 new shares of OpGen common stock, minus an aggregate of 635,421 shares of OpGen common stock to be reserved by OpGen for future issuances (i) to holders of outstanding options under the 2016 Stock Option Plan (as defined in the Shareholder Circular, which is defined below) for a

number of 135,421 shares and (ii) upon the conversion, if any, of the Curetis Convertible Notes (as defined in the Shareholder Circular) for a number of 500,000 shares (the "Transaction Shares"). These Transaction Shares received by Curetis N.V. can be reduced by up to 20% in order to sell these to obtain sufficient liquidity, which will then reduce the number of transaction shares to be distributed as part of the distribution to shareholders. Please refer to note 39.

The corporate tax loss carryforward for Curetis GmbH is kEUR 110,681 for 2019 (kEUR 96,587 for 2018) and trade tax loss carryforward for Curetis GmbH is kEUR 109,799 for 2019 (kEUR 96,094 for 2018).

The major classes of assets and liabilities of Curetis Business classified as held for sale as at 31 December 2019 are, as follows:

Assets		
in kEUR		31 December 2019
Current assets		5,090
	Cash and cash equivalents	2,274
	Trade receivables	255
	Inventories	1,865
	Other current assets	696
Non-current assets		12,311
	Intangible assets	7,260
	Property, plant and equipment	3,611
	Right of use assets	1,073
	Other non-current assets	208
	Other non-current financial assets	159
	Deferred tax assets	_
Assets held for sale		17,401

Liabilities		
in kEUR		31 December 2019
Current liabilities		8,432
	Trade and other payables	1,086
	Provisions current	161
	Tax liabilities	-
	Other current liabilities	815
	Contract Liabilities	1,157
	Other current financial liabilities	4,777
	Current lease liabilities	436
Non-current liabilities		20,709
	Provisions non-current	44
	Other non-current financial liabilities	20,016
	Non-current lease liabilities	649
Liabilities directly associated with assets classified as held for sale		29,141
Net assets of disposal gr	roup	(11,740)

The net cash flows incurred by Curetis Business are, as follows:

in kEUR	2019	2018
Operating	(9,161)	(3,990)
Investing	(1,547)	(787)
Financing	8,182	16,337
Net cash inflow	(2,526)	11,560

## 5. REVENUE

In order to present comparative amounts relating to revenue, kEUR 1,419 has been reclassified to discontinued operations for the year ended 2018. For detailed information concerning IFRS 5 discontinued operations for the years ended 2019 and 2018, refer to note 4.

# 6. Cost of Sales

In order to present comparative amounts relating to cost of sales, kEUR 2,233 has been reclassified to discontinued operations for the year ended 2018. For detailed information concerning IFRS 5 discontinued operations for the years ended 2019 and 2018, refer to note 4.

# 7. EXPENSES BY NATURE

in kEUR	2019	2018
Employee benefit expenses	90	99
Marketing and travel expenses	65	60
Other consulting, advisory & 3rd party support	864	530
Other expenses	71	64
Total Cost of Sales, distribution costs, administrative expenses and research & development expenses	1,090	753

In order to present comparative amounts relating to expenses by nature, kEUR 24,298 has been reclassified to discontinued operations for the year ended 2018. For detailed information concerning IFRS 5 discontinued operations for the years ended 2019 and 2018, refer to note 4.

# 8. DISTRIBUTION COSTS

in kEUR	2019	2018
Personnel expenses	-	-
thereof from share-based payments equity-settled	-	-
Other operating expenses	-	-
thereof marketing expenses	-	-
thereof travel expenses	-	-
thereof consulting, advisory & 3rd party service	-	-
TOTAL	-	-

In order to present comparative amounts relating to distribution costs, kEUR 8,155 has been reclassified to discontinued operations for the year ended 2018. For detailed information concerning IFRS 5 discontinued operations for the years ended 2019 and 2018, refer to note 4.

## 9. ADMINISTRATIVE EXPENSES

in kEUR	2019	2018
Personnel expenses	90	99
thereof from share-based payments equity-settled	-	-
Depreciation and Amortization	-	-
Other expenses	1,000	654
thereof for remuneration of supervisory board	94	90
thereof from share-based payments equity-settled	-	-
thereof consulting, advisory & 3rd party service	770	440
TOTAL	1,090	753

Administrative expenses include personnel, depreciation and other costs of the central administrative areas, which are not related to production, sales or research and development.

In order to present comparative amounts relating to administrative expenses, kEUR 3,343 has been reclassified to discontinued operations for the year ended 2018. For detailed information concerning IFRS 5 discontinued operations for the years ended 2019 and 2018, refer to note 4.

## 10. RESEARCH & DEVELOPMENT EXPENSES

in kEUR	2019	2018
Personnel expenses	-	-
thereof from share-based payments equity-settled	-	-
TOTAL		_

In order to present comparative amounts relating to research and development, kEUR 10,568 has been reclassified to discontinued operations for the year ended 2018. For detailed information concerning IFRS 5 discontinued operations for the years ended 2019 and 2018, refer to note 4.

# 11. EMPLOYEE BENEFIT EXPENSES

in kEUR	2019	2018
Wages and salaries	90	93
Social security costs	-	6
EPOSs / PSOs granted to management and employees	-	-
Total employee benefits	90	99

In order to present comparative amounts relating to employee benefit expenses, kEUR 11,610 has been reclassified to discontinued operations for the year ended 2018. For detailed information concerning IFRS 5 discontinued operations for the years ended 2019 and 2018, refer to note 4.

## 12. OTHER INCOME

in kEUR	2019	2018
Other income	40	19

In order to present comparative amounts relating to other income, kEUR 700 has been reclassified to discontinued operations for the year ended 2018. For detailed information concerning IFRS 5 discontinued

operations for the years ended 2019 and 2018, refer to note 4.

# 13. FINANCE RESULT / NET

in kEUR	2019	2018
Finance income	1	-
Finance cost	(67)	(2)
Finance result/net	(66)	(2)

In order to present comparative amounts relating to finance result, kEUR 796 of net costs has been reclassified to discontinued operations for the year ended 2018. For detailed information concerning IFRS 5 discontinued operations for the years ended 2019 and 2018, refer to note 4.

Finance Results	2019	2019	2018	2018
in kEUR	Continued	Discontinued	Continued	Discontinued
Financial assets measured at amortized cost	(1)	(30)	(2)	372
Financial assets measured at fair value through profit or loss	-	-		-
Financial liabilities measured at amortized costs	(65)	(2,369)	-	(1,168)
Financial liabilities measured at fair value through profit or loss	-	(94)	-	11
Finance result/costs net	(66)	(2,493)	(2)	(785)

Financial liabilities measured at amortized cost include effective interest expenses as well as results from foreign currency translation.

Financial assets measured at amortized cost include effective interest expenses as well as results from foreign currency translation.

Financial liabilities at fair value through profit or loss comprise decreases / increases in the fair value as well as losses / gains from disposal of financial liabilities.

# 14. INCOME TAX EXPENSE

Income Tax Expenses in kEUR	2019	2018
Continued operations		
Current Income taxes		
Germany	-	-
other countries		-
Total current income taxes		-
Deferred taxes		-
Total		-
Discontinued operations		
in kEUR	2019	2018
Current taxes	2	29
Deferred taxes	71	7

In order to present comparative amounts relating to income tax, kEUR 36 have been reclassified to

discontinued operations for the year ended 2018. For detailed information concerning IFRS 5 discontinued operations for the years ended 2019 and 2018, refer to note 4.

In Germany, Income tax consists of trade tax ('Gewerbesteuer') and corporate income tax ('Körperschaftsteuer'). Corporate income tax is imposed at a uniform rate of 15% and is additionally subject to a solidarity surcharge of 5.5%, resulting in an effective tax rate of 15.825% (2018: 15.825%).

Municipalities impose a trade tax. Each municipality set its individual local multiplier rate, so that no uniform trade tax rate exists in Germany. In 2019, Curetis has a trade tax rate of 12.05% (2018: 12.05%).

The Company according to the double taxation treaty between Germany and the Netherlands is fully taxable in Germany, as only the Company's statutory seat is in the Netherlands without any permanent establishment there and with the place of effective management in Holzgerlingen, Germany.

The income tax expense for the year can be reconciled to the accounting profit (loss) as follows:

kEUR	2019	2018
Loss before income tax (continuing operations)	(1,116)	(736)
Loss before income tax	(23,297)	(22,973)
Expected income tax at a tax rate 2019: 27.88% (2018: 27.88%)	6,806	6,610
Non-taxable income and non-deductible expenses	(85)	(34)
Expenses resulting from Equity settled stock options	(68)	(138)
Non-recognition of deferred tax assets on tax loss carry-		
forwards	(4,332)	(5,202)
Effect from revaluation of DTA (in context with DTL)	17	73
Tax effect from local taxes	(4)	(33)
Transaction costs		829
Tax effect of the application of foreign tax rates and use of		
foreign tax losses carried forward	(2,193)	(2,128)
Other effects	(215)	(13)
Income tax as stated in Discontinued Operations Disclosure	(73)	(36)
Income tax as stated in P&L		-
Effective tax rate	0%	0%

Changes in the recognition of deferred tax assets on tax loss carry-forwards of kEUR 4,332 are due to not recognized deferred tax assets on tax loss carryforwards for 2019.

Tax effects of the application of foreign tax rates and use of foreign tax losses carried forward comprise mainly to not realized deferred tax assets for the loss of Curetis USA Inc. and ARES Genetics GmbH as there is no reliable certainty that these losses will be usable.

### 15. LOSS PER SHARE

Loss per common share is calculated by dividing the profit / loss of the period by the weighted average number of common shares outstanding during the period.

Basic loss per share		
in Euro	2019	2018
From continuing operations attributable to the ordinary equity holders of the Company	-0.05	-0.04
From discontinued operation	-1.00	-1.36
Total basic loss per share attributable to the ordinary equity holder of the Company	-1.05	-1.40

Diluted loss per share		
in Euro	2019	2018
From continuing operations attributable to the ordinary equity holders of the Company	-0.05	-0.04
From discontinued operation	-1.00	-1.36
Total diluted loss per share attributable to the ordinary equity holder of the Company	-1.05	-1.40

As the Group is suffering losses options have an anti-dilutive effect. As such, there is no difference between basic and diluted losses per ordinary share.

# RECONCILIATION OF LOSSES USED IN CALCULATING EARNINGS PER SHARE

Basic loss per share		
in kEUR	2019	2018
Loss attributable to the ordinary equity holders of the Company used in calculation basic loss per share:		
From continuing operations	(1,116)	(736)
From discontinued operation	(23,370)	(23,009)
TOTAL basic losses as basis for the calculation of loss per share	(24,486)	(23,745)
Diluted loss per share		
in kEUR	2019	2018
Loss attributable to the ordinary equity holders of the Company used in calculation basic loss per share:		
From continuing operations	(1,116)	(736)
From discontinued operation	(23,370)	(23,009)
TOTAL diluted losses as basis for the calculation of loss per share	(24,486)	(23,745)

Weighted average number of shares used as the denominator

weighted average number	2019	2018
Weighted average number of ordinary shares used as the denominator in calculating basic and diluted loss per share	23,311,710	16,788,963

As the Group is suffering losses options have an anti-dilutive effect. As such, there the denominator for both basic and diluted loss per share is the same. Stock Options equity settled are shown in the table below:

weighted average number	2019	2018
Stock options equity settled	1,385,496	951,443

# CURETIS N.V. – NOTES TO THE CONSOLIDATED STATEMENT OF FINANCIAL POSITION

# 16. CASH AND CASH EQUIVALENTS

On 31 December 2019, cash and cash equivalents amounted to kEUR 852 (31 December 2018: kEUR 10,279). These consist of bank balances and cash on hand. Cash & cash equivalents are at the Company's free disposal, none of these amounts are pledged.

The decrease in cash and cash equivalents is mainly due to a negative cash outflow from operating activities, only partly compensated by a positive cash-inflows from financing activities such as EIB financing, convertible loan facility. Additionally, further decrease in cash due to the classification of held for sale assets relating to IFRS 5 discontinued operations concerning the year ended 2019, refer to note 4.

## 17. TRADE RECEIVABLES

The carrying amounts of the trade receivables approximate to their fair values. Current trade receivables are non-interest bearing.

in kEUR	31 December 2019	31 December 2018	
Trade receivables, gross	396		325
less loss allowance	(141)		(2)
Assets held for sale	(255)		-
Trade receivables, net			323

The following table presents the trade receivables past due as of the reporting date.

in kEUR	31 December 2019	31 December 2019	31 December 2018
	Continued	Disposal Group	
	gross	gross	gross
Amounts not due	-	237	242
Past due o-30 days	-	146	60
Past due 31-60 days	-	13	23
Past due 61-90 days	-	-	-
Past due 91-180 days	-	-	-
Past due 181-270 days	-	-	-
Past due 271-360 days	-	-	-
More than one year	-	-	-
Total		396	325

As of 31 December 2019, trade receivables of kEUR 159 (31 December 2018 83 kEUR) were past due, the company made a write off receivables of kEUR 141. Details about the company's impairment policies and the calculation of the loss allowance are provided in note 3.19.

Movements in the Company's loss allowance on trade receivables are as follows:

in kEUR	2019	2018
Balance as of 1 January	(2)	(2)
Net additions (-) / reversals (+)	(139)	-
Use		-
Balance as of 31 December	(141)	(2)

## 18. Inventories

: LEUD	5 1	5 1 0
in kEUR	31 December 2019	31 December 2018
Raw materials	-	838
Semi-finished goods	_	61
Trade goods	_	8,113
Finished goods	-	65
Spare parts	-	101
Total inventories, gross		9,178
Valuation allowance	_	(2,444)
Total inventories, net	-	6,734

As outlined in note 2.3 the assessment of the obsolescence write-downs on inventories is considered a significant estimate with inherent uncertainty. Given Curetis does not yet have a reliable sales-track-record, the write-downs are based on the best estimate considering technical aging and estimated sales volumes and prices for systems. The change of write-off to net asset value of inventories is recognized as an expense and included in Cost of Sales.

Curetis has assessed as part of the preparation of these financial statements whether the sales-track-record thus far continues to allow for a largely forecast based valuation of the inventory balance. Sales of Unyvero Systems have been lower than anticipated across all regions and distribution types increasing the uncertainty of the valuation of the inventory balance. As a result, Curetis weighed historical sales higher due to the market development and thus identified a low double-digit number of systems which are deemed to represent the minimum sales volumes expected of Unyvero Systems in 2020. These systems have been valued at their cost price. The remaining Unyvero Systems have been valued at their residual value based on management's best estimate. After recording an impairment charge of kEUR 4,987, the valuation allowance recognized as of the reporting date is kEUR 7,431 (2018: kEUR 2,444).

Management has identified multiple opportunities where demand could lead to future sales which are not reflected in the valuation approach taken and thus lead to change in the obsolescence write-down as their occurrence cannot no longer be incorporated in the assessment. These includes the uptake of commercial use of Unyvero Systems in the US, the Unyvero Approval in China and market opportunities therein and others. Thus, an increase in sales volumes in excess of those anticipated for 2020 by 20% would decrease the allowance by kEUR 118.

## 19. OTHER CURRENT ASSETS

in kEUR	31 December 2019	31 December 2018
Advance on travel exp.	-	14
Rent Deposits	-	28
Income tax refunds	-	1
VAT receivables	-	404
Prepaid Expenses	28	200
Prepaid transaction exp. for future capital increases	-	99
Other current assets	-	13
TOTAL	28	759

## 20. INTANGIBLE ASSETS

in kEUR	Software	Licenses & Patents	Unyvero A30 technology	advance payments	Total
Balance as of 1 January	Software	a raterits	teermology	payments	10tui
2018	95	7.402	-	27	7,524
Reclassification Unyvero A <sub>3</sub> o	-	(5,000)	5,000	-	-
Additions	34	1	-	84	119
Disposals	-	-	-	-	-
Amortization	(76)	(142)	-	-	(218)
Reclassifications	-	-	-	-	-
Balance as of 31					
December 2018	53	2,261	5,000	111	7,425
Cost	691	7,485	-	111	8,287
Reclassification Unyvero A <sub>3</sub> o	-	(5,000)	5,000	-	-
Accumulated					
amortization	(638)	(224)	-	-	(862)
Balance as of 31 December 2018	52	2 261	5,000	111	7 (25
December 2016	53	2,261	5,000	111	7,425
A I Pro					
Additions	30	12	-	1	43
Disposals	-	-	-	-	-
Amortization	(66)	(141)	-	-	(207)
Reclassifications	111	-	-	(111)	-
Assets held for sale	(128)	(2,132)	(5,000)	(1)	(7,261)
Balance as of 31 December 2019		_	_	_	_

In principle intangible assets not yet available for use (Unyvero A30 RQ, formerly known as "Gyronimo") must be tested for impairment at least annually. Unyvero A30 RQ is expected to be developed by Curetis into a partnering-ready asset. The platform is still in a development phase and the development takes place by the same team that had developed and continues to maintain the Unyvero A50-multiplex-platform. As the Unyvero A30 RQ is not yet fully developed and ready for sale, it has no defined residual amortization period. The current value is based on actual cost incurred. During the annual impairment test, management assessed the fair value less costs of disposal which was compared to capital raisings from a peer group benchmarking on the value of such platforms either as early stage privately held or as venture capital backed assets. Based on this annual impairment test the Unyvero A30 RQ has not been impaired.

The GEAR platform, held within the Licenses & Patents, was transferred from Curetis GmbH in Q4-2017 to the wholly owned subsidiary Ares Genetics GmbH and continues under the name Aresdb. The platform had not been amortized from its acquisition in Q4-2016 until the transfer to Ares Genetics GmbH as it had not been available to be used. Subsequent to the transfer, the platform has been in commercial use and is being amortized according to the runtime of the main patent (17.8 years) and the remaining amortization period of the GEAR platform as of 31 December 2019 is 15.6 years. Curetis continues to invest further in these assets. For 2018 and 2019 there were no indicators of potential impairment as the recoverable amounts exceeded their carrying amount, hence no impairment loss has been recognized.

# 21. PROPERTY, PLANT AND EQUIPMENT

in kEUR	Land and buildings	Machines and technical installation	Other tangible assets	Assets under construction	Total
Balance as of 1 January 2018	23	2,609	645	289	3,566
Additions	-	31	215	424	670
Disposals	-	-	(81)	-	(81)
Amortization	(8)	(701)	(250)	-	(959)
Reclassifications		417	-	(417)	-
Balance as of 31 December 2018	15	2,356	529	296	3,196
Cost	72	8,300	2,770	296	11,438
Accumulated depreciation/impairments	(57)	(5,944)	(2,242)	-	(8,242)
Balance as of 31 December 2018	15	2,357	529	296	3,196
Additions	-	80	621	800	1,501
Disposals	-	(2)	(3)	-	(5)
Amortization	(8)	(739)	(336)	-	(1,082)
Reclassifications	-	1,089		(1,089)	-
Assets held for sale	(7)	(2,785)	(811)	(7)	(3,610)
Balance as of 31 December 2019	-	-	-	-	-

Other tangible assets comprise office equipment and Unyvero-Platforms used for internal demands. Curetis did not have ownership of these assets under any lease programs in 2018 or 2019. All property, plant and equipment are free from any rights held by third parties.

For further details, please refer to Note 4.

# 22. RIGHT-OF-USE ASSETS

in kEUR	Real estates	Other Right-of-use Assets	Total
Initial recognition 01.01.2019	1,450	44	1,494
Additions	6	22	28
Disposals	-	(13)	(13)
Depreciation	(414)	(22)	(436)
Assets held for sale	(1,042)	(31)	(1,073)
Balance as of 31 December 2019	-	-	-

For further details, please refer to Note 3.1. For classification as assets held for sale see Note 4.

## 23. OTHER NON-CURRENT FINANCIAL ASSETS

Other non-current financial assets solely include assigned accounts for rent and bank deposits as follows (for further details we refer to note 29):

in kEUR	31 December 2019	31 December 2018
Rent deposit	_	64
Bank deposit	_	94
Total		158

## 24. TRADE AND OTHER PAYABLES

in kEUR	31 December 2019	31 December 2018
Trade and other payables	82	957
Total	82	957

## **25.PSOP**

Prior to the IPO Curetis N.V. operated a share-based compensation plan, Curetis AG Phantom Stock Option Incentive Plan 2010 ("PSOP") under which the Company received services from employees and freelancers who received for Phantom Stock Options ("PSOs") as consideration.

As all PSOs have a fixed payment claim and already have been measured with the fair value of this payment claim as of 31 December 2015 and was fully expensed and recognized in equity prior to 2018 therefore there have been no changes in valuation and no effect to be accounted for in the statement of profit and loss and other comprehensive income in 2019 or 2018.

Under the PSOP-Roll-Over Agreements the beneficiaries were entitled to receive 659,237 new shares in Curetis.

In December 2019, the PSOs outstanding under the PSOP were fully settled and all PSOP Roll Over shares were issued, 52% of the issued shares were then sold as per terms of PSOP Roll Over Agreements, and the cash proceeds transferred to Curetis for settlement of taxes on behalf of the beneficiaries. The remaining 48% of the shares were transferred into the individual beneficiaries' recipient securities accounts. For further detail we refer to note 32.

### 26. PROVISIONS

The following table provides a breakdown of provisions by type:

in kEUR	31 December 2019	31 December 2018
Asset retirement obligations	-	38
Other provisions	-	71
Balance		109
- of which: current	-	65
- of which: non-current		44

## 27. OTHER CURRENT LIABILITIES

in kEUR	31 December 2019	31 December 2018
Accruals for vacation	18	362
Accruals for Employee Bonuses	-	10
Accrual for Severance / Restructuring	-	136
Accruals for employers liability & social insurance	-	119
Accruals for audit and preparation of financial statements	218	255
Other tax liabilities	32	174
Other liabilities	-	179
Balance	268	1,235

### 28. OTHER CURRENT FINANCIAL LIABILITIES.

in kEUR	31 December 2019	31 December 2018
Liabilities for outstanding invoices	61	334
Provision for deferred interest	-	342
Convertible notes	-	3,109
Balance	61	3,785

### **CONVERTIBLE NOTES**

# Key facts of the convertible note facility

On 2<sup>nd</sup> October 2018, Curetis N.V. established a convertible note facility with Yorkville Advisors (Yorkville), a US institutional investor, consisting of several tranches. Under the first tranche, 500 notes are available for issuance, whereby each note has a nominal value of kEUR 10 and a maturity of one year. As of 31<sup>st</sup> December 2018, the Company had issued all 500 notes from the first tranche with an issuance date of 2<sup>nd</sup> October 2018 (350 notes) and 150 notes 90 days after the subscription date or such later date that may be agreed between the parties. The notes were issued at an 8% discount, due to a 4% commitment fee and a 4% subscription fee. The Company incurred kEUR 120 in issuance costs related to due diligence and legal fees.

The holders of the outstanding notes have the right to convert the notes in exchange for shares of Curetis N.V. at any time. The number of shares to be issued upon conversion of a note is determined by the nominal amount of the note divided by 93% of the last 10-day lowest VWAP (volume weighted average price) of the common stock share of Curetis N.V. on the conversion date. As of 31 December 2019, 370 notes cumulatively have been converted to shares of Curetis N.V. with a remainder of 130 notes with a nominal value of EUR 1.3 million in unconverted notes.

All of the remaining unconverted notes issued as of 31 December 2019 have a maturity date of June 2020. Under the terms of the notes, the Company has the right to extend the maturity date (up to four times) by 12 months. When extending the maturity date, the Company must pay a 5% fee on the outstanding balance as of the extension date. Alternatively, Curetis also has the option to redeem the notes in cash at the maturity date. These remaining 130 unconverted notes including the right to extend maturity against cash payment fee shall be assumed by OpGen as part of a three-way agreement between Yorkville, Curetis and OpGen.

The conversion rights represent a financial liability, because ultimate settlement of the note would be based on a variable number of shares in the event the rights are exercised. As a result, the Company classifies the entire instrument as a liability.

The Company assumed an initial fair value of the notes, based on the Company's share price as of the issuance date divided by 93%. The Company accounts for the notes payable using the effective interest method, using an effective interest rate of 8% and the initial loan term of 12 months. The Company accounts

for the outstanding convertible notes as a current liability, as the likelihood for executing the extension option is remote.

For this reason, the convertible note is classified as liabilities as part of the disposal group held for sale, please refer to Note 4.

# 29. OTHER NON-CURRENT FINANCIAL LIABILITIES

In 2016 Curetis entered into a contract for an up to EUR 25 million senior, unsecured loan financing facility from the EIB (European Investment Bank). The financing in the first growth capital loan under the European Growth Finance Facility (EGFF), launched in November 2016. It is backed by a guarantee from the European Fund for Strategic Investment (EFSI), EFSI is an essential pillar of the Investment Plan for Europe (IPE), under which the EIB and the European Commission are working as strategic partners to support investments and bring back jobs and growth to Europe.

The funding can be drawn in up to five tranches within 36 months, under the EIB amendment, each tranche is to be repaid upon maturity five years after draw-down.

In April 2017 Curetis drew down a first tranche of EUR 10 million from this facility. This tranche has a floating interest rate of EURIBOR + 4% p.a. payable after each 12-month-period from the draw-down-date and another additional 6% p.a. that is deferred and payable at maturity together with the principal. In June 2018 another tranche of EUR 3 million was drawn down. The terms and conditions are analogous to the first one.

In June 2019 Curetis has drawn down a third tranche of EUR 5 million from the EIB (European Investment Bank). In line with all prior tranches, the majority of interest is also deferred into the bullet repayment structure upon maturity. In return for EIB waiving the condition precedent of a minimum cumulative equity capital raised of EUR 15 million to disburse this EUR 5 million tranche, the parties have agreed on a 2.1% participation percentage interest (PPI). Upon maturity of the tranche, i.e. not before around mid-2024 (and no later than mid-2025). EIB will be entitled to an additional payment that is equity-linked and equivalent to 2.1% of the then total valuation of Curetis. This right constitutes an embedded derivative, which is separated and measured at fair value with changes being accounted for through profit or loss. On 31 December 2019 Curetis has measured this derivative based on the then total valuation of Curetis. An agreement in principle – without being legally binding at the reporting date – was reached whereas the equity-linked participation will subsequently be measured on the then total valuation of OpGen Inc. Please refer to note 39 for details of the business combination with OpGen Inc.

Other non-current financial liabilities comprise the EIB debt facility taxes, calculated with the effective interest method. The effective interest rate applied by the Company is 9.12% for the EUR 10 million tranche and 9.16% for the EUR 3 million tranche. For the EUR 5 million tranche an effective interest rate of 9.01% is applied.

The EIB loan is classified as discontinued operation, please refer to note 4.

in kEUR	31 Decem	1ber 2019	31 December 2018		
	current	non-current	current	non-current	
Loan from EIB	18.000	-	-	13.000	
Deferred interest	2,301	-	343	949	
Fair value of PPI interest payment	163				
Liabilities directly associated with assets classified as held for sale	(20.464)		343		
Balance	-	-	686	13.949	

Following the successful equity capital raising of OpGen Inc. at the end of October 2019, OpGen and Curetis GmbH entered into an Interim Financing Facility whereby OpGen funds in several tranches of a short-term loan the operations of Curetis GmbH and its subsidiaries. As at 31 December 2019 a total of US\$ 2,500k had been funded. The loan under this facility is deeply subordinated e.g. to EIB and Yorkville and carries an

interest rate of 10% p.a. In case of the business combination transaction not closing as expected Curetis GmbH would be obligated to repay (subject to subordination) the loan amount within 15 business days. This loan is current and classified as discontinued operation, please refer to note 4.

Both the EIB and Yorkville agreements are subject to certain covenants. Since the end of the reporting period Curetis is in breach of covenants for both debt agreements due to the change of control clause of the contract. As a result, both EIB and Yorkville have been reclassified as current financial liabilities. Subsequently contractual amendments were reached by Curetis and its debt holders EIB and Yorkville in February 2020.

## 30. FINANCIAL INSTRUMENTS

For each class of financial instrument, the fair value of financial assets and liabilities, together with their carrying amounts contained in the consolidated financial statements are shown in the following schedules.

in kEUR	31 December 2019					
	Category in accordance with IFRS 9	Carrying amount	Fair <b>V</b> alue	Fair Value Level		
Non-Current Assets	n/a		n/a	n/a		
Current Assets						
Cash and Cash Equivalents	AC	852	n/a *	n/a*		
Trade Receivables	AC		n/a *	n/a*		
Assets classified as held for sale		17,401				
thereof Cash and Cash Equivalents	AC	2,342	n/a *	n/a*		
Thereof Trade receivables	AC	255	n/a *	n/a*		
thereof Other non-current financial assets	AC	159	159			
Other Assets classified as held for sale	n/a	14,645	n/a	n/a		

n/a \* ): For short-term financial instruments a fair value disclosure is not required as the carrying amount approximates the fair value.

in kEUR	31 December 2019				
	Category in accordance with IFRS 9	Carrying amount	Fair Value	Fair Value Level	
Non-Current Liabilities	n/a		n/a	n/a	
Current Liabilities					
Trade and other Payables	FLAC	82	n/a *	n/a	
Other current financial liabilities	n/a	61	n/a		
Liabilities directly associated with assets classified as held for sale		29,141			
thereof current lease liability	n/a	436	n/a	n/a	
thereof non-current lease liability	n/a	649	n/a	n/a	
thereof Other current financial liabilities EIB Loan	AC	20,301	n/a *	n/a *	
thereof Other current financial liabilities EIB Loan	FVTPL	163	163	3	
thereof Other current financial liabilities	AC	7,379	n/a *	n/a *	
thereof Other current financial liabilities	FVTPL	213	213	3	

n/a\*): For short-term financial instruments a fair value disclosure is not required as the carrying amount approximates the fair value.

For each class of financial instrument, the fair value of financial assets and liabilities, together with their carrying amounts contained in the consolidated financial statements are shown in the following schedules.

in kEUR	31 December 2018					
	Category in accordance with IFRS 9	Carrying amount	Fair <b>V</b> alue	Fair Value Level		
Current Assets						
Cash and Cash Equivalents	AC	10,279	n/a *	n/a		
Trade Receivables	AC	323	n/a *	n/a		
Non-current Assets						
Other non-current financial assets	AC	158	158	2		

n/a \*): For short-term financial instruments a fair value disclosure is not required as the carrying amount approximates the fair value.

in kEUR	31 December 2018				
	Category in accordance with IFRS 9	Carrying amount	Fair Value	Fair Value Level	
Current Liabilities					
Trade and other Payables	FLAC	957	n/a *	n/a	
Other current financial liabilities	FLAC	3,244	n/a *	n/a	
Other current financial liabilities	FVTPL	542	542	3	
Non-current Liabilities					
Other non-current financial liabilities	FLAC	13,949	13,546	2	

n/a \*): For short-term financial instruments a fair value disclosure is not required as the carrying amount approximates the fair value.

The fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly

transaction between market participants at the measurement date.

The fair value hierarchy is defined as follows:

**Level 1** Quoted (unadjusted) market prices in active markets for identical assets and liabilities.

**Level 2** Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable.

**Level 3** Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

The fair values of the Group's non-current other financial assets and the non-current financial liabilities were calculated based on cash flows discounted using market interest rates and a credit spread. The spread included in the calculation for the financial assets is derived by observable ratings of the counterparties (i.e. banks). The credit spread of the own credit risk is derived from the margin included in the interest rates of the own borrowings. The fair value of non-current financial assets and liabilities is included in level 2 of the fair value hierarchy, as the input factors for the fair value calculation are observable in the market. The fair value of the compound embedded derivative separated from the convertible note is determined using observable inputs (Curetis N.V. share price, own credit spread) and assumptions about the rational economic behavior of the related parties which are not observable input parameters. These assumptions lead to the inclusion of the fair value within level 3 of the fair value hierarchy.

Curetis has also allocated the separated embedded derivatives from the EIB loan to fair value level 3. The fair value of the embedded derivative separated from the third tranche of the EIB loan was determined using observable inputs (Curetis N.V. share price, own credit spread) and assumptions for not observable inputs (exercise of conversion rights regarding the convertible notes; date of requesting for PPI payment within a 12 months' period from about the due date of the third tranche of the EIB loan). These assumptions lead to the inclusion of the fair value within level 3 of the fair value hierarchy. The fair value of the compound embedded derivative separated from the convertible note is determined using observable inputs (Curetis N.V. share price, own credit spread) and assumptions about the rational economic behavior of the related parties which are not observable input parameters. These assumptions lead to the inclusion the fair value within level 3 of the fair value hierarchy.

The following table presents the most significant unobservable data and the impact of changes in them on the valuation of the derivatives.

kEUR		PPITranche	Embedded Derivative
Change in Share Price	+10%	-16	0
Change in Share Price	-10%	16	0
Change in execution period	+1 months	1	5
Change in execution period	-1 months	-1	-5
Change in shares outstanding	+10%	-16	0
Change in shares outstanding	-10%	16	0
Change in credit adjusted interest rate	+10%	16	0
Change in credit adjusted interest rate	-10%	-16	0

The fair value of all fair value level 3 instruments has been changed in the reporting period as follows:

kEUR	2019	2018
Carrying amount as of 1 January	542	-
Additions (including first-time recognition	-	514
Decreases in fair value recognized in profit/loss (including losses on disposal)	(94)	-
Increases in fair value recognized in profit/loss (including gains on disposal)	-	11
Decreases in fair value recognized directly in equity	-	-
Increases in fair value recognized directly in equity	87	17
Disposals	(535)	-
Deferred amount not amortized as of December 31		542

At initial recognition the fair value the convertible notes and EIB loan incl. the PPI feature differed from the cash amount received. The difference between the fair value of the liabilities at initial recognition and the expected transaction price amounted to 301 kEUR. It was deferred in other current assets and will be amortized over the term of the note resp. the EIB loan. In 2019 a loss of 32 kEUR (2018: 0 kEUR) was recognized from the amortization of the deferral. The difference yet to be amortized in the income statement developed as follows during the reporting year:

kEUR	
Deferred amount on initial recognition	301
Deferred amount amortized in profit or loss in the current period	(32)
Deferred amount not amortized as of December 31, 2019	269

Please note that all amounts deferred are part of assets which are held for sale.

# 31. TAXATION

Deferred taxes relate in total to assets and liabilities that were classified as held for sale on the balance sheet and refer to the following underlying items:

	31 December 2019		31 December 2018	
in kEUR	total	thereof Current	total	thereof Current
DTA	1,100	728	426	45
current income tax receivables	-	-	-	
DTL	1,100	2	426	146
current income tax liabilities	-	-	-	-

Deferred taxes relate to the following statement of financial position items:

	Deferred tax assets		Deferred to	ax liabilities
in kEUR	31 December 2019	31 December 2018	31 December 2019	31 December 2018
Assets				
Trade and other receivables	_	-	-	-
Inventories	-	-	91	93
Property, plant and equipment	_	-	202	280
other current assets	4	30	-	-
Right of Use			173	
Liabilities				
Financial liabilities	-	-	-	-
Provisions current	-	-	2	-
Other current liabilities	3	15	-	-
Other current financial liabilities	607	-		53
Provisions non-current	3	2	-	-
Other non-current financial liabilities	-	-	632	-
Lease liabilities	61			
current lease liabilities	114			
Equity				
loss-carry-forwards	308	379	-	-
Deferred Taxes (gross)	1,100	426	1,100	426
Offsetting	1,100	426	1,100	426
Deferred Taxes (net)	-	_	-	-

Deferred tax assets for losses carried forward have been recognized in the amount of existing deferred tax liabilities. Due to the uncertainty surrounding the Group's ability to realize taxable profits in the near future, the Company did not recognize any further deferred tax assets.

Due to differences in the valuation of the shares in Curetis GmbH (former AG) between IFRS and national (German) tax law, outside basis differences are existing at Curetis N.V. While the valuation under IFRS is based on the net asset value of Curetis GmbH (former AG), the valuation under German tax law is based on the taxable net book value. The resulting difference is however a permanent one which does not result in a deferred tax entry. In accordance with IAS 12.39, no further actions regarding DTL disclosure need to be

taken, although Curetis N.V. is intending to dispose of all Curetis GmbH shares in 2020.

As of 31 December 2019, Curetis N.V. had tax loss carryforwards that were not utilizable and for which no deferred taxes were recognized. These tax loss carryforwards amount to kEUR 13,369 for corporate tax purposes and kEUR 13,276 for trade tax purposes (31 December 2018: kEUR 11,754 for corporate tax purposes and kEUR 11,754 for trade tax purposes). In order to present comparative amounts relating to finance result, the tax loss carryforwards for Curetis GmbH has been reflected in the discontinued operations disclosure. The aforementioned tax loss carryforwards exist only in Germany hence they are only in Germany available unlimited for offsetting against future taxable profits of Curetis. Deferred tax assets have not been recognized in respect of these losses as no sufficient certainty is given, whether mid-term such tax loss carryforwards will enable Curetis to offset its future taxable profits, see note 1.5.

## 32. EQUITY

At 31 December 2019 the share capital of Euro 262,823 is divided into 26,282,366 fully paid common shares with a par value of EUR 0.01.

The common shares entitle the holder to participate in dividends, and to share in the proceeds of winding up the Company in proportion to the number of and amounts paid on the shares held.

On a show of hands every holder of ordinary shares presents at a meeting in person or by proxy, is entitled to one vote, and upon a poll each share is entitled to one vote.

As at December 31, 2019 no revaluation reserve exists.

The share capital increased during the year by kEUR 54 with a corresponding increase in Capital Reserve of kEUR 9,940. The increase is due to a) conversions of convertible notes which led to a total of 4,780,552 new shares (see note 29) and b) the issuing of shares as part of the Phantom Stock Option Incentive Plan 2010 ("PSOP") which led to a total of 593,012 new shares (see note 25). For changes in capital reserve due to the equity stock option program see note 3.22.

The following table illustrates the number and exercise prices of the movements in employee stock options during the year, as well as the grant date and the remaining term of the option:

	Tranche 1	Tranche 2	Tranche 3	Tranche 4	Tranche 5	Tranche 6
Grant date	1 July 2016	1 October 2016	1 January 2017	1 April 2017	1 July 2017	1 October 2017
Granted stock options	570,000	45,000	42,500	5,000	110,000	123,500
Remaining contractual term of the option	6.5 years	6.75 years	7.00 years	7.25 years	7.50 years	8.25 years
Exercise price	6.45 Euro	6.41 Euro	6.42 Euro	5.81 Euro	4.93 Euro	4.98 Euro
Outstanding at 1 January 2019	471,667	22,500	41,458	5,000	82,778	106,833
Granted during the year	-	-	-	-	-	-
Forfeited during the year	833	-	6,667	-	-	19,583
Exercised during the year	-	-	-	-	-	-
Expired during the year	-	-	-	-	-	-
Cancelled during the year	-	-	-	-	-	-
Outstanding at 31 December 2019	470,834	22,500	34,791	5,000	82,778	87,250
Exercisable at 31 December 2019	-	-	-	-	-	-

	Tranche 7	Tranche 8	Tranche 9	Tranche 10	Tranche 11	Tranche 12
Grant date	1 January 2018	1 March 2018	1 July 2018	1 October 2018	1 January 2019	1 July 2019
Granted stock options	25,000	102,000	90,500	110,000	322,000	226,000
Remaining contractual term of the option	8.00 years	8.17 years	8.50 years	8.75 years	9.00 years	9.50 years
Exercise price	3.86 EUR	6.51 EUR	4.62 EUR	3.29 EUR	1.40 EUR	1.61 EUR
Outstanding at 1 January 2019	25,000	97,000	87,500	110,000	-	-
Granted during the year	-	-	-	-	322,000	226,000
Forfeited during the year	16,389	21,445	23,181	-	92,528	5,000
Exercised during the year	-	-	-	-	-	-
Expired during the year	-	-	-		-	-
Cancelled during the year	-	-	-	-	-	-
Outstanding at 31 December 2019	8,611	75,555	64,319	110,000	229,472	221,000
Exercisable at 31 December 2019			-	-		

The balance outstanding of stock options as at 31 December 2019 is expected to be taken over as part of the Merger with OpGen Inc. post year end. Please refer to note 4.

The beneficiaries of the granted options are as follows:

Beneficiary	Tranche 1	Tranche 2	Tranche 3	Tranche 4	Tranche 5	Tranche 6
Oliver Schacht, CEO	100,000	-	-	-	-	-
Johannes Bacher, COO	100,000	-	-	-	-	-
Dr. Achim Plum, CCO	100,000	-	-	-	-	-
William Rhodes, Chairman of Supervisory Board	-	-	-	-	15,000	-
Nils Clausnitzer, Supervisory Board	-	-	-	-	15,000	-

Beneficiary	Tranche 1	Tranche 2	Tranche 3	Tranche 4	Tranche 5	Tranche 6
Mario Corvetto, Supervisory Board		-	-	-	15,000	-
Werner Schäfer, Supervisory Board	-	-	-	-	15,000	-
Prabhavati Fernandes. Supervisory Board	-	-	-	-	15,000	-
Other employees	170,834	22,500	34,791	5,000	7,778	87,250

Beneficiary	Tranche 7	Tranche 8	Tranche 9	Tranche 10	Tranche 11	Tranche 12
Oliver Schacht, CEO	-	-	-	-	-	58,500
Johannes Bacher, COO	-	-	-	-	-	40,000
Dr. Achim Plum, CCO	-	-	-	-	-	39,000
William Rhodes, Chairman of Supervisory Board	-		10,000	r	-	10,000
Nils Clausnitzer, Supervisory Board	-	-	10,000	-	-	10,000
Mario Corvetto, Supervisory Board	-	-	10,000		-	10,000
Werner Schäfer, Supervisory Board	-	-	10,000		-	10,000
Prabhavati Fernandes. Supervisory Board	-	-	10,000	r	-	10,000
Other employees	8,611	75,555	14,319	110,000	229,4720	33,500

# **VESTING CONDITIONS**

Each option grant will vest over a period of three years whereby the first third of any such option grant will vest at the first anniversary of the date of grant and the remaining two thirds of such granted options will vest in monthly increments over the following twenty-four months.

Upon the occurrence of a termination of employment event after the first anniversary of the date of grant,

the optionee's options shall either be forfeited, lapse or continue to be exercisable as set forth below:

- In case of termination for cause, both the options of such optionee that have vested (to the extent not
  exercised) and the options of such optionee that have not yet vested shall be forfeited at the date of
  termination for cause, unless agreed otherwise by the management board (with regard to optionees
  being managing directors or supervisory directors);
- In case of a termination without cause, the options of such optionee that have vested (to the extent not exercised) shall not be forfeited and the remaining part of the options of such optionee that have not yet vested shall be forfeited at the date of termination without cause.

#### **EXERCISE OF OPTIONS**

Vested options may not be exercised prior to the third anniversary of the date of grant and may be exercised until ten years from the date of grant or such shorter period of time remaining under the stock options plan. Options which have not been exercised prior to the end of the exercised period shall lapse automatically without any compensation whatsoever being due to the optionee.

#### VALUATION MODEL AND INPUT PARAMETERS

The fair value of the stock options is measured using a binominal option pricing model taking into account the terms and conditions upon which the options were granted. The following table lists the inputs to the model used for the options granted in 2016, 2017, 2018 and 2019 at the measurement date:

	Tranche 1	Tranche 2	Tranche 3	Tranche 4	Tranche 5	Tranche 6
Measurement date	5 July 2016 <sup>1</sup>	1 October 2016	1 January 2017	1 April 2017	1 July 2017	1 October 2017
Expected life of the option on the grant date (years)	5.0	5.0	5.0	5.0	5.0	5.0
Share price on the measurement date (€)	6.44	6.18	6.34	5.69	4.74	4.86
Weighted avg. exercise price	6.45	6.41	6.42	5.81	4.93	4.98
Expected dividend yield (%)	0.00	0.00	0.00	0.00	0.00	0.00
Risk-free interest rate (%)	-0.61	-0.61	-0.49	-0.40	-0.19	-0.28
Expected volatility of the share price (%)	78.15	81.36	60.90	57.99	55.75	55.55
Option value (€)	3.94	3.86	3.14	2.69	2.15	2.22

	Tranche 7	Tranche 8	Tranche 9	Tranche 10	Tranche 11	Tranche 12
Measurement date	1 January 2018	1 March 2018	1 July 2018	1 October 2018	1 January 2019	1 July 2019
Expected life of the option on the grant date (years)	5.0	5.0	5.0	5.0	5.0	5.0
Share price on the measurement date (€)	3.83	6.20	4.17	3.24	1.50	0.71
Weighted avg. exercise price	3.86	6.51	4.62	3.29	1.40	0.75
Expected dividend yield (%)	0.00	0.00	0.00	0.00	0.00	0.00
Risk-free interest rate (%)	-0.15	-0.01	-0.28	-0.10	-0.30	-0.69
Expected volatility of the share price (%)	65.33	65.63	62.42	62.01	64.25	62.88
Option value (€)	2.04	3.26	2.03	1.64	0.81	0.36

<sup>&</sup>lt;sup>1</sup>The measurement date represents the acceptance date of the options.

For stock option valuation the possibility of early exercise was considered in the binomial model. Early exercise is expected five years after the date of grant of the options. Management considered the following factors in estimating early exercise:

- The length of the vesting period has been considered since the share options cannot be exercised until the end of the 3-year vesting period i. e. the expected option life of 5 years is 2 years after the first possible exercise date.
- The Company has zero historical data points and no experience from past option programs. To date not a single ESOP has been exercised, but due to normal fluctuation as well as fluctuation triggered by the recent re-organization there have been multiple cases of forfeited ESOPs.

As a result, the Company does not have any actual data available regarding the average length of time that similar options have remained outstanding in the past or if the employee's level within the Company will impact the timing of exercise.

The risk-free interest rate is the implied yield currently available on German government issued bonds with a remaining term equal to the term of the options.

The future volatility for the lives of the options was estimated based on historical volatilities of peer group companies.

The expense recognized during 2019 and 2018 is shown in the following table:

kEUR	31 December 2019	31 December 2018
Expense arising from equity-settled share-based payment transactions	469	650
Expense arising from cash-settled share-based payment transactions	-	-
Total expense arising from share-based payment transactions	469	650

#### 33. FINANCIAL RISK MANAGEMENT

#### 33.1. FINANCIAL RISK FACTORS

This note explains the group's exposure to financial risks and how these risks could affect the group's future financial performance. Current year profit and loss information has been included where relevant to add further context.

Curetis' activities expose the Company to a variety of financial risks such as currency risks, risk to changes in fair value, cash flow risks, interest rate risks and price risks. Curetis' finance department has created controlling instruments and key metrics to identify and evaluate such risks in close co-operation with the operating units.

# a) Market Risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Curetis has a strong international business focus and therefore the Company is influenced by foreign currency exchange rates and interest rates.

#### aa) Foreign Exchange Risk

Curetis is exposed to foreign currency risks primarily through its financing activities. Curetis identifies the main currency risk in US Dollar, because certain purchase transactions are undertaken in US Dollar ("USD"). The net exposure to exchange differences of the monetary assets (being cash and cash equivalents) of the Group at the end of the reporting period are as follows:

in kEUR	31 December 2019	31 December 2018
USD	2,521	683

If the USD/EUR exchange rate were to increase/decrease by 10%, compared to year-end 2019 exchange rates, this would have a negative impact of kEUR 229 (2018: kEUR 62) / positive impact of kEUR 252 (2018: kEUR 76). The group considers a shift in the exchange rates of 10% as a realistic scenario.

#### ab) Interest Rate Risk

Curetis is exposed to interest rate risk because entities in the Group borrow funds at both fixed and floating interest rates. The following sensitivity analysis is prepared for floating rate liabilities; the analysis is prepared assuming the amount of liability outstanding at reporting date was outstanding for the whole year.

The Group's exposure to variable interest rates at the end amounted to EUR 18 million as of 31 December 2019 (EUR 13 million as of 31 December 2018).

If the interest rates had been one per cent higher/lower and all other variables were held constant, the Group's profit for the year ended 31 December 2019 would decrease/increase by kEUR 180 (2018: decrease/increase by kEUR 130). For sensitivity analysis due to fair value changes of derivatives please see Note 30

#### b) Credit Risk

The finance department works in close cooperation with the other operating departments to identify credit risks related to account receivables balances. Curetis analyzes the credit risk of each new client before standard payment and delivery terms and conditions are offered. Curetis has also implemented a well-organized dunning system. Curetis had had write-downs on trade receivables of kEUR o in 2019 (2018: kEUR o). The credit risk on the accounts receivables is limited because Curetis primarily sells to big laboratories, pharma-companies and major public hospitals in Curetis' direct markets in Central and Western Europe and in the USA, all of these partners have very good credit ratings. Outside of Europe and the USA Curetis works together with large and experienced distributors. If Curetis were to expand the business to other more credit-risky countries Curetis would consider implementing a commercial credit insurance to cover the risks.

Considering the aforementioned reasons Curetis summarizes all trade receivables under one risk category 'common credit risk' and impairs all trade receivables using an average default risk of approximately 1% deducted from observable credit risk parameters of the healthcare industry. Curetis is in exchange with different commercial credit insurers and is evaluation other credit risk mitigations periodically with the expansion of its customer base.

Furthermore, trade receivables and contract assets are written off where there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with the group, and a failure to make contractual payments.

Impairment losses on trade receivables and contract assets are presented as net impairment losses within operating profit. Subsequent recoveries of amounts previously written off are credited against the same line item.

Outside of one debtor with concerns in regards of recoverability in 2019 due to failure to uphold the repayment plan, Curetis had immaterial write-downs on trade receivables during 2018 and 2019.

In 2018 the following customer accounts each represented > 10% of total annual revenues: ATC Kuwait, Axonlab Austria, Synttergy Consult Ltd, Romania and in 2019 the following customers each represented > 10% of revenues: Qiagen, an undisclosed global leading IVD corporation, Synttergy Consult Ltd, Romania, Axonlab Austria and A. Menarini Diagnostics, Italy. Similarly, on the supplier side there is a significant concentration risk with single source suppliers of major strategic relevance such as Zollner Elektronik for Unyvero systems, Scholz HTIK for injection molding plastics parts, DMTPe for engineering support for A30 development, as well as certain single source suppliers of critical reagents

Cash and cash equivalents as well as short-term deposits which are disclosed under other financial assets are invested in EUR (with the exemption of the amounts mentioned under 'b) foreign exchange risk' in this note. Curetis follows a decisive 'no-risk-policy' which means that Curetis has sight deposits at banks only, and sometimes time deposits with short runtimes.

#### c) Liquidity Risk and Non-Going Concern

Liquidity risk is the risk that the Group will might encounter difficulties in meeting the obligations associated with its financial liabilities, which are normally settled by delivering cash. The Group's approach to managing liquidity is to ensure, as far as possible, that it will always have sufficient liquidity to meet its liabilities when due.

The Group monitors its risk of a shortage of funds using short and mid-term liquidity planning. This takes account of the expected cash flows from all activities. The supervisory board undertakes regular reviews of the budget and forecast.

In 2019 Curetis drew down a EUR 5 million tranche from the up to EUR 25 million debt financing facility from the EIB (European Investment Bank), in addition to the EUR 13 million already drew down in 2017 and 2018. It also drew down EUR 1.5 million gross from the Yorkville convertible notes facility.

For information concerning non-going concern see note 1.5.

The following table depicts an analysis of the Company's financial liabilities into relevant maturity groupings based on the remaining term on the balance sheet date.

Balance as at 31 December 2019	Up to 1 year	1-3 years	3-5 years	More than 5 years
Trade and other payables	82	-	-	-
Other financial liabilities	61		-	-
Liabilities directly associated with assets classified as held for sale	23,624	359	344	-
thereof Trade and other payables	1,086			
thereof Other financial liabilities				
thereof Lease Liability	483	359	344	
thereof Loans	20,755			
thereof Convertible note	1,300			
TOTAL	23,767	359	344	-
Balance as at 31 December 2018	Up to 1 year	1-3 years	3-5 years	More than 5 years
Trade and other payables	957	-	-	-
Other financial liabilities	334		-	-
Loans	-	-	13,000	-
Convertible note	3,200	-	-	-
Interests accrued	520	1,040	4,540	-
TOTAL	5,011	1,040	17,540	-

#### 33.2. CAPITAL MANAGEMENT

Capital comprises equity attributable to shareholders, cash and cash equivalents. Curetis' policy is to maintain a strong base in terms of equity capital and sufficient cash balance in order to maintain investor and creditors confidence and to sustain the future development of the business. Our primary goals when managing capital are to ensure sufficient liquidity to meet our working capital requirements, fund capital investments and purchases and to safeguard our ability to continue operating as a going concern.

Curetis monitors all capital positions regularly (at least monthly) within its financial reporting, discusses the capital status frequently within the management meetings and also within its supervisory board meetings.

#### 34. COMMITMENTS

Curetis places frame-work orders for Unyvero-Systems and for raw materials for its cartridge manufacturing to ensure availability during commercial ramp-up-phase and also to gain volume-scale-effects with regards to purchase prices. Some of the electronic parts used for the production of Unyvero-Systems have lead times of many months, hence it is necessary to order such systems with long-term framework-orders to ensure the demands from the market are covered. The future aggregate purchase commitments are as per the table below.

in kEUR	31 December 2019	31 December 2018
From operating lease contracts:		
No later than 1 year	-	482
Later than 1 year and no later than 5 years	-	819
Later than 5 years	-	-
Total from lease contracts	-	1,301
From purchase and service agreements:		
No later than 1 year	-	4,487
Later than 1 year and no later than 5 years	-	4,331
Later than 5 years	-	-
Total from purchase and service agreements	-	8,818
Total	-	10,119

As the future aggregate purchase commitments relate to the purchase of inventory, these commitments are a part of the Curetis Business disposal group for the year ended 2019. For information concerning discontinued operation see note 4.

#### 35. RELATED PARTIES

Transactions with related parties occur in the normal course of business. Related party transactions have been listed completely below.

#### COMPENSATION OF KEY MANAGEMENT

in kEUR	2019	2018
Salaries and other short-term employee benefits	640	705
Post-employment benefits <sup>1</sup>	0	8
Share based payments	38	180
Other	5	5
Total	683	898

 $<sup>^{\</sup>mathtt{1}}$  Post-employment benefits relate to the remuneration of a former managing director

For more details, we refer to the remuneration report in the annual business report.

#### COMPENSATION OF SUPERVISORY BOARD

The compensation of Supervisory Board is shown below:

in kEUR	2019	2018
William E. Rhodes	96	105
thereof from equity stock options	16	22
Dr. Werner Schäfer	78	83
thereof from equity stock options	16	22
Mario Crovetto	70	64
thereof from equity stock options	16	22
Prabhavathi Fernandes	68	53
thereof from equity stock options	16	22
Nils Clausnitzer	48	51
thereof from equity stock options	16	22
Dr. Holger Reithinger	-	-11
thereof from equity stock options	-	-11
Dr. Rudy Dekeyser	-	-
thereof from equity stock options	-	-
Total	360	345
thereof from equity stock options	80	99

The reason why equity stock options have been granted to the Supervisory Board Members are:

- (i) Alignment of strategic interest of Supervisory Board Members with the company and its shareholders.
- (ii) Ability to recruit, retain and incentivize Supervisory Board Members in line with what is market standard e.g. in the USA.

Curetis does not grant any loans, advance payments and guarantees to members of the Management and Supervisory Board. There have been no other notable related party transactions.

#### 36. AVERAGE NUMBER OF EMPLOYEES

In 2019 the Group employed on average 79 employees (FTEs) (2018: 110), of which nil (2018: nil) are working in the Netherlands.

### 37. Overview of Consolidation Scope

The parent company Curetis N.V. is domiciled in Germany, and only has its statutory seat in the Netherlands.

Details of the Group's subsidiaries at the end of the reporting period are as follows:

Name	Registration No.	Country	Participation	Main activity
Curetis GmbH	HRB 756134	Germany	100.00%	Development, manufacturing and sale of molecular diagnostic products
Curetis USA Inc.	EIN 81-3113346	USA	100.00 %	Sale of molecular diagnostic products
Ares Genetics GmbH	468899h	Austria	100.00 %	Maximize R&D and related scientific opportunities with Aresdb Bio-IT platform (previously GEAR)

The equity of Curetis GmbH at 31 December 2019 amounted to kEUR 11,794 (31 December 2018: kEUR

18,591) and the Company realized a loss of kEUR 11,757 in 2019 (2018: loss of kEUR 14,463).

The equity of Curetis USA Inc. at 31 December 2019 amounted to kEUR -15,064 (31 December 2018: kEUR -9,062) and the net result a loss of kEUR 6,034 in 2019 (2018: loss of kEUR 5,891).

The equity of Ares Genetics GmbH at 31 December 2019 amounted to kEUR -2,953 in 2019 (31 December 2018: kEUR -2,129) and the net result a loss of kEUR 861 in 2019 (2018: kEUR -1,741).

### 38. AUDIT FEES

The fees for services rendered by Curetis' independent auditor PricewaterhouseCoopers Accountants N.V., Eindhoven, The Netherlands and its member firms and affiliates to the Company and its subsidiaries were approved by the Audit Committee and the Supervisory Board and can be detailed as follows:

	Total PricewaterhouseCoopers
2019	
Financial statements audit	406,650
Audit-related services and other audit work 2019	1,134,052
Tax consultancy 2019	0
Total	1,540,702
2018	
Financial statements audit	161,000
Audit-related services and other audit work 2018	626,437
Tax consultancy 2018	0
Total	787,437

#### 39. EVENTS AFTER THE BALANCE SHEET DATE

#### TRANSACTION AGREEMENT - OPGEN INC.

OpGen Inc. and Curetis N.V. Definitive Implementation Agreement

- Yorkville and EIB have agreed to contractual amendments in support of the transaction agreement.
- Curetis N.V. and OpGen closed a business combination transaction on 1<sup>st</sup> April 2020 and OpGen Inc. becomes new parent company of Curetis GmbH including its subsidiaries Curetis USA Inc. and Ares Genetics GmbH.
- As a result, Supervisory Board members Rhodes, Crovetto and Fernandes resign from the SB of Curetis N.V. to join the Board of Directors of OpGen Inc. Dr. Werner Schaefer, Dr. Rudy Dekeyser, and Dr. Nils Clausnitzer will continue to serve on the Company's supervisory board.
- Curetis N.V. has appointed former Management Board Members to become Liquidators of the Company.
- Curetis N.V. has received 2,028,208 consideration shares on 2<sup>nd</sup> April 2020. Of these the liquidators have sold 405,640 consideration shares to obtain sufficient liquidity for Curetis N.V. Proceeds of these sales of consideration shares amount to kEUR 871.
- Curetis N.V. are delisted from the Euronext since 5<sup>th</sup> May, 2020.

#### **DEBT COVENANTS**

Both the EIB and Yorkville agreements are subject to certain covenants. Since the end of the reporting period Curetis is in breach of covenants for both debt agreements due to the change of control clause of the contract. Subsequently contractual amendments were reached by Curetis and its debt holders EIB and Yorkville in February 2020.

By way of the waiver agreement EIB waived certain provisions of the EIB agreement that could have been triggered by the change of control agreement and agreed with OpGen and Curetis that an amendment to the EIB agreements would be negotiated and signed within 90 days of closing of the transaction i.e. by around 30<sup>th</sup> June 2020. Such amendment amongst other things is expected to include a guarantee by OpGen Inc. in lieu of Curetis N.V.'s previous guarantee for the EIB loan to Curetis GmbH. It is also expected to include an amendment to the calculation of the PPI tranche to allow for calculation of such PPI amounts in the future based on OpGen Inc. market capitalization. Otherwise, the payment terms are expected to remain the same as prior to the breach of covenants.

Yorkville, OpGen and Curetis N.V. entered into a three-way agreement which assigned the entire remaining unconverted notes to OpGen Inc. upon closing of the business combination, specifies 500,000 new OpGen shares to be reserved for future conversions by Yorkville, and furthermore obligates OpGen Inc. to file a registration statement for up to 1 million additional OpGen shares. Otherwise, the terms of the agreement remain the same.

#### COVID-19

The novel coronavirus outbreak could adversely impact our business, financial condition and results of operations.

In December 2019, a strain of novel coronavirus surfaced in Wuhan, China. In January 2020, the World Health Organization declared the novel coronavirus outbreak a "Public Health Emergency of International Concern". The coronavirus has significantly impacted the global economy, capital markets, and may also significantly impact our business and operations, including the potential delay or reduction in commercial adoption by our direct customers as well as distributors as countries and healthcare systems focus on Covid19 rather than other indications and do not have the resources required to evaluate and clinically test our diagnostic platforms and solutions. Also impact could include the interruption of our clinical trial activities, regulatory submissions and our supply chain. As a result of the outbreak, certain of our distributors, suppliers, collaboration partners and CMOs may be affected and could experience closures and

labor shortages, which could disrupt their activities. We could therefore face difficulty sourcing key components necessary to produce our product candidates, which may negatively affect our commercial and clinical product development activities. Even if we are able to find alternate sources for some of these components, they may cost more, which could affect our results of operations and financial position. In addition, the coronavirus outbreak could delay enrollment in our commercial evaluations of Unyvero LRT as well as other CE IVD marked Unyvero cartridges, clinical studies, and clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services.

At this point in time, there is significant uncertainty relating to the potential effect of the novel coronavirus on our business. Infections may become more widespread, including in countries where we are commercializing products directly or via distributors, conducting clinical trials, and manufacturing closures and travel restrictions may remain or worsen, all of which would have a negative impact on our business, financial condition and results of operations. As such the company cannot estimate the impact on revenue, impairments, availability of employees, liquidity of cash flows, or limitations to cash and financial resources. Furthermore, as the consequences of the coronavirus outbreak are considered a non-adjusting subsequent event, no amounts in the financial statements are affected by the 2020 developments.

Due to the transaction being closed, as outlined in more detail above, and the non-going concern assumption as outlined in note 1.5, management does not expect a significant impact on Curetis N.V. as it has announced its delisting and liquidation following the shareholder approval of such on 10<sup>th</sup> March 2020.

Holzgerlingen, 30th June 2020 Curetis N.V. in Liquidation

Oliver Schacht, PhD Liquidator Johannes Bacher Liquidator **Dr. Achim Plum** Liquidator

**Dr. Werner Schaler** Supervisory Board Member

**Dr. Rudy DeKeyser**Supervisory Board Member

**Dr. Nils Clausnitzer**Supervisory Board Member

# IV. CURETIS N.V. - COMPANY FINANCIAL STATEMENTS

# **CURETIS N.V. – COMPANY INCOME STATEMENT**

For the period ended 31 December 2019 and 31 December 2018

in kEUR	2019	2018
Revenues	-	-
Cost of Sales	-	-
Gross profit	-	
Administrative expenses [3]	-2,293	-2,352
Other income [4]	40	19
Other income Group [4]	745	746
Operating loss	-1,508	-1,587
Finance income	1	-
Finance costs	-751	-95
Finance result - net	-750	-95
Loss before income tax	-2,258	-1,682
Income tax expenses		
Result from participations [5]	-11,723	-22,066
Loss for the year	-13,982	-23,748

<sup>[..]</sup> Bracketed numbers refer to the related notes to the financial statements which form an integral part of these financial statements.

# CURETIS N.V. - COMPANY BALANCE SHEET

For the period ended 31 December 2019 and 31 December 2018 - After profit appropriation

in kEUR	31.12.2019	31.12.2018
Fixed assets [6]	-	6,926
Financial fixed assets		
Interests in group companies	-	6,764
Other accounts receivable	-	162
Current assets [7]	1,612	6,166
Account receivable		
From group companies	259	187
Other accounts receivable	501	499
Cash at banks and in hand	852	5,480
Total	1,612	13,092
in kEUR	31.12.2019	31.12.2018
Capital and reserves [8]	-756	9,050
Called-up share capital	263	209
Share premium account	72,084	61,850
Legal reserves	-140	-140
Other reserves	3,064	9,176
Retained earnings	-76,027	-62,045
Current liabilities [9]	2,368	4,042
Convertible bonds	1,394	3,109
Trade creditors	82	36
Accounts payable to group companies	357	453
Other liabilities	535	444
Total	1,612	13,092

<sup>[..]</sup> Bracketed numbers refer to the related notes to the financial statements which form an integral part of these financial statements.

#### CURETIS N.V. - NOTES TO THE COMPANY FINANCIAL STATEMENTS

#### 1. GENERAL INFORMATION

Curetis N.V. (Curetis or the Company) is a Dutch Company with limited liability (naamloze vennootschap) and has its corporate seat in Holzgerlingen, Germany and also its statutory seat in Amsterdam, Netherlands. The Company was founded as Curetis B.V. on 8<sup>th</sup> October 2015 as a private Company with limited liability (besloten vennootschap met beperkte aansprakelijkheid) for the purpose of a corporate reorganization of Curetis AG; Curetis B.V. then converted its legal form under Dutch law to a public Company with limited liability for an initial public offering of its common shares on 10<sup>th</sup> November 2015.

The registration number of Curetis N.V. from the Dutch Chamber of commerce is 64302679.

The Company has one subsidiary, Curetis GmbH, Holzgerlingen, Germany where it holds 100% of the shares. As of 31<sup>st</sup> December 2019 Curetis GmbH holds 100% of the shares of:

- Curetis USA Inc., San Diego, CA, USA
- Ares Genetics GmbH, Vienna, Austria

#### 2. ACCOUNTING INFORMATION AND POLICIES

### BASIS OF PREPARATION

The Company's financial statements of Curetis N.V. (hereafter: the Company) have been prepared in accordance with Part 9, Book 2 of the Dutch Civil Code. In accordance with sub 8 of article 362, Book 2 of the Dutch Civil Code, the Company's financial statements are prepared based on the accounting principles of recognition, measurement and determination of profit, as applied in the consolidated financial statements. These principles also include the classification and presentation of financial instruments, being equity instruments or financial liabilities.

The Company prepared its consolidated financial statements in accordance with the International Financial Reporting Standards ('IFRS') as adopted by the European Union.

The financial statements have been prepared on a non-going concern basis (see note 1.5 of the consolidated financial statements of Curetis N.V.).

These financial statements cover the period from 1<sup>st</sup> January 2019 to 31<sup>st</sup> December 2019. The comparable numbers of 2018 cover the period from 1<sup>st</sup> January 2018 to 31<sup>st</sup> December 2018.

The functional currency of the Company is the Euro. The primary financial statements are presented in kEUR and the notes to the financial statements are presented in kEUR in accordance with commercial rounding practices unless stated otherwise. The financial year corresponds to the calendar year. The balance sheet and income statement references have been included. These refer to the notes.

In case no other policies are mentioned, please refer to the accounting policies as described in the summary of significant accounting policies in the consolidated financial statements. For an appropriate interpretation, the Company financial statements of Curetis N.V. should be read in conjunction with the consolidated financial statements.

## DISCONTINUITY OF THE COMPANY

The financial statements have been prepared assuming discontinuity of the Company. The accounting policies are based on the existing accounting policies as applied in prior years, taking into consideration necessary impairments of assets and recording of additional provisions. Management determined that the Company will be liquidated and the management expect that the Company will be able to fulfil its obligations.

#### INVESTMENTS IN CONSOLIDATED SUBSIDIARIES

Consolidated subsidiaries are all entities (including intermediate subsidiaries) over which the Company

has control. The Company controls an entity when it is exposed to, or has rights, to variable returns from its involvement with the subsidiary and has the ability to affect those returns through its power over the subsidiary. Subsidiaries are recognized from the date on which control is transferred to the Company or its intermediate holding entities. They are derecognized from the date that control ceases.

The Company applies the acquisition method to account for acquiring subsidiaries, consistent with the approach identified in the consolidated financial statements. The consideration transferred for the acquisition of a subsidiary is the fair value of assets transferred by the Company, liabilities incurred to the former owners of the acquire and the equity interests issued by the Company. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration arrangement. Identifiable assets acquired and liabilities and contingent liabilities assumed in an acquisition are measured initially at their fair values at the acquisition date, and are subsumed in the net asset value of the investment in consolidated subsidiaries. If the valuation of an investment in subsidiaries based on the net asset value is negative, it will be stated at nil. If and insofar as Curetis N.V. can be held fully or partially liable for the debts of the associate or has the firm intention of enabling the participation to settle its debts, a provision is recognized for this. Further reference is made to note 8.

#### RESULT FROM PARTICIPATIONS (VALUED AT NET ASSET VALUE)

The result is the amount by which the carrying amount of the participation has changed since the previous financial statements as a result of the earnings achieved by the participation to the extent that this can be attributed to Curetis N.V.

#### AMOUNTS DUE FROM INVESTMENTS

Amounts due from investments are stated initially at fair value and subsequently at amortized cost. Amortized cost is determined using the effective interest rate. The Company has assessed the recoverability of the amounts due from investments as not impaired, due to the business combination as part of the transaction with OpGen Inc. (see note 4 of the consolidated financial statements) being highly probable as at 31<sup>st</sup> December 2019.

# CURETIS N.V. - NOTES TO THE COMPANY INCOME STATEMENT

#### 3. ADMINISTRATIVE EXPENSES

Administrative expenses include personnel expenses for the management board members, the supervisory board members, consulting fees and other costs of the central administrative areas.

#### 4. OTHER INCOME

Other income comprises of intercompany income from management fees charged to subsidiaries for management services provided by Curetis N.V. for its subsidiaries with a total value of kEUR 745 (2018: kEUR 746) and other income of kEUR 40 (2018: kEUR 19).

### 5. RESULT FROM PARTICIPATIONS

Result from participations, measured at net asset value, was as follows:

	2019	2018
(x 1,000)	€	€
Result of Curetis GmbH	11,723	22,066
	11,723	22,066

Curetis GmbH has a negative value on the basis of equity accounting. No provision has been recognized as the criteria for recognition of a provision as at 31<sup>st</sup> December 2019 were not met. The part of the losses that is not recognized amounts to kEUR 10,518 (2018: nil). Further reference is made to note 8.

# CURETIS N.V. - NOTES TO THE COMPANY BALANCE SHEET

#### 6. FIXED ASSETS

#### INTERESTS IN GROUP COMPANIES

Curetis N.V. holds 100% of the shares of Curetis GmbH.

in kEUR	Investments in consolidated subsidiaries
At 1 January 2018	
Net book value	9,746
Movements in book value 2018	
investments - in cash	19,000
investments - ESOs	367
Share in result of investments	-22,066
Dividends received	-
Currency translation differences	-283
At 31 December 2018	
Net book value	6,764
Movements in book value 2019	
investments - in cash	4,600
investments - ESOs	360
Dividends received	-
Currency translation differences	-
Share in result of investments	-11,723
At 31 December 2019	
Net book value	

#### 7. CURRENT ASSETS

### ACCOUNTS RECEIVABLES FROM GROUP COMPANIES

The Management of Curetis N.V. also renders services and activities for Curetis GmbH and other subsidiaries of Curetis GmbH, and therefore Curetis N.V. charges Management Fees for the services provided to these companies. All intercompany receivables are due in less than one year. The fair value of the receivables approximates the nominal value, due to their short-term character.

### OTHER ACCOUNTS RECEIVABLE

As of 31<sup>st</sup> December 2019, other accounts receivable mainly comprises of VAT receivables amounting to kEUR 229 (31<sup>st</sup> December 2018: kEUR 378) and prepaid expenses amounting to kEUR 272 (31<sup>st</sup> December 2018: kEUR 122).

Deviating from the consolidated financial statements of Curetis N.V., the IPO insurance is shown in the prepaid expenses amounting to kEUR 208 in the standalone financial statements, as the legal obligation still existed on 31<sup>st</sup> December 2019. However, these were reclassified to current assets under other accounts receivables. In the consolidated financial statements this is shown under discontinued operations.

All other accounts receivables are due in less than one year.

#### CASH AT BANKS AND IN HAND

At 31<sup>st</sup> December 2019, cash and cash at banks and in hand amounted to kEUR 852 (31<sup>st</sup> December 2018: kEUR 5,480). That amount consists of bank balances and is at the Company's free disposal.

#### 8. CAPITAL AND RESERVES

in kEUR	Subscribed capital	Capital reserves	Other reserves	Legal reserve	Retained earnings	Total equity
Balance as of 31 December 2017	155	51,676	8,527	143	-38,297	22,204
Valuation of equity settled stock options IFRS 2			649			649
Capital increase	54	10,174				10,228
Currency translation differences on foreign subsidiaries				-283		-283
Loss of period					-23,748	-23,748
Balance as of 31 December 2018	209	61,850	9,176	-140	-62,045	9,050
Valuation of equity settled stock options IFRS 2			480			480
Capital increase	54	10,234	-6,592			3,696
Currency translation differences on foreign subsidiaries						
Loss of period					-13,982	-13,982
Balance as of 31 December 2019	263	72,084	3,064	-140	-76,027	-756

In 2016 Curetis N.V. implemented a new equity settled stock options program (ESOP). The expensed value of the stock options granted to management board members of Curetis N.V. and managers and employees of Curetis N.V.'s subsidiaries under this ESOP was accounted for as an increase of Other Reserves. The cumulative expenses as of 31<sup>st</sup> December 2019 amounted to kEUR 3,064 (2018: kEUR 2,583)

For more details on Equity movements during the year and the ESOP we refer note 32 of the consolidated IFRS statements.

### Differences in equity and loss between the company and consolidated financial statements:

The difference between equity according to the company balance sheet and equity according to the consolidated balance sheet is due to the consolidated participating interest Curetis GmbH. Curetis GmbH has a negative value on the basis of equity accounting. The part of the losses that is not recognized amounts to kEUR 10,518 (2018: nil).

The declaration of liability was provided for this company by Curetis N.V., but has been taken over by OpGen Inc. Due to the high probability that the transaction with OpGen Inc. being completed post year end, it was assessed as of 31<sup>st</sup> December 2019 that the criteria for recording a provision for the negative net asset value of Curetis GmbH are not met and as a consequence no liability should be recognized. Please refer to Note 39 of the consolidated financial statements.

Movements in the difference between the company and consolidated equity and profit/(loss) in the financial year are as follows:

Difference in equity:	
in kEUR as at 31 December 2019	
Equity according to consolidated financial statements	- 11,274
Negative net asset value of consolidated participating interests	10,518
Equity according to company financial statements	- 756
Difference in results:	
in kEUR for the year ended 31 December 2019	2,019
Loss according to consolidated financial statements	- 24,500
Unrecognized losses of Curetis GmbH in the company profit and loss account	10,518
Loss according to company financial statements	- 13,982

### 9. CURRENT LIABILITIES

### **CONVERTIBLE BONDS**

Please refer to note 29 in the consolidated financial statements.

Deviating from the consolidated financial statements of Curetis N.V., the Convertible bonds is shown in the current liabilities kEUR 1,394 in the standalone financial statements, as the legal obligation still existed on 31st December 2019. In the consolidated financial statements this is shown under discontinued operations.

## TRADE CREDITORS

The Trade payables are due within 1 year.

#### ACCOUNTS PAYABLE TO GROUP COMPANIES

The accounts payable to group companies are due within 1 year. The accounts payable to group companies comprise liabilities for reclaims of VAT-refunds from the German tax authorities of Curetis N.V. as the parent Company of Curetis GmbH with a value of kEUR 209 (31st December 2018: kEUR 303) and liabilities for Public relation services and investor relations services amounting to kEUR 147 (31st December 2018: kEUR 140).

#### **OTHER LIABILITIES**

in kEUR	31 December 2019	31 December 2018
Accruals for vacation	150	119
Other liabilities for annual financial statements	218	209
Unpaid invoices for services rendered	61	90
Other & tax liabilities	106	26
Total	535	444

#### 10. RELATED-PARTY TRANSACTIONS

All legal entities that can be controlled, jointly controlled or significantly influenced are considered to be a related party. Also, entities which can control the Company are considered a related party. In addition, directors, other key management of Curetis N.V. and close relatives are regarded as related parties.

The management of Curetis N.V. also manages the operating business of Curetis GmbH. Therefore, the salaries and other costs are partly invoiced to Curetis GmbH based on a Management Service contract.

#### COMPENSATION OF THE EXECUTIVE DIRECTORS

We refer to note 35 of the consolidated financial statement for detailed information on the compensation of the executive directors.

#### COMPENSATION OF SUPERVISORY BOARD

We refer to note 35 of the consolidated financial statement for detailed information on the compensation of the supervisory board.

#### 11. TAXATION

In Germany, income tax consists of trade tax ('Gewerbesteuer') and corporate tax ('Körperschaftsteuer'). Corporate tax is imposed at a uniform rate of 15% and is additionally subject to a solidarity surcharge of 5.5%, resulting in an effective tax rate of 15.825%. Municipalities impose a trade tax. Each municipality set its individual local multiplier rate, so that no uniform trade tax rate exists in Germany. In 2019, Curetis had a trade tax rate of 12.05% (2018: 12.05%).

In 2019 as well as in 2018, the income statement effect resulting from current and deferred taxes is kEUR o.

#### 12. EMPLOYEES

During the year 2019, the average number of employees, based on full time equivalents, was o (2018: 0).

#### 13. AUDIT FEES

The fees for services rendered by Curetis' independent auditor PricewaterhouseCoopers Accountants N.V. and its member firms and affiliates to the Company and its subsidiaries were approved by the Audit Committee and the Supervisory Board and are detailed in note 38 of the consolidated financial statements The fees listed above relate to the procedures applied to the Company and its consolidated group entities by accounting firms and external auditors as referred to in article 1(1) of the Dutch Accounting Firms Oversight Act (Dutch acronym: Wta).

#### PROPOSED PROFIT APPROPRIATION

Following the profit appropriation proposed by the management board and pursuant to article 36 of the Articles of Association, the amount on the net loss for 2019 of kEUR 13,982 will be added to the retained earnings.

# **OFF-BALANCE SHEET COMMITMENTS**

Curetis N.V. issued an unrestricted, unlimited comfort letter to its wholly owned subsidiary Curetis GmbH for all current and future liabilities to ensure their ability to fulfil all their financial obligations against third parties. This comfort letter has been cancelled as part of the definitive implementation agreement with OpGen Inc. Please refer to Events after the balance sheet date.

#### **EVENTS AFTER BALANCE SHEET DATE**

Please refer to note 39 of the consolidated financial statements.

Holzgerlingen, 30th June 2020 Curetis N.V. in Liquidation.

Oliver Schacht, PhD Liquidator Johannes Bacher Liquidator **Dr. Achim Plum** Liquidator

**Dr. Werner Schäfer** Supervisory Board Director

**Dr. Rudy DeKeyser** Supervisory Board Director

**Dr. Nils Clausnitzer**Supervisory Board Director

# **CURETIS N.V. – OTHER INFORMATION**

# ARTICLES OF ASSOCIATION GOVERNING PROFIT APPROPRIATION

Article 36.2 of the articles of association states the following regarding profit and loss allocation:

The management board may determine what part of the profits as shown by the annual accounts shall be added to the reserves. A resolution of the management board to reserve profits as shown by the annual accounts shall require the approval of the supervisory board. The profits remaining shall be at the free disposal of the general meeting. In the event of a tie vote regarding a proposal to distribute or reserve profits, the profits concerned shall be reserved.



# V. AUDITOR'S REPORT

# Independent auditor's report

To: the general meeting of Curetis N.V. in liquidation

# Report on the financial statements 2019

## **Our opinion**

In our opinion:

- the consolidated financial statements of Curetis N.V. i.l. together with its subsidiaries ('the Group') give a true and fair view of the financial position of the Group as at 31<sup>st</sup> December 2019 and of its result and cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code;
- the company financial statements of Curetis N.V. i.l. ('the Company') give a true and fair view of the financial position of the Company as at 31<sup>st</sup> December 2019 and of its result for the year then ended in accordance with Part 9 of Book 2 of the Dutch Civil Code.

#### What we have audited

We have audited the accompanying financial statements 2019 of Curetis N.V. i.l., Holzgerlingen, Germany. The financial statements include the consolidated financial statements of the Group and the company financial statements.

The consolidated financial statements comprise:

- the consolidated statement of financial position as at 31st December 2019;
- the following statements for 2019: the consolidated statement of profit and loss and other comprehensive income, changes in equity and cash flows; and
- the notes, comprising significant accounting policies and other explanatory information.

The company financial statements comprise:

- the company balance sheet as at 31<sup>st</sup> December 2019;
- the company income statement for the year then ended;
- the notes, comprising the accounting policies applied and other explanatory information.

The financial reporting framework applied in the preparation of the financial statements is EU-IFRS and the relevant provisions of Part 9 of Book 2 of the Dutch Civil Code for the consolidated financial statements and Part 9 of Book 2 of the Dutch Civil Code for the company financial statements.



### The basis for our opinion

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. We have further described our responsibilities under those standards in the section 'Our responsibilities for the audit of the financial statements' of our report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Independence

We are independent of Curetis N.V. i.l. in accordance with the European Union Regulation on specific requirements regarding statutory audit of public-interest entities, the 'Wet toezicht accountantsorganisaties' (Wta, Audit firms supervision act), the 'Verordening inzake de onafhankelijkheid van accountants bij assuranceopdrachten' (ViO, Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant independence requirements in the Netherlands. Furthermore, we have complied with the 'Verordening gedrags- en beroepsregels accountants' (VGBA, Dutch Code of Ethics).

# Our audit approach Overview and context

Curetis N.V. i.l. is a public limited liability company which main activities were to develop, produce and sell molecular diagnostics systems and cartridges which are used for rapid infectious disease testing for hospitalized patients. The Company is headquartered in Holzgerlingen (Germany) and had a listing on Euronext, Amsterdam (the Netherlands) and Brussels (Belgium). The Group is comprised of several components and therefore we considered our group audit scope and approach as set out in the section 'The scope of our group audit'. We paid specific attention to the areas of focus driven by the operations of the Group, as set out below.

The assessment of various strategic and tactical financing options characterised the financial year 2019 and up to now. A definitive implementation agreement with OpGen Inc. to combine businesses, as a merger of the subsidiary Curetis GmbH, has been announced in September 2019. Subsequently the Company has entered into this agreement with shareholder approvals obtained from both parties in 2020. This is followed by a delisting and a plan to liquidate Curetis N.V. i.l. during 2020. These events have affected our audit work related to the going concern assumption and the basis of preparation in the financial statements.

As part of designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we considered where the liquidators made important judgements, for example, in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. In paragraph 2.3 of the financial statements the Company describes the areas of judgement in applying accounting policies and the key sources of estimation uncertainty. Of these estimates we considered the estimation uncertainty and the related inherent risks of material misstatement in both the impairment assessment of intangible assets and the accounting of inventories at net realizable value as key audit matters as set out in the section 'Key audit matters' of this report. Furthermore, we identified the accounting for assets classified as held for sale, liabilities directly associated with those assets held for sale and results of discontinued operations as a key audit matter, because of the technical nature and the significant judgement related to this.



Other areas of focus, that were not considered as key audit matters, were accounting for share based payments, financial instruments and the application of IFRS 16. As in all of our audits, we also addressed the risk of management override of controls, including evaluating whether there was evidence of bias by the former management board or liquidators that may represent a risk of material misstatement due to fraud

We ensured that the audit team included the appropriate skills and competences which are needed for the audit of Curetis N.V. i.l. We therefore included experts and specialists in the areas of amongst others treasury, tax and share based payments in our team.

The outline of our audit approach was as follows:



#### Materiality

Overall materiality: €779,000.

#### Audit scope

- We conducted the audit work at the head office of the Group at Holzgerlingen, Germany.
- Audit coverage: 99% of consolidated revenue, 92% of consolidated total assets and 97% of consolidated loss before tax.

#### Key audit matters

- Impairment of intangible assets
- Valuation of inventory

Significant judgement and related accounting of assets classified as held for sale, liabilities directly associated with those assets held for sale and results of discontinued operations (IFRS 5)

### Materiality

The scope of our audit is influenced by the application of materiality, which is further explained in the section 'Our responsibilities for the audit of the financial statements'.

Based on our professional judgement we determined certain quantitative thresholds for materiality, including the overall materiality for the financial statements as a whole as set out in the table below. These, together with qualitative considerations, helped us to determine the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and to evaluate the effect of identified misstatements, both individually and in aggregate, on the financial statements as a whole and on our opinion.

Overall group materiality		materiality	€779,000 (2018: €245,000).
Basis	for	determining	We used our professional judgement to determine overall materiality. As a basis for our
materi	ality		judgement we used 3.5% of operating losses from continued and discontinued operations.



Rationale for benchmark applied	We used operating losses from continued and discontinued operations as the primary benchmark, based on our analysis of the common information needs of users of the financial statements. On this basis, we believe that operating losses from continued and discontinued operations are an important metric for the financial performance of the Company. We have changed our primary benchmark for materiality to operating losses from continued and discontinued operations, from total expenses used in prior year, because this better represents the cash need of the Company to fund its operations.
Component materiality	To each component in our audit scope, we, based on our judgement, allocate materiality that is less than our overall group materiality. The range of materiality allocated across components was between €262,500 and €447,000.

We also take misstatements and/or possible misstatements into account that, in our judgement, are material for qualitative reasons.

We agreed with the supervisory board that we would report to them misstatements identified during our audit above €32,500 (2018: €12,250) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

### The scope of our group audit

Curetis N.V. i.l. is the parent company of a group of entities. The financial information of this group is included in the consolidated financial statements of Curetis N.V. i.l.

We tailored the scope of our audit to ensure that we, in aggregate, provide sufficient coverage of the financial statements for us to be able to give an opinion on the financial statements as a whole, taking into account the management structure of the Group, the nature of operations of its components, the accounting processes and controls, and the markets in which the components of the Group operate. In establishing the overall group audit strategy and plan, we determined the type of work required to be performed at the component level.

The group audit primarily focused on the individually significant components: Curetis N.V. i.l., Curetis USA Inc., ARES Genetics GmbH and Curetis GmbH.

We subjected four components to audits of their complete financial information, as those components are individually financially significant to the Group.

In total, in performing these procedures, we achieved the following coverage on the financial line items:

Revenue	99%
Total assets	92%
Loss before income tax	97%

None of the remaining components represented more than 3% of total group revenue or total group assets. For those remaining components we performed, among other things, analytical procedures to corroborate our assessment that there were no significant risks of material misstatements within those components.

By performing the procedures above, we have been able to obtain sufficient and appropriate audit evidence on the Group's financial information, as a whole, to provide a basis for our opinion on the financial statements.



### Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in the audit of the financial statements. We have communicated the key audit matters to the supervisory board. The key audit matters are not a comprehensive reflection of all matters identified by our audit and that we discussed. In this section, we described the key audit matters and included a summary of the audit procedures we performed on those matters.

We addressed the key audit matters in the context of our audit of the financial statements as a whole, and in forming our opinion thereon. We do not provide separate opinions on these matters or on specific elements of the financial statements. Any comment or observation we made on the results of our procedures should be read in this context.

Compared to prior year, we have identified one new key audit matter that relates to the accounting for assets classified as held for sale, the liabilities directly associated with those assets held for sale and the results of discontinued operations.

#### Key audit matter

### Impairment of intangible assets Notes 3.18, 4 and 20 in the annual report

In the Company's consolidated financial statements, intangible assets amount to €7,260,000 as of 31st December 2019, which comprises 41.7% of the assets held for sale, as of 31st December 2019. This balance mainly consists of the Unyvero A30 RQ (Gyronimo) platform representing a carrying value of €5,000,000, which contains primarily technical development files of a mid-plex-molecular-diagnostic-platform, relating knowhow and IP. In 2016, the Company acquired this platform against cash consideration including a contractual agreement for future royalties and milestone payments.

The asset is accounted for at cost and has no assigned useful life as the platform is currently not available for commercial use and in development. At the end of the financial year, the liquidators performed an impairment assessment for the intangible assets, including the Unyvero A30 RQ platform. The liquidators have made judgements around the assumptions and inputs used in the impairment assessment, including the determination of valuations of platforms with similar technological characteristics, within various stages of development.

Taking into account expected partnering deals and related discussions, there is significant estimation uncertainty related to the recoverable amount of this intangible asset. As a result, it has been an important area for our audit, because a change in assumptions could have a material impact on the value of the intangible asset.

#### Our audit work and observations

We obtained the impairment assessment prepared by the liquidators to evaluate the recoverable amounts of the intangible assets.

We assessed the appropriateness of the valuations of platforms with similar technological characteristics as used by the liquidators in their impairment assessment, by making reference to third party evidence and other supporting documentation provided by management. We assessed such evidence for its appropriateness, for being 'at arms' length', and tested the mathematical accuracy of the underlying fair value calculations.

Based on the audit procedures performed, we did not identify material exceptions and we considered the liquidators' assumptions supported by available evidence.

Finally, we evaluated the sufficiency of the related disclosures and found them to be an appropriate reflection of the estimation uncertainty in line with the requirements of the accounting framework.

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Valuation of Inventory
Notes 2.3, and 18 in the annual report

In the Company's consolidated financial statements, Inventories amount to €1,865,000 as of 31<sup>st</sup> December 2019, which comprises 10.7% of the assets held for sale, as of 31<sup>st</sup> December 2019. The inventory balance mainly consists of the Unyvero A50 molecular diagnostics system (hereafter referred to as 'Unyvero System') amounting after a write down of €7,431,000 to a carrying value of €687,000. Inventory levels were increased during previous financial years to cover future demand for the Unyvero systems as expected by the former management board and these are currently not expected to be sold during 2020.

Inventories are accounted at the lower of cost and net realisable value. At year end, the valuation of inventory is reviewed by the liquidators and the cost of inventory is reduced where inventory is expected to be sold below cost price. In this evaluation, the liquidators have made judgements on the number of Unyvero systems expected to be sold for 2020 and years hereafter, based on the actual sales occurred during current and previous financial years. The increase in write down of the gross carrying amount of the Unyvero Systems the liquidators substantiated with sales forecasts not being met in the past. The liquidators thus put more focus on historical sales volume to take into consideration that this volume is a closer approximation of future sales. Judgements also include the expected realisable value of these Unyvero systems based on the aging of the Unyvero systems in the expected year of sale.

Due to limited historical sales data, there is significant estimation uncertainty related to the expected future sales volume of Unyvero systems per year, as well as the net realisable value and development of the expected sales price. As a result, this has been an important area for our audit. Furthermore, a change in assumptions could have a material impact on the value of inventory. Therefore, we consider this a key audit matter.

As part of our risk assessment procedures, we compared the net realisable value estimated in the prior year to the actual sales value for Unyvero systems sold in 2019, in order to evaluate whether the former management board and liquidators are capable of providing a reliable estimate of the expected sales value of a Unyvero system.

Knowing sales forecasts were not being met in the past, we compared sales volume forecasts of prior periods to actuals to assess whether the sales volumes in the past are an appropriate representation of future sales volumes. Based on this we concluded that the historical sales volume is a closer approximation of future sales. For estimated sales volumes of Unyvero Systems in 2020, we have tested the estimate by comparing these with historical sales over the last two financial years as well as obtaining audit evidence up to the date of our auditors' report including reconciling these with the existing contracts with the Company's customers.

We determined the appropriateness of the cost value and the ageing of the Unyvero systems by agreeing it back on a sample basis to the purchase invoice of the respective Unyvero System.

Based on the audit procedures performed, we did not identify material exceptions and we considered the liquidators' final assumptions supported by available evidence.

Finally, we evaluated the sufficiency of the related disclosures and found them to be an appropriate reflection of the estimation uncertainty and the related sensitivities, in line with the requirements of the accounting framework.

Significant judgement and related accounting of assets classified as held for sale, liabilities directly associated with those assets held for sale and results of discontinued operations (IFRS 5)

Note 1.5 and 4

The assessment of various strategic and tactical financing

We obtained the step plan prepared by the former management board for the execution of the business combination and evaluated the steps outlined therein for the liquidators' intent and the ability to carry out those steps.



options characterised the financial year 2019 and up to now. A definitive implementation agreement with OpGen Inc. to combine businesses, as a merger of Curetis GmbH and its subsidiaries, has been announced on 4<sup>th</sup> September 2019. Subsequently the Company has entered into this agreement with shareholder approvals obtained from both parties in March 2020, resulting into execution of the transaction as at 1<sup>st</sup> April 2020. This was followed by the delisting of Curetis N.V. i.l. following the closing of the transaction, and the planned liquidation of Curetis N.V. i.l. during 2020.

The former management board and liquidators have identified 24<sup>th</sup> December 2019 as highly probable for the "held for sale criterium". The probability was assessed taking into consideration key stakeholder of Curetis N.V. i.l., including the support of certain debt holders. Thus from 24<sup>th</sup> December 2019 onwards the assets and liabilities of the disposal group were measured under IFRS 5 accounting principles. The consolidated statement of profit or loss and other comprehensive income present those operations of the disposal group as discontinued operations as they represent a major line of the business.

A change in the date on which the held for sale criterium is deemed highly probable could have a material impact on the related accounting if it would have been post 31<sup>st</sup> December 2019. In addition, the accounting based on IFRS 5 principles is non-routine for the Company and therefore has been a key audit matter for our audit.

We obtained evidence of former management board and supervisory board approval of the sale of Curetis GmbH and its subsidiaries and the business combination with OpGen Inc. We reviewed the contracts and agreements with OpGen Inc. as well as with the debt holders of Curetis N.V. i.l. to support the liquidators' evaluation and plan.

Based on this review, we challenged the liquidators' assessment on the date on which the held for sale criterium was met. We concur with the liquidators' conclusion that the highly probable definition of the held for sale criterium for the transaction with OpGen was reasonable.

We have evaluated whether the disposal group assessment and the categorisation of continued and discontinued operations are in line with the contractual agreements between the Company and OpGen Inc. Furthermore, we tested whether the accounting policies applied are in accordance with IFRS 5.

Based on the audit procedures performed, we did not identify material exceptions.

Finally, we evaluated the sufficiency of the related disclosures and found them to be appropriate.

### Emphasis of matter – discontinuity of the Company

We draw attention to the paragraph 1.5 "Non-going concern" in the notes to the financial statements which indicates that the former management board has decided to liquidate the Company and that the liquidators expect that the Company will be able to meet its obligations. Our opinion is not modified in respect of this matter.

# Report on the other information included in the annual report

In addition to the financial statements and our auditor's report thereon, the annual report contains other information that consists of:

- the management review, including the remuneration report, as defined on page 4 to page 42 of the annual report;
- the corporate governance section of the annual report; and
- the other information pursuant to Part 9 of Book 2 of the Dutch Civil Code.

Based on the procedures performed as set out below, we conclude that the other information:

• is consistent with the financial statements and does not contain material misstatements;



• contains the information that is required by Part 9 of Book 2 and the sections 2:135b and 2:145 subsection 2 of the Dutch Civil Code.

We have read the other information. Based on our knowledge and understanding obtained in our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements.

By performing our procedures, we comply with the requirements of Part 9 of Book 2 and section 2:135b subsection 7 of the Dutch Civil Code and the Dutch Standard 720. The scope of such procedures was substantially less than the scope of those performed in our audit of the financial statements.

The liquidators are responsible for the preparation of the other information, including the management review, including the remuneration report, and the other information in accordance with Part 9 of Book 2 of the Dutch Civil Code and the remuneration report in accordance with the sections 2:135b and 2:145 subsection 2 of the Dutch Civil Code.

# Report on other legal and regulatory requirements

### Our appointment

We were appointed as auditors of Curetis N.V. i.l. firstly on 16<sup>th</sup> June 2016 by the supervisory board most recently followed by the passing of a resolution by the shareholders at the annual meeting held on 27<sup>th</sup> June 2019. Our appointment has been renewed annually by shareholders representing a total period of uninterrupted engagement appointment of 4 years.

# No prohibited non-audit services

To the best of our knowledge and belief, we have not provided prohibited non-audit services as referred to in Article 5(1) of the European Regulation on specific requirements regarding statutory audit of public-interest entities.

#### Services rendered

The services, in addition to the audit, that we have provided to the Company and its controlled entities, for the period to which our statutory audit relates, are disclosed in note 38 to the financial statements.

# Responsibilities for the financial statements and the audit

# Responsibilities of the liquidators and the supervisory board for the financial statements

The liquidators are responsible for:

- the preparation and fair presentation of the financial statements in accordance with EU-IFRS and with Part 9 of Book 2 of the Dutch Civil Code; and for
- such internal control as the liquidators determine is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of the financial statements, the liquidators are responsible for assessing the Company's ability to continue as a going concern. Based on the financial reporting frameworks mentioned, the liquidators should prepare the financial statements using the going-concern basis of accounting unless the liquidators either intend to liquidate the Company or to cease operations, or has no realistic alternative but to do so. The liquidators should disclose the events and circumstances that may cast significant doubt on the Company's ability to continue as a going concern in the financial statements.



The supervisory board is responsible for overseeing the Company's financial reporting process.

# Our responsibilities for the audit of the financial statements

Our responsibility is to plan and perform an audit engagement in a manner that allows us to obtain sufficient and appropriate audit evidence to provide a basis for our opinion. Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error and to issue an auditor's report that includes our opinion. Reasonable assurance is a high but not absolute level of assurance, which makes it possible that we may not detect all material misstatements. Misstatements may arise due to fraud or error. They are considered to be material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

Materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

A more detailed description of our responsibilities is set out in the appendix to our report.

Eindhoven, 30<sup>th</sup> June 2020 PricewaterhouseCoopers Accountants N.V.

Original has been signed by R.M.N. Admiraal RA



# Appendix to our auditor's report on the financial statements 2019 of Curetis N.V. i.l.

In addition to what is included in our auditor's report, we have further set out in this appendix our responsibilities for the audit of the financial statements and explained what an audit involves.

# The auditor's responsibilities for the audit of the financial statements

We have exercised professional judgement and have maintained professional skepticism throughout the audit in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. Our audit consisted, among other things of the following:

- Identifying and assessing the risks of material misstatement of the financial statements, whether due to fraud or error, designing and performing audit procedures responsive to those risks, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the intentional override of internal control.
- Obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the liquidators.
- Concluding on the appropriateness of the liquidators' use of the going-concern basis of accounting, and based on the audit evidence obtained, concluding whether a material uncertainty exists related to events and/or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report and are made in the context of our opinion on the financial statements as a whole.
- Evaluating the overall presentation, structure and content of the financial statements, including the disclosures, and evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

Considering our ultimate responsibility for the opinion on the consolidated financial statements, we are responsible for the direction, supervision and performance of the group audit. In this context, we have determined the nature and extent of the audit procedures for components of the Group to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole. Determining factors are the geographic structure of the Group, the significance and/or risk profile of group entities or activities, the accounting processes and controls, and the industry in which the Group operates. On this basis, we selected group entities for which an audit or review of financial information or specific balances was considered necessary.

We communicate with the supervisory board regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit. In this respect, we also issue an additional report to the audit committee in accordance with Article 11 of the EU Regulation on specific requirements regarding statutory audit of public-interest entities. The information included in this additional report is consistent with our audit



opinion in this auditor's report.

We provide the supervisory board with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the supervisory board, we determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not communicating the matter is in the public interest.

CURETIS N.V. in Liquidation 2019 Annual Report

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