



## Curetis N.V.

*(a public company with limited liability incorporated under the laws of the Netherlands with its statutory seat in Amsterdam, the Netherlands)*

### Offering of up to 7,428,349 ordinary shares

Curetis N.V. (the “**Company**”, and together with its consolidated subsidiaries, “**Curetis**”) is offering up to 7,428,349 newly issued ordinary shares with a nominal value of €0.01 each in its capital (the “**Offer Shares**”). At the mid-point of the Offer Price Range (as defined below), the Company would raise approximately €16.3 million of gross proceeds from the Offering (as defined below) but based on the maximum number of Offer Shares it has the possibility to raise up to approximately €18.4 million in gross proceeds from the Offering (assuming an Offer Price (as defined below) at the upper end of the Offer Price Range (as defined below) and excluding the PSOP Proceeds (as defined below)). The Offer Shares constitute up to approximately 45.13% of the current issued share capital of the Company.

The offering of the Offer Shares (the “**Offering**”) consists solely of private placements to certain institutional investors in various jurisdictions. The Offer Shares are being offered: (i) within the United States to qualified institutional buyers (“**QIBs**”) as defined in Rule 144A (“**Rule 144A**”) under the US Securities Act of 1933, as amended (the “**US Securities Act**”) in reliance on Rule 144A or pursuant to another exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act, and (ii) outside the United States in offshore transactions in reliance on Regulation S under the US Securities Act (“**Regulation S**”).

The ordinary shares in the capital of the Company, with a nominal value of €0.01 each, (“**Shares**”) are listed and traded under the symbol “**CURE**” on Euronext in Amsterdam (“**Euronext in Amsterdam**”), a regulated market of Euronext Amsterdam N.V. (“**Euronext Amsterdam**”) and Euronext in Brussels (“**Euronext in Brussels**”), a regulated market of Euronext Brussels NV/SA (“**Euronext Brussels**”, and together with Euronext Amsterdam, “**Euronext**”).

**Investing in the Offer Shares involves substantial risks and uncertainties. See “Risk Factors” for a description of the factors prospective investors should carefully consider before investing in the Offer Shares.**

**The price per Offer Share (the “Offer Price”) is expected to be in the range of €2.00 to €2.60 (inclusive) (the “Offer Price Range”)**

The Offering will take place during the period commencing at 09:00 Central European Time (“**CET**”) on 2 November 2018 and ending at 15:00 CET on 7 November 2018 (the “**Offer Period**”), subject to acceleration or extension of the timetable for the Offering. The Offer Price Range is an indicative price range. The Offer Price and the exact number of Offer Shares offered in the Offering will be determined after the end of the Offer Period on the basis of the results of the book-building process and taking into account the quoted share price, market conditions, a qualitative assessment of demand for the Offer Shares and other factors deemed appropriate. Prior to allocation of the Offer Shares (“**Allocation**”), the number of Offer Shares can be increased or decreased and the Offer Price Range can be changed. Any such change in the number of Offer Shares and/or the Offer Price Range will be announced in a press release on the Company’s website at [www.curetis.com](http://www.curetis.com). The Offer Price and the exact number of Offer Shares will be set out in a pricing statement (the “**Pricing Statement**”) that will be deposited with the Dutch Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*) (the “**AFM**”) and published through a press release on the Company’s website.

Baader Bank AG (“**Baader Bank**”) is acting as sole global coordinator, sole bookrunner and sole underwriter for the Offering (the “**Sole Global Coordinator**”) and goetzpartners securities Limited (“**goetzpartners**”) is acting as placement agent and co-manager for the Offering (the “**Co-Manager**”, and together with the Sole Global Coordinator, the “**Managers**”).

Subject to acceleration or extension of the timetable for the Offering, payment (in euro) for, and delivery of, the Offer Shares (“**Settlement**”) is expected to take place on or about 9 November 2018 (the “**Settlement Date**”) through the book entry systems of Nederlands Centraal Instituut voor Giraal Effectenverkeer B.V. (“**Euroclear Nederland**”). If Settlement does not take place on the Settlement Date, or at all, the Offering may be withdrawn, in which case all applications to purchase the Offer Shares will be disregarded, any allocations made will be deemed not to have been made and any payments made will be returned without interest or other compensation and transactions in the Offer Shares on Euronext in Amsterdam and Euronext in Brussels may be annulled. All dealings prior to Settlement are at the sole risk of the parties concerned. The Managers, the Company, ABN AMRO Bank N.V., in its capacity as listing agent for the Offer Shares (the “**Listing Agent**”), and Euronext do not accept any responsibility or liability with respect to any person as a result of the withdrawal of the Offering or the related annulment of any transaction in Offer Shares on Euronext in Amsterdam and Euronext in Brussels.

This Prospectus does not constitute an offer to sell or the solicitation of an offer to buy Offer Shares to any person in any jurisdiction to whom or in which such offer or solicitation is unlawful. The Offer Shares have not been and will not be registered under the US Securities Act or the applicable securities laws of any state or other jurisdiction of the United States and may not be offered, sold, pledged or otherwise transferred within the United States, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act and applicable state securities laws. Each investor in the Offer Shares, in making a purchase, will be deemed to have made certain acknowledgements, representations and agreements as set out in “**Selling and Transfer Restrictions**”.

This document (the “**Prospectus**”) is prepared for the admission to listing and trading on Euronext in Amsterdam and Euronext in Brussels of (i) the Offer Shares, (ii) the Conversion Shares (as defined herein) and (iii) to the extent necessary, the Shares issued in connection with and pursuant to the PSOP Roll-Over Agreements (as defined herein). This Prospectus constitutes a prospectus for the purposes of Article 3 of Directive 2003/71/EC of the European Parliament and of the Council, and

amendments thereto (including those resulting from Directive 2010/73/EU) (the “**Prospectus Directive**”), and has been prepared in accordance with Chapter 5.1 of the Dutch Financial Supervision Act (*Wet op het financieel toezicht*) and the rules promulgated thereunder (the “**Dutch Financial Supervision Act**”). The Company has requested the AFM to notify its approval in accordance with Article 18 of the Prospectus Directive to the competent authorities in Belgium, the Belgian Financial Services and Markets Authority (the “**FSMA**”), with a certificate of approval attesting that this Prospectus has been prepared in accordance with the Prospectus Directive. This Prospectus has been approved by and filed with the AFM.

**Sole Global Coordinator, Sole Bookrunner and Sole Underwriter**

**Baader Bank**

**Placement Agent and Co-Manager**

**goetzpartners**

2 November 2018

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## SUMMARY

Summaries are made up of disclosure requirements known as “**Elements**”. These Elements are numbered in Sections A-E (A.1 – E.7). This summary contains all the Elements required to be included in a summary for this type of security and issuer. Because some Elements are not required to be addressed, there may be gaps in the numbering sequence of the Elements.

Even though an Element may be required to be inserted in the summary because of the type of securities and issuer, it is possible that no relevant information can be given regarding the Element. In this case a short description of the Element is included in the summary with the mention of “**not applicable**”.

Section A – Introduction and warnings		
<b>A.1</b>	<b>Introductions and warnings</b>	<p>This summary should be read as an introduction to the prospectus (the “<b>Prospectus</b>”) for the admission to listing and trading on Euronext in Amsterdam and Euronext in Brussels of (i) the Offer Shares (as defined below) and (ii) newly issued ordinary shares with a nominal value of €0.01 each in the capital of Curetis N.V. (the “<b>Company</b>”, and together with its consolidated subsidiaries, “<b>Curetis</b>”) that may be issued upon the conversion of any and all convertible notes and/or exercise of any and all warrants that are from time to time issued under the Yorkville Agreement (as defined below) (such Shares, the “<b>Conversion Shares</b>”).</p> <p>The Company is offering (the “<b>Offering</b>”) up to 7,428,349 newly issued ordinary shares with a nominal value of €0.01 each in its capital (the “<b>Offer Shares</b>”), and to the admission to listing and trading of the Offer Shares under the symbol “<b>CURE</b>” on Euronext in Amsterdam (“<b>Euronext in Amsterdam</b>”), a regulated market operated by Euronext Amsterdam N.V., and on Euronext in Brussels (“<b>Euronext in Brussels</b>”), a regulated market operated by Euronext Brussels NV/SA. The Offer Shares constitute up to approximately 45.13% of the current issued share capital of the Company.</p> <p>Any decision to invest in the Offer Shares or the Company should be based on consideration of the Prospectus as a whole by the investor.</p> <p>Where a claim relating to the information contained in, or incorporated by reference into, the Prospectus is brought before a court, the plaintiff investor might, under the national legislation of the member states of the Economic European Area, have to bear the costs of translating the Prospectus before the legal proceedings are initiated.</p> <p>Civil liability attaches only to those persons who have tabled this summary, including any translation thereof, but only if this summary is misleading, inaccurate or inconsistent when read together with the other parts of the Prospectus or if it does not provide, when read together with the other parts of the Prospectus, key information in order to aid investors when considering whether to invest in the Offer Shares.</p>
<b>A.2</b>	<b>Consent, indication, conditions and notice</b>	Not applicable. The Company does not consent to the use of the Prospectus for the subsequent resale or final placements of Offer Shares by financial intermediaries.

Section B – Issuer		
<b>B.1</b>	<b>Legal and commercial name of the Company</b>	Curetis N.V.
<b>B.2</b>	<b>Domicile, legal form, legislation and country of incorporation</b>	The Company is a public limited liability company ( <i>naamloze vennootschap</i> ) incorporated under the laws of the Netherlands. The Company has its statutory seat ( <i>statutaire zetel</i> ) in Amsterdam, the Netherlands, and its principal place of business and domicile at Holzgerlingen, Germany. The Company is registered with the Dutch Trade Register of the Chamber of Commerce under number 64302679.
<b>B.3</b>	<b>Current operations and principal activities</b>	<p>Curetis is a molecular diagnostics company that focuses on the development and commercialisation of reliable, fast and cost-effective products for diagnosing severe infectious diseases in hospitalised patients, an indication with a high unmet medical need and significant prevalence in developed countries. Curetis’ unique Unyvero Platform (the “<b>Unyvero Platform</b>”) currently comprises the L4 Lysator, the Unyvero C8 Cockpit and the Unyvero A50 Analyzer at its core (collectively, the “<b>Unyvero System</b>”), together with proprietary software and the application-specific single use application cartridges (the “<b>Application Cartridges</b>”). 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 Conformité Européenne in vitro diagnostics (“<b>CE-IVD</b>”) marked since 2012 and is commercialised 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, United Arab Emirates, Israel and Singapore), and is in the process of being rolled out commercially in the US following <i>De Novo</i> clearance of the Unyvero System and the lower respiratory tract (“<b>LRT</b>”) Application Cartridge by the US Food and Drug Administration (the “<b>FDA</b>”) in April 2018.</p> <p>Today, the diagnosis of infectious diseases in the hospital setting is still largely carried out through traditional culture-based microbiology methods. This process is labour-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.</p> <p>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 delivers results within four to five hours and can cover over 100 diagnostic targets. The broad Unyvero test panels also</p>

		<p>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.</p> <p>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.</p> <p>The Unyvero Platform is marketed through a combination of direct sales in key European Union ("EU") countries, including Belgium, France, Germany, Luxembourg, the Netherlands, Switzerland and the United Kingdom, as well as the United States (the "US"), and distributors in selected European markets and the rest of the world. Curetis also intends to continue to expand internationally in certain additional Association of Southeast Asian Nations ("ASEAN") markets beyond Singapore (Indonesia, Malaysia, and Thailand) through its distribution agreement with Acumen Research Laboratories Pte Ltd. and in China, Taiwan and Hong Kong through its distribution agreement with Beijing Clear Biotech Co., Ltd, with the distribution rights for Hong Kong granted to Technomed (Hong Kong) Ltd. Curetis has recently entered into distribution agreements with Future Horizons Scientific (FHS) in Egypt, Quimica Valaner S.A. de C.V. in Mexico and Biko S.A. in Uruguay for commercialization of the Unyvero Platform and Application Cartridges, subject to obtaining regulatory clearance for the products in the respective markets, which is expected in the fourth quarter of 2018. As of 30 October 2018, Curetis' total installed base comprised 165 Unyvero A50 Analyzers. There are currently six commercially available Application Cartridges: the hospitalised pneumonia ("HPN") Application Cartridge, the implant and tissue infection ("ITI") Application Cartridge, the blood cultures ("BCU") Application Cartridge, the intra-abdominal infection ("IAI") Application Cartridge, the urinary tract infection ("UTI") Application Cartridge, all of which are CE-IVD-marked, and the LRT Application Cartridge, which is technically similar to the HPN Application Cartridge and addresses severe forms of pneumonia, which was cleared by the FDA in April 2018 and is now being marketed in the US. The HPN and BCU Application Cartridges have been approved by the Singapore Health Services Authority.</p> <p>To date, more than 90 clinical studies and evaluations with over 12,800 patient samples have been completed to validate these Application Cartridges and more than 40 clinical and scientific publications have been produced since the beginning of 2016. Additional trials with several thousand additional samples are ongoing or planned in the coming years. This includes clinical studies to</p>
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		<p>obtain FDA clearance for the LRT Application Cartridge for use with the bronchoalveolar lavage (“<b>BAL</b>”) specimen, in addition to the tracheal aspirate samples for which the Unyvero LRT Application Cartridge was cleared by the FDA in April 2018, and the invasive joint infections (“<b>IJI</b>”) Application Cartridge, as well as China Food and Drug Administration trials for the Unyvero System and the HPN, ITI, BCU and potentially other Application Cartridges.</p> <p>In addition to the current Unyvero System, Curetis also plans to launch its Unyvero A30 <i>RQ</i> Analyzer module, subject to completion of development and regulatory clearance for CE-IVD-marking, in Europe in late 2019. Currently in the development stage, the Unyvero A30 <i>RQ</i> Analyzer has been designed to offer a rapid time-to-result (potentially as fast as 45 to 90 minutes), qualitative and, where needed, quantitative real-time polymerase chain reaction (“<b>PCR</b>”) testing in a cartridge format that can provide up to 11 parallel multiplex (i.e. simultaneously measuring multiple analytes) quantitative PCR reactions from one sample, with up to three targets per reaction (for a total of up to 33 targets per cartridge). It is expected to be 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, addressing new markets and diversifying the product pipeline. A further advantage of the Unyvero A30 <i>RQ</i> 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.</p> <p>Curetis is continuously updating and improving the content and performance of existing Application Cartridges to meet evolving market needs and reflect the dynamically changing pathogen and antibiotic resistance landscape. Curetis also 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 infectious disease testing.</p> <p>Curetis’ other core business is its Ares Genetics’ bioinformatics, biostatistics, and artificial intelligence technology platform, which builds and expands upon the GEnetic Antibiotic Resistance and susceptibility Database and bioinformatics platform (“<b>GEAR</b>”) (the “<b>ARES Technology Platform</b>”) and its proprietary genetic database on antimicrobial resistances (“<b>ARESdb</b>”), which Curetis acquired from Siemens Technology Accelerator GmbH in 2016. The ARES Technology Platform and ARESdb build and expand upon the GEAR platform. Curetis believes ARESdb is the world’s most comprehensive database on the genetics of antibiotic resistance, which Curetis believes will enable it to enter into partnering deals and strategic collaborations with diagnostic companies, pharmaceutical companies and companies focused on public health and life science research. Curetis expects to increasingly utilise its proprietary biomarker content in its own assay and Application Cartridge development, as well as to out-license it to partners.</p> <p><b>Strengths</b></p>
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		<ul style="list-style-type: none"> <li>Commercial stage: 165 installed Unyvero A50 Analyzers as at 30 October 2018 in Europe, the Middle East, and recently launched in the US and the ASEAN region, with direct sales in the US and selected European countries.</li> <li>Targeting Large Market Opportunity: Curetis estimates that the addressable market for its current and nearer-term Unyvero Application Cartridges is more than 9.73 million cases eligible for testing per year in the EU and the US (see figure included in “Industry”— “Molecular Diagnostics Market by Application”).</li> <li>Comprehensive platform: processing numerous sample types and covering more microorganisms and resistance markers than competing platforms.</li> <li>Validated Unyvero Platform: extensive clinical studies (including US FDA trial for the LRT Application Cartridge) and endorsements from key opinion leaders and a top-tier investigator base.</li> <li>Expanding target market: planning to enter low- and medium-plex market segments through integration of the Unyvero A30 <i>RQ</i> Analyzer as complementary analyser module into Unyvero Systems at the same hospitals and accounts to complement the offering of Unyvero as a comprehensive solution in infectious disease testing.</li> <li>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 Next Generation Sequencing (“NGS”) space.</li> <li>Expanding Unyvero menu: multiple clinical studies underway or planned to continue expanding the use of a number of available Application Cartridges.</li> <li>Attractive health economics: Curetis believes that the Unyvero Platform supports improvements of hospital economics by allowing effective treatment to be administered more quickly.</li> <li>Seasoned management team: combining decades of technological, operational and commercial experience.</li> <li>Fully integrated company controlling all key aspects of its value chain such as development, manufacturing and commercialisation.</li> <li>Significant upside through partnering opportunities through the ARES Technology Platform and ARESdb as well as the Unyvero Platform (in indications and market segments not directly target by with Curetis’ core business).</li> </ul>
<b>B.4a</b>	<b>Most significant recent trends affecting the Company and industries in</b>	<p>The following key trends are expected to impact the infectious disease molecular diagnostics (“MDx”) market growth through molecular assay menu expansion, molecular diagnostic technology development, and greater adoption of these technologies in medical practice:</p> <ul style="list-style-type: none"> <li><b>Increase in ageing population:</b> According to the US Department of Health &amp; Human Services, around 15% of the US population was older than 65 in 2016. The percentage is expected to grow to 21% by 2030. As</li> </ul>



	<p><b>which it operates</b></p>	<p>the population is ageing, the incidence rates of infections are increasing, a trend that is also reinforced by overuse of antibiotics in nursing homes. Moreover, it is predicted that the elderly will require medical services more often – complicated by hospital-acquired infections – than young adults. In summary, as the population ages, people become more prone to infectious diseases, thereby reinforcing the need for faster molecular-based diagnostics</p> <ul style="list-style-type: none"> <li> <p><b>Clinical applications for multiplexed MDx:</b> The commercial availability of assays targeting pathogens causative for upper respiratory tract infections (“<b>URTI</b>”) is believed to be increasing current demand for MDx instrument placements, which, according to public sources, is demonstrated by bioMérieux molecular biology sales increasing year-on-year by approximately 40% largely driven by FilmArray sales constituting approximately 80% of such molecular biology sales between 2015 and 2017. Furthermore, as indicated by the product portfolios and product development pipelines of industry players such as Cepheid, bioMérieux/BioFire, Genmark, T2Biosystems, Luminex, and Curetis further market growth is expected to result from the increasing commercial availability of multiplex tests addressing other disease areas, such as lower respiratory tract infections, implant and tissue infections, gastrointestinal tract infections, intra-abdominal infections, bloodstream infections and sepsis, and urinary tract infections and urosepsis. CNS infections – all representing significant clinical needs.</p> </li> <li> <p><b>Antibiotic resistance – a global medical and economic burden:</b> According to the U.S. Centers for Disease Control and Prevention (“<b>CDC</b>”), 25,000 and more than 23,000 deaths per year in Europe and the U.S., respectively, are associated with antibiotic resistant pathogens, which lead to annual treatment costs of €1.5 billion for the EU alone. By 2050, experts predict that the number of global deaths related to antibiotic resistant infections could possibly increase from the current total of 700,000 to 10 million deaths with significant losses in global production if no action is taken. Anti-microbial resistance is expected to cause more deaths than cancer by 2050. However, on a global scale, antibiotics consumption increased by 65% from 2000 to 2015, although 80 million antimicrobial drug prescriptions in the U.S. alone each year are considered to be unnecessary. Therefore, Curetis believes that the demand for fast and accurate tests for microorganism identification and genetic antibiotic resistance detection will increase.</p> </li> <li> <p><b>Shortage of skilled labour in diagnostics:</b> an increase in the need for diagnostics is expected to result in increased demand for skilled workers to operate laboratories. However, a decrease in the number of laboratory training programs (25% since the 1990s), outflow of baby-boomers into retirement, and staff retention issues have all contributed to a shortage of qualified professionals in the diagnostics field in the U.S. Curetis believes that innovative fully automated solutions with less hands-on time are likely to play an important role in resolving this issue.</p> </li> </ul>
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		<ul style="list-style-type: none"> <li> <b>Personalised medicine and companion diagnostics:</b> The trend towards personalised medicine, defined as therapeutic interventions being tailored to the individual patient based on their individual risk, prognosis and/or predicted response to such intervention as assessed by testing for biomarkers or biomarker signatures, which Curetis believes also includes the molecular identification of relevant microorganisms and their antibiotic resistance markers for an early informed choice of antibiotics for any given patient, is expected to increase the demand for molecular diagnostic tests. </li> <li> <b>Progress in biomarker discovery, allowing Curetis to address unmet clinical needs such as sepsis:</b> Curetis believes that new modern molecular biology techniques, particularly NGS, will contribute to progress in biomarker discovery and increasingly allow for the systematic identification and validation of biomarkers for diagnosing specific diseases. However, Curetis also believes that the results of such research will lead to the need for large biomarker panels to be tested in order to sufficiently capture complex disease biology. Moving those complex biomarker panels into standard of care will require highly multiplexed molecular diagnostics platforms for routine testing. </li> <li> <b>Decentralisation of molecular testing - testing at point-of need:</b> Curetis believes that the need to have diagnostic test results as quickly as possible will lead to the development of near-patient testing and automated sample-to-answer diagnostic test solutions, which can be operated by non-specialist medical staff in a non-laboratory setting. The availability of, near-patient solutions is also expected to make molecular diagnostics accessible to less developed and remote geographic areas. Curetis believes that these trends will encourage adoption of multiplex testing. </li> <li> <b>Reforms in reimbursement systems:</b> New regulations in the U.S. and in certain countries in Europe are expected to introduce new test-specific reimbursement codes for molecular testing. These new coding systems are intended to help ease the billing and payment process. In addition, more countries are expected to adopt reimbursement systems based on diagnosis related groups (“<b>DRG</b>”) that also cover diagnostic tests in a lump-sum payment. New incentives have been put in place in the US to incentivise hospitals to optimise patients’ outcomes, such as Section 3025 of the Affordable Care Act, which requires the Center for Medicare and Medicaid Services (“<b>CMS</b>”) to reduce payments to acute care hospitals with readmission rates in excess of certain specified targets. As a result, in 2017, 2,597 hospitals forfeited US\$564,000 thousand to the CMS. Of these, 769 were penalised for having high rates of infection. Curetis believes such reforms and incentives will have the potential to encourage hospitals to adopt molecular diagnostics technologies. </li> <li> <b>Need for cost efficient diagnostics:</b> Constrained healthcare budgets, a growing world population and longer life expectancy are expected to increase the need for more cost-effective approaches in healthcare. In order to achieve best medical outcomes for patients, while saving money </li> </ul>
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		<p>through optimised care cycles and avoidance of ineffective therapies, Curetis believes that healthcare providers around the world would require timely and accurate test information enabling adequate treatment for infections, which in turn will drive demand for rapid multiplex infectious disease testing.</p> <ul style="list-style-type: none"> <li> <b>Consolidation:</b> Since 2015, several major diagnostic players have adopted external growth strategies and strengthened their presence in MDx through the acquisition of smaller, independent players. For example, Roche acquired Signature Diagnostics in February 2015, Luminex acquired Nanosphere in June 2016, Danaher acquired Cepheid in November 2016, Debiopharm acquired GenePOC in July 2016, Siemens Healthineers acquired Fast Track Diagnostics in December 2017 and Qiagen acquired STAT-DX in May 2018. Due to their financial strength and global presence, large multinational diagnostics providers have the capacity to accelerate the commercialisation of the acquired platforms as well as the development of new applications, which in turn should increase the adoption of MDx technologies in the healthcare market. </li> </ul>																											
<b>B.5</b>	<b>Description of the Group and the Company's position therein</b>	<p>The Company is the parent company of a group of operating companies and has no material direct business operations. The principal assets of the Company are the equity interests it directly or indirectly holds in its operating subsidiaries.</p>																											
<b>B.6</b>	<b>Major Shareholders</b>	<p>The public register of the Dutch Authority for the Financial Markets (<i>Stichting Autoriteit Financiële Markten</i>) (the “<b>AFM</b>”) identifies the following investors holding a substantial interest of 3% or more in the Company's share capital and/or voting rights on 30 October 2018.</p> <table border="1"> <thead> <tr> <th>Shareholder</th><th>Number of Shares</th><th>Percentage of share capital and voting rights<sup>1</sup></th></tr> </thead> <tbody> <tr> <td>LSP Curetis Pooling B.V.</td><td>2,822,780</td><td>18.68%</td></tr> <tr> <td>C Partners Holding GmbH<sup>2</sup></td><td>2,329,378</td><td>14.99%</td></tr> <tr> <td>Forbion Capital Fund II Coöperatief U.A.</td><td>1,387,059</td><td>9.10%</td></tr> <tr> <td>HBM BioCapital II Management Ltd.<sup>3</sup></td><td>1,309,676</td><td>8.67%</td></tr> <tr> <td>Aviva plc<sup>4</sup></td><td>1,125,000</td><td>7.45%</td></tr> <tr> <td>Milaya Invest NV</td><td>1,091,000</td><td>6.66%</td></tr> <tr> <td>Roche Finanz AG</td><td>966,018</td><td>6.39%</td></tr> <tr> <td>Federal Republic of Germany<sup>5</sup></td><td>926,930</td><td>6.14%</td></tr> </tbody> </table> <p> <sup>1</sup> Actual interests may differ as the holder of a substantial interest is only obliged to notify the AFM of any change in the percentage of share capital and/or voting rights if such holder, directly or indirectly, reaches, exceeds or falls below any of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%.  <sup>2</sup> Held indirectly through aeris CAPITAL Archer, L.P.  <sup>3</sup> Held indirectly through HBM BioCapital II L.P. and HBM BioCapital II Invest S.à r.l. </p>	Shareholder	Number of Shares	Percentage of share capital and voting rights <sup>1</sup>	LSP Curetis Pooling B.V.	2,822,780	18.68%	C Partners Holding GmbH <sup>2</sup>	2,329,378	14.99%	Forbion Capital Fund II Coöperatief U.A.	1,387,059	9.10%	HBM BioCapital II Management Ltd. <sup>3</sup>	1,309,676	8.67%	Aviva plc <sup>4</sup>	1,125,000	7.45%	Milaya Invest NV	1,091,000	6.66%	Roche Finanz AG	966,018	6.39%	Federal Republic of Germany <sup>5</sup>	926,930	6.14%
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- 4 Held indirectly, as follows: (i) 6,570 Shares are directly held by Aviva France SA, investment managed by Aviva Investors Global Services Limited, (ii) 1,096,611 Shares are directly held by Aviva Life & Pensions UK Limited, investment managed by Aviva Investors Global Services Limited and (iii) 21,819 Shares are directly held by RBS Collective Investment Funds Limited, investment managed by Aviva Investors Global Services Limited.
- 5 Held indirectly through KfW.

## B.7

### Selected key historical financial information

#### **Consolidated statement of profit or loss and other comprehensive income**

The table below sets forth the Company's consolidated statement of profit or loss and other comprehensive income for the six months ended 30 June 2018 and 2017 and for the years ended 31 December 2017 and 2016:

	For the six months ended 30 June		For the year ended 31 December	
	2018	2017	2017	2016
	<i>(in Ethousands)</i>			
	<b>(unaudited)</b>		<b>(audited)</b>	
<b>Revenue</b>	<b>807</b>	<b>595</b>	<b>1,187</b>	<b>1,306</b>
Cost of sales .....	(1,435)	(1,052)	(1,649)	(1,596)
Gross loss .....	<b>(628)</b>	<b>(457)</b>	<b>(462)</b>	<b>(290)</b>
Distribution costs .....	(4,214)	(3,846)	(7,302)	(5,091)
Administrative expenses .....	(2,111)	(1,848)	(3,755)	(3,024)
Research & development expenses .....	(4,683)	(3,161)	(7,362)	(7,027)
Other income .....	271	50	314	198
<b>Operating loss .....</b>	<b>(11,365)</b>	<b>(9,262)</b>	<b>(18,567)</b>	<b>(15,234)</b>
Finance income .....	274	20	21	101
Finance costs .....	(496)	(406)	(1,004)	(30)
<b>Finance result - net .....</b>	<b>(222)</b>	<b>(386)</b>	<b>(983)</b>	<b>71</b>
<b>Loss before income tax .....</b>	<b>(11,587)</b>	<b>(9,648)</b>	<b>(19,550)</b>	<b>(15,163)</b>
Income tax expenses .....	26	(14)	52	(10)
<b>Loss for the period .....</b>	<b>(11,561)</b>	<b>(9,662)</b>	<b>(19,498)</b>	<b>(15,173)</b>
Other comprehensive income for the year, net of tax * .....	(171)	117	171	(28)
<b>Total comprehensive loss for the period ** .....</b>	<b>(11,732)</b>	<b>(9,545)</b>	<b>(19,327)</b>	<b>(15,201)</b>
* Relates to exchange differences on translation of foreign operations, which may be recognised through profit and/or loss in the future.				
** Total comprehensive loss is solely attributable to owners of the Company.				

#### **Consolidated statement of financial position**

The table below sets forth the Company's consolidated statement of financial position as of 30 June 2018 and as of 31 December 2017 and 2016:

	30 June	31 December	
	2018	2017	2016
	<i>(in Ethousands)</i>		

	(unaudited)	(audited)	
<b>Assets</b>			
<b>Current assets</b> .....	<b>20,348</b>	<b>24,009</b>	<b>30,272</b>
Cash and cash equivalents .....	11,646	16,311	22,832
Trade receivables.....	250	200	101
Inventories .....	6,891	6,946	5,870
Other current assets .....	1,561	552	1,469
<b>Non-current assets</b> .....	<b>11,156</b>	<b>11,506</b>	<b>12,514</b>
Intangible assets .....	7,511	7,524	7,520
Property, plant and equipment....	3,193	3,566	4,466
Other non-current assets .....	172	182	212
Other non-current financial assets .....	157	156	316
Deferred tax assets .....	123	78	—
<b>Total assets</b> .....	<b>31,504</b>	<b>35,515</b>	<b>42,786</b>
<b>Liabilities and equity</b>			
<b>Current liabilities</b> .....	<b>3,180</b>	<b>2,926</b>	<b>2,384</b>
Trade and other payables .....	447	928	721
Provisions current.....	54	124	51
Tax liabilities .....	26	24	10
Other current liabilities .....	1,442	1,226	1,120
Other current financial liabilities.....	1,211	624	482
<b>Non-current liabilities</b> .....	<b>13,647</b>	<b>10,385</b>	<b>41</b>
Provisions non-current.....	43	43	41
Other non-current financial liabilities.....	13,604	10,342	—
<b>Total liabilities</b> .....	<b>16,827</b>	<b>13,311</b>	<b>2,425</b>
<b>Equity</b> .....	<b>14,677</b>	<b>22,204</b>	<b>40,361</b>
Share capital .....	164	155	155
Capital reserve.....	156,565	152,793	152,793
Other reserves .....	8,954	8,527	7,360
Currency translation differences	(30)	143	(29)
Retained earnings .....	(150,976)	(139,414)	(119,918)
<b>Total equity and liabilities</b> .....	<b>31,504</b>	<b>35,515</b>	<b>42,786</b>

***Selected consolidated statement of cash flow data***

The table below sets forth selected items from the Company's consolidated statement of cash flows for the six months ended 30 June 2018 and 2017 and for the years ended 31 December 2017 and 2016:

	For the six months ended 30 June	For the year ended 31 December
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		2018	2017	2017	2016
		<i>(in €thousands)</i>			
		<b>(unaudited)</b>		<b>(audited)</b>	
	Net cash flows provided by (used in) operating activities .....	(11,462)	(6,969)	(15,681)	(15,724)
	Net cash flow provided by (used in) investing activities .....	(230)	(197)	(421)	(7,430)
	Net cash flow provided by (used in) financing activities .....	6,780	9,952	9,952	(105)
	<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(4,912)</b>	<b>2,786</b>	<b>(6,150)</b>	<b>(23,259)</b>
	Net Cash and cash equivalents at the beginning of the period .....	16,311	22,832	22,832	46,060
	Effects of exchange rate changes on cash and cash equivalents .....	247	(217)	(371)	30
	Net Cash and cash equivalent at the end of the period .....	11,646	25,401	16,311	22,832
	<b>Significant change to the issuer's financial condition and operating results</b>	<p>As at the date of the Prospectus, there have been no significant changes in the Company's financial or trading position since 30 June 2018, except for:</p> <ul style="list-style-type: none"> <li>the decrease in the Company's cash and cash equivalents to €6,689 thousand as at 30 October 2018 (which, disregarding the net proceeds of €3,220 thousand from the issuance of convertible notes to Yorkville (as defined below)), represents a decrease of €8,177 thousand in the period since 30 June 2018), as a result of the Company's regular and expected cash burn that the Company experiences as a result of its stage of development; and</li> <li>the issue of €3,500 thousand in principal amount of convertible notes as part of the first tranche under the Yorkville Agreement, which raised a net proceeds amount of €3,220 thousand.</li> </ul>			
<b>B.8</b>	<b>Selected key pro forma financial information</b>	Not applicable. No pro forma financial information has been included in the Prospectus.			
<b>B.9</b>	<b>Profit forecast</b>	Not applicable. The Company has not issued a profit forecast.			
<b>B.10</b>	<b>Qualifications to audit reports</b>	Not applicable. There are no qualifications in the auditor's report on the audited consolidated financial statements of the Company for the financial years ended 31 December 2017 and 2016. The auditor's report for the financial year ended 31 December 2017 contains an emphasis of matter paragraph, in which the auditors draw attention to note 3.27 of the notes to the audited consolidated financial statements for the financial year ended 31 December			

		2017, which describe that the Company's ability to continue as a going concern is threatened by risks.
<b>B.11</b>	<b>Working capital</b>	<p>Curetis' current cash resources do not provide it with sufficient working capital for the next twelve months from the date of the Prospectus. Curetis believes that it has sufficient working capital to continue its current operations until January 2019. Curetis' current cash resources amounted to €6.7 million as at 30 October 2018 (including the initial €3.2 million in net proceeds received pursuant to the Yorkville Agreement). Based on its present requirements under its current business plan, which was prepared on the assumption of obtaining the net proceeds from the Offering and which includes, without limitation, costs for:</p> <ul style="list-style-type: none"> <li>• maintaining and continuing to expand a direct commercial marketing, sales and support presence in the US in order to more broadly commercialise the Unyvero Platform and LRT Application Cartridges in the US;</li> <li>• maintaining and continuing to expand its European commercial presence;</li> <li>• funding working capital requirements to finance the placement of the Unyvero System in the direct selling EMEA markets as well as the US;</li> <li>• continuing to expand its research and development pipeline of the Unyvero System, the Application Cartridges and the Unyvero A30 RQ for European, US and global markets;</li> <li>• research and development programs of its Ares Genetics subsidiary around ARESdb and the ARES Technology Platform; and</li> <li>• general corporate purposes, including to meet its obligations as a publicly listed company and cover administrative expenses,</li> </ul> <p>Curetis believes its operations will require additional cash resources of approximately €23 million assuming the execution of Curetis' current business plan, to provide it with sufficient working capital for the next twelve months from the date of the Prospectus. If the Offering is completed and additional available funds of approximately €16.8 million are generated in the Offering (which would only be the case if the Company raises the Top-End Proceeds (as defined below)), these proceeds together with the €1.4 million in net proceeds expected to be received from the remainder of the first tranche under the Yorkville Agreement and an additional €5.0 million debt financing which is expected to be available from the EIB Finance Contract (as explained further below) would provide it with additional working capital of €23.2 million, as a result of which the Company would have sufficient working capital for the next twelve months from the date of the Prospectus. The availability of the remainder of the first tranche of the Yorkville Agreement and the EIB Finance Contract are subject to certain conditions described below, including, in the case of the Yorkville Facility, the Yorkville Floor Price (as defined below).</p> <p>Curetis – as is typical in the biotech/medtech industry for development stage and early commercial stage companies – incurred net losses since its incorporation until year-end 2014 and again in 2016 and 2017. In 2015, Curetis incurred a profit for the first time due to an extraordinary gain. For the period of 2018 and 2019, Curetis expects to continue incurring significant net losses</p>

		<p>and also experience significantly higher cash burn than in 2017 due to the costly US commercial launch and roll out of Unyvero LRT as well as continuing EMEA commercial operations and global R&amp;D activities.</p> <p>If the Offering should be withdrawn or otherwise not be completed, or if the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, or if Curetis' cash burn is higher than expected due to lower revenues or for other reasons, Curetis will implement a detailed action plan to address the resulting working capital shortfall. The details of the plan would depend on the degree of the shortfall, but Curetis would initially focus on controlling its cash outflows through delaying planned increases in operating and capital expenditures and personnel hiring in favour of maintaining existing levels of expenditure. Curetis would in this case postpone the investment into injection molds and manufacturing line equipment for the Unyvero A30 <i>RQ</i> Application Cartridges, which would delay the development and commercial launch of the Unyvero A30 <i>RQ</i> platform. Curetis would further postpone the investment into additional multi-cavity injection molds, which are expected to result in cost savings in the manufacture of the Unyvero A50 Platform Application Cartridges.</p> <p>If these steps proved to be insufficient and the Offering fails to achieve at least approximately €16.3 million of gross proceeds (being the Mid-Point Proceeds (as defined below), Curetis would need to implement further significant cost reductions. Primarily, Curetis would in this scenario not continue the expansion of, or even reduce, its US commercial organisation and suspend its cost-intensive additional FDA clinical trials in the US. Such cost-cutting measures would significantly adversely impact Curetis' business. For example, they would prevent Curetis from obtaining FDA clearance for its IJI Application Cartridge or the BAL extension for its LRT Cartridge, and thus prevent Curetis from selling those products into the US market. As a consequence, future revenue expectations from the US would be greatly reduced. In addition, Curetis would reduce its staff expenditure by potentially reducing its workforce, which would have an adverse impact on its manufacturing capacity, research and development pipeline and/or ongoing commercialisation efforts.</p> <p>In conjunction with the above measures and subject to certain milestones being met, Curetis may seek to draw down up to an additional €12,000 thousand under the €25,000 thousand debt financing facilities with the European Investment Bank as lender (the “<b>EIB Finance Contract</b>”). Of this amount, €5,000 thousand will become available upon the Company having raised equity in excess of €15,000 thousand, which would be satisfied if the Company, in addition to the €4,100 thousand raised in May 2018, raises an additional €10,900 thousand (and which therefore would be available if the Offering raises at least €10,900 thousand). A further €7,000 thousand becomes available under the EIB Finance Contract upon Curetis having installed 350 Unyvero Analyzers globally as well as Curetis' consolidated revenues being at least €10,000 thousand over the 12 months preceding the request for the loan</p>
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		<p>disbursement. Subject to the relevant milestones being met, these amounts are available until 12 December 2019. Furthermore and subject to the relevant conditions being met, the Company may issue Shares to Global Corporate Finance corporation (“<b>GCF</b>”) under the US\$10,000 thousand equity facility dated 26 April 2018 (the “<b>GCF Equity Facility</b>”) or issue convertible notes and warrants under the financing facility agreement dated 2 October 2018 with YA II PN, Ltd, an investment fund managed by Yorkville Advisors Global LP, a U.S.-based management firm (“<b>Yorkville</b>” and such facility agreement, the “<b>Yorkville Agreement</b>”) for up to €20 million to raise additional funds. Curetis’ ability to utilise the EIB Finance Contract, the GCF Equity Facility and the Yorkville Agreement will depend on the relevant conditions thereunder being satisfied, waived or amended. In that respect:</p> <ul style="list-style-type: none"> <li>• certain of the measures described above to reduce cash outflows may make it difficult for Curetis to satisfy the conditions for disbursement of the €7,000 thousand tranche under the EIB Finance Contract, as cost control measures and cost reductions are expected to negatively impact Curetis’ ability to achieve the milestones of 350 installed Unyvero Analysers and €10,000 thousand consolidated revenues. In addition, the loans under the EIB Finance Contract are for the purpose of financing certain research and development activities, and may not exceed 50% of the total cost of such activities. A decline in research and development expenditure as a result of cost-cutting measures could therefore limit Curetis’ access to the EIB loans.</li> <li>• Curetis would be unable to utilise the GCF Equity Facility if the subscription price per share, which is equal to 95% of the volume weighted average price of the Shares on Euronext in Amsterdam over the five trading days following a sales notice by Curetis to GCF, falls below the floor price to be set by Curetis in the relevant sales notice (which floor price shall not be lower than €4.50 (the “<b>GCF Floor Price</b>”), unless otherwise agreed between Curetis and GCF), subject to adjustments to reflect variations in the share capital of the Company. As at 30 October 2018, the share price of the Company quoted on Euronext in Amsterdam was less than the GCF Floor Price and the Company therefore would, unless otherwise agreed with GCF, not have been permitted to make any drawings under the GCF Equity Facility until the subscription price per share exceeds the GCF Floor Price. Furthermore, the full US\$10,000 thousand under the GCF Equity Facility is not accessible by the Company at one time, but only in US\$500 thousand tranches which the Company is restricted from initiating more than one time in any three-week period, unless previously agreed with GCF. Furthermore, as described below, the Yorkville Agreement imposes certain restrictions on the ability of the Company to access the GCF Equity Facility.</li> <li>• under the Yorkville Agreement, the funding of a tranche of convertible notes under the Yorkville Agreement, including the remaining €1,500 thousand available under the first tranche of convertible notes, is subject to certain conditions precedent being satisfied or waived by Yorkville, including (i) a minimum closing Share price of €3.00 on Euronext in</li> </ul>
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		<p>Amsterdam (the “<b>Yorkville Floor Price</b>”) on the day prior to the sending of a request and (ii) the combined average daily Share value traded on Euronext in Amsterdam and Euronext in Brussels in the week prior to the request being at least €150 thousand. The upper end of the Offer Price Range and, as at 30 October 2018, the share price of the Company quoted on Euronext in Amsterdam, was less than the Yorkville Floor Price and the Company therefore would, unless otherwise agreed with Yorkville, not be permitted to make any additional drawings under the Yorkville Agreement, including the remaining part of the first tranche drawn under the Yorkville Agreement, until the share price of the Company quoted on Euronext in Amsterdam exceeds the Yorkville Floor Price. Furthermore, under the Yorkville Agreement, the convertible notes have an initial maturity of one year, which may be extended in certain circumstances. The Company is restricted from submitting a request to fund a subsequent tranche of convertible notes under the Yorkville agreement until after the tenth calendar day following the conversion into Shares and/or redemption of all the outstanding convertible notes issued under the previous tranches. The Company is not allowed under the Yorkville Agreement to participate in variable rate equity financing transactions (such as an issue of Shares under the GCF Equity Facility) from 30 days prior to the request for the disbursement of a tranche of convertible notes until the 20th business day following the redemption or conversion of such convertible notes.</p> <p>Curetis would also expect to pursue various non-dilutive financing alternatives such as government grants or licensing and partnering models (e.g. for the ARESdb and the ARES Technology Platform and Unyvero A30 RQ platform) to partially fund some of its operations in 2018 and 2019.</p> <p>If the Offering should be withdrawn or otherwise not be completed, or if the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, or if Curetis’ cash burn is higher than expected, Curetis would implement some or all of the foregoing measures to reduce cash outflows and raise financing and thereby seek to achieve, together with Curetis’ current cash resources, cash resources sufficient for 12 months of operations.</p> <p>Curetis believes that the cost reduction measures mentioned above and its ability to raise additional cash through the Yorkville Facility are likely to enable it to continue as a going concern for the next 12 months. However, in the event the Offering is withdrawn or otherwise not completed, and Curetis is not able to address its working capital shortfall, Curetis would, in addition to the cost reduction and financing measures outlined above, be required to raise additional financing by obtaining other equity and/or debt financing for it to have sufficient cash to maintain its operations until 31 October 2019 and as such to continue as a going concern for at least 12 months from the date of this Prospectus. Curetis will therefore continue to pursue various strategic and tactical financing alternatives to raise additional equity or debt capital</p>
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		<p>including, but not limited to, seeking additional investors, pursuing partnerships and obtaining further funding from existing strategic collaboration partners and issuing additional shares or debt instruments to financial and/or corporate strategic investors.</p> <p>The availability to Curetis of such additional financing is subject to a number of external factors, including the satisfaction of certain conditions precedent which may be beyond Curetis' control and the willingness of investors to provide additional equity or debt financing on terms acceptable to Curetis. As a result, it is uncertain if Curetis will be able to obtain sufficient financing to continue as a going concern for at least 12 months from the date of this Prospectus if the Mid-Point Proceeds are not raised.</p> <p>If Curetis fails to implement the above measures to remedy a working capital shortfall caused by a withdrawal of the Offering or a failure to raise the Mid-Point Proceeds or otherwise, such as the generation of sufficient funds from additional financing and the described cost reduction measures, it may be unable to continue as a going concern and may ultimately have to file for insolvency.</p>
<b>Section C – Securities</b>		
<b>C.1</b>	<b>Type and class, security identification number</b>	<p>The Offer Shares are ordinary shares in the issued and outstanding capital of the Company with a nominal value of €0.01 each (“<b>Shares</b>”).</p> <p>Application has been made to list the Offer Shares under the symbol “<b>CURE</b>” on Euronext in Amsterdam and Euronext in Brussels under ISIN Code NL0011509294.</p>
<b>C.2</b>	<b>Currency of the Offer Shares</b>	The Shares are denominated in and will trade in euro.
<b>C.3</b>	<b>Number of Shares issued, nominal value per Share</b>	As at the date of the Prospectus, the issued share capital of the Company consists of 16,458,802 Shares.
<b>C.4</b>	<b>Rights attached to the Shares</b>	<p>The Shares carry dividend rights. Each Share confers the right to cast one vote in the general meeting of the Company (the “<b>General Meeting</b>”). There are no restrictions on voting rights.</p> <p>Holders of Shares (“<b>Shareholders</b>”) have a pre-emptive right in the event of an issue of Shares or the granting of rights to subscribe for Shares. Shareholders do not have pre-emptive rights in respect of Shares issued against contribution in kind or Shares issued to employees of the Company and any of its group companies or Shares issued to persons exercising a previously granted right to subscribe for Shares.</p> <p>The Company's articles of association (the “<b>Articles of Association</b>”) provide that the General Meeting may, upon a proposal of the management board of the Company (the “<b>Management Board</b>” and each member a “<b>Managing Director</b>”) which is approved by the supervisory board of the Company (the “<b>Supervisory Board</b>” and each member a “<b>Supervisory Director</b>”), designate the Management Board as the body authorised, subject to approval</p>

		<p>of the Supervisory Board, to resolve to issue Shares and to grant rights to subscribe for Shares. 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. 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.</p> <p>The Management Board may also be designated to, subject to the approval of the Supervisory Board, limit or exclude the pre-emptive rights to which Shareholders are entitled if and to the extent that the General Meeting has authorised the Management Board for this purpose, and only if the Management Board at that time is also authorised to issue Shares or to grant rights to subscribe for Shares.</p> <p>The General Meeting has designated the Management Board as the corporate body authorised, subject to approval of the Supervisory Board, to issue Shares and grant rights to subscribe for Shares and to restrict or exclude statutory pre-emptive rights relating thereto. This designation of the Management Board ends on 21 December 2019 and is limited to (i) up to 10% of the total number of Shares issued on 21 June 2018, the date on which the designation was provided, plus (ii) up to an additional 10% of the total number of Shares issued on such date, which additional authorisation may be used in relation to mergers and acquisitions or strategic alliances involving any one or more of the Company and its group companies, plus (iii) up to an additional 1,639,257 Shares which may be used for Curetis' Equity Settled Option Plan, which was approved in the General Meeting in 2016 ("ESOP 2016"). The General Meeting has designated the Supervisory Board as the corporate body authorised to grant options for up to 60,000 Shares to Mr. Oliver Schacht, Ph. D. and options for up to 40,000 Shares to Dr. Achim Plum effective per 1 January 2019. In addition, the General Meeting has designated the Management Board as the corporate body authorised, subject to approval of the Supervisory Board, to issue Shares or grant rights to subscribe for Shares and to restrict or exclude statutory pre-emptive rights relating thereto. This designation of the Management Board ends on 21 December 2019 and is limited to 50% of the issued share capital of the Company on 21 June 2018, the date on which the designation was provided, and may be used to raise additional capital to support the execution of the Company's strategy and the development of its business. The Management Board, with the approval from the Supervisory Board, intends to issue the Offer Shares and exclude the statutory pre-emptive rights relating thereto pursuant to these authorisations. The relevant management and supervisory board resolutions shall be adopted prior to Settlement.</p>
<b>C.5</b>	<b>Restrictions on transferability of the Offer Shares</b>	<p>There are no restrictions on the transferability of the Offer Shares in the Articles of Association.</p> <p>However, the Offering to persons located or resident in, or who are citizens of, or who have a registered address in countries other than the Netherlands, and the transfer of Offer Shares into jurisdictions other than the Netherlands may be subject to specific regulations or restrictions.</p>

<b>C.6</b>	<b>Listing and admission to trading of the Offer Shares</b>	<p>The Company expects that the Offer Shares will be admitted to listing and that trading in the Offer Shares will commence on Euronext in Amsterdam and Euronext in Brussels on 30 October 2018, subject to acceleration or extension of the timetable for the Offering.</p> <p>The Shares are listed and traded on Euronext in Amsterdam and Euronext in Brussels under the symbol “CURE” and ISIN code NL0011509294.</p>
<b>C.7</b>	<b>Dividend policy</b>	<p>The Company expects to retain all earnings, if any, generated by Curetis’ operations for the development and growth of its business and does not anticipate paying any dividends to the Shareholders in the near future.</p>
<b>Section D – Risks</b>		
<b>D.1</b>	<b>Key risks relating to the Company and its industry</b>	<p>The following is a summary of selected key risks that, alone or in combination with other events or circumstances, could have a material adverse effect on Curetis’ business, results of operations, financial position, cash flows and prospects. In making the selection, Curetis has considered circumstances such as the probability of the risk materializing on the basis of the current state of affairs, the potential impact which the materialization of the risk could have on its business, results of operations, financial position, cash flows and prospects, and the attention that management would on the basis of current expectations have to devote to these risks if they were to materialize. Investors should read, understand and consider all risk factors, which risk factors are material and should be carefully read in their entirety, in the section entitled “Risk Factors” beginning on page 35 of the Prospectus, before making an investment decision with respect to any Offer Shares.</p> <ul style="list-style-type: none"> <li>• Curetis is a company with only a limited number of products approved for commercialisation, has incurred significant losses since inception and expects to continue to incur significant losses in the foreseeable future. In addition, Curetis expects its annual net cash burn to nearly double in 2018 compared to 2017 and believes that it may even increase in the next several years as it grows its commercial organisation and continues to develop and commercialise its products. Curetis’ ability to achieve profitability depends on many factors which are beyond its control, such as its ability to achieve regulatory clearance for its products in its key markets and whether its products are commercially accepted in those markets. Curetis may not be able to generate sufficient revenues to achieve or sustain profitability.</li> <li>• Curetis is particularly dependent on the success of, and the ability to market, its lead products, the HPN and ITI Application Cartridges in the EU and the LRT Application Cartridge in the US, on which it has so far focused almost all of its business and financial resources. If these Application Cartridges do not achieve long-term commercial success, Curetis’ business, results of operations, financial position, cash flows and prospects will be adversely affected, and Curetis may find it difficult or impossible to obtain new funding to operate its business.</li> <li>• Curetis’ cash position and operating cash flow may be insufficient to cover expected investment expenses, and Curetis may need to raise additional funds in the future. If the Offering does not generate sufficient</li> </ul>

		<p>proceeds or if Curetis' cash needs are higher than anticipated, and Curetis is not able to generate sufficient funds from other sources, Curetis' cash and cash equivalents will not be sufficient for the next 12 months and it may run out of cash in January 2019. This may lead to Curetis not being able to continue as a going concern or filing for insolvency. In such event, the Company will reduce cash outflows, cut costs and reduce or delay operating and capital expenditures. These steps, although necessary, would ultimately have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects. In respect of its future funding requirements, Curetis may not be able to obtain additional funds on acceptable terms, or at all. If Curetis is not able to raise such additional funds, it may need to reduce its spending on its US operations and on its research and development, production or sales, marketing and service in Europe and its other markets as well as postponing necessary capital expenditures, which would have a negative impact on Curetis' competitiveness.</p> <ul style="list-style-type: none"> <li>• Curetis depends on a few key suppliers for critical product components including its Unyvero System and certain parts used in its Application Cartridges. If any one of these or future suppliers were to terminate its business relationship with Curetis, go out of business, discontinue manufacturing any of the products Curetis uses, or otherwise become unable to meet its supply commitments, the process of securing alternate sources could be lengthy. Such a development could lead to a delay in Curetis' ability to develop and market its existing or future products and increase its development and marketing costs. While Curetis may be able to modify its product candidates to utilise a new source for such critical parts or components, it would need to secure regulatory clearance from the relevant regulatory bodies in its markets for the modified product, which could take considerable time and necessitate significant expenses. Any of these scenarios could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.</li> <li>• Curetis' sales cycles are lengthy, and sales may fluctuate, which makes it difficult to forecast revenue and product sales. Curetis' sales process involves numerous interactions with multiple individuals and different stakeholder groups at potential customers' sites or organisations testing Curetis' products and will often include in-depth analysis by potential customers of Curetis' products, performance of validation or proof-of-principle studies, preparation of extensive documentation and a lengthy review process. The time from initial contact with a customer to the receipt of a purchase order will vary significantly and could be 12 months or longer in Europe and nine months or longer in the US. As a result, Curetis will likely experience fluctuations in product sales on a period-to-period basis. Furthermore, expected revenue streams are highly dependent on hospitals' adoption and use of Curetis' products, and it cannot be assured that Curetis' hospital clients will use and purchase Application Cartridges regularly. The failure to do so could have a</li> </ul>
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		material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.
	<b>Other risks relating to the Company and its industry</b>	<p>The following is a summary of all other risks that, alone or in combination with other events or circumstances could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects. Investors should read, understand and consider all risk factors, which risk factors are material and should be carefully read in their entirety, the section entitled "Risk Factors" beginning on page 35 of the Prospectus, before making an investment decision with respect to any Offer Shares.</p> <ul style="list-style-type: none"> <li>• Curetis' future growth and profitability depends on its ability to secure further clearance from the FDA for its products.</li> <li>• The molecular diagnostics market is highly competitive and Curetis may not be able to compete effectively.</li> <li>• Curetis may be unable to successfully commercialise its products and may fail to achieve and sustain sufficient market acceptance.</li> <li>• Curetis is dependent on the success of developing new products, obtaining new approvals, clearances or registrations from regulatory bodies and commercialising new products in the future, and expects to invest significant sums in the development and roll-out of new products.</li> <li>• Curetis may be unable to successfully manage its growth.</li> <li>• The market potential and opportunities for Curetis' products may be smaller than currently anticipated, lowering potential revenue for Curetis.</li> <li>• Curetis may expand its limited financial and managerial resources to pursue a particular future product or indication and fail to capitalise on products or indications that may be more profitable or for which there is a greater likelihood of success.</li> <li>• Curetis relies on certain distributors to distribute its products in some of its markets and intends to enter into additional distribution agreements to distribute its products in other markets. If Curetis is unable to find suitable distributors, loses these distributors or if Curetis' distributors fail to sell its products in sufficient quantities, on commercially viable terms or in a timely manner, Curetis' commercialisation of its Application Cartridges and other future products could be materially delayed or harmed.</li> <li>• Curetis may be unable to recruit, train and retain key personnel.</li> <li>• Curetis may not be able to gain the support of leading hospitals and KOLs or to achieve favourable publication of the results of Curetis' clinical trials in peer-reviewed journals.</li> <li>• Curetis' future success is dependent upon its ability to create, maintain and expand a customer base for its products in large and leading hospitals.</li> </ul>

		<ul style="list-style-type: none"> <li>• The selling price level in the MDx market could decrease in the future, which would adversely affect Curetis' business, results of operations, financial position, cash flows and prospects.</li> <li>• Curetis' current and future customers are highly dependent on payments from third-party payers. Inadequate coverage and reimbursement for Curetis' diagnostic tests, as well as a faster increase of Curetis' costs of production compared to increases in reimbursement levels, could compromise the commercial success of Curetis' products.</li> <li>• The manufacture of many of Curetis' products is a highly precise and complex process, and if Curetis encounters problems with the manufacturing and the quality of its products, its reputation and business could suffer.</li> <li>• Curetis' diagnostics results may not perform as expected and deliver incomplete or incorrect results, which could subject Curetis to product liability claims.</li> <li>• Patient injuries resulting from defects in Curetis' products could potentially lead to the products being recalled from the market or significant decline in market demand for the products. Defects, errors or a lack of sensitivity or specificity of the Unyvero Application Cartridges could also hinder its commercial roll-out and the conduct of regulatory clearance procedures. A recall of Curetis' products, either voluntarily or at the direction of the relevant regulatory bodies, or the discovery of serious safety issues with Curetis' products that leads to corrective actions could have a material adverse impact on Curetis.</li> <li>• Curetis may not be able to develop new products or enhance the capabilities of its products and systems to keep pace with the rapidly changing technology and customer requirements in the MDx industry.</li> <li>• If the manufacturing, development or testing equipment used by or for Curetis were damaged or destroyed, or if Curetis experiences a significant disruption in its operations or experiences any problems with its manufacturing processes for any reason, Curetis' ability to continue to operate its business could be materially harmed.</li> <li>• A significant amount of Curetis' inventory consists of equipment held by prospective customers who are evaluating its products and may not be converted to revenue in the timeframe that Curetis anticipates or at all.</li> <li>• Curetis' intention to enter into agreements with strategic partners in possession of or with an interest in proprietary platforms, technologies, IT or biomarkers for diagnosis of indications, with a view to developing and commercialising new diagnostic products, could prove unsuccessful.</li> <li>• Ares Genetics may be unable to successfully enter into licensing, partnering or service agreements and may fail to generate sufficient revenues to sustain itself as a business.</li> <li>• Acquisitions or joint ventures could disrupt and otherwise harm Curetis' business, and cause dilution to Curetis' shareholders.</li> </ul>
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		<ul style="list-style-type: none"> <li>• Curetis may lose its current tax losses carry forwards in case of certain events.</li> <li>• Curetis' operating results could be materially adversely affected by unanticipated changes in tax laws and regulations, adjustments to its tax provisions or exposure to additional tax liabilities or tariffs.</li> <li>• Curetis currently generates a portion of its revenue internationally and expects to increase this portion in the future. It is therefore subject to various risks relating to its international activities, which could adversely affect Curetis' operating results.</li> <li>• Curetis is exposed to changes in foreign currency exchange rates.</li> <li>• Curetis' employees, independent contractors, principal investigators, distributors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.</li> <li>• Curetis relies on third parties to conduct and support clinical and evaluation studies of its products that are required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily.</li> <li>• Curetis' business could be significantly and negatively affected by current or new governmental regulations and clearance, approval and post-approval requirements, particularly in the EU and the US.</li> <li>• Healthcare policy changes in the EU, the US, or any other of Curetis' target markets, including in particular legislation to reform the US healthcare system, may have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.</li> <li>• Modifications to Curetis' products, if cleared or approved, may require new clearances, pre-market approvals or registrations, or may require Curetis to cease marketing or recall the modified products until clearances, approvals or registrations are obtained.</li> <li>• Curetis' operations in the US are subject to federal and state healthcare fraud and abuse laws and other federal and state laws applicable to Curetis' business activities. If Curetis is unable to comply with such laws, it could face substantial penalties.</li> <li>• Curetis faces risks related to handling hazardous materials and other regulations governing environmental safety.</li> <li>• Curetis depends on its information technology systems, and any failure of these systems could harm Curetis' business.</li> <li>• Curetis has entered into lease agreements for its headquarters, in which its laboratory facilities are located, for a manufacturing plant, as well as other lease agreements in the US and Austria. The unexpected termination or non-renewal of these lease agreements could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.</li> </ul> <p><b>Risks Related to Intellectual Property</b></p>
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		<ul style="list-style-type: none"> <li>• If Curetis is unable to obtain, protect or enforce its intellectual property effectively, its business would be harmed.</li> <li>• Curetis may face difficulties in certain jurisdictions and enjoy only limited geographical protection with respect to certain patents, which may diminish the value of intellectual property rights in those jurisdictions.</li> <li>• Curetis uses certain technologies that are licensed to it. Curetis does not control the intellectual property rights covering these technologies and any loss of its rights to these technologies or the rights licensed to it could prevent Curetis from selling its products.</li> <li>• Curetis may be involved in lawsuits and other actions or proceedings to protect or enforce its patents and proprietary rights, to determine the scope, enforceability and validity of others' proprietary rights, or to defend against third-party claims of intellectual property infringement, any of which could be time-intensive and costly and may adversely impact Curetis' business or price of Shares.</li> <li>• Curetis relies on trade secret protection, confidentiality agreements and invention and patent assignment agreements.</li> <li>• Curetis may be subject to damages resulting from claims that Curetis or its employees, consultants or independent contractors have wrongfully used or disclosed confidential information or trade secrets of its former employees or other third parties.</li> <li>• If Curetis' trademarks and trade names are not adequately protected, Curetis may not be able to build name recognition in its markets of interest, and its business, results of operations, financial position, cash flows and prospects may be materially adversely affected.</li> </ul>
<b>D.3</b>	<b>Key risks relating to the Shares and the Offering</b>	<p>The following is a summary of selected key risks relating to the Offer Shares and the Offering. In making the selection, Curetis has considered circumstances such as the probability of the risk materializing on the basis of the current state of affairs and the potential impact which the materialization of the risk could have on the Offer Shares, and the attention that management would on the basis of current expectations have to devote to these risks if they were to materialize. Investors should read, understand and consider all risk factors, which risk factors are material and should be carefully read in their entirety, in the section entitled "Risk Factors" beginning on page 35 of the Prospectus, before making an investment decision with respect to any Offer Shares.</p> <ul style="list-style-type: none"> <li>• Should the anticipated gross proceeds of the Offering (excluding the PSOP Proceeds) fall below €8 million, the Offering will in any event be withdrawn, no Shares will be issued and any applications to subscribe for Offer Shares will be disregarded. If the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, Curetis will implement a detailed action plan to address the resulting working capital shortfall. The availability of the remainder</li> </ul>

		<p>of the first tranche of the Yorkville Agreement and the EIB Finance Contract are subject to certain conditions described below, including, in the case of the Yorkville Facility, the Yorkville Floor Price. The details of the plan would depend on the degree of the shortfall, but Curetis would initially focus on controlling its cash outflows through delaying planned increases in operating and capital expenditures and personnel hiring in favour of maintaining existing levels of expenditure. If these steps proved to be insufficient and the Offering fails to achieve at least the Mid-Point Proceeds, Curetis would need to implement further significant cost reductions. Such an action plan, although necessary, would ultimately have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects and the value of the Offer Shares. If Curetis fails to remedy a working capital shortfall caused by a failure to raise the Mid-Point Proceeds or a withdrawal of the Offering or otherwise, it may be unable to continue as a going concern and may ultimately have to file for insolvency, and investors may lose all or part of their investment in the Offer Shares.</p> <ul style="list-style-type: none"> <li>• The market price of the Shares may fluctuate significantly and be lower than the Offer Price, and investors could lose all or part of their investment. The stock markets in general, and the markets for medical technology, pharmaceutical and biotechnology shares in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of the Shares may significantly reduce as a result of the occurrence of a number of factors and events, some of which are beyond Curetis' control and investors may not be able to (re)sell their Shares at or above the Offer Price, or at all.</li> <li>• Certain existing Shareholders holding a substantial interest may influence the decision-making in the General Meeting. Following the Offering, these Shareholders will continue to be able to influence or control matters requiring the approval of the General Meeting, including but not limited to the appointment and dismissal of Managing Directors and Supervisory Directors, the distribution of dividends, amendments to the Articles of Association, any proposed capital increase or the approval of significant transactions. The concentration of ownership of Shares may adversely affect the trading volume and market price of the Shares and there is no indication as to whether or not, when or to what extent these Shareholders will sell any of their Shares. The interests of such Shareholders could deviate from the interests of other Shareholders and the existing Shareholders may delay, prevent or postpone transactions that might be advantageous for other investors.</li> <li>• Future issuances or sales of substantial numbers of Shares or securities convertible into Shares, or the perception that these issuances or sales may occur, may adversely affect the market price of the Shares and any future issuance of Shares may further dilute investors' shareholdings. The General Meeting has designated the Management Board as the corporate body authorised to issue Shares and grant rights to subscribe</li> </ul>
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		<p>for Shares subject to the limitations described above under item C.4 “Rights attached to the Shares” and as of 30 June 2018, options for an aggregate of 919,389 Shares have been granted under the ESOP 2016. Any additional debt or equity financing Curetis may need may not be available on terms favourable to Curetis or at all, which could adversely affect Curetis’ future plans and the market price of the Shares and could increase volatility in the trading price of the Shares. As many of the existing Shareholders are private equity or venture capital investors it is possible that those investors might want to reduce their stake in Curetis. Furthermore, a sale of Shares by any or all of the Managing Directors and/or Supervisory Directors could be considered to be a lack of confidence in the performance and prospects of Curetis and could cause the market price of the Shares to decline.</p> <ul style="list-style-type: none"> <li>• If securities or industry analysts cease to publish research reports on Curetis’ business, or adversely change or make negative recommendations regarding the Shares, the market price and trading volume of the Shares could decline.</li> </ul>
	<b>Other risks relating to the Shares and the Offering</b>	<p>The following is a summary of all other risks relating to the Offer Shares and the Offering. Investors should read, understand and consider all risk factors, which risk factors are material and should be carefully read in their entirety, in the section entitled “Risk Factors” beginning on page 35 of the Prospectus, before making an investment decision with respect to any Offer Shares.</p> <ul style="list-style-type: none"> <li>• There may be limited liquidity of the Shares, which may cause Shares to trade at a discount and make it difficult for investors to sell Shares at or above the Offer Price or at all.</li> <li>• The Company has broad discretion in the use of the net proceeds from the Offering and may not use them effectively.</li> <li>• Holders of Shares who are resident or located in certain jurisdictions outside the Netherlands, including the US, may be unable to exercise pre-emptive rights in future offerings and, as a result, may experience dilution.</li> <li>• If Settlement does not occur, subscriptions for the Offer Shares may be disregarded and transactions effected in the Offer Shares will be annulled.</li> <li>• The Company does not intend to pay dividends for the foreseeable future.</li> <li>• Investors with a reference currency other than euro will become subject to foreign exchange rate risk when investing in the Shares.</li> <li>• The ability of Shareholders to bring action or enforce judgments against the Company, Managing Directors and Supervisory Directors may be limited.</li> <li>• The Company may be a passive foreign investment company for US federal income tax purposes, which could subject US investors in the Shares to significant adverse tax consequences.</li> </ul>
<b>Section E – Offer</b>		

E.1	Net proceeds	<p>At the mid-point of the Offer Price Range, the Company would raise approximately €16.3 million of gross proceeds from the Offering (the “<b>Mid-Point Proceeds</b>”, which term is based on an Offer Price at the mid-point of the Offer Price Range (as defined below) and excludes the PSOP Proceeds). On the basis of the maximum number of Offer Shares the Company has the possibility to raise up to approximately €18.4 million in gross proceeds from the Offering (the “<b>Top-End Proceeds</b>”, which term is based on an Offer Price at the upper end of the Offer Price Range and excludes the PSOP Proceeds).</p> <p>Assuming the Company raises the Mid-Point Proceeds and all PSOP Offer Shares are issued and sold as part of the Offering, after deducting the estimated expenses, commissions and taxes related to the Offering of €2.5 million, which include approximately €0.88 million of fees and commissions payable to the Managers (as defined below), the Company expects to receive approximately €13.8 million in net proceeds from the Offering. At the date of the Prospectus, approximately €0.9 million in expenses, commissions and taxes have already been paid. Assuming the Company raises the Mid-Point Proceeds, the Offering will, therefore, result in €14.7 million additional funds being available to the Company.</p>
E.2a	Reasons for the Offering	<p>The principal purpose of the Offering is to obtain additional capital to support the execution of Curetis’ strategy. In addition, the Offering is expected to increase trading liquidity for the Shares. Furthermore, the Company intends to use the Offering to satisfy the Company’s obligations under the PSOP Roll-Over Agreements (as defined below).</p> <p><b><i>Proceeds for the Company</i></b></p> <p>Assuming the Company raises the Top-End Proceeds, the Company expects to generate approximately €16.8 million in additional available funds in the Offering.</p> <p>Curetis currently anticipates that over the coming year it will use the net proceeds of the Offering, in order of importance, as follows:</p> <ul style="list-style-type: none"> <li>• approximately 20% to 25% of the net proceeds of the Offering to maintain and continue to expand a direct commercial marketing, sales and support presence in the US in order to more broadly commercialise the Unyvero Platform and LRT Application Cartridge in the US via its own sales and marketing organisation;</li> <li>• approximately 10% to 15% of the net proceeds of the Offering to maintain and continue to expand its European commercial presence;</li> <li>• approximately 15% to 20% of the net proceeds of the Offering to fund working capital requirements to finance the placement of the Unyvero System in the direct selling EMEA markets as well as the US;</li> <li>• approximately 25% to 35% of the net proceeds of the Offering towards continuing to expand its research and development pipeline for the Unyvero System, the Application Cartridges and the Unyvero A30 RQ Analyzer for European, US and global markets;</li> </ul>

		<ul style="list-style-type: none"> <li>• approximately 5% to 10% of the net proceeds of the Offering for research and development programs of its Ares Genetics subsidiary around ARESdb and the ARES Technology Platform; and</li> <li>• approximately 5% to 10% of the net proceeds of the Offering for general corporate purposes, including to meet its obligations as a publicly listed company and cover administrative expenses.</li> </ul> <p>As of the date of the Prospectus, the Company cannot predict with certainty all of the specific uses for the net proceeds from the Offering, or the amounts to be spent on the uses set forth above. The amounts and timing of its actual use of the net proceeds will vary depending on numerous factors. As a result, the Company assumes broad discretion in the use of the net proceeds of the Offering.</p> <p>Pending the use of the proceeds from the Offering, the Company intends to invest the net proceeds in interest-bearing, cash and cash equivalents instruments or short-term certificates of deposit.</p> <p><b><i>Proceeds for the PSOP Beneficiaries</i></b></p> <p>As part of the Offering, the Company intends to issue and sell up to 342,803 Shares (the “<b>PSOP Offer Shares</b>”) on behalf of certain of Curetis’ directors and employees as well as former employees and consultants (the “<b>PSOP Beneficiaries</b>”). Curetis AG (now Curetis GmbH) operated a share-based compensation plan, the Curetis AG Phantom Stock Option Incentive Plan 2010 (“<b>PSOP</b>”). The PSOP was restructured as part of the Company’s IPO in 2015 and beneficiaries of more than 1,000 phantom stock options agreed to be settled in Shares pursuant to roll-over agreements to effect such restructuring (the “<b>PSOP Roll-Over Agreements</b>”). The PSOP Beneficiaries are entitled to an aggregate of 659,237 Shares under the PSOP Roll-Over Agreements. The Company intends to issue and sell 52% of these Shares (being the PSOP Offer Shares) on behalf of the PSOP Beneficiaries to generate funds (the “<b>PSOP Proceeds</b>”) to satisfy the PSOP Beneficiaries’ German income tax obligations as a result of the settlement of the PSOP Roll-Over Agreements. The costs relating to the issuance and sale of the PSOP Offer Shares in the Offering will be borne by the Company. The remaining 48% of the Shares (up to 316,434 Shares) to which the PSOP Beneficiaries are entitled under the PSOP Roll-Over Agreements will be issued and delivered to the relevant PSOP Beneficiaries on or about the Settlement Date. If the number of PSOP Offer Shares is reduced, the number of Shares to be issued to PSOP Beneficiaries on or about the Settlement Date will be reduced on a pro rata basis, and the PSOP Beneficiaries will remain entitled to any Shares not issued under the PSOP Roll-Over Agreements.</p>
E.3	<b>Terms and conditions of the Offering</b>	<p><b>Offer Shares</b></p> <p>The Company is offering up to 7,428,349 Offer Shares. The statutory preemptive rights relating to the issuance of the Offer Shares will be excluded. The Offer Shares constitute up to approximately 45.13% of the current issued share capital of the Company.</p> <p>The Offering consists solely of private placements to certain institutional investors in various jurisdictions. The Offer Shares are being offered: (i)</p>

within the United States to qualified institutional buyers as defined in Rule 144A (“**Rule 144A**”) under the US Securities Act of 1933, as amended (the “**US Securities Act**”) in reliance on Rule 144A or pursuant to another exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act, and (ii) outside the United States in offshore transactions in reliance on Regulation S under the US Securities Act. The Offering is made only in those jurisdictions in which, and only to those persons to whom, the Offering may be lawfully made.

#### **Timetable**

Subject to acceleration or extension of the timetable for, or withdrawal of, the Offering, the timetable below lists certain expected key dates for the Offering:

<b>Event</b>	<b>Time (CET) and date</b>
Start of Offer Period	09:00 on 2 November 2018
End of Offer Period for institutional investors	15:00 on 7 November 2018
Expected pricing and allocation	7 November 2018
First day of trading after close of the Offer Period	8 November 2018
Settlement Date	9 November 2018

#### **Offer Period**

Subject to acceleration or extension of the timetable for the Offering, prospective investors may subscribe for Offer Shares during the period commencing at 09:00 Central European Time (“**CET**”) on 2 November 2018 and ending at 15:00 CET on 7 November 2018 (the “**Offer Period**”). In the event of an acceleration or extension of the Offer Period, pricing, allocation, admission and first trading of the Offer Shares, as well as payment (in euro) for, and delivery of, the Offer Shares may be advanced or extended accordingly.

If a significant new factor, material mistake or inaccuracy relating to the information included in the Prospectus, which is capable of affecting the assessment of the Offer Shares, arises or is noted before the end of the Offer Period, a supplement to the Prospectus will be published and the Offer Period will be extended, if so required by the Dutch Financial Supervision Act (*Wet op het financieel toezicht*) or the rules promulgated thereunder. A supplement to the Prospectus is subject to AFM approval.

#### **Offer Price and Number of Offer Shares**

At the date of the Prospectus, the Offer Price is expected to be in the range of €2.00 to €2.60 (inclusive) per Offer Share (the “**Offer Price Range**”). The Offer Price Range is an indicative price range. The Offer Price may be set within, above or below the Offer Price Range. The Offer Price and the exact number of Offer Shares offered will be determined and agreed upon by the Company and the Managers after the end of the Offer Period, including any acceleration or extension, on the basis of the book-building process and taking into account the quoted share price, economic and market conditions, a

qualitative and quantitative assessment of demand for the Offer Shares, and other factors deemed appropriate.

The Company, after consultation with the Sole Global Coordinator, reserves the right to change the Offer Price Range and/or to increase the maximum number of Offer Shares prior to the allocation of the Offer Shares (“**Allocation**”). Any such change will be announced in a press release that will also be posted on the Company’s website.

The Offer Price, the exact number of Offer Shares to be issued will be stated in a pricing statement which will be published through a press release that will also be posted on the Company’s website and deposited with the AFM.

#### **Subscription and Allocation**

Allocation is expected to take place after the end of the Offer Period, on or about 7 November 2018, subject to acceleration or extension of the timetable for the Offering. Allocation to investors who applied to subscribe for Offer Shares will be determined by the Company, after consultation with the Managers, and full discretion will be exercised as to whether or not and how to allot the Offer Shares. There is no maximum or minimum number of Offer Shares for which prospective investors may subscribe and multiple (applications for) subscriptions are permitted. In the event that the Offering is over-subscribed, investors may receive fewer Offer Shares than they applied to subscribe for. The Company and the Managers may, at their own discretion and without stating the grounds therefore, reject any subscriptions wholly or partly. Any monies received in respect of subscriptions which are not accepted in whole or in part will be returned to the investors without interest and at the investor’s risk.

The Managers will notify investors or the relevant financial intermediary of any allocation of Offer Shares to them on the date of, or immediately following the date of, Allocation.

#### **Payment**

Payment (in euro) for, and delivery of, the Offer Shares (“**Settlement**”) is expected to take place on the settlement date, which is expected to be on or about 9 November 2018 (the “**Settlement Date**”). Taxes and expenses, if any, must be borne by the investor. Investors must pay the Offer Price in immediately available funds in full in euro on or before the Settlement Date (or earlier in the case of an early closing of the Offer Period and consequent acceleration of pricing, Allocation, commencement of trading and payment and delivery).

#### **Delivery of Offer Shares**

The Offer Shares will be delivered in book-entry form through the facilities of Nederlands Centraal Instituut voor Giraal Effectenverkeer B.V. (“**Euroclear Nederland**”). Closing of the Offering may not take place on the Settlement Date or at all if certain conditions or events referred to in the Underwriting Agreement (as defined below) are not satisfied or waived or occur on or prior to such date. If Settlement does not take place on the Settlement Date as planned or at all, the Offering may be withdrawn, in which case all subscriptions for the Offer Shares will be disregarded, any allotments made



will be deemed not to have been made, any subscription payments made will be returned without interest or other compensation. All dealings in Offer Shares prior to Settlement and delivery are at the sole risk of the parties concerned. Should the anticipated gross proceeds of the Offering (excluding the PSOP Proceeds) fall below €8 million, the Offering will in any event be withdrawn, no Shares will be issued and any applications to subscribe for Offer Shares will be disregarded.

#### **Underwriting Agreement**

The Company and the Managers entered into an underwriting agreement (the “**Underwriting Agreement**”) on 2 November 2018 with respect to the Offering.

After entering into the pricing agreement between the Company and the Managers (the “**Pricing Agreement**”), which is a condition for the obligations of the Managers under the Underwriting Agreement, and on the terms and subject to the conditions set out in the Underwriting Agreement, the Company will agree to issue the number the Offer Shares specified in the Underwriting Agreement at the Offer Price, as specified in the Pricing Agreement, to subscribers procured for by the Managers and the Managers will severally but not jointly agree to procure subscribers for, or failing subscription by such procured subscribers to subscribe themselves for, such number of Offer Shares at the Offer Price.

The Underwriting Agreement provides that the obligations of the Managers to procure subscribers for, or failing subscription by such procured subscribers to subscribe themselves for, the Offer Shares are subject to, among other things, the following conditions: (i) the approval of the Prospectus by the AFM being in full force and effect, (ii) receipt of opinions on certain legal matters from counsel, (iii) receipt of customary officers’ certificates, (iv) the absence of a material adverse effect on the business, financial position, results of operations or prospects of Curetis or in financial markets since the date of the Underwriting Agreement, (v) the admission of the Offer Shares to listing on Euronext in Amsterdam and Euronext in Brussels occurring no later than 09:00 a.m. CET on the Settlement Date and (vi) certain other customary conditions.

Upon the occurrence of certain specific events, such as the occurrence of (i) a material adverse change in the business, financial position, results of operations or prospects of Curetis or in financial markets since the date of the Underwriting Agreement, (ii) a material breach of the Underwriting Agreement or (iii) a statement in the Prospectus, the Pricing Statement or any amendment or supplement to the Prospectus being untrue, inaccurate or misleading, the Sole Global Coordinator (acting on behalf of the Managers) may elect to terminate the Underwriting Agreement at any time prior to the Settlement Date.

#### **Sole Global Coordinator, Sole Bookrunner and Sole Underwriter**

Baader Bank AG is acting as sole global coordinator, sole bookrunner and sole underwriter for the Offering.

#### **Placement Agent and Co-Manager**

		<p>goetzpartners securities Limited is acting as placement agent and co-manager for the Offering</p> <p>Baader Bank AG and goetzpartners securities Limited are together acting as managers for the Offering (the “<b>Managers</b>”).</p> <p><b>Listing Agent</b></p> <p>ABN AMRO Bank N.V. is acting as listing agent with respect to the listing of Shares on Euronext in Amsterdam and Euronext in Brussels and is also acting as paying agent for the Shares in the Netherlands.</p>
<b>E.4</b>	<b>Interests material to the Offering (including conflicting interests)</b>	<p>Certain of the Managers and/or their respective affiliates have in the past been engaged, and may in the future, from time to time, engage in commercial banking, investment banking and financial advisory and ancillary activities in the ordinary course of their business with Curetis or any parties related to it, in respect of which they have received, and may in the future receive, customary fees and commissions.</p> <p>Additionally, the Managers may, in the ordinary course of their business, in the future hold the Company’s securities for investment. In respect of the aforementioned, the sharing of information is generally restricted for reasons of confidentiality by internal procedures or by rules and regulations. As a result of these transactions, the Managers may have interests that may not be aligned, or could potentially conflict, with the interests of purchasers or with the interests of the Company.</p>
<b>E.5</b>	<b>Person or entity offering to sell the Offer Shares and lockup arrangements</b>	<p>The Company is offering to sell the Offer Shares.</p> <p>The restrictions of the lock-up arrangement described below, including those on sales, issues or transfers of Shares, may be waived by the Sole Global Coordinator (acting on behalf of the Managers), in its sole discretion and at any time. If the consent of the Sole Global Coordinator (acting on behalf of the Managers) in respect of a waiver of the lock-up arrangements is requested as described below, the Sole Global Coordinator (acting on behalf of the Managers) shall not unreasonably withhold its consent and may give its consent conditionally.</p> <p>Pursuant to the Underwriting Agreement, the Company has agreed with the Managers that, for a period from the date of the Underwriting Agreement until 180 days from the Settlement Date, it will not, except as set forth below, without the prior consent of the Managers, (i) directly or indirectly, issue, offer, pledge, sell, contract to sell, sell or grant any option, right, warrant or contract to purchase, exercise any option to sell, purchase any option or contract to sell, or lend or otherwise transfer or dispose of any Shares or other shares of the Company or any securities convertible into or exercisable or exchangeable for Shares or other shares of the Company or file any registration statement under the US Securities Act or any similar document with any other securities regulator, stock exchange or listing authority with respect to any of the foregoing; (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of any Shares or other shares of the Company, whether any such transaction is to be settled by delivery of Shares or such other securities, in cash or otherwise; (iii) publicly announce such an</p>

		<p>intention to effect any transaction referred to in (i) or (ii) above; or (iv) submit to its Shareholders or any other body of the Company a proposal to effect any of the foregoing.</p> <p>The foregoing shall not apply to: (a) the issue and offer by or on behalf of the Company of the Offer Shares, (b) the Company's obligations pursuant to the Yorkville Agreement and (c) the granting of awards in options or Shares by the Company or the issuance of Shares upon exercise of options granted by the Company pursuant to employee incentive schemes disclosed in, and as such grant or issue is disclosed in, the Prospectus (including, for the avoidance of doubt, the issuance of Shares in connection with and pursuant to the PSOP Roll-Over Agreements).</p>
<b>E.6</b>	<b>Dilution</b>	<p>The voting interest of the existing Shareholders will be diluted as a result of the issuance of the Offer Shares. The maximum dilution for the existing Shareholders not participating in the Offering pursuant to the issuance of the Offer Shares would be 31.1%, assuming the issuance of the maximum number of Offer Shares.</p>
<b>E.7</b>	<b>Estimated expenses charged to the investors by the Company</b>	<p>Not applicable. No expenses have been or will be charged to the investors by the Company in relation to the Offering.</p>

## RISK FACTORS

*An investment in the Offer Shares involves substantial risks. Accordingly, before deciding whether to invest in the Offer Shares, prospective investors should carefully consider the risks and uncertainties described below, together with all the other information contained or incorporated in this Prospectus. The occurrence of any of the events or circumstances described in these risk factors, individually or together with other circumstances, could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects. In that event, the value of the Offer Shares could decline, and investors may lose all or part of their investment.*

*All of these risk factors and events described below are contingencies that may or may not occur. Curetis may face a number of these risks described below simultaneously and one or more of the risks described below may be interdependent. The order in which risks are presented is not necessarily an indication of the likelihood of the risks actually materialising, of the potential significance of the risks or of the scope of any potential harm to Curetis' business, results of operations, financial position, cash flows and prospects.*

*The risk factors are based on assumptions that could turn out to be incorrect. Furthermore, although Curetis believes that the risks and uncertainties described below are the material risks and uncertainties relating to Curetis and the Offer Shares, other risks, facts or circumstances not presently known to Curetis, or that it currently deems to be immaterial, could, individually or cumulatively, prove to be important and could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects. The value of the Offer Shares could decline as a result of the occurrence of any such risks, facts or circumstances or as a result of the events or circumstances described in these risk factors, and prospective investors could lose part or all of their investment.*

*Prospective investors should read and carefully review the entire Prospectus and should reach their own views before making an investment decision with respect to any Offer Shares. Furthermore, before making an investment decision with respect to any Offer Shares, prospective investors should consult their own stockbrokers, bank managers, lawyers, auditors or other financial, legal and tax advisers and carefully review the risks associated with an investment in the Offer Shares and consider such an investment decision in light of their personal circumstances.*

### **Risks Related to Business and Strategy**

***Curetis is a company with only a limited number of products approved for commercialisation, has incurred significant losses since inception and expects to incur significant losses in the foreseeable future. It is not certain that Curetis will achieve or sustain profitability.***

Curetis has incurred significant losses in each period since its inception in 2007, except for the financial year 2015 where Curetis had a net profit as a result of a reorganisation, and expects to incur significant losses in the foreseeable future. Since the date of its inception, the cumulative net losses of Curetis have amounted to €150,976 thousand as of 30 June 2018, and Curetis incurred net losses of €19,327 thousand for the year ended 31 December 2017 and €11,732 thousand for the six months ended 30 June 2018. Currently, Curetis expects its net cash burn, or cash outflow from operating activities and investing activities, to increase from €16,102 thousand in 2017 to approximately €30,000 thousand in 2018. Curetis expects that its cash burn rate will continue to be at similarly high levels or even increase in the next several years, as Curetis plans to invest significant additional funds towards further growth of its commercial organisation and the commercial roll-out of the Unyvero lower respiratory tract ("LRT") application cartridge (the "Application Cartridge") in the United States of America ("US"), as well as the development and commercialisation of its other products, which also includes obtaining and maintaining certification, regulatory clearance or registration of its products for markets where this is required. Curetis also expects that its distribution costs and administrative expenses will

continue to increase due to the establishment of, or further investments in, a dedicated sales force, a distribution network and other marketing efforts for its products. Costs associated with the Offering will also be incurred.

Curetis' ability to achieve profitability depends on numerous factors, many of which are beyond the control of Curetis. Examples include Curetis' ability to continue to comply with conformity assessment procedures and regulatory requirements in the European Union ("EU"), and achieve and maintain further regulatory clearances for Curetis' future products, including from the US Food and Drug Administration ("FDA") and the Food and Drug Administration in China ("CFDA"), as well as on regulatory clearance or registrations from regulators in markets that Curetis is in the process of developing, or which it plans to develop, such as Singapore, other ASEAN markets, Egypt, Brazil and Japan, among others. In addition, Curetis' ability to achieve profitability also depends on market acceptance of its products, Curetis' future product development and Curetis' market penetration and margins. Curetis may not be able to generate sufficient revenues to achieve or sustain profitability.

***Curetis is particularly dependent on the success of, and the ability to market, its lead products, the HPN and ITI Application Cartridges in the EU and the LRT Application Cartridge in the US, on which it has so far focused almost all of its business and financial resources.***

Curetis is currently not a broadly diversified company. Therefore, Curetis' ability to generate revenues in the near- to medium-term depends particularly on the success of its three lead products, the HPN and ITI Application Cartridges in the EU and the LRT Application Cartridge (which is technically similar to the HPN Application Cartridge) in the US. Curetis has invested significant time, money and effort on the development and commercialisation, including costs of clinical studies in the EU and the US, of the HPN/LRT and ITI Application Cartridges. In addition, Curetis expects to continue to focus a significant portion of its personnel and financial resources on the commercialisation of the LRT Application Cartridge and its roll-out in the US and to continue its commercial conversion campaign in Europe, the Middle East and Africa ("EMEA"), which is currently focused on the HPN and ITI Application Cartridges.

If the HPN and ITI Application Cartridges in European markets or LRT Application Cartridges in the US markets do not achieve long-term commercial success, Curetis' business, results of operations, financial position, cash flows and prospects will be adversely affected, and Curetis may find it difficult or impossible to obtain new funding to operate its business.

***Curetis' cash position and operating cash flow may be insufficient to cover expected investment expenses, and Curetis may need to raise additional funds in the future.***

As of 30 June 2018, following the successful completion of an equity offering in May 2018, Curetis had cash and cash equivalents of €11,646 thousand. In addition, Curetis has access to up to an additional €12,000 thousand of cash under a debt financing facility for up to €25,000 thousand total with the European Investment Bank ("EIB") as lender under the loan agreement originally dated 12 December 2016, as amended by an amendment letter (the "**Amendment Letter**") dated 20 April 2018, (the "**EIB Finance Contract**"). Curetis drew down the first tranche of €10,000 thousand under this facility in April 2017. Under the second tranche, with an aggregate commitment of €15,000 thousand, a disbursement of €3,000 thousand was drawn down and disbursed on 22 June 2018 following the fulfilment of the key condition in April 2018 that the FDA clear the Unyvero System and the LRT Application Cartridge. Pursuant to the Amendment Letter, the disbursement of the balance of the second tranche, with an aggregate commitment of €12,000 thousand, is subject to (i) the FDA clearance of Unyvero system and LRT Application Cartridge and disbursement of the €3,000 thousand, as described in the previous sentence, (ii) Curetis having raised cumulative new equity of at least €15,000 thousand, which was partly accomplished through the issuance of €4,100 thousand in an equity offering in May 2018, and in respect of which a second disbursement of up to €5,000 thousand will become available and (iii) following the fulfilment of conditions (i) and (ii) and the €5,000 thousand disbursement under (ii) having been

disbursed, Curetis having installed 350 Unyvero Analyzers globally as well as Curetis' consolidated revenues being at least €10,000 thousand over the 12 months preceding the request for the loan disbursement, in respect of which a third disbursement of €7,000 thousand will become available.

Curetis has furthermore entered into (i) a US\$10,000 thousand equity facility dated 26 April 2018 (the “**GCF Equity Facility**”) with Global Corporate Finance corporation (“**GCF**”) under which it may require GCF to subscribe for Shares and (ii) a financing facility agreement dated 2 October 2018 with YA II PN, Ltd, an investment fund managed by Yorkville Advisors Global LP, a U.S.-based management firm (“**Yorkville**” and such facility agreement, the “**Yorkville Agreement**”) for up to €20,000 thousand in aggregate principal amount through the issuance by the Company of convertible notes (the “**Convertible Notes**”) to Yorkville, in both cases subject to certain terms and conditions thereunder being met which are described in detail below. Curetis estimates its current cash burn rate, or cash outflow from operating activities and investing activities, will be approximately €30,000 thousand in the year ended 31 December 2018, compared to €16,102 thousand in the year ended 31 December 2017.

Curetis believes its operations will require additional cash resources of approximately €23 million assuming the execution of Curetis' current business plan to provide it with sufficient working capital for the next twelve months from the date of this Prospectus. If the Offering is completed and additional available funds of approximately €16.8 million are generated in the Offering (which would only be the case if the Company raises the Top-End Proceeds), these proceeds together with the €1.4 million in net proceeds expected to be received from the remainder of the first tranche under the Yorkville Agreement and an additional €5.0 million debt financing which is expected to be available from the EIB Finance Contract (as explained further above) would provide it with additional working capital of €23.2 million as a result of which the Company would have sufficient working capital for the next twelve months from the date of this Prospectus. The availability of the remainder of the first tranche of the Yorkville Agreement and the EIB Finance Contract are subject to certain conditions described below, including, in the case of the Yorkville Facility, the Yorkville Floor Price.

If the Offering should be withdrawn or otherwise not be completed, or if the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, or if Curetis' cash burn is higher than expected due to lower revenues or for other reasons, Curetis will implement a detailed action plan to address the resulting working capital shortfall. The details of the plan would depend on the degree of the shortfall, but Curetis would initially focus on controlling its cash outflows through delaying planned increases in operating and capital expenditures and personnel hiring in favour of maintaining existing levels of expenditure. Curetis would in this case postpone the investment into injection molds and manufacturing line equipment for the Unyvero A30 RQ Application Cartridges, which would delay the development and commercial launch of the Unyvero A30 RQ platform. Curetis would further postpone the investment into additional multi-cavity injection molds, which are expected to result in cost savings in the manufacture of the Unyvero A50 Platform Application Cartridges. If these steps proved to be insufficient and the Offering fails to achieve at least the Mid-Point Proceeds, Curetis would need to implement further significant cost reductions. Primarily, Curetis would in this scenario not continue the expansion of, or even reduce, its US commercial organisation and suspend its cost-intensive additional FDA clinical trials in the US. Such cost-cutting measures would significantly adversely impact Curetis' business. For example, they would prevent Curetis from obtaining FDA clearance for its IJI Application Cartridge or the BAL extension for its LRT Cartridge, and thus prevent Curetis from selling those products into the US market. As a consequence, future revenue expectations from the US would be greatly reduced. In addition, Curetis would reduce its staff expenditure by potentially reducing its workforce, which would have an adverse impact on its manufacturing capacity, research and development pipeline and/or ongoing commercialisation efforts. Such an action plan, although necessary, would ultimately have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects. See “— *Risks Related to the Offer Shares and the Offering* —

*Should the anticipated gross proceeds of the Offering (excluding the PSOP Proceeds) fall below €8 million, the Offering will in any event be withdrawn, no Shares will be issued and any applications to subscribe for Offer Shares will be disregarded. If the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, Curetis will implement a detailed action plan to address the resulting working capital shortfall. If delaying planned increases in expenditures is insufficient, such an action plan would include significant cost reductions which, although necessary, would ultimately have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects and the value of the Offer Shares.” and “Capitalisation, Indebtedness and Working Capital — Working Capital Statement”.*

In the event the Offering is withdrawn or otherwise not completed, and Curetis is not able to address its working capital shortfall, Curetis would, in addition to the cost reduction and financing measures outlined above, be required to raise additional financing by obtaining other equity and/or debt financing for it to have sufficient cash to maintain its operations and to continue as a going concern for at least 12 months from the date of this Prospectus. Curetis will therefore continue to pursue various strategic and tactical financing alternatives.

The availability to Curetis of such additional financing is subject to a number of external factors, including the satisfaction of certain conditions precedent which may be beyond Curetis' control and the willingness of investors to provide additional equity or debt financing on terms acceptable to Curetis. As a result, it is uncertain if Curetis will be able to obtain sufficient financing to continue as a going concern for at least 12 months from the date of this Prospectus if the Mid-Point Proceeds are not raised.

If Curetis fails to implement the above measures to remedy a working capital shortfall caused by a withdrawal of the Offering or a failure to raise the Mid-Point Proceeds or otherwise, such as the generation of sufficient funds from additional financing and the cost reduction measures described above, it may be unable to continue as a going concern and may ultimately have to file for insolvency. See also “*Capitalisation, Indebtedness and Working Capital — Working Capital Statement*”.

In addition, even if Curetis raises the Mid-Point Proceeds in the Offering and its cash and cash equivalents are sufficient for the next 12 months, in the future the Company may need to raise substantial additional capital to:

- expand Curetis' product offerings;
- expand Curetis' sales and marketing infrastructure, in particular, in the US;
- increase Curetis' manufacturing capacity;
- continue Curetis' research and development activities; and
- fund Curetis' operations and build its inventory of Unyvero Systems.

Curetis' future funding requirements will depend on many factors, some of which are beyond Curetis' control, including:

- the cost and timing of marketing or obtaining and maintaining regulatory clearances and registrations, including CE-IVD-marking and FDA clearance for pipeline and future products;
- market acceptance of Curetis' products;
- the cost and timing of establishing further sales, marketing and distribution capabilities;
- the cost of Curetis' research and development activities;

- the ability of healthcare providers to obtain coverage and adequate reimbursement by third-party payers for procedures using Curetis' products;
- the cost of goods associated with Curetis' products;
- the effect of competing technological and market developments; and
- the extent to which Curetis is to decide to invest in third-party businesses, products and technologies, including entering into licensing or collaboration arrangements for products.

In respect of its future funding requirements, Curetis may not be able to obtain additional funds on acceptable terms, or at all. If Curetis is not able to raise such additional funds, it may need to reduce its spending on its US operations and on its research and development, production or sales, marketing and service in Europe and its other markets as well as postponing necessary capital expenditures, which would have a negative impact on Curetis' competitiveness. In addition, Curetis would also have to suspend its further FDA trials and submissions in the US, which may prevent or delay further FDA clearances for its pipeline and other future products, such as the Unyvero A30 RQ Analyzer and any new Application Cartridges, and thus not be able to sell such products in the US market. As a consequence, Curetis' future revenues from the US and EMEA would be lower than expected or would be generated only with a significant delay.

If Curetis raises additional funds by issuing equity or equity-linked securities, Curetis' shareholders may experience dilution. Under the GCF Equity Facility, the Company may require GCF to subscribe for Shares up to an aggregate subscription amount of US\$10,000 thousand over a three-year period. GCF is however not under an obligation to subscribe for Shares if the Company is in breach of material obligations under the GCF Equity Facility, there is a reasonable allegation of fraud committed by the Company or its officers, the Company undergoes a change of control, the Shares cease to be listed or trading in the Shares is suspended continuously for more than five days on which Euronext in Amsterdam is open, or if the subscription price falls below a pre-set floor price (which floor price shall not be lower than €4.50 unless otherwise agreed between Curetis and GCF), subject to adjustments to reflect variations in the share capital of the Company. As at 30 October 2018, the share price of the Company quoted on Euronext was less than the GCF Floor Price (as defined below) and the Company therefore will, unless otherwise agreed with GCF, not have been permitted to make any drawings under the GCF Equity Facility until the subscription price per share, which is equal to 95% of the volume weighted average price of the Shares on Euronext in Amsterdam over the five trading days following a sales notice by Curetis to GCF, exceeds the GCF Floor Price. In addition, the full US\$10,000 thousand is not accessible by the Company at one time, but rather only in US\$500 thousand tranches which the Company is restricted from initiating more than one time in any three-week period, unless previously agreed with GCF. Furthermore, as described below, the Yorkville Agreement imposes certain restrictions on the ability of the Company to access the GCF Equity Facility. See "*Business – Material Contracts – Financing Arrangements – GCF Equity Facility*".

Under the terms of the Yorkville Agreement, Yorkville has committed to subscribe for up to 2,000 Convertible Notes with a principal amount of €10,000 per note, divided into multiple tranches, over a period of 36 months from the date of the agreement. The funding of a tranche of Convertible Notes under the Yorkville Agreement, including the remaining €1,500 thousand available under the first tranche of Convertible Notes, is subject to certain conditions precedent being satisfied or waived by Yorkville, including a minimum closing Share price of €3.00 on Euronext in Amsterdam (the "**Yorkville Floor Price**") on the day prior to the sending of a request and the combined average daily Share value traded on Euronext in Amsterdam and Euronext in Brussels in the week prior to the request being at least €150 thousand. The upper end of the Offer Price Range and, as at 30 October 2018, the share price of the Company quoted on Euronext in Amsterdam, was less than the Yorkville Floor Price and the Company therefore would, unless otherwise agreed with Yorkville, not be permitted to make any additional drawings under the Yorkville Agreement, including the remaining part of the first tranche drawn



under the Yorkville Agreement, until the share price of the Company quoted on Euronext in Amsterdam exceeds the Yorkville Floor Price. Furthermore, under the Yorkville Agreement, the Convertible Notes have an initial maturity of one year, which may be extended in certain circumstances. The Company is restricted from submitting a request to fund a subsequent tranche of Convertible Notes under the Yorkville agreement until after the tenth calendar day following the conversion into Shares and/or redemption of all the outstanding Convertible Notes issued under the previous tranches. Furthermore, the Company is not allowed under the Yorkville Agreement to participate in variable rate equity financing transactions (such as an issue of Shares under the GCF Equity Facility) from 30 days prior to the request for the disbursement of a tranche of Convertible Notes until the 20th business day following the redemption or conversion of such Convertible Notes. See “*Business – Material Contracts – Financing Arrangements – Yorkville Financing*”.

Debt financing, if available, may include covenants restricting Curetis’ operations or its ability to incur additional debt. For example, Curetis’ EIB Finance Contract includes restrictions on acquisitions, granting guarantees and security and incurring additional financial indebtedness. In addition, the granting of the loans under the EIB Finance Contract is limited to the purpose of financing the development of novel, future test panels on platforms such as the Unyvero platform provided that the loans made available by EIB, up to an aggregate amount of €25,000 thousand, shall not exceed 50% of the total cost of such development. Any debt or additional equity financing that Curetis raises may be on terms that are not favourable to Curetis or its shareholders. If Curetis raises additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to its Unyvero Platform, Unyvero A30 RQ Analyzer or ARES Technology Platform related assets, or to grant licences on terms that are not favourable to it, which could reduce its ability to generate future revenues and achieve profitability.

Any of the foregoing risks, if they materialize, could have a material adverse effect on Curetis’ business, results of operations, financial position, cash flows and prospects.

***Curetis depends on a few key suppliers for critical product components. In case of a loss of any of these suppliers or an interruption of supply, or if supplies were found to be faulty or contaminated, Curetis may not be able to manufacture or outsource manufacturing of its products in sufficient quantities, in a timely manner or at a cost that is economically attractive.***

Curetis currently depends on a number of key suppliers for critical product components, such as Zollner Elektronik AG (“**Zollner**”) for the manufacture of its Unyvero System, Contexo GmbH (“**Contexo**”) for the Application Cartridge manufacturing equipment and Horst Scholz GmbH & Co. KG (“**Scholz**”) for certain components (i.e. all plastic parts for the Unyvero Application Cartridges), as well as certain single source suppliers for specific Unyvero amplification primers, detection probes, reagents and the master mix (including traces of Triton X – a substance which the European Commission has indicated that it may ban in the EU in the future) (“**Master Mix**”), which is the enzyme required to start the polymerase chain reaction (“**PCR**”) and thus is one of the critical components of any PCR-based MDx test. Furthermore, Curetis may decide to outsource part of its cartridge manufacturing efforts to third parties in the future, which may result in delayed or interrupted supply of cartridges in case such third-party providers do not deliver on time or do not meet required quality levels.

If any one of these or future suppliers were to terminate its business relationship with Curetis, go out of business, discontinue manufacturing any of the products Curetis uses (which may be particularly relevant for the Unyvero A50 Analyzer, given its technical complexity with respect to its components and supply chain), or otherwise become unable to meet its supply commitments (for example, due to contamination, equipment malfunction, loss of regulatory compliance or registration, shortage of raw materials or components, or catastrophic events like fire), the process of securing alternate sources could be lengthy. Such a development could lead to a delay in Curetis’ ability to develop and market its existing or future products and increase its development and marketing costs.

For example, Curetis experienced significant delays and shortages arising from its instrument contract manufacturer, Zollner, in the early years of its Unyvero Platform's commercial roll-out after Zollner had not yet been able to produce sufficient quantities of the Unyvero System at the required quality level in 2012 and 2013, which led several distributors and customers to reduce or delay their purchases of Unyvero System. In addition, in 2014, due partly to those quality issues, Curetis had to put on hold its US clinical trials and the process of obtaining FDA clearance and could only resume with the new generation LRT Application Cartridge in 2015. While these quality issues have since been resolved with a series of additional technical changes to the Application Cartridges, Unyvero Systems and software packages, similar or other problems with the manufacturing process or more serious issues may occur in the future.

There can be no assurance that replacement products or components will be available that would meet Curetis' quality and performance requirements within an acceptable time or at all. In addition, although Curetis believes that it has resolved many of the early-stage production problems and supply-chain problems related to the Unyvero System that it encountered in the early phases of commercial development, such problems could recur due to a variety of reasons in the future (see "*— The manufacture of many of Curetis' products is a highly precise and complex process, and if Curetis encounters problems with the manufacturing and the quality of its products, its reputation and business could suffer.*"). While Curetis may technically be able to modify its product candidates to utilise a new source for such critical parts or components, it would need to secure CE-IVD-marking and regulatory clearance from the FDA and any other relevant regulatory body in other markets for the modified product, and it could take considerable time and necessitate significant expenses to perform the requisite tasks prior to, and in connection with, a petition for renewed market clearance.

Any loss of any of these suppliers or an interruption of supply, or if supplies were found to be faulty or contaminated, or if Curetis is unable to manufacture or outsource manufacturing of its products in sufficient quantities, in a timely manner or at a cost that is economically attractive, could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis' sales cycles are lengthy, and sales may fluctuate, which makes it difficult to forecast revenue and product sales.***

Curetis' sales process involves numerous interactions with multiple individuals and different stakeholder groups (such as microbiologists, intensive care unit ("ICU") clinicians and hospital administration) at potential customers' sites or organisations testing Curetis' products and will often include in-depth analysis by potential customers of Curetis' products, performance of validation or proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors and the budgetary cycles of Curetis' potential customers, the time from initial contact with a customer to the receipt of a purchase order will vary significantly and could be 12 months or longer in Europe and nine months or longer in the US. Sales cycles can be particularly long when key opinion leaders' ("KOLs") sites in university hospitals are involved because commercial conversion following the initial studies at KOL sites and scientific research and publications can take substantially longer.

Given the length and uncertainty of the anticipated sales cycle, Curetis will likely experience fluctuations in product sales on a period-to-period basis. For example, sales of Curetis' products often involve purchasing decisions by large public and private institutions, and any purchases can require multiple levels of pre-approval or public tender procedures. In addition, those large institutions, such as public universities and other KOL sites, frequently depend on government grants or public funding themselves, indirectly making Curetis' sales dependent on those funding sources. In case of large chains or purchasing pools of groups of hospitals, the decision to approve Curetis' products may impact multiple potential customer accounts and thus may have a significant positive or negative impact on revenues. Furthermore, expected revenue streams are highly dependent on hospitals' adoption and use of Curetis' products, and it cannot be assured that Curetis' hospital

clients will use and purchase Application Cartridges regularly. The failure to do so could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis' future growth and profitability depends on its ability to secure further clearance from the FDA for its products.***

Prior to and also following the clearance by the FDA of its Unyvero automated sample-to-answer molecular diagnostics ("MDx") system and its LRT Application Cartridge addressing LRT infections on 3 April 2018, Curetis has continued to develop its commercial organisation in the US to achieve a successful rollout of the Unyvero system, a system comprising of Unyvero L4 Lysator (the "**Unyvero L4 Lysator**"), Unyvero C8 Cockpit (the "**Unyvero C8 Cockpit**") and Unyvero A50 Analyzer (the "**Unyvero A50 Analyzer**"), (collectively the "**Unyvero System**" and together with proprietary software and the application-specific single use application cartridges, the "**Application Cartridges**", the "**Unyvero Platform**") and the LRT Application Cartridge. However, Curetis' ability to obtain FDA clearance for other Application Cartridges in Curetis' pipeline, including the Unyvero Invasive Joint Infections ("**IJI**") Application Cartridge, which is currently scheduled to be the second cartridge to go through an FDA trial, the additional clearance of bronchoalveolar lavage ("**BAL**") as a second sample type for the LRT Application Cartridge, and future Application Cartridges for the US market targeting other infectious disease indications in hospitalised patients, will be crucial to its long-term success in the US market.

The process of obtaining and maintaining FDA clearance is expensive and time-consuming and can vary substantially based upon, among other things, the type, complexity and novelty of Curetis' products, as well as upon access to a sufficient number of relevant clinical samples (see "*— Curetis' business could be significantly and negatively affected by current or new governmental regulations and clearance, approval and post-approval requirements, particularly in the EU and the US.*").

Despite recently clearing Curetis' Unyvero System and LRT Application Cartridge, the FDA has substantial discretion in the review and clearance processes and may refuse to clear future Application Cartridges. For example, the FDA may ultimately not clear the IJI Application Cartridges or may decide that Curetis' trial design is insufficient for clearance and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory clearance from the FDA. If, during future clinical trials, only an insufficient number of pathogens, clinical cases and samples can be found for the pathogens and resistance markers on the relevant Application Cartridge, the FDA might not clear all analytes that Curetis might submit for any given Application Cartridge in a first pass, and, as a result, costly and time-consuming additional filings would be required. For example, only 29 out of the 36 submitted assays were cleared by the FDA when it cleared the LRT Application Cartridge in April 2018. Clinical studies could also show that future Application Cartridges submitted by Curetis may not be sufficiently sensitive or specific to obtain or may prove to have other characteristics that preclude Curetis from obtaining, clearance from the FDA.

If Curetis' future attempts to obtain and maintain regulatory clearance from the FDA for its Application Cartridges are unsuccessful, or only partly successful, with some Application Cartridges being cleared and others not being cleared or only a subset of analytes being cleared, Curetis may be unable to justify the investments that it is currently making in the US, including the development of its commercial organisation. Even if regulatory clearance is obtained for its future Application Cartridges, the relevant clearances may have a restrictive scope or contain limitations, which make it commercially unattractive to Curetis to market such Application Cartridges. This could in turn have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***The molecular diagnostics market is highly competitive and Curetis may not be able to compete effectively.***

Curetis competes with other commercial diagnostics companies and anticipates that it will face strong competition in the future, as expected competitors develop new or improved products and as new companies enter the market with new technologies. There are several other companies who develop and commercialise 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 Inc. (T2DX™), Luminex Corporation (formerly known as Nanosphere) (Verigene System™ and Aries™), Atlas Genetics (with its io™ System), Roche (Cobas with the Liat™ and Genewave platform), Qiagen (QiaStat-dx™) and Biocartis N.V (Idylla™), Bosch with the Vivalytic™ platform and the GenePOC Revogene™ system. (see “Industry — Competition”).

Many of Curetis’ competitors are either publicly traded or are divisions of publicly traded companies, and have a number of competitive advantages over it, including:

- greater name and brand recognition;
- greater financial and human resources;
- established and broader product lines;
- larger sales forces and more established distribution networks;
- more substantial intellectual property portfolios;
- larger and more established customer bases and relationships; and
- better established, larger scale and lower-cost manufacturing capabilities.

Curetis may not effectively compete or be successful in the face of increasing competition from new products and technologies introduced by Curetis’ existing competitors or new companies entering Curetis’ markets. In addition, it is possible that Curetis’ future competitors will have or develop competitive products or technologies with greater capabilities or lower costs than Curetis’ products. GenMark, for example, has developed a directly competitive product (ePlex platform) to the Unyvero Platform, which also targets rapid pathogen identification. In addition, other companies like STAT Diagnostica (recently acquired by Qiagen) Accelerate Diagnostics, Luminex and bioMérieux have announced similar technologies and respiratory tests. As an example of antibiotic resistance testing, one competing product is offered by Roche, following the acquisition of Genewave Biosciences, which promises faster phenotypic testing (about four hours) via its Smarticles™ Technology. Competitors may also be able to respond more quickly and effectively than Curetis to new or changing opportunities, technologies, standards, customer or regulatory requirements. If Curetis fails to compete successfully, it could have a material adverse effect on its business, results of operations, financial position, cash flows and prospects.

***Curetis may be unable to successfully commercialise its products and may fail to achieve and sustain sufficient market acceptance.***

Curetis began marketing and selling its products in 2012. So far, Curetis has built up its direct sales and marketing platform for the Unyvero System and Application Cartridges addressing hospitalised pneumonia (“HPN”), implant and tissue infection (“ITI”), bloodstream infection from positively flagged blood cultures (“BCU”), intra-abdominal infection (“IAI”) and urinary tract infection (“UTI”) in Germany, the United Kingdom (the “UK”), France, Switzerland, Belgium, the Netherlands and Luxembourg, and has only recently begun to commercialise its Unyvero System and the LRT Application Cartridge in the US following the

clearance by the FDA. Thus, it has relatively limited experience in marketing and selling its products in Europe and in the US.

In other markets, Curetis relies on a third-party distribution model. As at 30 October 2018, Curetis has entered into distribution agreements with 17 distributors covering 29 countries (*see “— Curetis relies on certain distributors to distribute its products in some of its markets and intends to enter into additional distribution agreements to distribute its products in other markets. If Curetis is unable to find suitable distributors, loses these distributors or if Curetis’ distributors fail to sell its products in sufficient quantities, on commercially viable terms or in a timely manner, Curetis’ commercialisation of its Application Cartridges and other future products could be materially delayed or harmed.”*). Although Curetis has made progress in expanding its network of distributors, many of these commercial relationships are quite recent, and cover a relatively narrow range of products. As a result, Curetis has relatively limited experience in marketing and selling its products in other jurisdictions.

Curetis’ future sales of diagnostic products will depend in large part on Curetis’ ability to successfully commercialise its current and future products in its target markets and sustain sufficient market acceptance. In particular, its future sales will depend on Curetis’ ability to sell its products in the US. However, its development of a sales force in the US was only recently initiated. Curetis’ ability to forecast demand in the US and to develop and maintain the infrastructure required to support such demand and the sales cycle of Curetis’ potential customers is largely unproven. If Curetis does not maintain an efficient and effective sales force and distribution network in the US or cannot successfully expand its distribution network in Europe or elsewhere, Curetis’ business, results of operations, financial position, cash flows and prospects may be materially and adversely affected.

In addition, Curetis may not be able to sufficiently demonstrate to physicians, hospitals and other healthcare providers that its currently available Application Cartridges and future Application Cartridges are appropriate or preferable options for aiding in the diagnosis of infectious diseases. In particular, the price of Curetis’ Application Cartridges is much higher than, and will be incurred in addition to, the costs for conventional microbiology culture tests. There can be no assurance that hospitals will be willing to incur the direct costs to purchase Curetis’ products or that the government or commercial payers will be willing or able to reimburse hospitals for them. If tightened budgets prevent hospitals from being able to pay for Curetis’ products, or if government or commercial payers refuse to reimburse such hospitals for these payments, it could have a material adverse effect on Curetis’ business, results of operations, financial position, cash flows and prospects.

Furthermore, Curetis may encounter significant difficulty in having its current and future Application Cartridges included in treatment guidelines of hospitals worldwide, as well as in complying with applicable local regulations and guidelines, which is often a prerequisite for hospitals purchasing Curetis’ products in any significant quantity, or in gaining broad market acceptance by healthcare providers, third-party payers and patients using the Unyvero System and Application Cartridges. Furthermore, changes in reimbursements policies in one or more markets, may impact the ability of Curetis’ customers to purchase its products.

If Curetis fails to successfully commercialise its products, it may not be able to receive a return on the significant investments it has made and will continue to make in product development, sales and marketing, regulatory clearance, manufacturing and quality assurance, and it may fail to generate sufficient revenues and gain economies of scale from such investments, all of which could have a material adverse effect on Curetis’ business, results of operations, financial position, cash flows and prospects.

***Curetis is dependent on the success of developing new products, obtaining new approvals, clearances or registrations from regulatory bodies and commercialising new products in the future, and expects to invest significant sums in the development and roll-out of new products.***

Curetis expects to invest significant sums in the development and roll-out of new products. For example, the real-time quantitative PCR (“qPCR”)-based Gyronimo platform, a prototype version of the Unyvero A30 RQ Analyzer (the “**Unyvero A30 RQ Analyzer**”), was acquired from Carpegen GmbH (“**Carpegen**”) and Systec Elektronik und Software GmbH (“**Systec**”) in December 2016 (the “**Gyronimo Acquisition**”). The Unyvero A30 RQ Analyzer is currently in the development stage and is intended to be integrated into the Unyvero System suite of products. Marketing is expected to begin in Europe in late 2019. In consideration for the Gyronimo Acquisition, Curetis made a one-time up-front cash payment of €5,000 thousand. In addition, Carpegen and Systec are eligible for two discrete, one-time milestone payments upon obtaining Conformité Européenne in vitro diagnostic marking (“**CE-IVD-marking**”) for the platform and first cartridge and upon FDA clearance, respectively, up to a maximum of €2,500 thousand, subject to certain specified conditions. Pursuant to the Gyronimo Acquisition agreement, Carpegen and Systec may also be entitled to certain royalty-based earn-outs at an industry-typical mid-single digit percentage rate, up to a cumulative maximum cap of €9,000 thousand.

Pipeline products in development for the Unyvero A50 Analyzer include Application Cartridges targeting an extended respiratory panel (“**XRP**”), cardiology-associated infections (“**CAI**”) and sepsis host response (“**SHR**”), as well as Application Cartridges for use with the Unyvero A30 RQ Analyzer. If such additional Application Cartridges do not comply with the regulatory requirements, including the conformity assessment procedures in the EU or do not receive regulatory clearance in the US, or if such regulatory clearance is delayed, limited in scope or withdrawn after being granted, or if the roll-out of new products, such as the Unyvero A30 RQ Analyzer and corresponding Application Cartridges, do not achieve long-term commercial success in Europe, the US or Curetis’ other target markets, Curetis’ business, results of operations, financial position, cash flows and prospects will be materially adversely affected, and Curetis may find it difficult or impossible to obtain new funding.

In addition, Curetis acquired by way of an asset acquisition agreement with Siemens Technology Accelerator GmbH (“**STA**”) the sole commercial rights from STA to the GENetic Antibiotic Resistance and susceptibility database and platform (“**GEAR**”) database in September 2016. In consideration, STA received an upfront payment from Curetis, and Curetis is required to make additional 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. Curetis believes that the ARES AMR (as defined below) Database (“**ARESdb**”), which builds and expands on GEAR, is the world’s most comprehensive database on the genetics of antibiotic resistance, which permits Curetis to increasingly utilize the proprietary biomarker content in its own assay and cartridge development, as well as to out-licence it to partners. To further advance ARESdb and the ARES technology platform, which builds on the GEAR bioinformatics platform (the “**Ares Technology Platform**”), Curetis founded Ares Genetics GmbH (“**Ares Genetics**”), an operationally autonomous yet wholly-owned subsidiary, based in Vienna, Austria in the second quarter of 2017.

If Curetis fails to successfully commercialise these products, it will not earn a return on the significant investments it has made and will continue to make in product development, sales and marketing, regulatory and quality, manufacturing and quality assurance. This could in turn have a material adverse effect on Curetis’ business, results of operations, financial position, cash flows and prospects.

***Curetis may be unable to successfully manage its growth.***

During the past few years, Curetis has significantly expanded its operations with regard to the development, manufacturing, marketing, sales, servicing and distribution of a much greater variety of product and service

offerings, especially in its direct sales territories in the EU and the US, as well as its distribution markets. In connection with such expansion, the corporate structure of Curetis has grown, and Curetis now wholly owns subsidiaries in the US, the UK, France, the Netherlands, Switzerland and Austria, and has significantly increased its number of employees from 54 as of 30 June 2015 (prior to Curetis' initial public offering, or IPO), to 126 as of 30 June 2018 (including four employees on maternity and parental leave). It also expanded into Asian markets by entering into distribution agreements for certain Association of Southeast Asian Nations ("ASEAN") markets (i.e. Indonesia, Malaysia, Thailand and Singapore), as well as China, Taiwan and Hong Kong (together "Greater China"), and has entered into a strategic partnering arrangement with MGI Tech Co., Ltd. ("MGI") in China for the development and marketing of solutions based on next generation sequencing ("NGS") combined with Curetis' sample preparation technology and Ares Genetics' ARESdb and ARES technology Platform for NGS assay design and interpretation.

Curetis expects this expansion to continue, as it has recently been granted regulatory clearance for its Unyvero System and LRT Application Cartridge by the FDA and has recently significantly expanded its commercial organisation in the US in order to commercialise these products. This US growth is expected to continue if the Unyvero LRT Application Cartridge is successfully commercialised in the US and if Curetis succeeds in receiving FDA clearances for additional Application Cartridges in the US. Curetis also anticipates a significant expansion resulting from the expected roll-out of the Unyvero A30 RQ Analyzer and from the ARES Technology Platform in its target markets, through a variety of strategic collaboration, licensing and commercial partnerships.

Curetis' growth has placed, and will continue to place, a significant strain on Curetis' management, operating and financial systems, and sales, marketing and administrative resources. As a result of Curetis' growth, operating costs may escalate faster than planned, and some of Curetis' internal systems and processes, including those related to manufacturing, quality assurance, quality control, quality management and regulatory compliance of Curetis' products, may need to be enhanced, updated or replaced. If Curetis cannot effectively manage its expanding operations, manufacturing capacity and costs, including scaling to meet increased demand, Curetis may not be able to continue to grow or may grow at a slower pace than expected. This could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***The market potential and opportunities for Curetis' products may be smaller than currently anticipated, lowering potential revenue for Curetis.***

Curetis makes projections on the number of people who have severe disease indications, such as pneumonia, implant and tissue infections, bloodstream infections, intra-abdominal infections, urinary tract infections and other indications that Curetis is targeting. These projections are derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, governmental statistics and market research, but are highly contingent on a number of variables that are difficult to predict and may prove to be too high, resulting in a smaller population of patients who could benefit from Curetis' products than Curetis currently anticipates, which would result in lower potential revenue for Curetis. Any of the foregoing could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis may expand its limited financial and managerial resources to pursue a particular future product or indication and fail to capitalise on products or indications that may be more profitable or for which there is a greater likelihood of success.***

To grow its business in the future with its limited financial and managerial resources, Curetis will have to carefully choose the products it believes will achieve the most commercial success. Accordingly, it will need to carefully focus its limited financial and managerial resources on the selection of such products. Such selection process is difficult and time-consuming, with no guarantee that the selected products will prove to be successful

or profitable. Pipeline products in development include Application Cartridges targeting XRP, CAI and SHR. In addition, Curetis expects to broaden its future pipeline by adding its Unyvero A30 RQ Analyzer, which is currently still in development, for use in indications that require low- to medium-level multiplexing, such as infection control tests, central nervous system (“CNS”) infections, viral panels, tests for immunocompromised patients or other third-party partner content. If Curetis uses its limited financial and managerial resources to promote a particular product or indication such as the aforementioned or other future products or indications, which are not ultimately sufficiently commercially successful, it could have a material adverse effect on the business, results of operations, financial position, cash flows and prospects of Curetis.

***Curetis relies on certain distributors to distribute its products in some of its markets and intends to enter into additional distribution agreements to distribute its products in other markets. If Curetis is unable to find suitable distributors, loses these distributors or if Curetis’ distributors fail to sell its products in sufficient quantities, on commercially viable terms or in a timely manner, Curetis’ commercialisation of its Application Cartridges and other future products could be materially delayed or harmed.***

Curetis’ products are currently being, and are planned to be, distributed by third-party distributors in some of its current and future markets. As at 30 October 2018, Curetis has entered into distribution agreements with 17 distributors covering 29 countries, including Austria, Bulgaria, Croatia, the Czech Republic, Greece, Italy, Portugal, Romania, Slovakia, Slovenia and Spain in the EU, as well as Belarus, China, Egypt, Hong Kong, Indonesia, Israel, Kazakhstan, Kuwait, Malaysia, Mexico, Qatar, Russia, Singapore, Taiwan, Thailand, the United Arab Emirates (the “UAE”), Ukraine and Uruguay. In Europe, Curetis has for example entered into a distribution agreement with Axon Lab AG (“**Axon Lab**”) covering Austria, Croatia, the Czech Republic, Slovakia and Slovenia in May 2016 and with Arrow Diagnostics Srl (“**Arrow Diagnostics**”) in Italy. In line with its strategic objectives, Curetis entered into distribution agreements with Beijing Clear Biotech Co. Ltd (“**Beijing Clear Biotech**”) for Greater China in September 2015 and with Acumen Research Laboratories Pte Ltd. (“**Acumen**”) covering certain ASEAN markets (Indonesia, Malaysia, Thailand and Singapore) in October 2015. In addition, Curetis entered into a distribution agreement with Eldan Electronic Instruments Ltd. (“**Eldan**”) in Israel in January 2017 and also into a distribution agreement with Advanced Technology Company (“**ATC**”) covering Kuwait, and with Al Zahrawi Medical LLC (“**Al Zahrawi**”) covering UAE and Qatar in June 2012 and April 2015, respectively.

Failure to find suitable additional distributors or to conclude or renew distribution agreements with current or future distributors at commercially attractive terms could delay or prevent Curetis from selling its products or make it unreasonably expensive to do so. At the same time, certain potential distributors may not distribute Curetis’ products because they are less incentivised to distribute them than products of other companies or because such distribution agreements would otherwise conflict with their existing or future distribution obligations towards third parties. As a result, existing and potential distributors may fail to effectively sell Curetis’ products in sufficient quantities, on commercially viable terms or in a timely manner, and there is no certainty that Curetis’ distributors will be willing or able to market or distribute the products to the extent Curetis expects.

In addition, under Curetis’ distribution agreements, the failure of a distribution partner to achieve minimum purchase quantities does not normally lead to a “forced” purchase of the minimum quantities, but to a termination of the relevant distribution agreement or termination of exclusivity in the relevant territories for such distributor. Accordingly, minimum purchase requirements do not guarantee future minimum levels of revenues.

Furthermore, Curetis has only a limited influence over its distributors’ marketing activities. For example, Curetis’ products could be used outside of its cleared or approved indication (so-called “off-label” use). Although Curetis trains its distributors not to promote its products for “off-label” uses, and Curetis’ instructions for use in all markets specify that its products are not intended for use outside of those indications cleared for



use, it cannot provide any assurance that no competent regulatory agency will hold Curetis responsible for “off-label” promotion of its distributors. The occurrence of any of these events or circumstances could materially delay or harm the further commercialisation of its products, which could have a material adverse effect on Curetis’ business, results of operations, financial position, cash flows and prospects.

***Curetis may be unable to recruit, train and retain key personnel.***

Curetis’ future success depends on its ability to recruit, train, retain and motivate key personnel, including Curetis’ management and leadership, research and development, science and engineering, manufacturing, quality and regulatory affairs and sales, marketing and customer service personnel. In particular, in connection with the commercialisation of its products, Curetis will become more and more dependent on its sales, marketing and customer service personnel, in particular, its sales force in the US in connection with the commercial roll-out of its Unyvero System and the LRT Application Cartridge. In addition, Curetis will continue to depend on the technology expertise of its key management and leadership team members, as well as certain key research and development employees. Competition for qualified sales personnel is intense in Europe as well as in the US, and Curetis’ growth depends, in particular, on attracting, retaining and motivating highly trained sales personnel with the necessary scientific background and ability to understand Curetis’ Unyvero Platform at a technical level. In addition, Curetis may need additional employees at its manufacturing facilities to meet the demand for its products as Curetis scales up its sales and marketing operations. Because of the complex and technical nature of Curetis’ products and the dynamic market in which it competes, any failure to attract, train, retain and motivate qualified personnel could materially harm Curetis’ growth prospects and could have a material adverse effect on Curetis’ business, results of operations, financial position, cash flows and prospects.

***Curetis may not be able to gain the support of leading hospitals and KOLs or to achieve favourable publication of the results of Curetis’ clinical trials in peer-reviewed journals.***

Curetis’ strategy includes developing relationships with leading hospitals and KOLs in the industry, including, for example, leading hospitals in New York, Chicago, Baltimore, Los Angeles, Rochester, Berlin, Paris and London, as well as leading hospitals in other countries. Individuals considered as KOLs include, *inter alia*, reputable clinicians or microbiologists, as well as members of clinical societies and editors of scientific journals. If these hospitals and KOLs determine that the Unyvero System and related Application Cartridges are not clinically safe and effective or that alternative technologies are equally or more effective, or if Curetis otherwise encounters difficulty promoting the adoption of the Unyvero Platform, Curetis’ revenue growth and ability to achieve profitability could be significantly limited.

Curetis believes that publication of scientific and medical results in peer-reviewed journals and presentation of data at leading conferences are critical to the broad adoption of the Unyvero Platform. Publications in leading medical journals are subject to a peer-review process, and reviewers may not consider the results of studies involving the Unyvero Platform sufficiently novel or worthy of publication. In addition, the publication of less favourable results or questions surrounding the effectiveness of the Unyvero System and related Application Cartridges in scientific or medical journals or presentations may make it more difficult for Curetis to gain the support of hospitals and KOLs in the further commercialisation of its products. This could have a material adverse effect on Curetis’ business, results of operations, financial position, cash flows and prospects.

***Curetis’ future success is dependent upon its ability to create, maintain and expand a customer base for its products in large and leading hospitals.***

In Europe, Curetis currently markets its products mainly to large and leading hospitals in which patients with severe infections are treated. As of 30 June 2018, Curetis’ products were sold to approximately 25 European hospitals. Curetis is currently targeting approximately 745 large and leading hospitals in its direct sales territories in Europe as well as up to 1,208 relevant hospitals via its 17 distributors covering 29 countries. In

the US, Curetis initially intends to focus on the approximately 700 to 1,000 large and/or leading hospitals in which patients who have the highest risk of suffering from pneumonia are concentrated.

The adoption of Curetis' products by large and leading hospitals may not be successful for a number of reasons. These include a lack of funding of hospitals, burdensome administrative and validation procedures, a lack of clinical or commercial interest in the Unyvero Platform, a lack of adequate reimbursement of the hospital and the introduction of new competing technologies. With respect to the US, only the LRT Application Cartridge has so far obtained regulatory clearance, limiting the potential range of applications that Curetis can offer to its US customers. Non-acceptance of Curetis' products would make it difficult for Curetis to expand its market in Europe, to successfully introduce its products in the US and to continue its distribution efforts in other markets. This could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***The selling price level in the MDx market could decrease in the future, which would adversely affect Curetis' business, results of operations, financial position, cash flows and prospects.***

The MDx market is relatively young and Curetis competes with a large and growing number of commercial diagnostics companies. Curetis expects that economies of scale and continuous technological improvements will lead to reduced prices for MDx products, and therefore Curetis' Application Cartridges, as this market matures. If Curetis is not able to offset a decrease in product prices by a corresponding reduction of its costs of goods sold, including research and development expenses, this could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis' current and future customers are highly dependent on payments from third-party payers. Inadequate coverage and reimbursement for Curetis' diagnostic tests, as well as a faster increase of Curetis' costs of production compared to increases in reimbursement levels, could compromise the commercial success of Curetis' products.***

Successful commercialisation of Curetis' diagnostic products depends, in large part, on the extent to which the costs of Curetis' products are reimbursed to its customers, either separately or through bundled payment, by third-party private and governmental payers and private health insurances, as well as public health systems. Coverage and reimbursement will also depend on the applicable healthcare policy framework in the relevant jurisdiction. For example, in the EU and the US, there is significant uncertainty surrounding third-party coverage and reimbursement for the use of tests that incorporate new technology, such as the Unyvero Platform, under current reimbursement frameworks (see “— *Healthcare policy changes in the EU, the US, or any other of Curetis' target markets, including in particular legislation to reform the US healthcare system, may have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects*”).

Hospitals, clinical laboratories and other healthcare providers generally bill various third-party payers to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of Curetis' products. Curetis' current products are used in a hospital in-patient setting. In most of Curetis' markets, governmental payers, public and private health insurance companies or funds and other national equivalents generally reimburse hospitals on the basis of a single bundled payment per patient. Accordingly, third-party payers may deny coverage if they determine that Curetis' products are not cost-effective compared to the use of an alternative testing method or deem them to be experimental or medically unnecessary. Even if third-party payers make coverage and reimbursement available, such reimbursement may not be adequate, which could result in reduced demand for Curetis products from hospitals and clinical laboratories, which could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***The manufacture of many of Curetis' products is a highly precise and complex process, and if Curetis encounters problems with the manufacturing and the quality of its products, its reputation and business could suffer.***

The manufacture of many of Curetis' products is a highly precise and complex process, due in part to strict regulatory requirements. Problems such as quality issues may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials (e.g. contamination) and components, natural disasters and environmental factors, and, if not discovered before the product is released to market, such problems could result in recalls and product liability exposure. Product quality has had a material impact on Curetis' results of operations prior to the periods under review and may have an impact in the future. In addition, much of the manufacturing of Curetis' products is outsourced (see “— Curetis depends on a few key suppliers for critical product components. In case of a loss of any of these suppliers or an interruption of supply, or if supplies were found to be faulty or contaminated, Curetis may not be able to manufacture or outsource manufacturing of its products in sufficient quantities, in a timely manner or at a cost that is economically attractive.”) and additional manufacturing steps may be outsourced in the future to existing or new contract manufacturers. No decisions have yet been made where and who shall manufacture the new A30 RQ instruments and cartridges, which may impact timely availability of such products for the A30 RQ market introduction.

Curetis' revenues and other operating results will depend, in large part, on its ability to manufacture and deliver its Application Cartridges in sufficient quantities and quality, in a timely manner, and at a cost that is economically attractive. Curetis expects to be required to significantly increase Application Cartridge manufacturing capacity as commercialisation progresses. It may not be able to do so for a variety of reasons, such as an inappropriate assessment of the quantities of Application Cartridges needed, which would lead to a delayed capacity expansion. Such expansion is also time-consuming and error-prone due to the level of sophistication of the Application Cartridges. In addition, because of the time required to approve and licence certain regulated manufacturing facilities, an alternative manufacturer may not be available on a timely basis to replace such production capacity. Any of these manufacturing problems could result in significant costs and liability, as well as negative publicity and damage to Curetis' reputation that could reduce demand for its products.

Any failure or delay in delivery or the supply of insufficient quantities or deficient quality of products caused by, among other things, quality issues, manufacturing disruptions, mechanical breakdown, a fire or other incident (e.g. water damage due to roof leakage during a storm) or a delay in supply of components could also result, for example, in a delivery shortage to customers or in the complete shut-down of an ongoing clinical trial. This could, in turn, have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects and damage its reputation.

***Curetis' diagnostics results may not perform as expected and deliver incomplete or incorrect results, which could subject Curetis to product liability claims.***

Curetis' success will depend on the market's confidence that the Unyvero Platform can provide reliable, high quality diagnostic results. The Company believes that Curetis' customers are likely to be particularly sensitive to any defects, errors or a perceived lack of sensitivity or specificity in Curetis' products. If the Unyvero Platform failed to correctly detect the presence or absence of critical bacterial pathogens or critical antibiotic resistance markers, patients could continue to suffer from respective infections or a potential overtreatment as a result of such misdiagnosis. In reaction, patients, hospitals, surgeons or other parties could try to hold Curetis responsible for all or part of the medical decisions underlying the treatment and expose Curetis to product liability claims. These developments could occur even if hospitals correctly use Curetis' products and follow the warning instructions provided by Curetis. Product liability claims could also be based on an allegation that one of Curetis' products contains a design or manufacturing defect. In addition, patients or volunteers in

hospitals or during the course of any interventional clinical trials could hold Curetis responsible for side effects from sample taking or an incorrect treatment therapy arising from defects in Curetis' products.

Any product liability claim could result in substantial damages and could be costly and time consuming to defend, which could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects and damage its reputation and the market acceptance of the Unyvero Platform. Moreover, any product liability claim brought against Curetis, with or without merit, could increase product liability insurance rates. As of the date of this Prospectus, Curetis' upper limit for its insurance policy against third-party claims for product liability or body injuries amounts to €20,000 thousand. It is uncertain whether Curetis' existing or future insurance policies are or will be sufficient to cover the risks as set forth above or whether Curetis would even be able to renew its insurance policies to such an extent that it could cover any such eventualities. As a result, the amount of any costs, including fines or damages, that Curetis might occur in such circumstances could substantially exceed any upper limits of insurance policies Curetis has in place to cover losses. This means that, in case those upper limits are exceeded, Curetis would have to fully compensate the difference between the insurance upper limits and the actual damage, which could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Patient injuries resulting from defects in Curetis' products could potentially lead to the products being recalled from the market or significant decline in market demand for the products. Defects, errors or a lack of sensitivity or specificity of the Unyvero Application Cartridges could also hinder its commercial roll-out and the conduct of regulatory clearance procedures. A recall of Curetis' products, either voluntarily or at the direction of the relevant regulatory bodies, or the discovery of serious safety issues with Curetis' products that leads to corrective actions could have a material adverse impact on Curetis.***

The relevant regulatory bodies may require a recall of Curetis' commercialised products in the event of material deficiencies, or defects in design or manufacture, or in the event that a product is considered to pose an unacceptable risk to health. A government-mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labelling defects or other deficiencies (e.g. contamination) and issues. Manufacturers, on their own initiative, may recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labelling defects or other deficiencies and issues.

For example, as a manufacturer of CE-IVD-marked and FDA-cleared IVD products sold on the European and US market, Curetis must maintain a vigilance system that enables it to track incidents occurring with its products and to ensure compliance with statutory reporting requirements, notifying relevant regulatory authorities of incidents which may lead to (or may have led to) death or serious health consequences for individuals, or to a recall of the relevant product. This includes obligations to submit reports to the relevant national competent authority for recording and evaluating when incidents (e.g. any malfunction or deterioration in the characteristics or performance of a device) occur, to disseminate information that could be used to prevent a recurrence of the incident or to alleviate the consequences of such incidents, and, where appropriate, to implement a "Field Safety Corrective Action" (such as a product recall) to reduce the risk of death or serious injury associated with the use of the device.

Recalls of any of Curetis' products would divert managerial and financial resources and have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects, and could impair Curetis' ability to produce its products in a cost-effective and timely manner. New approvals or clearances from regulatory bodies may also need to be obtained before the corrected part of the Unyvero Platform can be marketed or distributed again. Seeking such approvals or clearances may delay Curetis' ability to replace the recalled devices in a timely manner. Curetis may further be required to bear other costs or take other actions

that may have a negative impact on Curetis' sales, as well as face significant adverse publicity or regulatory consequences, which could harm Curetis' business, including Curetis' ability to market its products in the future.

***Curetis may not be able to develop new products or enhance the capabilities of its products and systems to keep pace with the rapidly changing technology and customer requirements in the MDx industry.***

Curetis' industry is characterised by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. Curetis' success depends on its ability to develop new products and applications for its technology in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of Curetis' existing products. New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and systems that Curetis currently sells or plans to sell in the future.

The market in Europe, the US and Asia is characterised by rapid technological change and innovation. It is critical to its success that Curetis anticipates changes in technology and customer requirements and physician, hospital and healthcare provider practices and successfully introduces new, enhanced and competitive technologies to meet Curetis' existing and prospective customers' needs on a timely and cost-effective basis.

At the same time, however, Curetis must carefully manage its introduction of new products, including the Unyvero A30 RQ Analyzer platform and the ARES Technology Platform and its product maintenance. If potential customers believe that new products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. Curetis may also have excess or obsolete inventory of older products as it transitions to new products and has limited experience in managing product transitions. If Curetis does not successfully innovate and introduce new technology into its anticipated product lines or manage the transitions of its technology to new product offerings, its business, results of operations, financial position, cash flows and prospects could be materially adversely affected.

In addition, Curetis may have problems applying its technologies to other areas, and its new Application Cartridges and technologies may not be as effective as its initial Application Cartridges. Any failure or delay in creating a customer base or launching new Application Cartridges may compromise Curetis' ability to achieve its growth objectives.

***If the manufacturing, development or testing equipment used by or for Curetis were damaged or destroyed, or if Curetis experiences a significant disruption in its operations or experiences any problems with its manufacturing processes for any reason, Curetis' ability to continue to operate its business could be materially harmed.***

Curetis currently develops its products exclusively in its facility in Holzgerlingen, Germany, whereas it manufactures and tests some components at its facility in Bodelshausen, Germany and outsources manufacturing and testing of its Unyvero System to a facility operated by Zollner in Cham. Additional Unyvero System testing may also occur at Curetis' facility in Holzgerlingen and at its logistics provider in Karlsruhe, Germany. If these or any future facilities were to be damaged, destroyed or otherwise unable to operate, whether due to natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if Curetis' business is disrupted for any other reason, Curetis may not be able to manufacture its products and develop and test its products in a timely manner or at all.

The manufacturing of components of Curetis' products at the facility in Bodelshausen and at Zollner's facility involves complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Any unforeseen manufacturing problems, such as those caused by contamination, equipment malfunction, quality problems or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in the production of Curetis' products or the loss of Curetis' and Zollner's critical ISO 13485 certifications and FDA establishment registration. Identifying and resolving the cause of any manufacturing

issues could require substantial time and resources. If Curetis is unable to keep up with future demand for its products by successfully manufacturing and shipping its products in a timely manner, Curetis' revenue growth could be impaired and market acceptance of its products could be materially adversely affected.

Currently, Curetis maintains insurance coverage against damage to its property and equipment and against business interruption in line with what it believes to be standard practice. This coverage is subject to deductibles, certain ceilings and other limitations. For example, Curetis' policy limit for property damage is between €2,500 thousand and €5,000 thousand, depending on the cause of damage, such as natural hazards, burglary or vandalism by third parties. In case of shipping risks, Curetis' policy limit ranges between €2,000 and €500,000 for each conveyance, depending on the type of damage. If Curetis has underestimated its insurance needs with respect to an interruption, or if an interruption is not subject to coverage under its insurance policies, Curetis may not be able to cover its losses, which could have a material adverse effect on its business, results of operations, financial position, cash flows and prospects.

***A significant amount of Curetis' inventory consists of equipment held by prospective customers who are evaluating its products and may not be converted to revenue in the timeframe that Curetis anticipates or at all.***

As of 30 June 2018, €1,991 thousand of Curetis' inventory consisted of Unyvero Systems in possession of customers that were evaluating and testing its products. If a material number of prospective customers does not adopt the Unyvero Platform within the estimated sales cycles of 12 months in Europe and nine months in the US or at all, Curetis will not be able to use the inventory held by these customers to generate revenues. If Curetis is unable to sell or otherwise commercially utilise this inventory to or with other customers or distributors, or if such inventory becomes obsolete as Curetis develops the next generation of the Unyvero Platform, it may be required to write off a significant portion of this inventory. This could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis' intention to enter into agreements with strategic partners in possession of or with an interest in proprietary platforms, technologies, IT or biomarkers for diagnosis of indications, with a view to developing and commercialising new diagnostic products, could prove unsuccessful.***

Curetis has already entered into and intends to enter into further agreements with strategic partners for diagnostic products, including in respect of its current Unyvero System or on the future Unyvero A30 RQ Analyzer system, as well as in connection with its ARES Technology Platform and ARES-related platforms and capabilities.

For example, on 24 September 2015, Curetis entered into a research and development collaboration and licensing agreement with Acumen, under which Curetis has obtained a worldwide non-exclusive licence to Acumen's proprietary sepsis biomarker panel for host response. However, there is no assurance that this or other similar collaboration arrangements will be successful. Establishing these relationships can be difficult and time-consuming. Discussions may not lead to agreements on favourable terms, if at all. To the extent Curetis agrees to work exclusively with a party in a given area, Curetis' opportunities to collaborate with others or to develop opportunities independently would be limited. Even if new strategic relationships were established, this may not result in the successful development or commercialisation of future products. This could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Ares Genetics may be unable to successfully enter into licensing, partnering or service agreements and may fail to generate sufficient revenues to sustain itself as a business***

Ares Genetics, a wholly owned subsidiary of Curetis, is in the process of entering into partnering discussions relating to ARESdb. This newly developed database on the genetics of antimicrobial resistances ("AMR") builds on and expands the GEAR database acquired from STA in September 2016. Ares Genetics has been

engaged in numerous partnering discussions with life sciences, public health, diagnostic, and pharmaceutical companies as well as public health institutions. If Curetis fails to successfully convert these discussions into licensing, partnering or service agreements and to generate revenues, Ares Genetics may not be able to sustain itself as a business and may require additional financial support from Curetis. This could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Acquisitions or joint ventures could disrupt and otherwise harm Curetis' business, and cause dilution to Curetis' shareholders.***

Curetis may acquire other businesses, products or technologies in the future as it has done in the past (e.g. with the acquisition of the Gyronimo (now Unyvero A30 RQ Analyzer) platform from Carpegen and Systec, as well as the GEAR database asset acquisition from STA), as well as joint ventures or investments in complementary businesses. Any of these transactions could be material to Curetis' business, results of operations, financial position, cash flows and prospects and expose Curetis to many risks, including:

- disruption in Curetis' relationships with current or future customers or with current or future distributors or with suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies or assets;
- difficulties integrating acquired personnel, technologies and operations into Curetis' existing business;
- diversion of management time and focus from operating Curetis' business to acquisition integration challenges;
- increases in Curetis' expenses and reductions in Curetis' cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses or intangible assets;
- inability to develop a sales force for any additional products; and
- a negative impact on Curetis' share price if such a transaction were not perceived as beneficial for Curetis and its shareholders.

Curetis has only made a few small acquisitions to date and therefore its ability to do so successfully is largely unproven. Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

In addition, the anticipated benefit of any acquisition may not materialise. Future acquisitions or dispositions could result in potentially dilutive issuances of Curetis' equity securities, the incurrence of debt, contingent liabilities or amortisation expenses or write-offs of goodwill, any of which could harm Curetis' financial position. Curetis cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on Curetis' operating results.

***Curetis may lose its current tax losses carry forwards in case of certain events.***

As of 31 December 2017, Curetis had tax loss carry forwards in the amount €89,562 thousand for corporate tax purposes and €89,452 thousand for trade tax purposes which could not be used to offset profits and for which no deferred taxes were recognized. Under German tax law, such tax losses carry forwards will be forfeited completely, if, *inter alia*, a change of control occurs, i.e. if a person or a group of acquirers with similar interests acquires directly or indirectly more than 50% of the interest in the Company, and such carry forwards will be partially forfeited if such a person or group acquires directly or indirectly between 25% and 50% of the interest in the Company, or if certain other changes occur. If such events occur with respect to Curetis, it could lose some or all of its tax carry forwards. This would, if and once Curetis reaches profitability, result in a higher tax

burden than would otherwise be the case and could have an adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis' operating results could be materially adversely affected by unanticipated changes in tax laws and regulations, adjustments to its tax provisions or exposure to additional tax liabilities or tariffs.***

The determination of Curetis' provision for income taxes and other tax liabilities requires significant judgement, including the adoption of certain accounting policies and Curetis' determination of whether its deferred tax assets are, and will remain, available. Although management believes its estimates and judgements are reasonable, they remain subject to review by the relevant tax authorities. Curetis cannot guarantee that its interpretation will not be questioned by the relevant tax authorities, or that the relevant tax laws and regulations, or the interpretation thereof by the relevant tax authorities, will not be subject to change. Any adverse outcome of such a review may lead to adjustments in the amounts recorded in Curetis' financial statements and could have a materially adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

Curetis' effective tax rates could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically, including possible changes to the patent income deduction regime and other tax incentives, or the way they proportionally impact Curetis' effective tax rate. Any increase of the effective tax rates or tariffs could have an adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis currently generates a portion of its revenue internationally and expects to increase this portion in the future. It is therefore subject to various risks relating to its international activities, which could adversely affect Curetis' operating results.***

A portion of Curetis' revenue is derived from international sources, which is expected to include revenue from the US in future periods as a result of the recent US commercialisation of the Unyvero Platform and LRT Application Cartridge. Curetis expects this portion to increase in the future as it continues to expand internationally. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign healthcare and other regulatory requirements, in particular changes in healthcare policy in the US (see “— *Healthcare policy changes in the EU, the US, or any other of Curetis' target markets, including in particular legislation to reform the US healthcare system, may have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.*”) and laws, such as those relating to patient privacy or handling of bio-hazardous waste;
- required compliance with data protection laws, such as the US Health Insurance Portability and Accountability Act of 1996 or the UK Data Protection Act;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favouring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;



- foreign exchange controls;
- difficulties and costs of staffing and managing foreign operations;
- difficulties protecting or procuring intellectual property rights; and
- required compliance with anti-bribery laws, such as the US Foreign Corrupt Practices Act and the UK Bribery Act, labour laws and anti-competition regulations.

If Curetis is unable to manage the risks arising out of its international operations effectively, this could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis is exposed to changes in foreign currency exchange rates.***

Curetis currently records its transactions, prepares its financial statements and incurs the main portion of its costs in euro. Its results of operations and cash flows will, however, increasingly become subject to fluctuations due to changes in foreign currency exchange rates, in particular the US\$, but potentially also other currencies such as the British Pound Sterling, the Swiss franc and certain Asian currencies such as the Chinese Yuan, as Curetis continues to expand its operations in China as a result of its distribution agreement with Beijing Clear Biotech for Greater China. Curetis' expenses are primarily denominated in euro, because Curetis' operations are located in Germany, and in US\$, as a result the revenues generated in the US and costs incurred in clinical trials and its recent commercialisation activities in respect of the Unyvero Platform and LRT Application Cartridge in the US are subject to the US\$/EUR exchange rate fluctuations. Curetis currently does not apply any currency hedging strategies other than forward purchases of required foreign currencies. If the value of the euro increases relative to foreign currencies in the future, and Curetis does not otherwise increase the prices of its products in such local markets, Curetis' future revenues could be adversely affected as it converts future revenues from local currencies to euro.

***Curetis' employees, independent contractors, principal investigators, distributors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

Curetis is exposed to the risk of fraud or other misconduct by its employees, independent contractors, principal investigators conducting clinical studies, distributors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless or negligent failures: to comply with the regulations of the national regulatory bodies in the EU, the US and other countries; to provide true, complete and accurate information; to comply with established manufacturing standards; to comply with healthcare fraud and abuse laws and regulations in the EU, the US and similar foreign national fraudulent misconduct laws; to report financial information or data accurately; or to disclose unauthorised activities to Curetis. These failures may impact, among other things, Curetis' clinical studies and research subjects, as well as Curetis' sales, marketing and education programmes.

In particular, the promotion, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programmes and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to Curetis' reputation if Curetis or its employees, independent contractors, principal investigators, distributors, consultants, commercial partners or vendors were alleged to have engaged in such activities. In addition, Curetis only has very limited control over its distributors. Any non-compliance by them of their distribution agreements, in particular by granting economic benefits to persons at customers in charge of making purchase decisions, can also trigger sanctions against Curetis. Non-compliance

by, any of these individuals or entities, with local applicable laws and regulations, may also result in a loss of local registrations for Curetis products.

In connection with employee misconduct, Curetis currently has different rules in place, such as internal business principles, that are applicable to all of its employees. In addition, Curetis has established a Code of Conduct, an Insider Trading Policy, a Whistle-blower Policy and a Policy on Bilateral Contacts with its shareholders. However, it is not always possible to identify and deter employee misconduct, and Curetis' internal rules and the other precautions taken to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses, or in protecting Curetis from governmental investigations or other actions or lawsuits.

If any regulatory or other actions are instituted against Curetis, and it is not successful in defending or asserting its rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, individual imprisonment, possible exclusion from participation in government healthcare programmes, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of Curetis' operations. Any of these actions or investigations could result in substantial costs, including legal fees, and divert the attention of management from operating Curetis' business, and could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis relies on third parties to conduct and support clinical and evaluation studies of its products that are required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily.***

Curetis has conducted, and is conducting, a large number of clinical and evaluation studies. The vast majority of these are conducted by third-party investigators. Curetis therefore relies and expects to continue to rely in the future on third parties, to conduct or support studies of its existing and future products. Such third parties may not complete activities on schedule or conduct studies in accordance with regulatory requirements or with Curetis' study design. Curetis' reliance on third parties that are not controlled by it does not relieve Curetis of any applicable requirements to ensure compliance with procedures required under good clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or fail to meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to Curetis' clinical protocols or regulatory requirements or for other reasons, Curetis' studies may be extended, delayed, suspended or terminated, and Curetis may not be able to obtain regulatory clearance for its products from the FDA or other regulatory authorities.

***Curetis' business could be significantly and negatively affected by current or new governmental regulations and clearance, approval and post-approval requirements, particularly in the EU and the US.***

In each country in which Curetis is or may become active, Curetis' products are or may become subject to various and different government regulations and, depending on the jurisdiction, may become subject to review by a number of governmental authorities governing clinical studies, vigilance reporting and self-certification or approval/clearance procedures. Such regulations govern activities such as product development, testing, clinical validation, labelling, storage, manufacturing and distribution. These regulatory requirements vary greatly from country to country. Failure to comply with these regulatory requirements, or to obtain required clearances, approvals or certifications, could impair Curetis' ability to commercialise Curetis' diagnostic products. In addition, the level of regulation could even increase in the future and may become more comprehensive. Curetis cannot predict the effect that any future legislation or regulation will have on it.

## EU

In a number of EU member countries and certain other countries recognising CE-IVD-marked devices, Curetis markets and sells its CE-IVD-marked products comprising the HPN, ITI, BCU, IAI and UTI Application Cartridges.

On 5 April 2017, the new Regulation (EU) 2017/746 of the European Parliament and of the Council (the “**IVD Regulation**”) on in vitro diagnostic medical devices was adopted, repealing the European Directive 98/79/EC (in vitro diagnostic medical devices) (the “**IVD Directive**”) and Commission Decision 2010/227/EU. The IVD Regulation entered into force on 25 May 2017 and will replace the existing IVD Directive after a five-year transition period following its entry into force. The new IVD Regulation will apply directly in all EU member states with the intention of providing more legal certainty for market stakeholders.

Any market clearance for Curetis’ Unyvero Platform which has already been or will have been achieved prior to the end of the five years transitional period (May 2022) through CE-IVD-marking, pursuant to which Curetis has self-certified its products after having conducted clinical trials, will remain valid until the end of the transitional period.

Under the current regime, review by an organisation designated by an EU country to assess the conformity of certain products before being placed on the market (a “**Notified Body**”) is not required for Curetis’ products with the exception of the HPN Application Cartridge which is already subject to such review under the IVD Directive. The IVD Directive subdivides IVD devices into different classes. Whilst high-risk products can only be CE-IVD-marked after certification by a Notified Body, other products can be CE-IVD-marked following a self-certification process conducted by the manufacturer. Failure to comply with the certification requirements under the IVD Directive (e.g. self-certification of a product instead of certification of a product by a Notified Body due to a wrong classification of a product risk category) could require Curetis to make changes to the Unyvero System or Application Cartridges, could lead to Curetis no longer being permitted to affix the CE-IVD-marking to its products and could require it to cease marketing and/or recall the relevant products until certification in compliance with the IVD Directive is obtained.

The new IVD Regulation departs from the current system of self-certification under the IVD Directive, insofar as it requires a conformity assessment by the competent Notified Bodies for all IVD devices other than certain low risk devices. Under the IVD Regulation, all of Curetis’ Application Cartridges will require a conformity assessment by a Notified Body.

Despite the five-year transition period of the IVD Regulation, it is unclear whether the competent Notified Bodies will have the capacity, and be ready in time, to complete required assessments in a timely manner and to ensure a smooth transition from the old regime due to the large number of devices that will require review by the limited number of Notified Bodies. Curetis estimates that obtaining CE-IVD-marking clearance from a Notified Body under the IVD Regulation is likely to increase the time it takes to bring a product to market in the EU by, on average, six months or longer. There is also the possibility that the Notified Body may find that Curetis has done insufficient validation and withhold its endorsement, effectively requiring Curetis to make changes to a product candidate as part of the conformity assessment, or take other action that could further delay certification. Any failure or material delay in the required assessment process for Curetis’ products following the transition to the new IVD Regulation regime, whether caused by Curetis or any Notified Body, could have a material adverse effect on Curetis’ business, results of operations, financial position, cash flow and prospects.

In addition, violations of the applicable regulations of the IVD Directive or IVD Regulation or national laws implementing the IVD Directive or IVD Regulation could also result in administrative fines payable by Curetis. Curetis also has to ensure that it is in ongoing compliance with the IVD Directive and IVD Regulation as

applicable. Any such fines or failure to comply with applicable regulations could also have a material adverse effect on Curetis' business, results of operations, financial position, cash flow and prospects.

## US

Following the regulatory clearance for its Unyvero System and LRT Application Cartridge by the FDA, Curetis is currently in the process of commercialising these products, and, in addition, plans to file for the additional clearance of BAL as a second sample type at a later stage, and has submitted a pre-submission package to the FDA, which outlines the intended use claims and clinical trial efforts. Curetis also intends to conduct a clinical trial for the IJI Application Cartridge and will be working closely with the FDA on that submission once filed.

In general, before labelling and marketing Curetis' products for use as clinical diagnostics in the US, Curetis is required to obtain either: (i) clearance from the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act (the "FDCA"), or (ii) a grant of a *De Novo* 510(k) request for Curetis' products, or (iii) pre-market approval ("PMA") from the FDA, unless an exemption from pre-market review applies. In the 510(k)-clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to its intended use, technology, safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The *De Novo* provision section (513(f)(2)) is an alternative pathway to classify novel devices of low to moderate risk for which no substantially equivalent device exists. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device, based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labelling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. The PMA pathway is typically much more costly and uncertain than the 510(k)-clearance process.

The Unyvero System has been cleared as part of the Unyvero LRT *De Novo* grant in April 2018 and Curetis expects that additional Application Cartridges, e.g. the IJI Application Cartridge and the BAL extension will therefore most likely be subject to a Section 510(k) clearance or another *De Novo* grant, but there can be no guarantee that these or future products will not be subjected to the more onerous PMA pathway.

The process of obtaining regulatory clearances or approvals, or completing a *De Novo* classification process, to market a medical device can be costly, time consuming and sometimes unpredictable, and Curetis may not be able to successfully obtain marketing authorisations for its current or future products on a timely basis, if at all.

Obtaining FDA clearance generally takes from several months to several years, and generally requires detailed and comprehensive scientific data and/or clinical data. New FDA guidance may lead to new requirements, e.g. for study protocols or software development and validation. If the FDA requires Curetis to go through a lengthier, more rigorous examination for any of its current or future products than originally expected, Curetis' product introductions or modifications could be delayed or cancelled, which could cause Curetis' sales to decline and could have a material adverse effect on Curetis' reputation, business, results of operations, financial position, cash flows and prospects. In addition, the FDA may determine that Curetis' products require the even more costly, lengthy and uncertain PMA process, which could lead to significant delays in Curetis' attempt to launch further products into the US market.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- Curetis may not be able to demonstrate to the FDA's satisfaction that its products are substantially equivalent to a legally marketed predicate device or safe and effective, sensitive and specific diagnostic tests, for their intended uses (as may be required);
- the data from Curetis' pre-clinical studies and clinical trials may be considered insufficient to support clearance or approval, where required; and

- the manufacturing process or facilities Curetis uses may not meet applicable requirements.

Even if granted, a 510(k) clearance, granted *De Novo* request or PMA approval for any future product would likely place substantial restrictions on how Curetis' device is marketed or sold, and the FDA will continue to place considerable restrictions on Curetis' products and operations. Medical devices are subject to the FDA's advertising and promotion regulations under the FDCA, which require Curetis to ensure that its advertising and promotion of its products are in accordance with the FDCA. If the FDA believes that Curetis is not advertising and promoting its products in accordance with the FDCA, the FDA can take stringent enforcement action, from issuing warning letters to forcing a recall of the affected products. Such actions by the FDA could serve as a background for enforcement action by the Department of Justice and other enforcement agencies, possibly leading to civil and criminal fines and penalties.

Additionally, the manufacture of medical devices must comply with the FDA's Quality System Regulation ("QSR", Code of Federal Regulations Title 21, Part 820). Manufacturers must also register their manufacturing facilities, list their products and comply with requirements relating to labelling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals and import and export. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If Curetis' facilities or those of its contract manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if Curetis or its manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take various enforcement actions, including, but not limited to, notices of inspectional observations, warning letters, operating restrictions or total shutdown of production or withdrawing 510(k) regulatory clearances or PMA approvals that have already been granted. Any of these sanctions could impair Curetis' ability to produce its products in a cost-effective and timely manner and could have a material adverse effect on Curetis' reputation, business, results of operations, financial position, cash flows and prospects. In addition, the FDA may change its clearance policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay clearance of Curetis' products or impact Curetis' ability to modify any future cleared products on a timely basis. This could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

#### *Other jurisdictions*

The regulatory admission and clearance process and supervision in other countries requires approval procedures prior to commercialisation and subjects Curetis to risks comparable to the ones described above. In China, analytical testing of the HPN Application Cartridge was initiated by Curetis' partner, Beijing Clear Biotech, in the fourth quarter of 2017, and completed with all assays of the HPN Application Cartridge cleared for subsequent clinical evaluation in the third quarter of 2018 under the auspices of the Beijing Institute of Medical Device Testing of the Beijing Center for Medical Device Quality Supervision and Testing of the CFDA with the goal of obtaining market clearance for Mainland China. Pursuant to the agreement with Beijing Clear Biotech, Beijing Clear Biotech is expected to conduct any prospective clinical trials required for the approval of the Unyvero System and the HPN, ITI, BCU and potentially also other Application Cartridges in China and will be responsible for the CFDA approval and registration process. There is no guarantee, however, that Beijing Clear Biotech will be successful in securing the CFDA approval. There is also no guarantee that CFDA approval would happen on a timely basis with a commercially attractive panel or at all. In addition, the impact and timing of the CFDA reform, which was announced in March 2018, and under which CFDA will be replaced by the State Market Regulatory Administration, cannot yet be assessed. Regulatory clearance of Curetis' products in other jurisdictions where regulatory clearance is required, including Singapore, other ASEAN markets, Egypt, Japan and Brazil, is also not assured, and may be particularly difficult in jurisdictions like Japan and Brazil, where Curetis has no prior experience with regulatory submissions nor local partner to manage or assist in the clearance process. In addition, as current regulatory requirements change or become more comprehensive, or additional regulations may come into force, this may adversely affect Curetis' ability to obtain or maintain

approval of its products or to comply with ongoing regulations in the countries in which it operates, which, in turn, may have a material adverse effect on its business, results of operations, financial position, cash flows and prospects.

***Healthcare policy changes in the EU, the US, or any other of Curetis' target markets, including in particular legislation to reform the US healthcare system, may have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.***

From time to time, legislation is enacted that could significantly change the healthcare policy and statutory provisions governing the reimbursement of Curetis' products by third parties, for example, from public health administrations or private health insurers. In addition, existing regulations and guidance are often revised or reinterpreted in ways that may significantly affect Curetis' business and results of operations.

For example, changes in healthcare policy in the US could substantially impact the sales of Curetis' tests and increase costs. The Affordable Care Act (the "ACA"), enacted in March 2010, introduced changes that significantly impacted the pharmaceutical and medical device industries and clinical laboratories. Under the ACA, for example, expansion in the pool of covered lives may expand the market for clinical diagnostic testing, while at the same time, various policies aimed at reducing costs or bundling care may reduce the rates paid for such services. The net impact of these factors on the market for Curetis' products is not clear. Moreover, since 2013, certain medical device manufacturers have had to pay an excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. Curetis expects that this excise tax will also apply to some or all of its diagnostic products in the US. Clinicians may decide not to order or offer clinical diagnostic tests if third-party payments are inadequate, and Curetis cannot predict whether third-party payers will offer adequate reimbursement for procedures utilising Curetis' products to make them commercially attractive.

In addition, the ACA established an Independent Payment Advisory Board (the "IPAB") to reduce the *per capita* rate of growth in spending of the US health insurance programme for Americans aged 65 and older ("Medicare") if expenditures exceed certain targets. The IPAB has broad discretion to propose policies to reduce healthcare expenditures, which may have a negative impact on payment rates for services, including Curetis' tests. The full impact on Curetis' business of the ACA is still uncertain. To the extent that the reimbursement amounts for pneumonia and/or IJI testing decrease in the US, this could adversely affect the market acceptance and hospital adoption of Curetis' technologies.

Since its enactment, there have been judicial and Congressional challenges to numerous aspects of the ACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017 that, while not a law, is widely viewed as the first step toward the passage of legislation to repeal the ACA. In May 2017, the House of Representatives passed legislation to repeal and replace portions of the ACA. Furthermore, on 20 January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress could also consider subsequent legislation to replace elements of the ACA that are repealed. Curetis cannot predict how the ACA, its possible repeal, or any legislation that may be proposed to replace the ACA will impact its business.

Other legislative changes have been proposed and adopted in the US since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A joint select committee on deficit reduction, tasked with recommending a targeted deficit reduction of at least US\$ 1.2 trillion for the years 2012 to 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programmes. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect until 2024 unless additional Congressional action is taken. In January 2013, the

American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centres and cancer treatment centres, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Curetis cannot predict what healthcare programmes and regulations will be ultimately implemented at the EU or US federal or state levels or within the implementing legislation of the individual EU member states, or in Greater China or any of its other target markets, or the effect of any future legislation or regulation. However, these types of provisions, as adopted, could materially change the way healthcare is delivered and financed, and may materially impact numerous aspects of Curetis' business. In particular, any changes that lower reimbursements for tests performed using Curetis' products could materially adversely affect Curetis' business, results of operations, financial position, cash flows and prospects.

***Modifications to Curetis' products, if cleared or approved, may require new clearances, pre-market approvals or registrations, or may require Curetis to cease marketing or recall the modified products until clearances, approvals or registrations are obtained.***

In the EU, any substantial changes or modifications that are made to the design, function or safety of Curetis' products with the intention of altering the original operation, the original goal or type and which would constitute a major change may be considered a new product for which Curetis has to undertake a new CE performance evaluation and CE-IVD conformity assessment. This could lead to additional costs (e.g. for the carrying out of new clinical studies), and a delay in the commercialisation of Curetis' products.

In the US, any modification to a device authorised for marketing that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires, for example, a new 510(k) clearance or, possibly, approval of a new or revised PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with Curetis' decisions as to whether new clearances or approvals are necessary. In such case, Curetis may be required to cease marketing or to recall the modified product until clearance or approval is obtained, and Curetis may be subject to significant regulatory fines or penalties.

In addition, if treatment guidelines change or the standard of care evolves, Curetis may need to redesign and seek new regulatory clearance or approval from the FDA for Curetis' products. If treatment guidelines change so that different treatments become desirable for different species currently subject to the same recommended treatment, the clinical utility of Curetis' Application Cartridges could be diminished and Curetis could be required to seek regulatory clearance from the FDA for a revised test that would be able to distinguish between the different species. Similar risks also apply with the CFDA as well as other regulatory bodies in other territories.

***Curetis' operations in the US are subject to federal and state healthcare fraud and abuse laws and other federal and state laws applicable to Curetis' business activities. If Curetis is unable to comply with such laws, it could face substantial penalties.***

Curetis' operations in the US are subject to various federal and state fraud and abuse laws. Such laws include the federal and state anti-kickback statutes, physician payment transparency laws and false claims laws. These laws may impact, among other things, Curetis' proposed sales and marketing and education programmes and require it to implement additional internal systems for tracking certain marketing expenditures and to report to governmental authorities. In addition, Curetis may be subject to patient privacy and security regulations by both the federal government and the states in which Curetis conducts its business. The laws that Curetis needs to comply with include, *inter alia*:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly or wilfully soliciting, receiving, offering or paying any remuneration, overtly or covertly,

directly or indirectly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order, arranging for, or recommendation of, any good, facility, item or services for which payment may be made, in whole or in part, under a federal healthcare programme;

- federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from or approval by a governmental payer programme that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, which established new federal crimes for, among other things, knowingly and wilfully executing, or attempting to execute, a scheme to defraud any healthcare benefit programme, wilfully obstructing a criminal investigation of a healthcare offence, concealing a material fact, or making materially false statements in connection with the delivery of or payment for healthcare benefits, items or services; and
- the federal physician sunshine requirements under the Patient Protection and ACA, as amended by the Health Care and Education Reconciliation Act, which requires certain manufacturers of drugs, devices, biologicals and medical supplies to report annually to the Centres for Medicare & Medicaid Services information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

If Curetis' operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to it, it may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of Curetis' operations, the exclusion from participation in federal and state healthcare programmes and individual imprisonment, any of which could have a material adverse effect on Curetis' business, financial position, cash flows and results of operations.

***Curetis faces risks related to handling hazardous materials and other regulations governing environmental safety.***

Curetis' operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. Curetis' activities that are subject to these regulations include, among other things, Curetis' use of hazardous materials, such as patient samples containing pathogens or clinical isolates of pathogens. Curetis may not be in material compliance with these regulations, and costs to achieve compliance may be significant. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to Curetis, whether retroactively or prospectively, that may have a negative effect on Curetis' business and results of operations. It is also impossible to eliminate completely the risk of accidental environmental contamination or damage to the health of individuals. In such an event, Curetis could be liable for any damages, which could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis depends on its information technology systems, and any failure of these systems could harm Curetis' business.***

Curetis depends on information technology systems for critical parts of its operations, including the storage of data and retrieval of critical business information. Curetis has installed, and expects to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas. These information technology systems may support a variety of functions, including laboratory operations, test validation, quality control and research and development activities. Curetis' clinical trial data for the LRT Application Cartridge trials was stored on a third-party server. Curetis did this also for the EU trial for the HPN Application Cartridge in the past and expects to do this also for future FDA trials, as well as other larger multi-center trials for future Application Cartridges. The FDA set forth in its issuance "Content of Premarket



Submissions for Management of Cybersecurity in Medical Devices” from 2 October 2014 which information related to cybersecurity that manufacturers should provide in their pre-market submission for their medical devices. The FDA also expresses the view that manufacturers should develop a set of cybersecurity controls to assure medical device cybersecurity and maintain medical device functionality and safety, and should provide, in the pre-market submission, information related to the cybersecurity of their medical device. On 28 December 2016, the FDA issued its “Postmarket Management of Cybersecurity in Medical Devices” in which it expresses the view that given the evolving nature of potential cybersecurity threats, there is a need to continue to monitor, identify and address potential cybersecurity risks after a device has been released to the market. As a result, the FDA provides recommendations and tools for manufacturers to structure and comprehensively manage the postmarket cybersecurity vulnerability for marketed and distributed medical devices throughout the product’s lifecycle. Although Curetis intends to comply with FDA guidance on cybersecurity for its future submissions, there is no assurance that it will always be in compliance with such guidance.

Information technology systems are vulnerable to damage from a variety of sources, including network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of Curetis’ servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Failures or significant downtime of Curetis’ information technology systems or those used by Curetis’ third-party service providers could prevent Curetis from conducting its general business operations. Any disruption or loss of information technology systems on which critical aspects of Curetis’ operations depend could have an adverse effect on Curetis’ business. Furthermore, Curetis stores highly confidential information on its information technology systems, including information related to clinical data, product designs, trade secret information, software codes, engineering drawings and plans to create new products.

Despite security measures, it cannot be ruled out that the confidentiality of data and information may be breached, as a result of cybersecurity attacks or otherwise, or that doubts may arise regarding the security of the data and information collected and managed by or for Curetis. Particularly within the European Economic Area (“EEA”), data protection legislation is comprehensive and complex and there has been a recent trend toward more stringent enforcement of requirements regarding protection and confidentiality of personal data. Data protection authorities from the different member states of the EU may interpret the legislation differently, which adds to this complexity, and data protection is a dynamic field where guidance is often revised, sometimes with limited, if any, regard to legacy equipment or systems in use. Additionally, in some instances, in order to fulfil the requirements of applicable US laws, Curetis may be faced with deciding whether to comply with EEA data protection rules. Failure or partial failure to comply with data protection rules and regulations across the EEA could result in substantial monetary fines. Furthermore, enforcement of data protection and privacy laws is likely to increase after Regulation 2016/679/EU of the European Parliament and of the Council of April 27, 2016 (the “**General Data Protection Regulation**”) entered into force on 25 May 2018. Although Curetis believes that it is in compliance with the General Data Protection Regulation as of the date of this Prospectus, the competent regulatory authorities may conclude otherwise.

If Curetis’ servers or the servers of the third party on which Curetis’ clinical data is stored are attacked by a physical or electronic break-in, computer virus or other malicious human action, or if Curetis’ servers or the servers of the third-party on which Curetis’ clinical data is stored are attacked as an electronic break-in point with respect to other electronic devices, for example, the IT systems of hospitals, Curetis’ confidential information could be stolen, altered or destroyed, which, in turn, could result in damage to Curetis’ reputation, to customers stopping buying Curetis’ products, lawsuits and potential liability, and could have a material adverse effect on Curetis’ business, results of operations, financial position, cash flows and prospects.

***Curetis has entered into lease agreements for its headquarters, in which its laboratory facilities are located and for a manufacturing plant, as well as other lease agreements in the US and Austria. The***

***unexpected termination or non-renewal of these lease agreements could have a material adverse effect on Curetis’ business, results of operations, financial position, cash flows and prospects.***

Curetis has entered into a lease agreement for office and laboratory space at its Holzgerlingen headquarters, with a lease term that has been extended until 31 August 2021 and Curetis is currently in discussions with the landlord to look at possible future extension terms. However, there can be no guarantee that a further extension would be possible or would be possible at attractive terms to Curetis. Curetis has also entered into a lease agreement with Joma-Polytec GmbH (“**Joma-Polytec**”) for 1,600 sqm of manufacturing and logistics space for its manufacturing plant in which its Bodelshausen laboratory facilities are located. The lease term has been extended until 30 June 2020 and, under the current lease agreement, Curetis has an option to further extend the lease by an additional five-year term. Curetis has invested significantly in the installation of tailored clean rooms, automated Application Cartridge manufacturing equipment and laboratory facilities in the buildings located at this plant. As a consequence, the untimely termination or failure to renew its lease agreement with Joma-Polytec would force Curetis to invest significant monetary and managerial resources to move to an alternative manufacturing facility, and Curetis may have difficulty in meeting deadlines for customer orders due to the significant production downtime such relocation would cause. In addition, Curetis USA Inc (“**Curetis USA**”) has entered into a lease agreement originally dated 10 March 2017 with Fenway X LLC (“**Fenway X**”) as landlord and assumed by PRH XVI, LP (“**PRH XVI**”) in July 2017 for office space and into a warehouse storage agreement with Total Transportation Logistics Inc. (“**TTL**”), which includes not only storage, but also transportation from the airport to either TTL’s warehouse or Curetis’ offices in San Diego. The Austrian subsidiary, Ares Genetics, has entered into two lease agreements with Marx Realitäten GmbH (“**Marx Realitäten**”) for, together, approximately 153 sqm of office space in Vienna, Austria as well as a sub-lease agreement with Allcyte GmbH, for approximately 97 sqm of laboratory space in Vienna. As a result, the unexpected termination or non-renewal of the lease agreements could have a significant adverse effect on Curetis’ business, results of operations, financial position, cash flows and prospects.

## **Risks Related to Intellectual Property**

***If Curetis is unable to obtain, protect or enforce its intellectual property effectively, its business would be harmed.***

Curetis relies on patent protection as well as trademark, copyright, trade secret protection and confidentiality agreements to protect the intellectual property rights related to its proprietary technologies (see “*Business — Intellectual Property*”). The strength of patents in Curetis’ field involves complex legal and scientific questions. Uncertainty created by these questions means that Curetis’ patents may provide only limited protection and may not adequately protect Curetis’ rights or may reduce its ability to gain or keep any competitive advantage. If Curetis fails to protect its intellectual property, third parties may be able to compete more effectively against Curetis and it may incur substantial litigation costs in its attempts to recover or restrict use of its intellectual property. In addition, some of Curetis’ patents and patent applications were not filed by it, but were either acquired by it or are licensed from third parties. Thus, these patents and patent applications were not drafted by Curetis or its attorneys, and Curetis did not control or have any input into the prosecution of these patents and patent applications either prior to Curetis’ acquisition of, or entry into a license with respect to, such patents and patent applications.

As a result, there can be no assurance that any of Curetis’ or in-licensed currently pending or future patent applications will result in issued patents with claims that cover Curetis’ products and technologies in the EU, the US or other jurisdictions, and Curetis cannot predict how long it will take for such patents to be issued. Typically, patents in this field are granted in a time frame of two to seven years after filing and patents can, in general, only be enforced from the moment they are granted.

Furthermore, the issuance of a patent is not conclusive as to its inventorship or scope, and there is no guarantee that Curetis' issued patents will include claims that are sufficiently broad to cover Curetis' technologies or to provide meaningful protection from Curetis' competitors. It is possible that not all relevant prior art relating to Curetis' patents and patent applications has been found, which could invalidate Curetis' issued patents or prevent a patent from being issued. Also, since patent applications in most countries are confidential for a period of time after filing and in some countries may remain so until issued, Curetis cannot be certain that it was the first to file any patent application related to any particular technology or product.

Even if patents are issued and even if such patents cover Curetis' products and technologies, other parties may challenge the validity, enforceability or scope of such issued patents in the US, in the EU or in other jurisdictions. Moreover, there is no guarantee that if such patents were challenged, the patent claims will be held valid, enforceable, will be sufficiently broad to cover Curetis' technologies or provide meaningful protection from its competitors. Nor can it be guaranteed that a court or competent authority will uphold Curetis' ownership rights in such patents, which could adversely affect Curetis' business, results of operations, financial position, cash flows and prospects.

In particular, recent changes to the US patent laws may impact Curetis' ability to obtain and enforce its patent rights in the US. For example, recent decisions by US federal courts, including the US Supreme Court, have limited the protection available for clinical diagnostic innovations that rely on naturally occurring genetic sequences and metabolic phenomena. In addition, the Leahy-Smith America Invents Act (the "AIA") included a number of significant changes to US patent law. The US Patent and Trademark Office ("PTO") has implemented and is periodically revising regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA were enacted 16 March 2013. However, it is not clear what, if any, impact the AIA will have on the operation of Curetis' business. The AIA and its implementation, including any future revisions to current PTO regulations, might require the adaptation of the claim structure for US patent applications, which in turn could increase the uncertainties and costs surrounding the prosecution of Curetis' patent applications, all of which could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

Furthermore, even if they are unchallenged, Curetis' patents and patent applications may not adequately protect its intellectual property, provide exclusivity for Curetis' products and technologies or prevent others from designing around Curetis' claims. Others may independently develop similar or alternative products and technologies or duplicate any of Curetis' products and technologies. These products and technologies may not be covered by claims of issued patents owned by Curetis. Any of these outcomes could impair Curetis' ability to prevent competition from third parties. In addition, competitors could purchase Curetis' products and attempt to replicate some or all of the competitive advantages that Curetis derives from its development efforts. If Curetis' intellectual property, including licensed intellectual property, does not adequately protect its market position against competitors' products and methods, Curetis' competitive position could be adversely affected, as could Curetis' business.

Furthermore, as patents have a limited lifespan, if Curetis encounters delays in regulatory approvals, the period of time during which Curetis could market a product under patent protection could be reduced. In the US and Europe, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is still limited.

***Curetis may face difficulties in certain jurisdictions and enjoy only limited geographical protection with respect to certain patents, which may diminish the value of intellectual property rights in those jurisdictions.***

The laws of countries outside the EU or the US do not always protect intellectual property rights to the same extent, and many companies have encountered significant problems in protecting and defending such rights in

foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not support or provide legal measures for the enforcement of patents and other intellectual property protection, particularly those pertaining to technologies relating to biotechnology, which could make it difficult for Curetis to stop an infringement of its patents. In this case, the value of these rights may be diminished and Curetis may face additional competition from others in those jurisdictions. Proceedings to enforce Curetis' patent rights in foreign jurisdictions could result in substantial cost. Additionally, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licences to third parties. Furthermore, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If Curetis or any of its licensors is forced to grant a licence to third parties with respect to any patents relevant to Curetis' business, Curetis' competitive position may be impaired, and its business and results of operations may be adversely affected.

Also, because Curetis has not pursued patents in all countries where such protection is available, there are certain jurisdictions where Curetis is not protected against third parties using its proprietary technologies. In addition, Curetis may decide to abandon national and regional patent applications before grant. Finally, the grant of each national/regional patent is an independent decision made by the relevant patent office. This may lead to a situation in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also common that depending on the country, the scope of patent protection may vary for the same technology.

***Curetis uses certain technologies that are licensed to it. Curetis does not control the intellectual property rights covering these technologies and any loss of its rights to these technologies or the rights licensed to it could prevent Curetis from selling its products.***

Curetis is party to a number of strategic license and supply agreements, including with Acumen as licensor for certain markers used in the sepsis host response Application Cartridges (see also "*Business — Material Contracts*"), under which Curetis is, *inter alia*, granted rights to intellectual property that is important to Curetis' business. Curetis expects that it may need to enter into additional licence agreements in the future. Curetis relies on these licences to be able to use various proprietary technologies that are material to its business. Curetis also relies on non-exclusive licences from other third parties related to materials used in Curetis' research and development activities. Curetis' rights to use these technologies and employ the inventions claimed in the licensed patents are subject to the continuation of and Curetis' compliance with the terms of those licences.

As Curetis has done previously, it may need to obtain licences from third parties to advance its research or allow commercialisation of its products and technologies. Curetis cannot provide any assurances that third-party patents do not exist which might be enforced against Curetis' current or future products and technologies in the absence of such a licence. Curetis may fail to obtain any of these licences on commercially reasonable terms, if at all. In that event, Curetis may be required to expend significant time and resources to develop or license replacement technology. If Curetis is unable to do so, it may be unable to develop or commercialise the affected products and technologies, which could materially harm Curetis' business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting Curetis' sales or an obligation on Curetis' part to pay royalties or other forms of compensation. Even if Curetis is able to obtain a licence, it may be non-exclusive, thereby giving Curetis' competitors access to the same technologies licensed to it. In addition, in some cases, Curetis does not control the prosecution, maintenance, or filing of the patents that are licensed to it, or the enforcement of these patents against infringement by third parties.

Licensing of intellectual property is important to Curetis' business and involves complex legal, business and scientific issues. The licences entered into by Curetis impose, and Curetis expects that future licence agreements will impose, various reporting, prosecution, diligence, fee payment, royalty and other obligations on Curetis. Disputes may arise between Curetis and its licensors regarding Curetis' rights or obligations under the licence

agreements, including arising from Curetis' failure to satisfy payment obligations under such agreement. As a result of any such disputes, Curetis may owe damages, the licensor may have a right to terminate the affected licence, and Curetis' ability to utilise the affected intellectual property in its technology may be adversely affected.

If disputes over intellectual property that Curetis has licensed prevent or impair its ability to maintain its current licensing arrangements on acceptable terms, Curetis may be unable to successfully develop and commercialise the affected products and technologies, and this could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis may be involved in lawsuits and other actions or proceedings to protect or enforce its patents and proprietary rights, to determine the scope, enforceability and validity of others' proprietary rights, or to defend against third-party claims of intellectual property infringement, any of which could be time-intensive and costly and may adversely impact Curetis' business or price of Shares.***

Curetis' commercial success will depend in part on its ability to develop, manufacture and commercialise its Unyvero Platform as well as its future products (including the Unyvero A30 RQ Analyzer and corresponding A30 RQ Application Cartridges) and its ARES Technology Platform (including the GEAR database) without infringing the patents and other intellectual property rights of third parties. While Curetis has not received notices of claims of infringement or misappropriation or misuse of other parties' proprietary rights in the past, it may receive such notices in the future. Some of these claims may lead to litigation. Third parties may assert that Curetis is employing their proprietary technology without authorisation. Curetis may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in Curetis' patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that Curetis' products may infringe, or which such third parties claim are infringed by the use of Curetis' technologies. There can be no assurance that Curetis will prevail in such actions, or that other actions alleging misappropriation or misuse by Curetis of third-party trade secrets or infringement by Curetis of third-party patents, trademarks or other rights, or challenging the validity of Curetis' patents, trademarks or other rights, will not be asserted against Curetis.

Costly and time-consuming litigation may be necessary for Curetis to enforce its patent and proprietary rights or to determine the scope, enforceability or validity of the proprietary rights of others. In the event that third parties accuse Curetis of infringing their patents, Curetis could also incur substantial costs and consume substantial resources in defending against these claims. If such claims prove to be valid, this could lead to significant damages, royalty payments and other financial remedies and an injunction preventing the sale of certain of Curetis' products, which could have a materially adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects. In addition, Curetis may lose valuable intellectual property rights. Litigation or threatened litigation could also result in significant demands on the time and attention of Curetis' management team.

The outcome of any litigation or other proceeding is inherently uncertain and may not be favourable to Curetis. In the event of a successful claim of infringement against Curetis, it could be required to redesign its infringing products or obtain a licence from such third party to continue developing and commercialising Curetis' products and technology (see "*— Curetis depends on certain technologies that are licensed to it. Curetis does not control the intellectual property rights covering these technologies and any loss of its rights to these technologies or the rights licensed to it could prevent Curetis from selling its products.*"). These licences may not be available on acceptable terms, if at all. Even if Curetis or its licensors were able to obtain a licence, the rights may be non-exclusive, which could result in Curetis' competitors gaining access to the same intellectual property. Furthermore, if the scope of protection provided by Curetis' patents or patent applications is threatened or

reduced as a result of litigation, it could discourage third parties from entering into collaborations with Curetis that are important to the commercialisation of its products.

Curetis may not have identified all relevant third party intellectual property rights that may be infringed by Curetis' technology, nor can there be any assurance that patents will not issue in the future from currently pending applications that may be infringed by Curetis' technology or products.

During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, ruling on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of Curetis' technology, product candidates and products, research programmes or intellectual property could be diminished. This could have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.

***Curetis relies on trade secret protection, confidentiality agreements and invention and patent assignment agreements.***

Curetis relies on trade secret protection and confidentiality agreements with Curetis' employees, consultants, corporate partners, advisers and other third parties to protect proprietary know-how, information, discovery and development processes or technology that is not patentable or that it elects not to patent, in order to maintain its competitive position. Curetis also enters into confidentiality agreements and, in jurisdictions where rights in inventions created by employees do not automatically vest in the employer, invention or patent assignment agreements with its employees and consultants that obligate them to assign to Curetis any inventions developed in the course of their work.

Curetis' agreements may not be enforceable or may not provide meaningful protection for Curetis' trade secrets or other proprietary information in the event of unauthorised use or disclosure or other breaches of the agreements, and Curetis may not be able to prevent such unauthorised disclosure. Monitoring unauthorised disclosure is difficult, and Curetis may not have taken sufficient and adequate measures to prevent such disclosure. In addition, Curetis' trade secrets may otherwise become known or be independently discovered by competitors, or competitors could patent proprietary know-how for which Curetis only relies on trade secret protection. If Curetis was to enforce a claim that a third party had illegally obtained and was using its trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. If any of the technology or information that Curetis protects as trade secrets were to be lawfully obtained or independently developed by a competitor, Curetis would have no right to prevent them from using that technology or information to compete with it. Misappropriation or unauthorised disclosure of Curetis' trade secrets could impair Curetis' competitive position and may have a material adverse effect on its business, results of operations, financial position, cash flows and prospects.

In addition, Curetis may not have entered into, and may not in the future enter into, invention or patent assignment agreements with all relevant employees, consultants or other third parties, and any such agreements which are entered into may not be enforceable. As a result, there is a risk that certain of Curetis' patents for inventions created by its employees, consultants or other third parties may be subject to challenge by such employees, consultants or other third parties. Curetis may also be subject to claims that former employees, consultants or other third parties have an ownership interest in Curetis' patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership, and, even if Curetis is successful in defending against such claims, Curetis could incur substantial costs and consume substantial resources in the defence of such claims. If Curetis fails in defending any such claims, it may, in addition to paying monetary damages, lose valuable intellectual property rights, or the exclusive ownership of, or right to use, such intellectual property. This could impair Curetis' competitive position and may have a material adverse effect on its business, results of operations, financial position, cash flows and prospects.

***Curetis may be subject to damages resulting from claims that Curetis or its employees, consultants or independent contractors have wrongfully used or disclosed confidential information or trade secrets of its former employees or other third parties.***

Many of Curetis' employees were previously employed at universities or other medical device companies, including Curetis' competitors or potential competitors. Curetis may be subject to claims that these employees or Curetis have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of its employees' former employers or may be subject to ownership disputes in respect of intellectual property created by these employees during the course of their employment by Curetis. In addition, Curetis could also be subject to claims that Curetis or its employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their former employers. Any of such claims could impair Curetis' competitive position and may have a material adverse effect on its business, results of operations, financial position, cash flows and prospects.

***If Curetis' trademarks and trade names are not adequately protected, Curetis may not be able to build name recognition in its markets of interest, and its business, results of operations, financial position, cash flows and prospects may be materially adversely affected.***

Curetis has not yet registered certain of its trademarks, including Curetis and Unyvero, in all of its current markets. If Curetis applies to register these trademarks, Curetis' applications may not be allowed for registration, and Curetis' registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against Curetis' trademark applications and registrations, and Curetis' trademarks may not survive such proceedings. If Curetis does not secure registrations for its trademarks, Curetis may encounter more difficulty in enforcing them against third parties than it otherwise would. The failure to protect its trademarks could also impair Curetis' competitive position and may have a material adverse effect on its business, results of operations, financial position, cash flows and prospects.

Furthermore, Curetis' registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Curetis may not be able to protect its rights to the trademarks and/or trade names it needs to build name recognition by potential partners or customers in its future key growth markets, such as the US and China as well as other international markets. Over the long term, if Curetis is unable to establish name recognition based on its trademarks and trade names, Curetis may not be able to compete effectively in the MDx market and its business, results of operations, financial position, cash flows and prospects may be adversely affected.

## **Risks Related to the Offer Shares and the Offering**

***Should the anticipated gross proceeds of the Offering (excluding the PSOP Proceeds) fall below €8 million, the Offering will in any event be withdrawn, no Shares will be issued and any applications to subscribe for Offer Shares will be disregarded. If the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, Curetis will implement a detailed action plan to address the resulting working capital shortfall. If delaying planned increases in expenditures is insufficient, such an action plan would include significant cost reductions which, although necessary, would ultimately have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects and the value of the Offer Shares.***

If the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, Curetis will implement a detailed action plan to address the resulting

working capital shortfall. The details of the plan would depend on the degree of the shortfall, but Curetis would initially focus on controlling its cash outflows through delaying planned increases in operating and capital expenditures and personnel hiring in favour of maintaining existing levels of expenditure. If these steps proved to be insufficient and the Offering fails to achieve at least the Mid-Point Proceeds, Curetis would need to implement further significant cost reductions. Such an action plan, although necessary, would ultimately have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects and the value of the Offer Shares. Should the anticipated gross proceeds of the Offering (excluding the PSOP Proceeds) fall below €8 million, the Offering will in any event be withdrawn, no Shares will be issued and any applications to subscribe for Offer Shares will be disregarded. See “— *Risks Related to Business and Strategy* — *Curetis' cash position and operating cash flow may be insufficient to cover expected investment expenses, and Curetis may need to raise additional funds in the future.*” and “*Capitalisation, Indebtedness and Working Capital — Working Capital Statement*” for more details about the action plan Curetis would implement.

If Curetis fails to remedy a working capital shortfall caused by a failure to raise the Mid-Point Proceeds or a withdrawal of the Offering or otherwise, it may be unable to continue as a going concern and may ultimately have to file for insolvency, and investors may lose all or part of their investment in the Offer Shares.

***The market price of the Shares may fluctuate significantly and be lower than the Offer Price, and investors could lose all or part of their investment.***

The stock markets in general, and the markets for medical technology, pharmaceutical and biotechnology shares in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Any one of the following factors, among others, may cause a substantial decline in the markets in which Curetis operates: general economic conditions; geopolitical conditions, including war, acts of terrorism and other man-made or natural disasters; regulatory developments in the EU, the US and other jurisdictions; changes in the structure of healthcare payment systems; publication of significant new scientific research; announcements of technological innovations or new products by Curetis or its competitors; developments in regulatory clearance processes of Curetis or its competitors; publication of research reports about the pharmaceutical or biotechnology industries by securities or industry analysts; changes in estimates by stock market analysts and other events and factors beyond Curetis' control. These factors, and the factors described elsewhere in this section, could significantly reduce the trading price of the Shares. Curetis cannot assure that the market price of the Shares will not decline, and the Shares may trade at prices significantly below the Offer Price, regardless of Curetis' actual operating performance or prospects. As a result, investors may not be able to (re)sell their Shares at or above the Offer Price, or at all.

***Certain existing Shareholders holding a substantial interest may influence the decision-making in the general meeting of the Company. This concentration of ownership may adversely affect the trading volume and market price of the Shares, and the interests of such shareholders may be inconsistent with those of other Shareholders.***

Several existing Shareholders hold a substantial interest in the Company. The eight largest Shareholders hold, according to the public register of the AFM, in aggregate approximately 72.7% of the Shares as at 30 October 2018. See “*Major Shareholders and Related Party Transactions*”. Even if such Shareholders do not participate in the Offering and the maximum number of Offer Shares is issued and sold, such Shareholders would still retain an aggregate of approximately 50.06% of the Shares following completion of the Offering. These large Shareholders will continue to be able to influence or control matters requiring approval by the general meeting of the Company, being the corporate body, or where the context so requires, the physical meeting of Shareholders (the “**General Meeting**”) and may vote their Shares in a way with which other Shareholders do not agree.



Therefore, as a result of their large shareholdings, these existing large Shareholders will be able to exert significant influence on the General Meeting, and, consequently, on matters decided by the General Meeting, including but not limited to the appointment and dismissal of members of the Company management board (the “**Management Board**”, each member a “**Managing Director**”) or the Company’s supervisory board the “**Supervisory Board**”, each member a “**Supervisory Director**”), the distribution of dividends, amendments to the Company’s articles of association (the “**Articles of Association**”), any proposed capital increase or the approval of significant transactions. These Shareholders’ interest would enable them to block certain corporate measures that require the approval of the General Meeting. Furthermore, this concentration of ownership could adversely affect the trading volume and market price of the Shares and there is no indication as to whether or not, when or to what extent these Shareholders will sell any of their Shares. If certain of these Shareholders were to jointly exercise their voting rights and/or to participate in the Offering, their influence may be further strengthened to the extent that they acquire additional Shares.

In any of the above instances, the interests of such Shareholders could deviate from the interests of the other Shareholders and the existing Shareholders may delay, postpone or prevent transactions that might be advantageous for investors.

***Future issuances or sales of substantial numbers of Shares or securities convertible into Shares, or the perception that these issuances or sales may occur, may adversely affect the market price of the Shares and any future issuance of Shares may further dilute investors’ shareholdings.***

The General Meeting has designated the Management Board as the corporate body authorised, subject to approval of the Supervisory Board, to issue Shares and grant rights to subscribe for Shares and to restrict or exclude statutory pre-emptive rights relating thereto. This designation of the Management Board ends on 21 December 2019 and is limited to (i) up to 10% of the total number of Shares issued on 21 June 2018, the date on which the designation was provided, plus (ii) up to an additional 10% of the total number of Shares issued on such date, which authorisation may be used in relation to mergers and acquisitions or strategic alliances involving any one or more of the Company and its group companies, plus (iii) up to an additional 1,639,257 Shares which may be used for Curetis’ Equity Settled Option Plan 2016 (“**ESOP 2016**”). Such authorisations may from time to time be extended by a resolution of the General Meeting. In addition, the General Meeting has designated the Management Board as the corporate body authorised, subject to approval of the Supervisory Board, to issue Shares or grant rights to subscribe for Shares and to restrict or exclude statutory pre-emptive rights relating thereto. This designation of the Management Board ends on 21 December 2019 and is limited to 50% of the issued share capital of the Company on 21 June 2018, the date on which the designation was provided, and may be used to raise additional capital to support the execution of Curetis’ strategy and the development of its business. The Management Board, with the approval from the Supervisory Board, intends to issue the Offer Shares and exclude the statutory pre-emptive rights relating thereto pursuant to these authorisations. The relevant management and supervisory board resolutions shall be adopted prior to Settlement.

The Company has currently granted options under its ESOP 2016 to certain Managing Directors, Supervisory Directors, managers and key employees which, subject to certain vesting conditions, entitle the participants in the ESOP 2016 to receive an aggregate of 919,389 Shares as of 30 June 2018. The equity interests of Shareholders will be diluted to the extent that Shares are issued as a result of the vesting of options under the ESOP 2016.

Curetis may in the future seek to raise capital through public or private debt or equity financings by issuing additional Shares (for example under the GCF Equity Facility), debt or equity securities convertible into Shares (for example pursuant to the Yorkville Agreement) or rights to acquire these securities and exclude the pre-emptive rights pertaining to the then outstanding Shares. In addition, Curetis may in the future seek to issue additional Shares as consideration for or otherwise in connection with the acquisition of new businesses.

Furthermore, Curetis may issue new Shares in the context of any new employment arrangement for involving employees in the capital of the Company. To allow for the foregoing, the Management Board may seek further authorisations from the General Meeting to issue, subject to the approval of the Supervisory Board, Shares and grant rights to subscribe for Shares and to restrict or exclude statutory pre-emptive rights relating thereto. Such authorisations could relate to the full authorised but unissued share capital of the Company. The issuance of any additional Shares may dilute an investor's shareholding interest in the Company. Furthermore, any additional debt or equity financing Curetis may need may not be available on terms favourable to Curetis or at all, which could adversely affect Curetis' future plans and the market price of the Shares.

The Company and the Managers, entered into an underwriting agreement on 2 November 2018 (the “**Underwriting Agreement**”) pursuant to which the Company has agreed to certain restrictions on its ability to issue, offer, sell or transfer Shares for a period of 180 days from the Settlement Date. After the expiry of this period, the Company may issue and sell Shares in the public markets. In addition, the Sole Global Coordinator (acting on behalf of the Managers) has discretion to waive the lock-up restrictions applicable to the Company at any time prior to its expiry. This could result in the Company issuing and selling Shares in the public markets before the expiry of the lock-up restrictions. See “*Plan of Distribution – Lock-up Arrangements*”. See also “*Risk Factors — Risks Related to the Offer Shares and the Offering — Should the anticipated gross proceeds of the Offering (excluding the PSOP Proceeds) fall below €8 million, the Offering will in any event be withdrawn, no Shares will be issued and any applications to subscribe for Offer Shares will be disregarded. If the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, Curetis will implement a detailed action plan to address the resulting working capital shortfall. If delaying planned increases in expenditures is insufficient, such an action plan would include significant cost reductions which, although necessary, would ultimately have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects and the value of the Offer Shares.*”.

Any additional offering or issuance of Shares by the Company or the perception that an offering or issuance may occur could also have a negative impact on the market price of the Shares and could increase the volatility in the trading price of the Shares. As many of the existing Shareholders are private equity or venture capital investors it is possible that those investors might want to reduce their stake in Curetis. Furthermore, a sale of Shares by any or all of the Managing Directors and/or Supervisory Directors could be considered as a lack of confidence in the performance and prospects of Curetis and could cause the market price of the Shares to decline.

***If securities or industry analysts cease to publish research reports on Curetis' business, or adversely change or make negative recommendations regarding the Shares, the market price and trading volume of the Shares could decline.***

Whether there is an active trading market for the Shares will be influenced by, among other things, the availability and recommendations of research reports covering Curetis' business. Directive 2014/65/EU of the European Union on markets in financial instruments (“**MiFID II**”), which entered into force on 1 January 2018, requires research to be priced and charged separately from execution. As a result of MiFID II, it is possible that research coverage will be reduced in general, and that remaining coverage will be more focused on certain companies, industries or geographic markets. This may negatively affect the coverage by research analysts of Curetis' business. If one or more research analysts ceases to cover Curetis' business or fails to regularly publish reports on its business, Curetis could lose visibility in the financial markets, which could cause the market price or trading volume of the Shares to decline. In addition, if research analysts do not make positive recommendations regarding the Shares, or if negative research is published on the industry or geographic markets serves, the price and trading volume of the Shares could decline.

***There may be limited liquidity of the Shares, which may cause Shares to trade at a discount and make it difficult for investors to sell Shares at or above the Offer Price or at all.***

Historically, the volume of trading in the Shares on Euronext in Amsterdam and Euronext in Brussels was relatively low. The average monthly trading volume in the Shares on Euronext in Amsterdam and Euronext in Brussels in the twelve-month period from 1 October 2017 up to and including 30 September 2018 was €322,759.75 million and 54,916 Shares (source: Euronext market data). There is no guarantee that there will be sufficient liquidity in the Shares to sell any number of Shares at or above the Offer Price or at all. The price of the Shares will in addition be subject to volatility and investors may be unable to sell their Shares at or above the Offer Price or at all. Although the Company has retained a liquidity provider to support the trading of the Shares under certain conditions, there is no guarantee that there will be sufficient liquidity in the Shares to sell any number of Shares at or above the Offer Price or at all.

***The Company has broad discretion in the use of the net proceeds from the Offering and may not use them effectively.***

The Company's management will have broad discretion in the application of the net proceeds from the Offering and could spend the proceeds in ways that do not improve the Company's results of operations or enhance the value of the Shares. The Company intends to use the net proceeds from the Offering, *inter alia*, to maintain and continue to expand a direct commercial marketing, sales and support presence in the US in order to more broadly commercialise the Unyvero Platform and the LRT Application Cartridge in the US via its own sales and marketing organisation, towards continuing to expand its research and development pipeline of the Unyvero System, the Application Cartridges and the Unyvero A30 RQ Analyzer for European, US and global markets, to fund working capital requirements to finance the placement of the Unyvero System in the European markets where Curetis makes direct sales as well as the US and as further described under "*Reasons for the Offering and Use of Proceeds*". However, the Company's actual use of these proceeds may differ substantially from the Company's current plans and investors will not have the opportunity as part of their investment decision to assess whether the net proceeds are being used appropriately. The failure by the Company's management to apply these funds effectively could result in financial losses that could have a material adverse effect on Curetis' business and cause the market price of the Shares to decline. Pending their use, the Company may invest the net proceeds from the Offering in a manner that does not produce income or that loses value.

***Holders of Shares who are resident or located in certain jurisdictions outside the Netherlands, including the US, may be unable to exercise pre-emptive rights in future offerings and, as a result, may experience dilution.***

In the event of an increase in the Company's share capital, Shareholders are generally entitled to pre-emptive rights, unless these rights are restricted or excluded either by a resolution of the General Meeting or of the Management Board, with the approval of the Supervisory Board (if the Management Board has been designated by the General Meeting).

However, the securities laws of certain jurisdictions may restrict the Company's ability to allow Shareholders to participate in offerings of the Company's securities and to exercise pre-emptive rights. Accordingly, subject to certain exceptions, Shareholders with registered addresses, or who are resident or located in certain jurisdictions outside the Netherlands, including the US, will not be eligible to exercise pre-emptive rights. As a result, such Shareholders may experience dilution of their ownership and voting interests in the Company's share capital.

***If Settlement does not occur, subscriptions for the Offer Shares may be disregarded and transactions effected in the Offer Shares will be annulled.***

The Shares in issue on the date of this Prospectus have been, and the Offer Shares are expected to be, admitted to listing and trading on Euronext in Amsterdam and Euronext in Brussels under the symbol "CURE". Curetis

expects that trading in the Offer Shares will commence prior to the Settlement Date. Settlement may not take place on the Settlement Date or at all if certain conditions or events referred to in the Underwriting Agreement are not satisfied or waived or occur on or prior to such date (see “*Plan of Distribution*”). Trading in the Offer Shares before Settlement will take place subject to the condition that, if the Offering does not take place, the Offering will be withdrawn, all subscriptions for the Offer Shares will be disregarded, any allotments made will be deemed not to have been made, any subscription payments made will be returned without interest or other compensation and transactions on Euronext in Amsterdam and Euronext in Brussels will be annulled. All dealings in the Offer Shares prior to Settlement are at the sole risk of the parties concerned. The Company, the Managers, the Listing Agent and Euronext do not accept any responsibility or liability for any loss incurred by any person as a result of a withdrawal of the Offering or the related annulment of any transactions on Euronext in Amsterdam and Euronext in Brussels. Should the anticipated gross proceeds of the Offering (excluding the PSOP Proceeds) fall below €8 million, the Offering will in any event be withdrawn, no Shares will be issued and any applications to subscribe for Offer Shares will be disregarded.

***The Company does not intend to pay dividends for the foreseeable future.***

The Company does not intend to pay any dividends for the foreseeable future. Payment of future dividends to Shareholders will effectively be at the discretion of the Management Board, subject to the approval of the Supervisory Board, after taking into account various factors including Curetis’ business prospects, cash requirements, financial performance and new product development. Accordingly, investors cannot rely on dividend income from the Shares and any returns on an investment in the Shares will likely depend entirely upon any future appreciation in the price of the Shares. The Company can provide no assurance that the price of the Shares will appreciate after the Offering or that the market price for the Shares will not fall below the Offer Price.

***Investors with a reference currency other than euro will become subject to foreign exchange rate risk when investing in the Shares.***

The Shares are denominated in and will trade in euro. Dividends on the Shares, if any will ever be paid, will be paid by the Company in euro. Investors whose reference currency is a currency other than the euro may be materially and adversely affected by any reduction in the value of the euro relative to the value of the investor’s reference currency. In addition, such investors could incur additional transaction costs in converting euro into another currency. Investors whose reference currency is a currency other than euro are therefore urged to consult their financial advisers.

***The ability of Shareholders to bring action or enforce judgments against the Company, Managing Directors and Supervisory Directors may be limited.***

The ability of Shareholders to bring an action against the Company may be limited under law. The Company is a public company with limited liability (*naamloze vennootschap*) incorporated under the laws of the Netherlands. The rights of Shareholders are governed by Dutch law and the Articles of Association. These rights differ from the rights of Shareholders in typical US corporations and other non-Dutch corporations. It may be difficult for a Shareholder to prevail in a claim against the Company or to enforce liabilities predicated upon non-Dutch laws.

It may not be possible for a Shareholder to effect service of process upon the Managing Directors or the Supervisory Directors within such Shareholder’s country of residence, or to enforce against the Directors or the Supervisory Directors judgments of courts of such Shareholder’s country of residence based on civil liabilities under that country’s securities laws. There can be no assurance that a Shareholder will be able to enforce any judgment in civil and commercial matters or any judgments against the Managing Directors or the Supervisory Directors who are residents of countries other than those in which the judgment is made. See also “*Important Information — Enforceability of Judgments*”.

***The Company may be a passive foreign investment company for US federal income tax purposes, which could subject US investors in the Shares to significant adverse tax consequences.***

A non-U.S. corporation, such as the Company, is a passive foreign investment company (a “PFIC”) for U.S. federal income tax purposes for any taxable year, if either (i) 75% or more of its gross income for such year consists of certain types of “passive” income or (ii) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. Passive income generally includes dividends, interest, royalties, rents, annuities, net gains from the sale or exchange of property producing such income and net foreign currency gains. For this purpose, cash and assets readily convertible into cash are categorized as passive assets and the company’s unbooked intangibles associated with active business activity are taken into account as non-passive assets. In addition, a non-U.S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the income of any other corporation in which it owns, directly or indirectly, 25% or more (by value) of the stock.

Based on Curetis’ current income and assets and the expected value of the Offer Shares, it is possible that the Company could be a PFIC for the current taxable year and/or in future taxable years. Even if the Company is not currently a PFIC, changes in the nature of the Company’s income or assets, or fluctuations in the market price of Offer Shares, may cause the Company to become a PFIC for future taxable years. If the Company is classified as a PFIC for any taxable year during which a U.S. Holder (as defined in “*Taxation—US Federal Income Tax Considerations*”) holds Offer Shares, such U.S. Holder may incur significantly increased U.S. federal income tax on gain recognized on the sale or other disposition of Offer Shares and on the receipt of distributions on Offer Shares to the extent such gain or distribution is treated as an “excess distribution” under the applicable U.S. federal income tax rules. If the Company is so classified during a U.S. Holder’s holding period, Offer Shares will generally continue to be treated as shares in a PFIC for all succeeding years during which such U.S. Holder holds Offer Shares, even if the Company ceases to be a PFIC, unless certain elections are made. See the discussion under “*Taxation—US Federal Income Tax Considerations—Passive Foreign Investment Company Rules*” concerning the U.S. federal income tax considerations of an investment in Offer Shares if the Company is or becomes classified as a PFIC, including the possibility of making certain elections.

## **IMPORTANT INFORMATION**

### **General**

Prospective investors are expressly advised that an investment in the Offer Shares entails certain risks and that they should therefore read and carefully review the content of this Prospectus. A prospective investor should not invest in the Offer Shares unless it has the expertise (either alone or with a financial adviser) to evaluate how the Offer Shares will perform under changing conditions, the resulting effects on the value of the Shares and the impact this investment will have on its overall investment portfolio. Prospective investors should also consult their own tax advisers as to the tax consequences of the purchase, ownership and disposition of the Offer Shares.

The content of this Prospectus is not to be considered or interpreted as legal, financial or tax advice. It should not be considered as a recommendation by any of the Company, the members of the Management Board and the Supervisory Board or any of the Managers or any of their respective representatives that any recipient of this Prospectus should subscribe for or purchase any Offer Shares. Prior to making any decision whether to purchase the Offer Shares, prospective investors should read this Prospectus. Investors should ensure that they read the whole of this Prospectus and not just rely on key information or information summarised within it. Each prospective investor should consult his or her own stockbroker, bank manager, lawyer, auditor or other financial, legal or tax advisers before making any investment decision with regard to the Offer Shares, to among other things consider such investment decision in light of his or her personal circumstances and in order to determine whether or not such prospective investor is eligible to subscribe for the Offer Shares. In making an investment decision, prospective investors must rely on their own examination of the Company, the Offer Shares and the terms of the Offering, including the merits and risks involved.

Prospective investors should rely only on the information contained in this Prospectus, the Pricing Statement and any supplement to this Prospectus within the meaning of Section 5:23 of the Dutch Financial Supervision Act. The Company does not undertake to update this Prospectus, unless required pursuant to Section 5:23 of the Dutch Financial Supervision Act, and therefore potential investors should not assume that the information in this Prospectus is accurate as of any date other than the date of this Prospectus. No person has been authorised to give any information or to make any representations in connection with the Offering, other than those contained in this Prospectus, and, if given or made, such information or representations must not be relied upon as having been authorised by or on behalf of the Company, the members of the Management Board or the Supervisory Board, the Listing Agent, any of the Managers or any of their respective representatives. The delivery of this Prospectus at any time after the date hereof will not, under any circumstances, create any implication that there has been no change in Curetis' affairs since the date hereof or that the information set forth in this Prospectus is correct as of any time since its date.

No representation or warranty, express or implied, is made or given by or on behalf of any of the Managers, the Listing Agent or any of their affiliates or any of their respective directors, officers or employees or any other person, as to the accuracy, completeness or fairness of the information or opinions contained in this Prospectus, or incorporated by reference herein, and nothing contained in this Prospectus, or incorporated by reference herein, is, or shall be relied upon as, a promise or representation by the Managers, the Listing Agent or any of their respective affiliates as to the past, present or future. None of the Managers or the Listing Agent accepts any responsibility whatsoever for the contents of this Prospectus or for any other statements made or purported to be made by either itself or on its behalf in connection with Curetis, the Offering, or the Offer Shares. Accordingly, the Managers and the Listing Agent disclaim, to the fullest extent permitted by applicable law, all and any liability, whether arising in tort or contract or which they might otherwise be found to have in respect of this Prospectus and/or any such statement.

Although the Managers are party to various agreements pertaining to the Offering and each of the Managers has or might enter into a financing arrangement with the Company and/or any of its affiliates, this should not be considered as a recommendation by any of them to invest in the Offer Shares.

The Listing Agent is acting exclusively for the Company and no one else in connection with the Offering. It will not regard any other person (whether or not a recipient of this Prospectus) as its respective customer in relation to the Offering and will not be responsible to anyone other than the Company for providing the protections afforded to their respective customers or for giving advice in relation to, respectively, the Offering and the listing or any transaction or arrangement referred to herein.

The distribution of this Prospectus and the Offering may, in certain jurisdictions, be restricted by law, and this Prospectus may not be used for the purpose of, or in connection with, any offer or solicitation by anyone in any jurisdiction in which such offer or solicitation is not authorised or to any person to whom it is unlawful to make such offer or solicitation. This Prospectus does not constitute an offer of, or an invitation to, purchase any of the Offer Shares in any jurisdiction in which such offer or invitation would be unlawful. The Company and the Managers require persons into whose possession this Prospectus comes to inform themselves of and observe all such restrictions. None of the Company or the Managers accepts any legal responsibility for any violation by any person, whether or not a prospective investor of Offer Shares, of any such restrictions. The Company and the Managers reserve the right in their own absolute discretion to reject any offer to purchase Offer Shares that the Company, the Managers or their respective agents believe may give rise to a breach or violation of any laws, rules or regulations.

## **Responsibility Statement**

This Prospectus is made available by the Company. The Company accepts responsibility for the information contained in this Prospectus. The Company declares that, having taken all reasonable care to ensure that, to the best of its knowledge, the information contained in this Prospectus is in accordance with the facts and contains no omission likely to affect its import.

## **Information to Distributors**

Solely for the purposes of the product governance requirements contained within: (a) MiFID II; (b) Articles 9 and 10 of Commission Delegated Directive (EU) 2017/593 supplementing MiFID II; and (c) local implementing measures (together, the “**MiFID II Product Governance Requirements**”), and disclaiming all and any liability, whether arising in tort, contract or otherwise, which any “manufacturer” (for the purposes of the MiFID II Product Governance Requirements) may otherwise have with respect thereto, the Offer Shares have been subject to a product approval process, which has determined that the Offer Shares are: (i) compatible with an end target market of, retail investors and investors who meet the criteria of professional clients and eligible counterparties, each as defined in MiFID II; and (ii) eligible for distribution through all distribution channels as are permitted by MiFID II (the “**Target Market Assessment**”). Notwithstanding the Target Market Assessment, “distributors” (for the purposes of the MiFID II Product Governance Requirements) should note that: the Offering has explicitly been limited to investors who meet the criteria of professional clients and eligible counterparties on the basis of the substantial risks and uncertainties that are involved with investing in the Offer Shares (see inter alia “Risk Factors” and “Capitalisation, Indebtedness and Working Capital – Working Capital Statement”); the price of the Offer Shares may decline and investors could lose all or part of their investment; the Offer Shares offer no guaranteed income and no capital protection; and an investment in the Offer Shares is compatible only with investors who do not need a guaranteed income or capital protection, who (either alone or in conjunction with an appropriate financial or other adviser) are capable of evaluating the merits and risks of such an investment and who have sufficient resources to be able to bear any losses that may

result therefrom. The Target Market Assessment is without prejudice to the requirements of any contractual, legal or regulatory selling restrictions in relation to the Offering which, amongst other things limit offers to institutional investors only.

For the avoidance of doubt, the Target Market Assessment does not constitute: (a) an assessment of suitability or appropriateness for the purposes of MiFID II; or (b) a recommendation to any investor or group of investors to invest in, or purchase, or take any other action whatsoever with respect to the Offer Shares. Prospective investors should read and carefully review the entire Prospectus and should reach their own views before making an investment decision with respect to any Offer Shares. Furthermore, before making an investment decision with respect to any Offer Shares, prospective investors should consult their own stockbrokers, bank managers, lawyers, auditors or other financial, legal and tax advisers and carefully review the risks associated with an investment in the Offer Shares and consider such an investment decision in light of their personal circumstances.

Each distributor is responsible for undertaking its own target market assessment in respect of the Offer Shares and for determining appropriate distribution channels for the Offer Shares.

## **Presentation of Financial and Other Information**

### ***Financial information***

This Prospectus incorporates by reference the audited consolidated financial statements of the Company as of and for the financial years ended 31 December 2017 and 2016 (the “**Annual Financial Statements**”) and the unaudited consolidated financial statements of the Company as of 30 June 2018 and for the six months ended 30 June 2018 and comparative information for the six months ended 30 June 2017 (the “**Interim Financial Statements**”), as specified below.

The Annual Financial Statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union (EU). The Annual Financial Statements were audited by PricewaterhouseCoopers Accountants N.V. (“**PwC**”), Flight Forum 840, 5600 HJ Eindhoven, The Netherlands. The auditor signing the auditor’s report on behalf of PwC is a member of the Royal Netherlands Institute of Chartered Accountants (*Koninklijke Nederlandse Beroepsorganisatie van Accountants*). The Interim Financial Statements are unaudited and have not been reviewed.

There are no qualifications in the auditor’s reports on the Annual Financial Statements. The auditor’s report for the financial year ended 31 December 2017 contains an emphasis of matter paragraph, in which the auditors draw attention to note 3.27 of the notes to the audited consolidated financial statements of the Company for the financial year ended 31 December 2017, which describe that the Company’s ability to continue as a going concern is threatened by risks.

### ***Rounding***

Certain figures contained in this Prospectus, including financial information, have been subject to rounding adjustments. Accordingly, in certain instances (i) the sum or percentage change of such numbers may not conform exactly with the total figure given; (ii) the sum of the numbers in a column or a row in certain tables may not conform exactly with the total figure given for that column or row; and (iii) the corresponding percentage change of certain numbers that have been subject to rounding adjustments may be based on unrounded numbers.

### ***Currencies***

In this Prospectus, unless otherwise indicated: all references to the “EU” are to the European Union; all references to “euro” or “€” are to the lawful currency of the European Union; all references to the “United



States” or the “US” are to the United States of America; all references to “US dollars” or “US\$” are to the lawful currency of the United States.

### ***Exchange rate information***

The exchange rates below are provided solely for information and convenience. The rates may differ from the actual rates used in the preparation of the financial information appearing in this Prospectus. No representation is made that euros could have been, or could be, converted into US dollars at any particular rate indicated or any other rate. The table below sets forth high, low, average and period end exchange rates of US dollars per euro for each year indicated (source: Bloomberg). The average rate for a year means the average of the Bloomberg composite rates on the last day of each month during a year.

<b>Year</b>	<b>High</b>	<b>Low</b>	<b>Average</b>	<b>Period end</b>
		<i>(US dollars per €1)</i>		
2014 .....	1.393	1.210	1.328	1.210
2015 .....	1.201	1.049	1.110	1.087
2016 .....	1.153	1.038	1.107	1.055
2017 .....	1.203	1.043	1.129	1.202
2018 (through 30 June 2018) .....	1.249	1.155	1.211	1.168

The table below sets forth high, low, average and period end exchange rates of US dollars per euro for each month indicated (source: Bloomberg).

<b>Month</b>	<b>High</b>	<b>Low</b>	<b>Average</b>	<b>Period end</b>
		<i>(US dollars per €1)</i>		
January 2018.....	1.249	1.192	1.220	1.242
February 2018.....	1.248	1.221	1.235	1.221
March 2018.....	1.244	1.221	1.234	1.233
April 2018 .....	1.239	1.210	1.228	1.210
May 2018 .....	1.202	1.155	1.182	1.167
June 2018 .....	1.181	1.157	1.168	1.168

On 29 June 2018 the exchange rate of US\$ per €1 was 1.168.

### ***Supplements***

If a significant new factor, material mistake or inaccuracy relating to the information included in this Prospectus which is capable of affecting the assessment of the Offer Shares, arises or is noted between the date of this Prospectus and the later of the end of the Offer Period and the start of trading of the Offer Shares on Euronext in Amsterdam and Euronext in Brussels, a supplement to this Prospectus is required. Such a supplement will be subject to approval by the AFM in accordance with Section 5:23 of the Dutch Financial Supervision Act and will be made public in accordance with the relevant provisions under the Dutch Financial Supervision Act. The summary shall also be supplemented, if necessary to take into account the new information included in the supplement.

Furthermore, solely for the purpose of admission to listing and trading of the Conversion Shares on Euronext in Amsterdam and Euronext in Brussels following the date of this Prospectus, if a significant new factor,

material mistake or inaccuracy relating to the information included in this Prospectus which is capable of affecting the assessment of the Conversion Shares, arises or is noted during the twelve month period following the date of this Prospectus, a supplement to this Prospectus is required. Such a supplement will be subject to approval by the AFM in accordance with Section 5:23 of the Dutch Financial Supervision Act and will be made public in accordance with the relevant provisions under the Dutch Financial Supervision Act. The summary shall also be supplemented, if necessary to take into account the new information included in the supplement.

Statements contained in any such supplement (or contained in any document incorporated by reference therein) shall, to the extent applicable (whether expressly, by implication or otherwise), be deemed to modify or supersede statements contained in this Prospectus or in a document which is incorporated by reference in this Prospectus. Any shall specify which statement is so modified or superseded and shall specify that such statement shall, except as so modified or superseded, no longer constitute a part of this Prospectus. For the avoidance of doubt, references in this paragraph to any supplement being published by the Company do not include the Pricing Statement.

### **Notice to Investors**

EXCEPT AS OTHERWISE SET OUT IN THIS PROSPECTUS, THE OFFERING DESCRIBED IN THIS PROSPECTUS IS NOT BEING MADE TO INVESTORS IN THE UNITED STATES, CANADA, AUSTRALIA OR JAPAN, AND THIS PROSPECTUS SHOULD NOT BE FORWARDED OR TRANSMITTED IN OR INTO THE UNITED STATES, AUSTRALIA, CANADA OR JAPAN OR ANY OTHER JURISDICTIONS IN WHICH IT IS UNLAWFUL TO DO SO.

The Offer Shares may not be a suitable investment for all investors. Each prospective investor in the Offer Shares must determine the suitability of that investment in light of its own circumstances. In particular, each prospective investor (either alone or with a financial adviser) should:

- have sufficient knowledge and experience to make a meaningful evaluation of the Offer Shares, the merits and risks of investing in the Offer Shares and the information contained or incorporated by reference in this Prospectus, including the financial risks and other risks described in the section “*Risk Factors*”.
- have the expertise to evaluate how the Offer Shares will perform under changing conditions, the resulting effects on the value of the Offer Shares and the impact this investment will have on the prospective investor’s overall investment portfolio.

Because of the following restrictions, prospective investors are advised to consult legal counsel prior to making any offer for, resale, pledge or other transfer of the Offer Shares.

This Prospectus does not constitute or form part of any offer or invitation to sell, or any solicitation of any offer to acquire Offer Shares in any jurisdiction in which such an offer or solicitation is unlawful or would result in the Company becoming subject to public company reporting obligations outside the Netherlands.

The distribution of this Prospectus, and the offer or sale of Offer Shares is restricted by law in certain jurisdictions. This Prospectus may only be used where it is legal to offer, solicit offers to purchase or sell Offer Shares. Persons who obtain this Prospectus must inform themselves about and observe all such restrictions. None of the Company or the Managers accepts any legal responsibility for any violation by any person, whether or not a prospective purchaser of Offer Shares, of any such restrictions. The Company and the Managers reserve the right in their own absolute discretion to reject any offer to purchase Offer Shares that the Company, the Managers or their respective agents believe may give rise to a breach or violation of any laws, rules or regulations.

No action has been or will be taken to permit a public offer or sale of Offer Shares, or the possession or distribution of this Prospectus or any other material in relation to the Offering in any jurisdiction outside the Netherlands and Germany where action may be required for such purpose. Accordingly, neither this Prospectus nor any advertisement or any other related material may be distributed or published in any jurisdiction except under circumstances that will result in compliance with any applicable laws and regulations.

Shareholders who have a registered address in, or who are resident or located in, jurisdictions other than the Netherlands and Germany and any person (including, without limitation, agents, custodians, nominees and trustees) who has a contractual or other legal obligation to forward this Prospectus to a jurisdiction outside the Germany should read the section “*Selling and Transfer Restrictions*”.

## **NOTICE TO PROSPECTIVE INVESTORS IN THE UNITED STATES**

The Offer Shares have not been and will not be registered under the US Securities Act or under the securities laws of any state or other jurisdiction in the United States. The Offer Shares may be offered, sold or otherwise transferred only in the following circumstances: (i) within the United States to qualified institutional buyers (“**QIBs**”) as defined in Rule 144A under the US Securities Act (“**Rule 144A**”) in reliance on Rule 144A or pursuant to another exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act, and (ii) outside the United States in offshore transactions in reliance on Regulation S under the US Securities Act. Transfers of the Shares will be restricted, and each purchaser of the Shares will be deemed to have made acknowledgments, representations and agreements, as described in the section “*Selling and Transfer Restrictions*”.

In addition, until the end of the 40th calendar day after the commencement of the Offering, an offer or sale of the Offer Shares within the United States by a dealer (whether or not participating in the Offering) may violate the registration requirements of the US Securities Act if such offer or sale is made otherwise than in accordance with Rule 144A or another exemption from registration under the US Securities Act. None of the Company and the Managers accept any legal responsibility for any violation by any person, whether or not a prospective investor in the Offer Shares, of any of the foregoing restrictions.

**THE SHARES OFFERED HEREBY HAVE NOT BEEN RECOMMENDED BY ANY US FEDERAL OR STATE SECURITIES COMMISSION OR REGULATORY AUTHORITY. FURTHERMORE, THE FOREGOING AUTHORITIES HAVE NOT PASSED UPON OR ENDORSED THE MERITS OF THE OFFERING OF THE RIGHTS OR THE SHARES OR CONFIRMED THE ACCURACY OR DETERMINED THE ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENCE IN THE UNITED STATES.**

In the United States, this Prospectus is being furnished on a confidential basis solely for the purpose of enabling a prospective purchaser to consider purchasing the particular securities described herein. The information contained in this Prospectus has been provided by the Company and the other sources identified herein. Distribution of this Prospectus to any person other than the offeree specified by the Company and those persons, if any, retained to advise such offeree with respect thereto, is unauthorised, and any disclosure of its contents, without the Company’s prior written consent, is prohibited.

This Prospectus is personal to each offeree and does not constitute an offer to any other person or to the public generally to subscribe for or otherwise acquire the securities described herein. Investors agree to the foregoing by accepting delivery of this Prospectus.

## NOTICE TO PROSPECTIVE INVESTORS IN THE UNITED KINGDOM

In the United Kingdom, this Prospectus is for distribution only to, and is only directed at, persons who (i) have professional experience in matters relating to investments falling within article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, (the “**Financial Promotion Order**”), (ii) are persons falling within article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the Financial Promotion Order or (iii) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000) in connection with the issue or sale of the Offer Shares may otherwise lawfully be communicated (all such persons together being referred to as “relevant persons”). This Prospectus is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this Prospectus relates is available only to relevant persons and will be engaged in only with relevant persons.

Furthermore, the Managers have warranted that they: (i) have only invited or will only invite participation in investment activities in connection with the Offering or the sale of the Offer Shares within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended (“**FSMA 2000**”), and have only initiated or will only initiate such investment activities to the extent that Section 21(1) of the FSMA 2000 does not apply to the Company; and (ii) have complied and will comply with all applicable provisions of FSMA 2000 with respect to all activities already undertaken by each of them or will undertake in the future in relation to the shares in, from, or otherwise involving the United Kingdom.

## NOTICE TO PROSPECTIVE INVESTORS IN THE EUROPEAN ECONOMIC AREA

This Prospectus has been prepared on the basis that all offers of Offer Shares in any member state of the European Economic Area which has implemented the Prospectus Directive (each a “**Relevant EEA Member State**”) will be made under the exemption for offers to qualified investors as defined in the Prospectus Directive, as implemented in that Relevant EEA Member State, from the requirement to publish a prospectus for offers of Offer Shares. Accordingly, any person making or intending to make an offer in a Relevant EEA Member State of Offer Shares which are the subject of the Offering contemplated in this Prospectus may only do so in circumstances in which no obligation arises for the Company or the Managers to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor any Underwriter has authorised, nor do they authorise, the making of any offer of Offer Shares in circumstances in which an obligation arises for the Company or any Underwriter to publish a prospectus for such offer.

## Documents Incorporated by Reference

The Articles of Association (the Dutch version and an English translation thereof), the Annual Financial Statements and Interim Financial Statements as specified below are incorporated into, and form part of, this Prospectus and can be obtained free of charge from the Company’s website <http://www.curetis.com/en/investors/share-information/offering.html>.

	<b>Pages of the 2017 Annual Report</b>
<b>2017 Annual Financial Statements</b>	
Consolidated statement of profit or loss and other comprehensive income .....	82
Consolidated statement of financial position.....	83
Consolidated statement of cash flows.....	84

<b>2017 Annual Financial Statements</b>	<b>Pages of the 2017 Annual Report</b>
Consolidated statement of changes in equity .....	85
Notes to the consolidated financial statements for the year 2017 .....	86-134
Independent auditor's report .....	150-159
 <b>2016 Annual Financial Statements</b>	 <b>Pages of the 2016 Annual Report</b>
Consolidated statement of profit or loss and other comprehensive income .....	78
Consolidated statement of financial position.....	79
Consolidated statement of cash flows.....	80
Consolidated statement of changes in equity .....	81
Notes to the consolidated financial statements for the year 2016 .....	82-121
Independent auditor's report .....	134-142
 <b>Interim Financial Statements</b>	 <b>Pages of the 2018 First Half Year Business and Financial Update</b>
Consolidated interim statement of profit or loss and other comprehensive income (unaudited).....	1
Consolidated interim statement of financial position (unaudited).....	2-3
Consolidated interim statement of cash flows (unaudited).....	4
Consolidated interim statement of changes in equity (unaudited) .....	5
Notes to the unaudited consolidated interim financial statements .....	6-40

Prospective investors should rely only on the information that the Company incorporates by reference or provides in this Prospectus. No other documents or information, including the content of Curetis' website – [www.curetis.com](http://www.curetis.com) – or of websites accessible from hyperlinks on that website, form part of, or are incorporated by reference into, this Prospectus.

For the purposes of this Prospectus, the management review, corporate governance report and the non-consolidated financial statements of the Company are not incorporated by reference. In each case, unless stated otherwise, the entire document is incorporated by reference into this Prospectus. Where parts of documents are incorporated by reference into this Prospectus, the non-incorporated parts are either not relevant for the investor or are described elsewhere in this Prospectus. Notwithstanding the foregoing, where the documents incorporated by reference themselves incorporate information by reference, such information does not form part of this Prospectus.

## **Available Information**

For so long as any of the Offer Shares are “restricted securities” within the meaning of Rule 144(a)(3) under the US Securities Act, the Company will, during any period in which it is not subject to Section 13 or 15(d) of the US Securities Exchange Act of 1934, as amended (the “**US Exchange Act**”), nor exempt from reporting under the US Exchange Act pursuant to Rule 12g3-2(b), make available to any holder or beneficial owner of the Offer Shares, or to any prospective investor of the Offer Shares designated by such holder or beneficial owner, upon the request of such holder, beneficial owner or prospective investor, the information specified in, and meeting the requirements of, Rule 144A(d)(4) under the US Securities Act.

## **Enforceability of Judgments**

The Company is a public company with limited liability (*naamloze vennootschap*) under the laws of the Netherlands. Most of the Supervisory Directors, the Managing Directors and the Company’s employees are citizens or residents of countries other than the United States. All or a substantial portion of the assets of such persons and a substantial portion of the Company’s assets, including the Company’s IP rights, are located outside the United States. As a result, it may be difficult for investors to effect service of process within the United States upon the Company or such persons or to enforce against any of them in the US courts judgments obtained in US courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any State or territory within the United States.

The United States and the Netherlands currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. In addition, the countries of residence of the members of the Management Board and the Supervisory Board and of the Company’s employees may also not have a treaty providing for the reciprocal recognition and enforcement of judgments. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon US securities laws, would not be enforceable in the Netherlands. In order to obtain a judgment which is enforceable in the Netherlands, the party in whose favour a final and conclusive judgment of the US court has been rendered will be required to file its claim with a court of competent jurisdiction in the Netherlands. Such party may submit to the Dutch court the final judgment rendered by the US court. If and to the extent that the Dutch court finds that the jurisdiction of the US court has been based on grounds which are internationally acceptable and that proper legal procedures have been observed, the Dutch court will, in principle, give binding effect to such final judgment, without substantive re-examination or re-litigation on the merits of the subject matter thereof, insofar as it finds that such judgment (i) does not contravene principles of public policy of the Netherlands and (ii) is not irreconcilable with a judgment of a Dutch court given between the same parties, or with an earlier judgment of a foreign court given between the same parties in a dispute involving the same cause of action and subject matter, provided that such earlier judgment fulfils the conditions necessary for it to be given binding effect in the Netherlands. It is uncertain whether this practice extends to default judgments as well. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a US court and recognise damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of US courts in the Netherlands are subject to the Dutch rules of civil procedure.

## **Market Data and Other Information from Third Parties**

Unless the source is otherwise stated, the market, economic and industry data in this document constitute the estimates of Curetis’ management, using underlying data from independent third parties. Curetis has obtained market data and certain industry forecasts used in this document from internal surveys, academic and other reports and studies, where appropriate, as well as market research, publicly available information and industry

publications. Where third-party information has been used in this document, the source of this information has been identified.

The information in this Prospectus that has been sourced from third parties has been accurately reproduced and, as far as Curetis is aware and able to ascertain from the information published by that third party, no facts have been omitted that would render the reproduced information inaccurate or misleading. Industry publications generally state that their information is obtained from sources they believe reliable but that the accuracy and completeness of such information is not guaranteed and that the projections they contain are based on a number of significant assumptions. Although Curetis believes these sources to be reliable, as Curetis does not have access to the information, methodology and other bases for such information, Curetis has not independently verified the information. Curetis is not aware of any exhaustive industry or market reports that cover or address its specific markets.

In this Prospectus, Curetis makes certain statements regarding the markets and the competitive position in the sectors and geographies in which Curetis competes. Curetis believes these statements to be true based on market data and industry statistics which are in the public domain, but has not independently verified the information. For further information, see “*Annex I — List of References*”.

### **Information Regarding Forward-looking Statements**

This Prospectus contains certain statements that are or may be forward-looking statements with respect to, without limitation, Curetis’ plans, objectives, strategies, products and their expected performance, impact of healthcare costs, marketing authorisation from the FDA, regulatory clearance, reimbursement for Curetis’ products, research and development costs, intellectual property protection, timing of regulatory filings, anticipated development in molecular diagnostics industry, Curetis’ results of operations and financial position. In some cases, investors can identify forward-looking statements by terms such as “believe”, “anticipate”, “expect”, “estimate”, “may”, “could”, “should”, “would”, “will”, “intend”, “plan” and similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause Curetis’ actual results, financial condition, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements.

These forward-looking statements speak only as of the date of this Prospectus and are subject to a number of risks, uncertainties and assumptions described in the sections in this Prospectus entitled “*Risk Factors*” and elsewhere in this Prospectus. These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- Curetis’ status as a development-stage company and Curetis’ expectation to incur losses in the future;
- Curetis’ ability to obtain marketing authorisation or regulatory clearance, e.g. from the FDA, for Curetis’ products;
- the market acceptance of Curetis’ Unyvero technology;
- Curetis’ ability to timely and successfully develop and commercialise Curetis’ existing products and future products;
- the length of Curetis’ anticipated sales cycle;
- Curetis’ ability to gain the support of leading hospitals and key opinion leaders (KOLs) and publish the results of Curetis’ clinical trials in peer-reviewed journals;
- Curetis’ future capital needs and Curetis’ need to raise additional funds;

- the performance of Curetis’ diagnostics;
- Curetis’ ability to successfully manage Curetis’ growth;
- Curetis’ ability to successfully procure all necessary supplies and to manufacture all products in sufficient numbers and quality to satisfy market demand;
- Curetis’ ability to compete in the highly competitive diagnostics market;
- Curetis’ ability to protect and enforce Curetis’ intellectual property rights, including Curetis’ trade secret protected proprietary rights in Unyvero;
- regulatory requirements, including FDA regulation of Curetis’ products; and
- other risks described under “*Risk Factors*”.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond Curetis’ control, investors are cautioned not to place any undue reliance on such forward-looking statements. The events and circumstances reflected in Curetis’ forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, Curetis operates in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Any forward-looking statements should not be regarded as a representation or warranty by Curetis, the Managers or any other person with respect to the achievement of the results set out in such statements or that the underlying assumptions used will in fact be the case.

Curetis and the Managers disclaim any obligation to update any such forward-looking statements in this Prospectus to reflect future events or developments.

## **References to Defined Terms and Incorporation of Terms**

Certain terms used in this Prospectus, including capitalised terms and certain technical and other terms are explained or defined in the section “*Glossary*”.



## REASONS FOR THE OFFERING AND USE OF PROCEEDS

### Reasons for the Offering

The principal purpose of the Offering is to obtain additional capital to support the execution of Curetis’ strategy (as described in “*Business — Strategy*”). In addition, the Offering is expected to increase liquidity for the Shares. Furthermore, the Company intends to use the Offering to satisfy the Company’s obligations under the PSOP Roll-Over Agreements (as defined and described below).

### Proceeds and Expenses of the Offering

At the mid-point of the Offer Price Range, the Company would raise approximately €16.3 million of gross proceeds from the Offering (the “**Mid-Point Proceeds**”, which term is based on an Offer Price at the mid-point of the Offer Price Range and excludes the PSOP Proceeds (as defined below)). On the basis of the maximum number of Offer Shares, the Company however has the possibility to raise up to approximately €18.4 million in gross proceeds from the Offering (the “**Top-End Proceeds**”, which term is based on an Offer Price at the upper end of the Offer Price Range and excludes the PSOP Proceeds). Assuming the Company raises the Mid-Point Proceeds and all PSOP Offer shares are issued and sold as part of the Offering, the estimated expenses, commissions and taxes related to the Offering of approximately €2.5 million, which include approximately €0.88 million of fees and commissions payable to the Managers, the Company expects to receive approximately €13.8 million in net proceeds from the Offering. At the date of this Prospectus, approximately €0.9 million in expenses, commissions and taxes have already been paid. Assuming the Company raises the Mid-Point Proceeds, the Offering will, therefore, result in €14.7 million additional funds being available to the Company.

The following table sets forth the gross proceeds, net proceeds, additional available funds generated in the Offering, and aggregate expenses, costs and fees of the Offering (including fees payable to the Managers, assuming no payment of the incentive fee) in the scenarios set forth below.

Scenario	Gross proceeds for the Company	Net proceeds for the Company	Additional available funds for the Company (including net proceeds)	Aggregate expenses, costs and fees
		<i>(in €million)</i>		
Mid-Point Proceeds raised.....	16.3	13.8	14.7	2.5
Top-End Proceeds raised.....	18.4	15.9	16.8	2.5

### Use of Proceeds

#### *Proceeds for the Company*

Assuming the Company raises the Top-End Proceeds, the Company expects to generate approximately €16.8 million in additional available funds in the Offering.

Curetis currently anticipates that over the coming year it will use the net proceeds of the Offering, in order of importance, as follows:

- approximately 20% to 25% of the net proceeds of the Offering to maintain and continue to expand a direct commercial marketing, sales and support presence in the US in order to more broadly commercialise the Unyvero Platform and LRT Application Cartridge in the US via its own sales and marketing organisation;
- approximately 10% to 15% of the net proceeds of the Offering to maintain and continue to expand its European commercial presence;
- approximately 15% to 20% of the net proceeds of the Offering to fund working capital requirements to finance the placement of the Unyvero System in the direct selling EMEA markets as well as the US;
- approximately 25% to 35% of the net proceeds of the Offering towards continuing to expand its research and development pipeline for the Unyvero System, the Application Cartridges and the Unyvero A30 RQ Analyzer for European, US and global markets;
- approximately 5% to 10% of the net proceeds of the Offering for research and development programs of its Ares Genetics subsidiary around ARESdb and the ARES Technology Platform; and
- approximately 5% to 10% of the net proceeds of the Offering for general corporate purposes, including to meet its obligations as a publicly listed company and cover administrative expenses.

As of the date of this Prospectus, the Company cannot predict with certainty all of the specific uses for the net proceeds from the Offering, or the amounts to be spent on the uses set forth above. The amounts and timing of its actual use of the net proceeds will vary depending on numerous factors. As a result, the Company assumes broad discretion in the use of the net proceeds of the Offering.

Pending the use of the proceeds from the Offering, the Company intends to invest the net proceeds in interest-bearing, cash and cash equivalents instruments or short-term certificates of deposit.

If the Offering should be withdrawn or otherwise not be completed, or if the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, or if Curetis' cash burn is higher than expected due to lower revenues or for other reasons, Curetis will implement a detailed action plan to address the resulting working capital shortfall. The details of the plan would depend on the degree of the shortfall, but Curetis would initially focus on controlling its cash outflows through delaying planned increases in operating and capital expenditures and personnel hiring in favour of maintaining existing levels of expenditure. If these steps proved to be insufficient and the Offering fails to achieve at least the Mid-Point Proceeds, Curetis would need to implement further significant cost reductions. Primarily, Curetis would in this scenario not continue the expansion of, or even reduce, its US commercial organisation and suspend its cost-intensive additional FDA clinical trials in the US. In these circumstances, the use of the net proceeds of the Offering and the relative proportions set forth above would need to be adjusted to reflect the corresponding delays in expenditure or cost reductions that Curetis finds it necessary to undertake. See "*Capitalisation, Indebtedness and Working Capital – Working Capital*" for more details.

#### ***Proceeds for the PSOP Beneficiaries***

As part of the Offering, the Company intends to issue and sell up to 342,803 Shares (the "**PSOP Offer Shares**") on behalf of certain of Curetis' directors and employees as well as former employees and consultants (the "**PSOP Beneficiaries**"). Curetis AG (now Curetis GmbH) operated a share-based compensation plan, the Curetis AG Phantom Stock Option Incentive Plan 2010 ("**PSOP**"). The PSOP was restructured as part of the

Company's IPO in 2015 and beneficiaries of more than 1,000 phantom stock options agreed to be settled in Shares pursuant to roll-over agreements to effect such restructuring (the "**PSOP Roll-Over Agreements**"). The PSOP Beneficiaries are entitled to an aggregate of 659,237 Shares under the PSOP Roll-Over Agreements. The Company intends to issue and sell 52% of these Shares (being the PSOP Offer Shares) on behalf of the PSOP Beneficiaries to generate funds (the "**PSOP Proceeds**") to satisfy the PSOP Beneficiaries' German income tax obligations as a result of the settlement of the PSOP Roll-Over Agreements. The costs relating to the issuance and sale of the PSOP Offer Shares in the Offering will be borne by the Company. The remaining 48% of the Shares (up to 316,434 Shares) to which the PSOP Beneficiaries are entitled under the PSOP Roll-Over Agreements will be issued and delivered to the relevant PSOP Beneficiaries on or about the Settlement Date. If the number of PSOP Offer Shares is reduced, the number of Shares to be issued to PSOP Beneficiaries on or about the Settlement Date will be reduced on a pro rata basis, and the PSOP Beneficiaries will remain entitled to any Shares not issued under the PSOP Roll-Over Agreements.

## **DIVIDENDS AND DIVIDEND POLICY**

### **General**

Pursuant to Dutch law and the Articles of Association, the distribution of profits will take place following the adoption of the Company's annual accounts by the General Meeting. The Company may only make distributions to the Shareholders, whether from profits or from its freely distributable reserves, insofar as its shareholders' equity exceeds the sum of the paid-up and called-up share capital plus the minimum reserves required under Dutch law or pursuant to its Articles of Association.

Subject to the approval of the Supervisory Board and subject to Dutch law and the Articles of Association, the Management Board may determine which part of the Company's profits as per its financial statements for the relevant financial year will be added to the reserves. The remaining part of the profits will be at the disposal of the General Meeting. Distributions of dividends will be made pro rata to the nominal value of each Share.

Subject to the approval of the Supervisory Board and subject to Dutch law and the Articles of Association, the Management Board may resolve to distribute an interim dividend if it determines such interim dividend to be justified by the Company's profits. For this purpose, the Management Board must prepare an interim statement of assets and liabilities. Such interim statement shall show the financial position of the Company not earlier than on the first day of the third month before the month in which the resolution to make the interim distribution is announced. An interim dividend can only be paid if (a) an interim statement of assets and liabilities is drawn up showing that the funds available for distribution are sufficient, and (b) the Company's shareholders' equity exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law or pursuant to its Articles of Association.

On proposal of the Management Board which has been approved by the Supervisory Board, the General Meeting may resolve that the Company makes distributions to Shareholders from one or more of its freely distributable reserves. Distributions from the Company's distributable reserves may be made throughout the financial year, and need not be based on the Company's annual accounts adopted by the General Meeting. Any such distributions will be made pro rata to the nominal value of each Share.

### **Entitlement to Dividends**

All Shares, including the Offer Shares, are equally entitled to dividends and other distributions, if and when declared.

### **Dividend Policy and History**

The Company has never declared or paid any dividends.

The Company expects to retain all earnings, if any, generated by Curetis' operations for the development and growth of its business and does not anticipate paying any dividends to the Shareholders in the near future.

The Company's dividend policy will be reviewed and may be amended from time to time taking into account Curetis' earnings, cash flow, financial condition, capital expenditure requirements and other factors considered important by the Management Board and the Supervisory Board.

### **Dividend Ranking of Shares**

All of the Shares, including the Offer Shares, will rank equally and will be eligible and equally entitled to dividend that may be declared on the Shares.

### **Manner and Time of Dividend Payments**

Payment of dividend on the Offer Shares in cash will be made in euro, paid to the Shareholders through Euroclear Nederland, the Dutch centralised securities custody and administration system, and credited automatically to the Shareholders' accounts without the need for the Shareholder to present documentation proving ownership of the Shares.

### **Uncollected Dividends**

An entitlement to any dividend distribution will be barred five years after the date on which those dividends were released for payment. Any dividend that is not collected within this period reverts to the Company and is allocated to its general reserves.

### **Taxation of Dividends**

In relation to dividend distributions, there are no restrictions under Dutch law in respect of holders of Offer Shares who are non-residents of the Netherlands. Dividends are generally subject to Dutch withholding tax in the Netherlands. See the section "*Taxation*" for a discussion of certain aspects of taxation of dividends and refund procedures.

## CAPITALISATION, INDEBTEDNESS AND WORKING CAPITAL

This section sets forth the Company's consolidated capitalisation and indebtedness as of 30 June 2018 on an actual basis and as adjusted to reflect the receipt of the estimated net proceeds from the Offering of €13,797 thousand (based on the assumption that the Company has raised the Mid-Point Proceeds).

### Capitalisation

The data presented in the following table shows the Company's consolidated capitalisation as of 30 June 2018 on a historical basis, which has been derived from the Interim Financial Statements, and as adjusted. The data presented in the "adjusted" column has been prepared on the basis of (i) the assumption that the Company had already obtained the net proceeds from the Offering of €13,797 thousand (based on the assumption that the Company has raised the Mid-Point Proceeds and the estimated directly attributable transaction costs for the Offering in the amount of €2,500 thousand having been deducted from the gross proceeds), (ii) including the issue of Shares under the PSOP Roll-Over Agreement, assuming the maximum number of 659,237 Shares are issued, (iii) excluding the net proceeds of €3,220 thousand from the issuance of Convertible Notes to Yorkville.

	As of 30 June 2018 (actual)	As of 30 June 2018 (as adjusted)
	(in €thousands)	
	(unaudited)	
<b>Total current liabilities</b> .....	3,180	3,180
of which is guaranteed.....	—	-
of which is secured.....	—	-
unguaranteed/unsecured .....	3,180	3,180
<b>Total non-current liabilities</b> .....	13,647	13,647
of which is guaranteed.....	—	-
of which is secured.....	—	-
unguaranteed/unsecured .....	13,647	13,647
<b>Total liabilities</b> .....	16,827	16,827
<b>Equity</b> .....	14,677	28,474
of which is share capital .....	164	241 <sup>(1)</sup>
of which is capital reserve .....	156,565	176,877 <sup>(2)</sup>
of which is currency translation differences.....	(30)	(30)
of which is other reserves .....	8,954	2,362 <sup>(3)</sup>
of which is retained earnings .....	(150,976)	(150,976)
<b>Total capitalisation</b> .....	<u>31,504</u>	<u>45,301</u>

Notes:

- (1) Based on the key assumption that 7,085,546 new Shares are issued in the Offering as well as 659,237 Shares are issued in connection with and pursuant to the PSOP Roll-Over Agreements.
- (2) The increase of the capital reserve reflects the share premium of the Shares issued in the Offering (assuming a share price of €2.30) and the fair value of the PSOP claim, excluding the estimated directly attributable transaction costs for the Offering in the amount of €2,500 thousand.

As of 30 June 2018 (actual)	As of 30 June 2018 (as adjusted)
<i>(in €thousands)</i>	
<b>(unaudited)</b>	

- (3) The increase of other reserves reflects the reduction in fair value of equity-settled claim for Shares under the PSOP Roll-Over Agreement previously recorded in equity (€6,592 thousand per 30 June 2018, which entitles the PSOP Beneficiaries to subscribe for a number of Shares to be calculated by dividing the payment claim by the offer price for the Company's IPO (i.e. €10) resulting in 659,237 Shares).

## Net Financial Indebtedness

The data presented in the following table shows the Company's consolidated financial indebtedness of 30 June 2018 on a historical basis, which has been derived from the Interim Financial Statements, and as adjusted. The data presented in the "adjusted" column has been prepared on the basis of the assumption that the Company had already obtained the net proceeds from the Offering of €13,797 thousand (based on the assumption that the Company has raised the Mid-Point Proceeds).

	As of 30 June 2018 (actual)	As of 30 June 2018 (as adjusted)
<i>(in €thousands)</i>		
<b>(unaudited)</b>		
Cash and cash equivalents .....	11,646	25,443
Trading securities .....	—	—
<b>Liquidity</b> .....	11,646	25,443
<b>Current financial receivables</b> .....	—	—
Current bank debt <sup>(1)</sup> .....	80	80
Current portion of non-current debt .....	—	—
Other current financial debt .....	—	—
<b>Current financial debt</b> .....	80	80
<b>Net current financial debt</b> <sup>(2)</sup> .....	(11,566)	(25,363)
Non-current bank loans .....	13,604	13,604
Bonds issued .....	—	—
Other non-current loans .....	—	—
<b>Non-current financial indebtedness</b> .....	13,604	13,604
<b>Net financial indebtedness</b> .....	2,038	(11,759)

Notes:

(1) "Current bank debt" is equal to deferred interest related to bank debt.

(2) "Net current financial debt" is equal to current financial debt minus current financial receivables minus liquidity

As at 30 June 2018, the Company did not have any indirect or contingent liabilities.

As at the date of the Prospectus, there have been no material changes in the Company's capitalisation or net financial indebtedness since 30 June 2018, other than:

- the decrease in cash and cash equivalents to €6,689 thousand as at 30 October 2018 (which, disregarding the net proceeds of €3,220 thousand from the issuance of Convertible Notes to Yorkville, represents a decrease of €8,177 thousand in the period since 30 June 2018), as a result of the Company's regular and expected cash burn that the Company experiences as a result of its stage of development. See *"Operating and Financial Review and Prospects – Key Factors Affecting the Results of Operation -- Cash Burn"*; and
- the issue of €3,500 thousand in principal amount of Convertible Notes as part of the first tranche under the Yorkville Agreement, thereby raising a net proceeds amount of €3,220 thousand. See *"Business – Material Contracts – Financing Arrangements – Yorkville Financing"*.

### **Working Capital Statement**

Curetis' current cash resources do not provide it with sufficient working capital for the next twelve months from the date of this Prospectus. Curetis believes that it has sufficient working capital to continue its current operations until January 2019. Curetis' current cash resources amounted to €6.7 million as at 30 October 2018 (including the initial €3.2 million in net proceeds received pursuant to the Yorkville Agreement). Based on its present requirements under its current business plan, which was prepared on the assumption of obtaining the net proceeds from the Offering and which includes, without limitation, costs for:

- maintaining and continuing to expand a direct commercial marketing, sales and support presence in the US in order to more broadly commercialise the Unyvero Platform and LRT Application Cartridges in the US;
- maintaining and continuing to expand its European commercial presence;
- funding working capital requirements to finance the placement of the Unyvero System in the direct selling EMEA markets as well as the US;
- continuing to expand its research and development pipeline of the Unyvero System, the Application Cartridges and the Unyvero A30 RQ for European, US and global markets;
- research and development programs of its Ares Genetics subsidiary around ARESdb and the ARES Technology Platform; and
- general corporate purposes, including to meet its obligations as a publicly listed company and cover administrative expenses,

Curetis believes its operations will require additional cash resources of approximately €23 million assuming the execution of Curetis' current business plan, as more fully described in this Prospectus, to provide it with sufficient working capital for the next twelve months from the date of this Prospectus. If the Offering is completed and additional available funds of approximately €16.8 million are generated in the Offering (which would only be the case if the Company raises the Top-End Proceeds), these proceeds together with the €1.4 million in net proceeds expected to be received from the remainder of the first tranche under the Yorkville Agreement and an additional €5.0 million debt financing which is expected to be available from the EIB Finance Contract (as explained further below) would provide it with additional working capital of €23.2 million, as a result of which the Company would have sufficient working capital for the next twelve months from the date of this Prospectus. The availability of the remainder of the first tranche of the Yorkville Agreement and the EIB



Finance Contract are subject to certain conditions described below, including, in the case of the Yorkville Facility, the Yorkville Floor Price.

Curetis – as is typical in the biotech/medtech industry for development stage and early commercial stage companies - incurred net losses since its incorporation until year-end 2014 and again in 2016 and 2017. In 2015, Curetis incurred a profit for the first time due to an extraordinary gain. For the period of 2018 and 2019, Curetis expects to continue incurring significant net losses and also experience significantly higher cash burn than in 2017 due to the costly US commercial launch and roll out of Unyvero LRT as well as continuing EMEA commercial operations and global R&D activities.

If the Offering should be withdrawn or otherwise not be completed, or if the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, or if Curetis' cash burn is higher than expected due to lower revenues or for other reasons, Curetis will implement a detailed action plan to address the resulting working capital shortfall. The details of the plan would depend on the degree of the shortfall, but Curetis would initially focus on controlling its cash outflows through delaying planned increases in operating and capital expenditures and personnel hiring in favour of maintaining existing levels of expenditure. Curetis would in this case postpone the investment into injection molds and manufacturing line equipment for the Unyvero A30 RQ Application Cartridges, which would delay the development and commercial launch of the Unyvero A30 RQ platform. Curetis would further postpone the investment into additional multi-cavity injection molds, which are expected to result in cost savings in the manufacture of the Unyvero A50 Platform Application Cartridges.

If these steps proved to be insufficient and the Offering fails to achieve at least the Mid-Point Proceeds, Curetis would need to implement further significant cost reductions. Primarily, Curetis would in this scenario not continue the expansion of, or even reduce, its US commercial organisation and suspend its cost-intensive additional FDA clinical trials in the US. Such cost-cutting measures would significantly adversely impact Curetis' business. For example, they would prevent Curetis from obtaining FDA clearance for its IJI Application Cartridge or the BAL extension for its LRT Cartridge, and thus prevent Curetis from selling those products into the US market. As a consequence, future revenue expectations from the US would be greatly reduced. In addition, Curetis would reduce its staff expenditure by potentially reducing its workforce, which would have an adverse impact on its manufacturing capacity, research and development pipeline and/or ongoing commercialisation efforts.

In conjunction with the above measures and subject to certain milestones being met, Curetis may seek to draw down up to an additional €12,000 thousand under the €25,000 thousand debt financing facilities with the European Investment Bank as lender (the “**EIB Finance Contract**”). Of this amount, €5,000 thousand will become available upon the Company having raised equity in excess of €15,000 thousand, which would be satisfied if the Company, in addition to the €4,100 thousand raised in May 2018, raises an additional €10,900 thousand (and which therefore would be available if the Offering raises at least €10,900 thousand). A further €7,000 thousand becomes available under the EIB Finance Contract upon Curetis having installed 350 Unyvero Analyzers globally as well as Curetis' consolidated revenues being at least €10,000 thousand over the 12 months preceding the request for the loan disbursement. Subject to the relevant milestones being met, these amounts are available until 12 December 2019. Furthermore and subject to the relevant conditions being met, the Company may issue Shares to Global Corporate Finance corporation (“**GCF**”) under the US\$10,000 thousand equity facility dated 26 April 2018 (the “**GCF Equity Facility**”) or issue convertible notes and warrants under the financing facility agreement dated 2 October 2018 with YA II PN, Ltd, an investment fund managed by Yorkville Advisors Global LP, a U.S.-based management firm (“**Yorkville**” and such facility agreement, the “**Yorkville Agreement**”) for up to €20 million to raise additional funds. Curetis' ability to utilise the EIB

Finance Contract, the GCF Equity Facility and the Yorkville Agreement will depend on the relevant conditions thereunder being satisfied, waived or amended. In that respect:

- certain of the measures described above to reduce cash outflows may make it difficult for Curetis to satisfy the conditions for disbursement of the €7,000 thousand tranche under the EIB Finance Contract, as cost control measures and cost reductions are expected to negatively impact Curetis' ability to achieve the milestones of 350 installed Unyvero Analysers and €10,000 thousand consolidated revenues. In addition, the loans under the EIB Finance Contract are for the purpose of financing certain research and development activities, and may not exceed 50% of the total cost of such activities. A decline in research and development expenditure as a result of cost-cutting measures could therefore limit Curetis' access to the EIB loans.
- Curetis would be unable to utilise the GCF Equity Facility if the subscription price per share, which is equal to 95% of the volume weighted average price of the Shares on Euronext in Amsterdam over the five trading days following a sales notice by Curetis to GCF, falls below the floor price to be set by Curetis in the relevant sales notice (which floor price shall not be lower than €4.50 (the "**GCF Floor Price**"), unless otherwise agreed between Curetis and GCF), subject to adjustments to reflect variations in the share capital of the Company. As at 30 October 2018, the share price of the Company quoted on Euronext in Amsterdam was less than the GCF Floor Price and the Company therefore would, unless otherwise agreed with GCF, not have been permitted to make any drawings under the GCF Equity Facility until the subscription price per share exceeds the GCF Floor Price. Furthermore, the full US\$10,000 thousand under the GCF Equity Facility is not accessible by the Company at one time, but only in US\$500 thousand tranches which the Company is restricted from initiating more than one time in any three-week period, unless previously agreed with GCF. Furthermore, as described below, the Yorkville Agreement imposes certain restrictions on the ability of the Company to access the GCF Equity Facility.
- under the Yorkville Agreement, the funding of a tranche of convertible notes under the Yorkville Agreement, including the remaining €1,500 thousand available under the first tranche of convertible notes, is subject to certain conditions precedent being satisfied or waived by Yorkville, including (i) a minimum closing Share price of €3.00 on Euronext in Amsterdam (being the Yorkville Floor Price) on the day prior to the sending of a request and (ii) the combined average daily Share value traded on Euronext in Amsterdam and Euronext in Brussels in the week prior to the request being at least €150 thousand. The upper end of the Offer Price Range and, as at 30 October 2018, the share price of the Company quoted on Euronext in Amsterdam, was less than the Yorkville Floor Price and the Company therefore would, unless otherwise agreed with Yorkville, not be permitted to make any additional drawings under the Yorkville Agreement, including the remaining part of the first tranche drawn under the Yorkville Agreement, until the share price of the Company quoted on Euronext in Amsterdam exceeds the Yorkville Floor Price. Furthermore, under the Yorkville Agreement, the convertible notes have an initial maturity of one year, which may be extended in certain circumstances. The Company is restricted from submitting a request to fund a subsequent tranche of convertible notes under the Yorkville agreement until after the tenth calendar day following the conversion into Shares and/or redemption of all the outstanding convertible notes issued under the previous tranches. The Company is not allowed under the Yorkville Agreement to participate in variable rate equity financing transactions (such as an issue of Shares under the GCF Equity Facility) from 30 days prior to the request for the disbursement of a tranche of convertible notes until the 20th business day following the redemption or conversion of such convertible notes.

Curetis would also expect to pursue various non-dilutive financing alternatives such as government grants or licensing and partnering models (e.g. for the ARESdb and the ARES Technology Platform and Unyvero A30 RQ platform) to partially fund some of its operations in 2018 and 2019.

If the Offering should be withdrawn or otherwise not be completed, or if the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, or if Curetis' cash burn is higher than expected, Curetis would implement some or all of the foregoing measures to reduce cash outflows and raise financing and thereby seek to achieve, together with Curetis' current cash resources, cash resources sufficient for 12 months of operations.

Curetis believes that the cost reduction measures mentioned above and its ability to raise additional cash through the Yorkville Facility are likely to enable it to continue as a going concern for the next 12 months. However, in the event the Offering is withdrawn or otherwise not completed, and Curetis is not able to address its working capital shortfall, Curetis would, in addition to the cost reduction and financing measures outlined above, be required to raise additional financing by obtaining other equity and/or debt financing for it to have sufficient cash to maintain its operations until 31 October 2019 and as such to continue as a going concern for at least 12 months from the date of this Prospectus. Curetis will therefore continue to pursue various strategic and tactical financing alternatives to raise additional equity or debt capital including, but not limited to, seeking additional investors, pursuing partnerships and obtaining further funding from existing strategic collaboration partners and issuing additional shares or debt instruments to financial and/or corporate strategic investors.

The availability to Curetis of such additional financing is subject to a number of external factors, including the satisfaction of certain conditions precedent which may be beyond Curetis' control and the willingness of investors to provide additional equity or debt financing on terms acceptable to Curetis. As a result, it is uncertain if Curetis will be able to obtain sufficient financing to continue as a going concern for at least 12 months from the date of this Prospectus if the Mid-Point Proceeds are not raised.

If Curetis fails to implement the above measures to remedy a working capital shortfall caused by a withdrawal of the Offering or a failure to raise the Mid-Point Proceeds or otherwise, such as the generation of sufficient funds from additional financing and the described cost reduction measures, it may be unable to continue as a going concern and may ultimately have to file for insolvency.

*See "Risk Factors — Risks Related to Business and Strategy — Curetis' cash position and operating cash flow may be insufficient to cover expected investment expenses, and Curetis may need to raise additional funds in the future." and "Risk Factors — Risks Related to the Offer Shares and the Offering — Should the anticipated gross proceeds of the Offering (excluding the PSOP Proceeds) fall below €8 million, the Offering will in any event be withdrawn, no Shares will be issued and any applications to subscribe for Offer Shares will be disregarded. If the additional available funds generated from the Offering fall below the €16.6 million needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, Curetis will implement a detailed action plan to address the resulting working capital shortfall. If delaying planned increases in expenditures is insufficient, such an action plan would include significant cost reductions which, although necessary, would ultimately have a material adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects and the value of the Offer Shares."*

## SELECTED FINANCIAL INFORMATION

### Selected Financial Information

The selected consolidated financial information of the Company below as of and for the years ended 31 December 2017 and 2016, was taken or derived from the Annual Financial Statements. The selected financial information as of and for the six months ended 30 June 2018 and 2017 was taken or derived from the Interim Financial Statements.

For more information on the content and interpretation of this information, see “Important Information — Presentation of Financial and Other information — Financial information”.

Where financial data is labelled “audited”, this means that it was taken from the Annual Financial Statements. The label “unaudited” is used to indicate financial data that was taken from a source other than the Annual Financial Statements, including the Interim Financial Statements, or recomputed from the Annual Financial Statements.

The figures in the following have been rounded in accordance with established commercial practice. Figures or additions within a table may therefore result in sums different from those shown in the same table and do not always add up to 100%.

### Consolidated Statement of Profit or Loss and Other Comprehensive Income

The table below sets forth the Company’s consolidated statement of profit or loss and other comprehensive income for the six months ended 30 June 2018 and 2017 and for the years ended 31 December 2017 and 2016.

	For the six months ended 30 June		For the year ended 31 December	
	2018	2017	2017	2016
	(in €thousands)			
	(unaudited)		(audited)	
<b>Revenue</b> .....	807	595	1,187	1,306
Cost of sales.....	(1,435)	(1,052)	(1,649)	(1,596)
Gross loss .....	(628)	(457)	(462)	(290)
Distribution costs .....	(4,214)	(3,846)	(7,302)	(5,091)
Administrative expenses .....	(2,111)	(1,848)	(3,755)	(3,024)
Research & development expenses .....	(4,683)	(3,161)	(7,362)	(7,027)
Other income .....	271	50	314	198
<b>Operating loss</b> .....	(11,365)	(9,262)	(18,567)	(15,234)
Finance income.....	274	20	21	101
Finance costs .....	(496)	(406)	(1,004)	(30)
<b>Finance result - net</b> .....	(222)	(386)	(983)	71
<b>Loss before income tax</b> .....	(11,587)	(9,648)	(19,550)	(15,163)
Income tax expenses .....	26	(14)	52	(10)
<b>Loss for the period</b> .....	(11,561)	(9,662)	(19,498)	(15,173)
Other comprehensive income for the year, net of tax *	(171)	117	171	(28)

	For the six months ended 30 June		For the year ended 31 December	
	2018	2017	2017	2016
	<i>(in € thousands)</i>			
	(unaudited)		(audited)	
<b>Total comprehensive loss for the period**...</b>	<b>(11,732)</b>	<b>(9,545)</b>	<b>(19,327)</b>	<b>(15,201)</b>

Note:

\* Relates to exchange differences on translation of foreign operations, which may be recognised through profit and/or loss in the future.

\*\* Total comprehensive loss is solely attributable to owners of the Company.

## Consolidated statement of financial position

The table below sets forth the Company's consolidated statement of financial position as of 30 June 2018 and as of 31 December 2017 and 2016:

	30 June	31 December	
	2018	2017	2016
	<i>(in € thousands)</i>		
	(unaudited)	(audited)	
<b>Assets</b>			
Current assets.....	20,348	24,009	30,272
Cash and cash equivalents .....	11,646	16,311	22,832
Trade receivables .....	250	200	101
Inventories .....	6,891	6,946	5,870
Other current assets .....	1,561	552	1,469
<b>Non-current assets</b> .....	<b>11,156</b>	<b>11,506</b>	<b>12,514</b>
Intangible assets.....	7,511	7,524	7,520
Property, plant and equipment .....	3,193	3,566	4,466
Other non-current assets .....	172	182	212
Other non-current financial assets.....	157	156	316
Deferred tax assets .....	123	78	-
<b>Total assets</b> .....	<b>31,504</b>	<b>35,515</b>	<b>42,786</b>
<b>Liabilities and equity</b>			
<b>Current liabilities</b> .....	<b>3,180</b>	<b>2,926</b>	<b>2,384</b>
Trade and other payables .....	447	928	721
Provisions current .....	54	124	51
Tax liabilities .....	26	24	10
Other current liabilities.....	1,442	1,226	1,120

	30 June	31 December	
	2018	2017	2016
	<i>(in €thousands)</i>		
	(unaudited)	(audited)	
Other current financial liabilities .....	1,211	624	482
Non-current liabilities .....	13,647	10,385	41
Provisions non-current .....	43	43	41
Other non-current financial liabilities.....	13,604	10,342	-
<b>Total liabilities</b> .....	16,827	13,311	2,425
<b>Equity</b> .....	14,677	22,204	40,361
Share capital .....	164	155	155
Capital reserve .....	156,565	152,793	152,793
Other reserves .....	8,954	8,527	7,360
Currency translation differences .....	(30)	143	(29)
Retained earnings.....	(150,976)	(139,414)	(119,918)
<b>Total equity and liabilities</b> .....	31,504	35,515	42,786

### Selected consolidated statement of cash flow data

The table below sets forth selected items from the Company's consolidated statement of cash flows for the six months ended 30 June 2018 and 2017 and for the years ended 31 December 2017 and 2016:

	For the six months ended 30 June		For the year ended 31 December	
	2018	2017	2017	2016
	<i>(in €thousands)</i>			
	(unaudited)		(audited)	
Net cash flows provided by (used in) operating activities.....	(11,462)	(6,969)	(15,681)	(15,724)
Net cash flow provided by (used in) investing activities.....	(230)	(197)	(421)	(7,430)
Net cash flow provided by (used in) financing activities.....	6,780	9,952	9,952	(105)
<b>Net decrease in cash and cash equivalents ...</b>	<b>(4,912)</b>	<b>2,786</b>	<b>(6,150)</b>	<b>(23,259)</b>
Net Cash and cash equivalents at the beginning of the period .....	16,311	22,832	22,832	46,060
Effects of exchange rate changes on cash and cash equivalents .....	247	(217)	(371)	30
Net Cash and cash equivalent at the end of the period.....	11,646	25,401	16,311	22,832

## OPERATING AND FINANCIAL REVIEW AND PROSPECTS

*The following is a review of Curetis' results of operations, financial position and cash flows as of and for the financial years ended 31 December 2017 and 2016 and as of and for the six months ended 30 June 2018 and 2017. It is based on the Annual Financial Statements and the Interim Financial Statements.*

*Where financial information in this section is labelled "audited", this means that it was taken from the Annual Financial Statements. The label "unaudited" is used in this section to indicate financial data that was taken from the Interim Financial Statements or another source other than the Annual Financial Statements, or recomputed from the Annual Financial Statements.*

*The figures in the following have been rounded in accordance with established commercial practice. Figures or additions within a table may therefore result in sums different from those shown in the same table and do not always add up to 100 %.*

*This section should be read in conjunction with the sections entitled "Important Information – Presentation of Financial and Other Information", "Selected Financial Information" and the Annual Financial Statements and Interim Financial Statements together with the notes to those financial statements, incorporated by reference in this Prospectus.*

### Overview

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 and Singapore), and is in the process of being rolled out commercially in the US following *De Novo* clearance of the Unyvero System and the LRT Application Cartridge by the FDA in April 2018. In 2016, 2017 and the first six months of 2018, Curetis generated its revenues primarily from the sale of the Unyvero System, its components, and its Application Cartridges.

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. 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 delivers results within four to five hours and can cover over 100 diagnostic targets depending on the relevant Application Cartridge.

The Unyvero Platform is marketed through a combination of direct sales in key EU countries, including Belgium, France, Germany, Luxembourg, the Netherlands, Switzerland and the UK, as well as the US, and sales to distributors in selected European markets and the rest of the world. Curetis also intends to continue to expand internationally in certain additional ASEAN markets beyond Singapore (Indonesia, Malaysia, and Thailand) through its distribution agreement with Acumen and in Greater China through its distribution agreement with Beijing Clear Biotech, with the distribution rights for Hong Kong granted to Technomed (Hong Kong) Ltd. Curetis has recently entered into distribution agreements with Future Horizons Scientific (FHS) in Egypt,

Quimica Valaner S.A. de C.V. in Mexico and Biko S.A. in Uruguay for commercialization of the Unyvero Platform and Application Cartridges, subject to obtaining regulatory clearance for the products in the respective markets, which is expected in the fourth quarter of 2018.

As of 30 October 2018, Curetis' total installed base comprised 165 Unyvero A50 Analyzers. There are currently five Application Cartridges commercially available in markets outside the United States: 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 and is now being marketed in the US. The HPN and BCU Application Cartridges have also been approved by the Singaporean HSA.

In addition to the current Unyvero System, Curetis also plans to launch its Unyvero A30 *RQ* Analyzer module, subject to completion of development and regulatory clearance for CE-IVD-marking, in Europe in late 2019. Currently in the development stage, the Unyvero A30 *RQ* Analyzer has been 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 measuring multiple analytes) quantitative PCR reactions from one sample, with up to three targets per reaction (for a total of up to 33 targets per cartridge). It will be fully integrated into Curetis' Unyvero System suite of products with respect to system architecture, design, software and handling, thereby expanding the Unyvero Platform to include "any plex" capabilities, addressing new markets, diversifying the application pipeline and leading to increased revenue. A further advantage of the Unyvero A30 *RQ* Analyzer is that the costs of the system 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.

Curetis' other core business is its ARES Technology Platform and its proprietary genetic database on AMR, *ARESdb*. The ARES Technology Platform and *ARESdb* build and expand upon the GEAR assets acquired from Siemens Technology Accelerator ("STA") in 2016. Curetis believes that *ARESdb* is the world's most comprehensive database on the genetics of antibiotic resistance, which Curetis believes will enable it to enter into partnering deals and strategic collaborations with diagnostic companies, pharmaceutical companies and companies focused on public health and life science research. Curetis expects to increasingly utilize the proprietary biomarker content in its own assay and Application Cartridge development, as well as to out-license it to partners. Curetis established its subsidiary Ares Genetics in Austria in 2017 to advance *ARESdb* and the ARES Technology Platform. On 4 September, 2018, Curetis announced that Ares Genetics has 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 laboratory workflow. Curetis 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.

### **Key Factors Affecting the Results of Operations**

Set forth below are factors that Curetis believes have materially impacted its results of operations in the periods under review and/or that Curetis expects to materially impact its results of operations in future periods.

#### ***Success of Curetis' business model in growing its Unyvero System and Application Cartridge business***

Curetis expects that its results will be materially affected by the level of success it has in growing the revenues that it earns from its Unyvero System and Application Cartridges.



In 2016, 2017 and the first six months of 2018, Curetis generated its revenues primarily from the sale of the Unyvero System and its key components (Unyvero A50 Analyzer, Unyvero L4 Lysator and Unyvero C8 Cockpit) and the sale of its Application Cartridges, in both cases, through a combination of direct sales and sales to distributors. Curetis' revenues were €1,306 thousand in 2016, €1,187 thousand in 2017, €595 thousand in the first six months of 2017 and €807 thousand in the first six months of 2018. Revenues from Application Cartridges increased from €573 thousand in 2016 to €736 thousand in 2017, and increased from €359 thousand in the first six months of 2017 to €464 thousand in the first six months of 2018. Revenue from Unyvero System and services sales decreased from €733 thousand in 2016 to €451 thousand in 2017, and increased from €236 thousand in the first six months of 2017 to €343 thousand in the first six months of 2018. As a consequence of this product focus, Curetis expects that a majority of its revenues in the near-term will continue to come from these products.

Curetis has generated, and will continue to generate, revenue from the sale of the Unyvero System and Application Cartridges. In particular, all placements made to distributors are accounted for as sales. Distributors purchase the Unyvero Systems from Curetis (whereupon Curetis immediately recognizes sales revenue) and then resell them on their own or place them without payment on their own account, at their sole discretion and risk with their own customers. After selling or placing such Unyvero Systems, the distributors purchase Application Cartridges directly from Curetis for their customers.

Curetis' commercial model for direct sales, in contrast, often involves the placement of Unyvero Systems without payment, together with the temporary provision of free Application Cartridges, to target hospitals to enable those hospitals to evaluate the Unyvero System during a demonstration and clinical evaluation phase that can last for many months. Over time, Curetis intends for these direct sales customers to become commercial customers of Curetis who will purchase Application Cartridges for use in their clinical diagnostic routines at a sufficiently high price to cover the cost of the Unyvero System to Curetis (which typically takes two to three years to recoup, and sometimes longer, taking into account the cost of the Application Cartridges and also depending on Application Cartridge sales volumes). Curetis believes that the increase of revenue from the sale of Application Cartridges, as described above, is an indication that this model will be validated over time.

The increases in revenues from Application Cartridge sales in 2016, 2017 and the first six months of 2018 were driven in substantial part by higher utilization of the installed base of Unyvero Systems as well as increases in the number of commercially converted accounts within the installed base in EMEA over the periods, despite (in the case of 2017) a decline in revenue from the sale of Unyvero Systems compared to the prior year.

As of 30 October 2018, Curetis had a total installed base of 165 Unyvero A50 Analyzers, including both those sold and those placed without payment, compared to 175 at the end of 2017 and 142 at the end of 2016. The decline from 175 to 165 resulted mainly from the exercise by Curetis of a unique buy-back option it had with one of its pharmaceutical industry partners, enabling it to repurchase five Analyzers at an attractive price below fair market value, as well as the decision by Curetis to arrange for the return to Curetis of eight non-revenue generating demo models installed in certain hospitals in EMEA direct selling markets. Curetis has since either redeployed or is in the process of redeploying without payment these repurchased or returned models to more promising target hospital accounts in EMEA and the United States where they are being used as demonstration models for evaluation purposes by relevant accounts. Curetis hopes that the provision of a demonstration unit at these accounts will result in conversion of such accounts into commercial, revenue-generating accounts. Some of the relevant Unyvero Systems may also be returned to Curetis and sold as used systems to its distributors. Curetis does not currently have any buy-back options with any other customers or partners. Curetis expects the decline in its installed base to be temporary and anticipates seeing increases in the coming quarters as the U.S. commercial expansion proceeds and Curetis continues to make deployments to new target accounts in EMEA and sales to its growing list of distribution partners.

Curetis estimates that the average lead time from the first contact with a customer to the customer conversion to a commercial account and routinely purchasing Application Cartridges to be approximately 9-12 months in the EU market, based on experience there so far, but estimates that the average will be closer to 6-9 months in the US, based on the experience of competitors and peer firms such as GenMark and AXDX. For each customer with one installed Unyvero System purchasing and using between 150 and 500 Application Cartridges per year, which is Curetis' typical target range for customers once they have attained full clinical routine usage of the Unyvero Platform, Curetis estimates that it will typically generate annual revenues of approximately €30-€75 thousand per Unyvero A50 Analyzer at the current list prices of the Application Cartridges (excluding those Unyvero Systems placed for free for demo or evaluation purposes, which do not generate revenue until they become commercial accounts as described above). High volume customers using more than one Unyvero A50 Analyzer can generate more than €100 thousand per year in annual Application Cartridge based revenues.

The success of Curetis' business model will depend on its ability to (i) grow the installed base of Unyvero Systems, resulting in a larger pool of potential commercial accounts who will purchase Application Cartridges on an ongoing basis; (ii) convert existing purchasers of the Unyvero System and target hospitals where Unyvero Systems have already been placed without payment into routine commercial customers of Application Cartridges; (iii) encourage a gradual increase over time in utilisation of the Unyvero System by commercial customers as they come to rely on Application Cartridges as a diagnostic tool; and (iv) develop, launch and distribute new Application Cartridges covering additional indications, resulting in additional demand from commercial customers seeking diagnostic solutions for those indications.

Curetis believes that the FDA clearance in April 2018 of the Unyvero System and LRT Application Cartridge will provide it with the opportunity to significantly increase its customer base for the Unyvero System and the sale of its Application Cartridges through direct sales in the U.S., beginning with the LRT Application Cartridge and continuing with new Application Cartridges if and when FDA clearance is obtained for additional Application Cartridges. Curetis' success in this regard will depend substantially on its ability to grow and maintain its direct marketing and sales organisation in the US. Building on its stable revenues in 2016, 2017 and the first six months of 2018, and its ongoing commercial launch in the US, Curetis aims to at least double year-over-year revenue in 2018.

Since the launch of the Unyvero System and LRT Application Cartridge in the U.S., Curetis' U.S. commercial team has initially qualified more than 140 accounts as potential first buyers of Unyvero Systems out of a total approximately 1,000 hospitals identified by Curetis to be initial targets for the Unyvero LRT Application Cartridge. Of those qualified accounts, more than 60 have been thoroughly vetted by Curetis and many are expected to be converted to commercial accounts over the next several quarters with approximately ten accounts constituting near term opportunities currently at the contract negotiation stage. These initial ten accounts on average are expected to have Unyvero LRT Application Cartridge volumes of 700 to 800 annually once they become commercial customers. The estimated Unyvero LRT Cartridge volume potential for the more than 60 accounts in advanced stages of qualification range from approximately 250 to over 1,600 per year.

### ***New sources of revenue***

In addition to the Unyvero System and its current and planned Application Cartridges, Curetis expects revenue growth to be driven in the future by the Unyvero A30 *RQ* Analyzer, Curetis' new mid-plex analyser currently in development, and the ARES Technology Platform, Curetis' proprietary database focused on antibiotic resistance.

The Unyvero A30 *RQ* Analyzer was acquired as a prototype, then called 'Gyronimo' from Carpegen and Systec in December 2016, for an upfront cash payment of €5,000 thousand, plus future milestone and other payments. It is currently in the development stage and is an integral part of Curetis' product pipeline and intended to be fully and seamlessly integrated into the Unyvero Platform suite of products, to be used alongside the current

Unyvero A50 Analyzer, while also being suitable for stand-alone operation. Curetis aims for marketing to begin in Europe in late 2019, to be followed by other markets, but successful commercialisation is conditioned on the completion of development, verification, clinical validation, clinical trials and regulatory clearance in Europe, the US and other markets, as applicable. Application Cartridges for the Unyvero A30 *RQ* Analyzer are also in development, targeting indication areas such as a respiratory viral panel, central nervous system panel, immune-compromised patient panel and infection control panel.

If Curetis succeeds in launching Unyvero A30 *RQ* Analyzer commercially in its target markets, it may or may not be as commercially successful as Curetis expects for any number of reasons. Whether the Unyvero A30 *RQ* Analyzer can be successfully commercialised in Europe, the US, China and other key markets over time will have an impact on Curetis' results of operations. If it is successfully commercialized, Carpegen and Systec are eligible for two discrete, one-time milestone payments upon obtaining CE marking for the platform and first cartridge and upon FDA clearance, respectively, in total, up to €2,500 thousand, subject to certain specified conditions. Pursuant to the Gyronimo Acquisition agreement, Carpegen and Systec may also be entitled to certain royalty-based earn-outs at an industry-typical mid-single digit percentage rate, up to a cumulative and capped total of €9,000 thousand.

Curetis expects the ARESdb and the ARES Technology Platform, building and expanding upon the GEAR assets acquired for an upfront cash payment, plus future milestone payments, from STA in 2016 to result in additional revenue growth by enabling Curetis to enter into partnering deals and strategic collaborations with diagnostic companies, pharmaceutical companies and companies focused on public health and life science research, among others. Curetis expects to increasingly utilise the proprietary biomarker contents of the database in its own assay and cartridge development, as well as to license it out to partners. Curetis is in discussions with a number of potential counterparties, including large industry players and public health institutions in connection with possible collaboration agreements and believes that the ARESdb and the ARES Technology Platform has significant future revenue-generation potential. However, it has yet to generate any revenues. Curetis' future results will be impacted by whether it is able to successfully commercialise its ARES Technology Platform to enter into profitable partnerships and collaborations. As with the Unyvero A30 *RQ* Analyzer, however, Curetis is required pursuant to the acquisition agreement with STA to make future milestone payments upon obtaining CE-IVD-marking for the database and upon FDA clearance (or similar regulatory clearance), respectively as well as royalty payments to STA in industry-typical percentage ranges on net sales of future products based on use of the GEAR platform or GEAR biomarkers, as well as certain sublicensing fees.

### ***Market acceptance of molecular microbiology in diagnostics***

Curetis believes that its innovative solutions for using molecular diagnostics to improve the diagnosis of pneumonia, implant and tissue infections and other indications will address high unmet needs in some of the most prevalent infectious disease indications, which it believes will result in demand for its products and the growth of its business. Curetis' success will therefore depend on its ability to demonstrate to physicians, hospitals and other healthcare providers in Europe, the US and its other target markets that its Unyvero System and HPN/LRT and ITI, BCU, IAI, UTI Application Cartridges are valuable additions to conventional diagnostic tools for aiding in the diagnosis of pneumonia and implant and tissue infections, the other infectious diseases currently targeted by the existing Application Cartridges as well as future indications that Curetis may target.

In addition, given that the price of Curetis' Application Cartridges will be incurred in addition to, the costs of the conventional microbiology culture tests currently employed by hospitals around the world, Curetis must succeed in convincing hospitals that the improved health economics and better patient outcomes justify the direct costs of Curetis' products, and persuade government or commercial payers to reimburse hospitals for them. The success of these efforts may in turn depend on Curetis' ability to gain inclusion in the pneumonia and implant and tissue infection treatment guidelines of hospitals, and inclusion of its other current or future

Application Cartridges in the respectively applicable guidelines, which might be a prerequisite for hospitals purchasing Curetis' products in any significant quantity.

Curetis relies on numerous published studies and medical publications, articles and reports to demonstrate the potential benefits provided by the Unyvero System and Application Cartridges compared to traditional culture-based diagnostics, such as shorter turnaround time, the identification of more potential pathogens per specimen, the higher levels of sensitivity and specificity, as well as improved microorganism detection and that the rapid identification of pathogens offered by Curetis' Unyvero Platform is associated with shorter and less expensive hospital stays compared to standard culture methods.<sup>1</sup>

In addition to clinical studies and reports, Curetis typically places its Unyvero System in hospitals without charge for demos and evaluation and offers free or discounted Application Cartridges to potential customers in order to demonstrate the value of its products. See “— *Growth of Unyvero System and Application Cartridge business*”. These investments, which are recorded in distribution costs, are intended to help Curetis win regular customers for its Application Cartridges, thereby generating revenues. In cases where demos or evaluations are completed and the hospital does not convert to a commercial account by starting to purchase Application Cartridges, Curetis on a case by case basis may decide to remove the placed Unyvero Systems and re-allocate them into the pool of available demo systems for other potential future customers.

Revenues from Application Cartridges increased from €573 thousand in 2016 to €736 thousand in 2017, and from €359 thousand in the first six months of 2017 to €464 thousand in the first six months of 2018. Nevertheless, the process of customer acceptance of the Unyvero System in some of Curetis' markets, in particular Europe, is variable, with some customers requesting free cartridges to conduct studies for prolonged periods of time, sometimes years, without committing to buy them in the future. Such customers add to Curetis' costs over time, and some or all of them may never generate revenues.

#### ***Research and development costs, in particular for clinical trials***

Curetis' research and development costs are significant and will likely remain so for the foreseeable future. In 2016, 2017 and the first six months of 2018, Curetis' research and developments costs amounted to €7,027 thousand, €7,362 thousand and €4,683 thousand, respectively. Research and development costs relate primarily to design improvements and upgrades to the Unyvero System and life cycle management of its current Application Cartridges in response to customer feedback; the development of new Application Cartridges in the pipeline; the development of the Unyvero A30 RQ Analyzer platform and the first cartridges to be used with it; clinical trials and studies such as the additional FDA trials relating to clearance for the extension of the BAL indication and the IJI Application Cartridge; and the ongoing research activities relating to ARESdb and the ARES Technology Platform (although ARESdb and the ARES Technology Platform costs are partly funded by Curetis' collaboration partners, such as MGI, as well as grants and awards, the remainder of these costs are funded by Curetis).

A large proportion of Curetis' research and development costs are incurred to obtain regulatory clearances, namely designing and carrying out clinical trials and engaging in analytical testing as well as preparation of regulatory filings. In jurisdictions such as the US, the satisfactory outcome of medical and clinical studies is required to obtain regulatory clearance prior to commercialisation. In the EU, analytical verification and clinical validation is required prior to CE marking. In other countries or regions where separate clinical and medical studies are not explicitly required, such as the Middle East, Singapore and Israel, favourable results, for example from CE performance evaluation studies, are nevertheless likely to improve the perception of the Unyvero

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<sup>1</sup> Ozongwu *et al.*, *Biomol Detect Quantif.* 2017 June 28; 13:1-6. Investigational device.; Burrack-Lange *et al.*, (2018) submitted; Torres *et al.*, poster presented at European Congress of Clinical Microbiology (ECCMID) 2017.

Platform and the Application Cartridges with potential customers and therefore are more likely to lead to an increase in sales and revenues.

Generally speaking, it takes Curetis approximately 6-12 months from the initiation of development of a new Application Cartridge to the point in time when it is ready for internal verification and subsequent validation in a clinical study. Curetis estimates that the average cost per Application Cartridge development for this pre-trial stage is less than €1,000 thousand. The actual clinical trial phase per Application Cartridge ranges from three to six months in Europe and 12 to 18 months in the US, where FDA requirements and the need for third party service providers adds to the required trial time and expense. Clinical trial costs per Application Cartridge, including personnel costs for the research and development personnel who design and carry out clinical studies in house, the analytical testing as well as the costs of third party consultants and specialists who carry out external clinical trials for Curetis, range from an amount equal to the personnel costs plus a nominal amount (typically the cost of the Application Cartridges used) in Europe, while in the US, clinical trials can cost from €4,000 thousand to €6,000 thousand, per FDA trial and submission, depending on the number of clinical trial sites and cost per institutional review board (“IRB”) approval, complexity of the study protocol, amount of microbiology and clinical data required, need for external consultant services and support, type of samples and indication and the potential need for clinical trial insurance), and the balance of prospective versus retrospective specimens.

Since 2012, Curetis has incurred significant research and development expenses to finance various trials for the HPN Application Cartridge, the ITI Application Cartridge and the BCU, IAI, UTI and SHR Application Cartridges in various European countries. In the US, Curetis’ FDA trial for the Unyvero System and the LRT Application Cartridge began in June 2015 and Curetis incurred approximately €5,000 thousand in costs, of the type described above, before clinical study was completed in June 2016. Initiation of clinical trial sites for the IJI Application Cartridge trial, Curetis’ second FDA trial for its next US product, and Curetis estimates total clinical trial costs including preclinical and analytical studies, data analysis and regulatory filings, will range from €4,000 thousand to €6,000 thousand.

Clinical trials are expected to remain a major part of Curetis’ research and development operations and to result in significant expenses as more trials will be required for multiple clinical indications and Application Cartridges in multiple geographies as Curetis’ business grows. While Curetis expects to have collaboration partners share in the cost of clinical trials, for example in China and other Asian markets, these studies will nevertheless require investment and resources on Curetis’ part. As a result, Curetis believes that clinical trials will continue to represent a significant portion of its annual research and development costs, and therefore will continue to have an impact on its results of operations for the foreseeable future.

### ***Regulatory clearance***

In order to successfully commercialise its products, Curetis must obtain regulatory clearance in its current markets where it is required, including the US, China, and Singapore, as well as certain markets it hopes to enter, including Japan, and Brazil. In the EU, the self-certification regime currently in force for certain IVD products, including most of those produced by the Company, is transitioning to a regime that, among other things, will subject Curetis’ Application Cartridges to review by Notified Bodies, as described below. Application Cartridges which have been cleared in some markets, but not others, also have to undergo the clearance process in new markets where regulatory clearance is mandated. For more details, see “Regulation”.

### ***FDA clearance***

Before labelling and marketing Curetis’ products for use as clinical diagnostics in the US, Curetis is required to obtain clearance from the FDA. Curetis received FDA clearance for its Unyvero System and its LRT Application Cartridge in April 2018. Curetis’ ability to obtain FDA clearance for other Application Cartridges in Curetis’ pipeline, including the IJI Application Cartridge, which is currently scheduled to be the second cartridge to go

through an FDA trial, as well as the additional clearance of BAL as a second sample type for the LRT Application Cartridge, and future Application Cartridges for the US market targeting other infectious disease indications in hospitalised patients, will therefore be crucial to its long-term success in the US market.

The process of obtaining FDA clearance is expensive and time-consuming, potentially lasting from several months to several years, and can vary substantially based upon, among other things, the type, complexity and novelty of Curetis' products as well as upon access to a sufficient number of relevant clinical samples. Moreover, despite recently granting clearance for Curetis' Unyvero System and LRT Application Cartridge, the FDA may or may not accept or clear future Application Cartridges. For example, the FDA may ultimately not clear the IJI Application Cartridge, or may decide that Curetis' trial design is insufficient for clearance and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory clearance from the FDA. Such delays can have a significant impact on Curetis' financial results. The delay in securing FDA clearance for the Unyvero System and LRT Application Cartridge, which Curetis originally hoped to receive in the second half of 2017, but which was ultimately received in April 2018, impacted Curetis' results through the incremental costs of responding to additional FDA inquiries, conducting additional analytical testing and benefit/risk analysis, continued cash burn, foregone revenues and declines in margins over the period. Curetis believes that it will ultimately be able to obtain clearance for the IJI Application Cartridge and other future products, but there can be no assurance that this will be the case, and the clearance process may prove more expensive or take longer than expected.

#### *CFDA Clearance*

Analytical testing of the HPN Application Cartridge by Curetis' partner in Mainland China, Beijing Clear Biotech, was initiated in the fourth quarter of 2017 and was successfully completed with all assays of the HPN panel cleared for clinical trials in the third quarter of 2018 under the auspices of the Beijing Institute of Medical Device Quality Supervision and Testing of the CFDA. Analytical testing is a key requirement and precondition to Beijing Clear Biotech initiating the prospective CFDA clinical trials in the second half of 2018. Pursuant to the agreement with Beijing Clear Biotech, Beijing Clear Biotech is also expected to conduct prospective clinical trials required for the approval of the Unyvero System and the ITI, and potentially other Application Cartridges in China and will be responsible for the CFDA registration and the approval process. It is unclear how long the CFDA approval process will take, given that the CFDA is still developing the regulatory pathway to approval for products like those developed by Curetis. Further, it is unclear the extent to which clinical trial data generated outside China can supplement a regulatory submission to the CFDA. The "Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Pharmaceutical and Medical Devices", issued by the General Office of the Communist Party of China Central Committee and the General Office of the State Council in October 2017, allow the application of clinical trial data obtained from multiple overseas centers that are in line with the relevant requirements of Chinese drug and medical device registration for registration of medical devices in China. While Curetis and Beijing Clear Biotech intend to make use of this novel regulation and use data from Curetis' U.S.-FDA trial for the Unyvero LRT Application Cartridge in a submission for approval to the CFDA, it is currently uncertain how far such data may augment a submission to the CFDA and may help to accelerate market access in China.

The duration of the period between the initiation of analytical testing and the approval of Curetis' Unyvero System and HPN and other Application Cartridges will impact Curetis' results by contributing to the incremental costs of responding to additional CFDA inquiries, any additional studies or analytical work packages required, continued cash burn and foregone revenues over the period. Curetis regards the Mainland Chinese market as being of significant commercial importance to its future growth and success. As a result, the ability of Curetis and Beijing Clear Biotech to obtain clearance for its current and future products will have a significant impact on Curetis' future results of operations.

### *EU CE Marking under IVDR*

Under the current IVD Directive regime, high-risk products can only be CE-IVD-marked after certification by a Notified Body, whereas other products can be CE-IVD-marked following a self-certification process conducted by the manufacturer. A so-called conformity assessment of an IVD product candidate involving a Notified Body is not required for most of Curetis' products, except for the HPN Application Cartridge, which is subject to such review. Such a procedure by a Notified Body, where applicable, includes an audit and examination of the quality system of the manufacturer and, in the case of a high-risk device, an examination of the design and a validation of the device before approving the manufacturer's certification. Curetis received the required Notified Body approval for its HPN Application Cartridge and has certified its other products and registered them with the appropriate authorities. As a result, Curetis is able to CE-IVD-mark its products and market them in the EU as well as other countries recognising CE-IVD-marked IVD devices.

The new IVD Regulation, which entered into force in May 2017, repealed the IVD Directive, and will replace it after a five-year transition period ending in 2022. CE-IVD-marking of Curetis' products will remain valid until the end of this transitional period, after which both new and existing products will have to comply with the new IVD Regulation. Under the new IVD Regulation, all of Curetis' Application Cartridges will require a conformity assessment by a Notified Body, as they will not be considered low risk devices.

Despite the transition period under the IVD Regulation, Curetis does not believe that the competent Notified Bodies will have the capacity, and be ready in time, to complete required assessments in a timely manner and to ensure a smooth transition from the old regime, due to the large number of devices that will require review by the limited number of Notified Bodies under the IVD Regulation. Curetis estimates that obtaining CE-IVD-marking clearance from a Notified Body under the IVD Regulation is likely to increase the time it takes to bring a product to market in the EU by, on average, six months or longer. There is also the possibility that the Notified Body may find that Curetis has done insufficient validation and withhold its endorsement, effectively requiring Curetis to make changes to a product candidate as part of the conformity assessment, or take other action that could delay certification. Any delay in certifying its products for the EU market could impose incremental costs on the Company of responding to the Notified Body, result in additional cash burn and delayed revenue.

### *Regulatory clearance in the rest of the world*

The regulatory admission and clearance process and supervision in other countries requiring approval procedures, including the ASEAN countries, Japan and Brazil, prior to commercialisation subjects Curetis to costs and uncertainties comparable to the ones described above in relation to the US, China and Europe. The HPN and BCU Application Cartridges were recently approved by the Singapore Health Services Authority (the "HSA"), and the process with respect to other ASEAN markets is ongoing. Curetis and its local partner Acumen plan to submit the ITI and possibly also IAI and UTI Application Cartridges for HSA approval in the future. Curetis understands that the regulatory clearance process in Japan and Brazil is broadly similar to that in the US and China, for example requiring large clinical trials and the submission of extensive analytical and clinical data, all of which, as described above, can be costly and take longer than expected.

### *Distribution models*

Curetis follows a dual strategy of direct sales in key European markets and the US, and distribution partnerships in other territories, including the broader EMEA region and Asia. Generally speaking, the direct sales model requires more investment by Curetis, but has the potential to generate higher revenues and margins, whereas the distributor model requires less investment by Curetis but generates less net income once distributor margins are subtracted. The choice between direct sales and indirect sales distribution is based on the attractiveness of the market in terms of size, pricing, and reimbursement, the ease of market access in terms of regulatory clearance, 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 the economics permit establishing a direct sales infrastructure.

#### *Direct sales*

Since it began marketing and selling its products in 2012 and especially during the period under review, Curetis has built up and expanded its direct sales and marketing platform for the HPN, ITI, BCU, IAI and UTI (which was launched as CE-IVD-marked in the second quarter of 2018) Application Cartridges for its Unyvero System in Germany, Austria, the UK, France, Switzerland, Belgium, and the Netherlands, and has recently begun to commercialise its Unyvero System and the LRT Application Cartridge in the US following the FDA clearance in April 2018. As a result, Curetis has incurred significant distribution costs during the periods under review, amounting to €5,091 thousand, €7,302 thousand and €4,214 thousand for the years ended 31 December 2016 and 2017 and the six months ended 30 June 2018, respectively.

Although Curetis generates revenue from the sale of the Unyvero System, its commercial model for direct sales typically involves the placement of Unyvero Systems without payment, together with the temporary provision of free Application Cartridges, for free demonstration phase testing and evaluation. Curetis estimates that its investment per installed Unyvero System placed without payment amounts to approximately €40 thousand and that its investment per demo test and evaluation costs it between €1 thousand and €4 thousand in free Application Cartridges. Curetis believes that over time it will generate returns on these investments to the extent that such demonstration customers are converted to commercial customers and begin to routinely purchase Application Cartridges. See “- *Success of Curetis’ business model in growing its Unyvero System and Application Cartridge business*”.

Curetis also incurs costs for marketing and distribution staff to advise potential customers on various aspects of the Unyvero System and Application Cartridges, as well as the costs of building up a direct sales network of sales representatives, application specialists, and field service support and marketing personnel. For example, personnel expenses increased from €2,987 thousand in 2016 to €4,628 thousand in 2017 and were €2,874 thousand in the first six months of 2018 compared to €2,370 thousand for the first six months in 2017 as a result of the hiring of additional sales and marketing employees, mainly to strengthen the international direct sales organisation and in particular building up the US-based sales force in anticipation of the FDA clearance and commercial rollout of the Unyvero System and LRT Application Cartridge in the US.

All of these expenses, however, are incurred long before the corresponding investments generate revenues and, in this respect, increase Curetis’ distribution costs and its loss for the period. Curetis expects that its distribution costs and administrative expenses will continue to increase due to the establishment of, or further investments in, a dedicated sales force, a distribution network and other marketing efforts for its products.

#### *Distributor sales*

In the rest of the world, Curetis relies on a model of indirect sales and marketers with whom it has distribution agreements. The Company’s distributors are required to purchase the Unyvero Systems and Application Cartridges from the Company (whereupon the Company immediately recognizes sales revenue) and then resell them or place them without payment for their own account, at their sole discretion and risk, with such distributors’ customers. As at 30 October 2018, Curetis has entered into distribution agreements with 17 distributors covering 29 countries. See “*Business — Material Contracts — Distribution Agreements*”. Although using distributor arrangements in these markets requires less upfront investment, given that free Unyvero Systems and Application Cartridges are not typically offered to distributors as they have to bear the investment and cost of market development in their respective territories, and Curetis is not required to build a sales and marketing network in those jurisdictions, Curetis does maintain a core team of commercial partner management personnel to oversee distributor relationships, as well as second line support to provide technical assistance to



distributors and their customers. In addition, distributor sales result in substantially less gross profit per customer for Curetis because distributor margins range from 30% to 40% of Curetis' end-customer list prices in the relevant markets; however, unlike direct sales, distributor sales result in immediate revenue and cash inflows at the time of sale of the Unyvero Systems and/or Application Cartridges to the relevant distributor. Curetis expects that the sales of Unyvero Systems to distributors and collaborators will remain a material component of its total revenues, particularly in the next few years. Curetis' collaboration partner in China, Beijing Clear Biotech, for example, is responsible for the CFDA registration and approval process for the Application Cartridge in China, and, in a recent amendment to the distributor agreement, has committed to purchase a minimum number of 360 Unyvero Systems and more than 1.5 million Application Cartridges in the eight years following CFDA approval (assuming approval of the HPN, ICI and BCU Application Cartridges). See *"Business – Material Contracts – Strategic Partnerships and Collaboration Agreements – Beijing Clear Biotech"*. In 2016 and 2017, Curetis generated revenues of €828 thousand and €478 thousand in Germany, Switzerland, Austria and the rest of Western Europe, which broadly corresponds to its direct sales territories, and €478 thousand and €709 thousand in Asia and the rest of the world, which broadly corresponds to the territories where it sells through distributors. Sales of Unyvero Systems to distributors contributed revenues of €312 thousand in 2016 and €447 thousand in 2017.

Curetis believes that its dual distribution strategy is the optimum strategy for it to pursue at this stage of its development, and will allow it to manage its investment costs while maximising revenues. As its business grows, however, Curetis' revenues and profitability will continue to be impacted by both distribution models and, in particular, the degree to which it adopts the most revenue-efficient model in each of its markets.

#### ***Sale of Unyvero Systems to certain third parties***

Curetis has in the past sold, and may in the future sell, Unyvero Systems that are part of its installed base to third party finance companies in circumstance where the hospital in which the relevant Unyvero System was placed has converted to a commercial customer, but has no budget to purchase the actual Unyvero System itself. Generally, following the commercial conversion of the customer pursuant to the direct sales model, Curetis offers to sell the Unyvero System in the relevant hospital to a third party finance company at a pre-agreed price, as a result of which the finance company assumes all rights, responsibilities and risks associated with the system, and Curetis recognizes revenue from the sale. The hospital is then required to run Curetis' Application Cartridges, which it purchases from Curetis, on that system. As part of the agreement, Curetis pays a fixed, contractually defined and volume-capped sales commission to the finance company based on the number of cartridges sold to the hospital, which is the end customer. Some of these agreements include an agreed annual volume cap and for Application Cartridges sold to the hospital in excess of this cap, Curetis pays only a nominal sales commission per cartridge. This arrangement benefits Curetis by allowing it to preserve its working capital, generate cash flow upon the sale of the underlying Unyvero System, and recognize revenue.

In 2016, for example, Curetis sold several Unyvero Systems to DiaMed Care GmbH ("**DiaMed Care**") for €218 thousand. Two additional pools of commercial stage Unyvero Systems were sold to DiaMed Care in the first six months of 2018 for a total of €304 thousand. As part of these sales, Curetis agreed to pay DiaMed Care a sales commission per Application Cartridge sold to each hospital using a Unyvero System owned by DiaMed Care each year until a predefined number of Application Cartridges has been sold, after which the usage fee steps down. At the end of a four-year period following the original sale, if a predefined number of Application Cartridges has been sold to the hospital over the four-year period, Curetis pays DiaMed Care a reduced sales commission per additional Application Cartridge sold. This arrangement expires under several circumstances, including if the Unyvero System is sold to the hospital for residual value, in which case Curetis and DiaMed Care will divide the sales proceeds.

DiaMed Care has no contractual or other relationship with Curetis' customers, and Curetis continues to sell the Application Cartridges directly to the customer and recognise revenues for those sales. The costs of such sales

commissions and discounts are recorded in distribution costs. Curetis may engage in such sales in the future with DiaMed Care or other third parties, and as its business grows, such sales may have an increasingly large impact on its revenues and costs.

### ***Taxation***

Since its inception in 2007, Curetis has not generated any profits and, as a result, has not paid corporate income taxes. As of 31 December 2017, Curetis had tax loss carry forwards in the amount €89,562 thousand for corporate tax purposes and €89,452 thousand for trade tax purposes which could not be used to offset profits and for which no deferred taxes were recognized. They are, however, available for offsetting against future taxable profits of Curetis under the German regime. Under German tax law, such tax losses carry forwards will be forfeited completely, if, *inter alia*, a change of control occurs, i.e. if a person or a group of acquirers with similar interests acquires directly or indirectly more than 50% of the interest in Curetis, and such tax carry forwards will be partially forfeited if such person or group acquires directly or indirectly between 25% and 50% of the interest in Curetis, or if certain other changes occur. If such events occur with respect to Curetis, it could lose some or all of its tax carry forwards. This would, if and once Curetis reaches profitability, result in a higher tax burden than would otherwise be the case. In the absence of such events, however, Curetis would be able to apply such tax losses against its future profits. Curetis expects to continue to accumulate losses for the next few years. This will likely lead to additional losses carried forward which could then be set-off against future profits for tax purposes, thus reducing the basis for income taxation for future periods.

### ***Cash burn***

Curetis' cash outflow from operating activities and investing activities has been a significant component of its financial results since its inception. In 2016, 2017 and the first six months of 2018, Curetis' cash outflow from operating activities was €15,724 thousand, €15,681 thousand and €11,462 thousand, respectively and its cash outflow from investing activities was €7,430 thousand, €421 thousand and €230 thousand, respectively. As a result of Curetis' operating and investment activities described above, and in particular the costs associated with the expansion of its US commercial organization in late 2017 and early 2018, in anticipation of the FDA clearance and commercial rollout of its Unyvero System and LRT Application Cartridge in the US, as well as the continued development of the Unyvero A30 RQ Analyzer and further Application Cartridges, Curetis expects its cash outflow from operating activities and investing activities to increase from €16,102 thousand in 2017 to approximately €30,000 thousand in 2018. Cash outflow from operating activities and investing activities for the six months ended 30 June 2018 was €11,692 thousand. Curetis' cash burn has implications for its working capital needs and will impact its results of operations in 2018 and beyond. See "Capitalisation, Indebtedness and Working Capital".

## ***Recent Developments and Outlook***

### ***Recent Developments***

*Key developments in the Company's business since 30 June 2018 include:*

*Commercial Progress in the U.S. Market.* Since the U.S. commercial launch in June 2018, the U.S. commercial team has initially qualified more than 140 accounts as potential first buyers of Unyvero Systems out of a total about 1,000 hospitals considered by Curetis to be initial targets for the Unyvero LRT Application Cartridge. Of those qualified accounts, more than 60 have been thoroughly vetted by Curetis. and many are expected to be converted to commercial accounts over the next several quarters with approximately ten accounts constituting near term opportunities currently at the contract negotiation stage.

*The Yorkville Financing.* In October 2018, the Company entered into the Yorkville Agreement for up to €20,000 thousand in aggregate principal amount through the issuance by the Company of Convertible Notes to Yorkville,

subject to certain terms and conditions being met. At the same time, the Company issued €3,500 thousand in principal amount of Convertible Notes as part of the first tranche under the Yorkville Agreement, thereby raising a net proceeds amount of €3,220 thousand. See “*Business – Material Contracts – Financing Arrangements – Yorkville Financing*”.

*New distribution agreements in North Africa and Latin America.* Curetis recently entered into distribution agreements with Future Horizons Scientific (FHS) in Egypt, Quimica Valaner S.A. de C.V. in Mexico and Biko S.A. in Uruguay for commercialization of the Unyvero Platform and Application Cartridges, subject to obtaining regulatory clearance for the products in the respective markets as described in detail under “*Business – Material Contracts – Distribution Agreements*”.

### **Outlook**

In the U.S., the initial ten accounts which Curetis considers to be near term opportunities are on average expected to have Unyvero LRT Application Cartridge volumes of 700 to 800 annually once they become commercial customers. The estimated Unyvero LRT Cartridge volume potential for the more than 60 accounts in advanced stages of qualification range from around 250 to over 1,600 per year. Curetis expects to place 60-80 Unyvero Analyzers within the first full year following the U.S. commercial launch in June 2018. Curetis also expects to continue to make progress on its Unyvero LRT Application Cartridge label claim extension for BAL and its IJI clinical studies in the U.S.

Outside the U.S., Curetis expects to continue to expand its distribution network and commercial reach through further partnerships with suitably positioned distributors in new geographic markets. Curetis also plans to launch its Unyvero A30 RQ Analyzer module, subject to completion of development and regulatory clearance for CE-IVD-marking, in Europe in late 2019.

More generally, Curetis expects to continue to develop ARESdb and ARES Technology Platform and to enter into further value-adding research and development and commercial partnerships with industry partners, clinicians, and public health and life science research companies around ARESdb and the ARES Technology Platform and the Unyvero Platform.

The foregoing outlook discussion assumes that the Company raises the Top-End Proceeds in the Offering. If the Offering should be withdrawn or otherwise not completed, or if the additional available funds generated from the Offering fall below €16.6 million, needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, or if Curetis’ cash burn is higher than expected, then Curetis will implement an action plan to control and potentially reduce costs, which in turn would result in changes to the outlook. For more detail on this subject, see “*Capitalisation, Indebtedness and Working Capital – Working Capital Statement*”.

## **Description of Principal Items of the Statement of Profit or Loss and Other Comprehensive Income**

### **Revenue**

Curetis is a single-segment entity. Revenues are generated through the sale of Unyvero Systems, Application Cartridges and spare parts for Unyvero Systems and the provision of services. If Curetis gives discounts to its customers, these are deducted from revenues.

### **Cost of sales**

Cost of sales includes the total acquisition and manufacturing costs incurred for products, goods and services that are sold. Curetis manufactures cartridges and disposables at its manufacturing plant and purchases Unyvero Systems from Zollner.

Manufacturing costs for products manufactured in-house include the directly allocable individual material and production costs, the allocable parts of the overhead costs for production including depreciation of production equipment and reduction in inventories, as well as fixed and idle costs for the manufacturing plant. The estimated obsolescence write-downs on Unyvero Systems included in cost of sales reflect the expected lifetime and usage of a Unyvero System. So far Curetis has no reliable sales-track-record. Therefore, the write-downs are based on management's best estimate considering technical aging and estimated sales prices for used systems. Cost of sales also includes significant idle costs (comprising mainly overhead production costs and depreciation costs for manufacturing equipment for unused capacities) for the manufacturing of cartridges.

#### ***Distribution costs***

Distribution costs include all individual sales and overhead sales costs. They include all expenses for personnel, marketing, materials and depreciation, in addition to other sales expenditures and delivery costs. Distribution costs include the costs of placing Unyvero Systems without payment with, and giving free Application Cartridges to, certain customers and potential customers for demo testing and evaluation.

#### ***Administrative expenses***

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

#### ***Research and development expenses***

Research expenses are defined as costs incurred for research conducted to gain 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.

For the periods under review, Curetis' research and development expenses mainly reflect salaries of research and development personnel and the costs of certain outsourced research and development services with respect to (i) manufacturing, engineering and operations not included in the cost of goods sold, (ii) research and development programmes focused on the expansion of the menu of application-specific cartridges and general life cycle management of the existing Application Cartridges, (iii) the development of the Unyvero A30 RQ Analyzer platform and initial cartridges for use with the Unyvero A30 RQ Analyzer, (iv) ARESdb and ARES Technology Platform-related research activities, to the extent not funded by grants or by partners, and (v) system engineering.

It also includes the costs of reagents and Application Cartridges that are used in the research and development of assays and other experiments with the Unyvero Platform, costs of consultants, as well as expenses related to quality assurance, clinical, regulatory and medical affairs, clinical trial operations, including the costs of conducting FDA trials such as those for the BAL extension and the IJI Application Cartridge, and to filing new patents and maintaining Curetis' intellectual property portfolio. Finally, it also includes the annual depreciation expenses related to production equipment, laboratory and engineering equipment, capitalised Unyvero Systems for internal use, amortisation of intangible fixed assets such as software, as well as depreciation related to the share of Curetis' offices and facilities used in research and development activities.

#### ***Other income***

Other income mainly comprises income from grants for research and development projects and gains from the reversal of other current liabilities and other current financial liabilities, as well as income from the re-charging of transportation costs to customers and claims against employees for the compensation of the partially private use of business cars.

*Operating profit*

Operating profit measures Curetis' earning power from on-going operations and corresponds to earnings before financial result and taxes.

**Finance income/costs/net**

Finance income (costs)/net consists mainly of interest on bank deposits, net of finance costs, and also includes net foreign currency gains or losses.

## Results of Operations

The following table presents the statement of profit or loss and other comprehensive income of Curetis for the six months ended 30 June 2018 and 2017, which was taken from the Interim Financial Statements, and for the years ended 31 December 2017 and 2016, which was taken from the Annual Financial Statements.

	For the six months ended 30 June		For the year ended 31 December	
	(unaudited)		(audited)	
	2018	2017	2017	2016
		(€thousand)		
<b>Revenue</b> .....	807	595	1,187	1,306
Cost of sales .....	(1,435)	(1,052)	(1,649)	(1,596)
Gross loss .....	(628)	(457)	(462)	(290)
Distribution costs .....	(4,214)	(3,846)	(7,302)	(5,091)
Administrative expenses .....	(2,111)	(1,848)	(3,755)	(3,024)
Research and development expenses .....	(4,683)	(3,161)	(7,362)	(7,027)
Other income .....	271	50	314	198
<b>Operating loss</b> .....	(11,365)	(9,262)	(18,567)	(15,234)
Finance income .....	274	20	21	101
Finance costs .....	(496)	(406)	(1,004)	(30)
<b>Finance result – net</b> .....	(222)	(386)	(983)	71
<b>Loss before income tax</b> .....	(11,587)	(9,648)	(19,550)	(15,163)
Income tax expenses .....	26	(14)	52	(10)
<b>Loss for the period</b> .....	(11,561)	(9,662)	(19,498)	(15,173)
Other comprehensive loss for the period, net of tax .....	(171)	117	171	(28)
<b>Total comprehensive loss for the period</b> .....	(11,732)	(9,545)	(19,327)	(15,201)

*Comparison of the six months ended 30 June 2018 and 2017*

## Revenues

The following table sets forth a breakdown of Curetis' revenues in the six months ended 30 June 2018 and 30 June 2017 based on the Interim Financial Statements.

	<b>For the six months ended 30 June</b>	
	<b>(unaudited)</b>	
	<b>2018</b>	<b>2017</b>
	<i>(€thousand)</i>	
Sale of Unyvero Systems.....	369	229
Sales of Application Cartridges.....	464	359
Sales of Services .....	3	14
Discounts.....	(29)	(7)
<b>Total revenues</b> .....	<b>807</b>	<b>595</b>

The following table sets forth a breakdown of Curetis' revenues by geography for each of the periods presented based on the Interim Financial Statements: The geographic categories presented in the table below differ from the geographic categories set forth in the analogous revenue discussion for the years ended 31 December 2017 and 2016 (see "Comparison of the years ended 31 December 2017 and 2016 – Revenues" below) because (i) Curetis has expanded its commercial operations in the United States; and (ii) Austria changed from being a direct sales territory, like Germany and Switzerland, to one covered by a distributor, and (iii) there has been an expansion of direct sales territories to include Belgium, Netherlands, and Luxembourg, each of which had previously been covered by distributors, as well as the UK and France which are new direct sales territories. As a result, Curetis considered it more appropriate to rename its direct sales category as "EMEA direct markets", rather than listing out each direct sales jurisdiction as it had previously done with Germany, Austria and Switzerland; add a separate category for the United States; and reclassify its European markets served by distributors as the "*Rest of the World*". Asia remains unchanged.

	<b>For the six months ended 30 June</b>	
	<b>(unaudited)</b>	
	<b>2018</b>	<b>2017</b>
	<i>(€thousand)</i>	
EMEA direct markets <sup>(1)</sup> .....	514	144
USA .....	33	3
Asia <sup>(2)</sup> .....	118	154
Rest of the World <sup>(3)</sup> .....	142	294
<b>Total revenues</b> .....	<b>807</b>	<b>595</b>

Notes:

(1) Includes Germany, Switzerland, Belgium, Netherlands, Luxembourg, UK and France

(2) Includes Kuwait, Qatar, UAE, Singapore, China, Hong Kong

(3) Includes Italy, Austria, Russia, Romania, Spain, Greece, Bulgaria

Revenue increased from €595 thousand in the first six months 2017 by €212 thousand or 35.6% to €807 thousand in the first six months 2018. This was mainly due to (i) an increase in the first half of 2018 in the sale of Unyvero-Systems in EMEA direct markets, notably France, to a business partner, DiaMed, to whom Curetis sold commercial stage devices placed at hospitals after those hospitals were converted from demo- / evaluation-sites to commercial accounts in the fourth quarter of 2017 and the first half of 2018, and (ii) to an increase in the sale of Application Cartridges due to a growth in the number of commercial accounts in EMEA direct selling markets. Revenue attributable to Asia and the rest of the world declined due to initial investments in Unyvero Systems from new distributors in Romania, Greece and Bulgaria in the first half of 2017, which did not recur in the first half of 2018, and a decline in the number of Application Cartridges purchased by the distributor in Kuwait in the first half of 2018.

#### *Cost of sales*

Cost of sales includes the total acquisition and manufacturing costs incurred for products, goods and services that are sold. In the six months ended 30 June 2018, cost of sales amounted to €1,435 thousand, an increase of 36.4% compared to €1,052 thousand in the six months ended 30 June 2017. Curetis manufactures cartridges and disposables at its manufacturing plant and purchases Unyvero-Systems from its OEM-supplier. The increase of cost of sales in the first six months 2018 compared to the first six months 2017 mainly resulted from:

- higher total revenues and increased revenues generated from the sale of Unyvero-Systems, which have higher costs-of-materials than Application Cartridges;
- higher marketability discounts in respect of Unyvero System sales, which increased from €237 thousand in the first six months 2017 to €396 thousand in the first six months 2018; and
- higher cartridge demand for internal quality control testing to ensure high levels of quality.

Cost of sales exceeded revenues for both the first half of 2018 and the first half of 2017 as the cost of sales also included fixed and idle costs for the manufacturing plant, the production capacity of which exceeded its levels of utilisation over the period.

#### *Gross profit*

As a result of the increased costs of sales, gross loss increased from €457 thousand in the six months ended 30 June 2017 to €628 thousand in the first six months ended 30 June 2018.

#### *Distribution costs*

The following table sets forth a breakdown of distribution costs in the six months ended 30 June 2018 and 2017.

	<b>For the six months ended 30 June</b>	
	<b>(unaudited)</b>	
	<b>2018</b>	<b>2017</b>
	<i>(€thousand)</i>	
Personnel expenses .....	2,874	2,370
<i>thereof from share-based payments equity-settled</i> .....	160	350
Depreciation and amortisation .....	51	89

	<b>For the six months ended 30 June</b>	
	<b>(unaudited)</b>	
	<b>2018</b>	<b>2017</b>
	<i>(€thousand)</i>	
Other operating expenses.....	1,289	1,387
<i>thereof marketing expenses</i> .....	712	653
<i>thereof travel expenses</i> .....	365	257
<i>thereof consulting, advisory and third-party service</i> .....	107	141
<b>Total</b> .....	<b>4,214</b>	<b>3,846</b>

Distribution costs increased by 9.6%, from €3,846 thousand in the six months ended 30 June 2017 to €4,214 thousand in the first six months ended 30 June 2018, due mainly to an increase in personnel expenses due to the recruitment of additional sales and marketing employees, mainly to strengthen the international direct sales organization. The average number of full-time employees employed in marketing and sales increased from 28.2 during the first six months 2017 to 39.3 during the first six months 2018 with most of that increase attributable to the build-up of the US commercial organization.

The increase in other operating expenses in the first six months 2018 compared to the first six months in 2017 was mainly due to expanded marketing activities driven by increased staff and higher shipment costs for Unyvero-Systems.

#### *Administrative expenses*

The following table sets forth a breakdown of Curetis' administrative costs in the six months ended 30 June 2018 and 2017.

	<b>For the six months ended 30 June</b>	
	<b>(unaudited)</b>	
	<b>2018</b>	<b>2017</b>
	<i>(€thousand)</i>	
Personnel expenses .....	885	883
<i>thereof from share-based payments equity-settled</i> .....	101	195
Depreciation and amortisation .....	44	60
Other expenses.....	1,182	905
<i>thereof for remuneration of supervisory board</i> .....	174	119
<i>thereof from share-based payments equity-settled</i> .....	45	0
<i>thereof consulting, advisory and third-party service</i> .....	507	346
<b>Total</b> .....	<b>2,111</b>	<b>1,848</b>



Administrative expenses increased by 14.2%, from €1,848 thousand in the six months ended 30 June 2017 to €2,111 thousand in the six months ended 30 June 2018, due mainly to an increase of other operating expenses in the six months ended 30 June 2018 compared to the same period in 2017 which was mainly due to

- higher remuneration for supervisory board members due to additional members that joined the board at the AGM in mid-2017 and the valuation of granted equity settled stock options to the supervisory board members;
- higher recruiting expenses, which increased significantly from €35 thousand in the first six months of 2017 to €184 thousand in the first six months of 2018 as part of Curetis' efforts to hire for key commercial positions and to strengthen the US-based team for the commercial ramp-up following the FDA approval in April 2018.

#### *Research and development expenses*

The following table sets forth a breakdown of Curetis' research and development expenses in the six months ended 30 June 2018 and 2017.

	<b>For the six months ended 30 June</b>	
	<b>(unaudited)</b>	
	<b>2018</b>	<b>2017</b>
	<i>(€thousand)</i>	
Personnel expenses .....	2,193	1,799
<i>thereof from share-based payments equity-settled</i> .....	105	151
Depreciation and Amortisation .....	354	361
Material expenses.....	139	128
Other expenses.....	1,997	873
<i>thereof IP-fees and expenses for patent lawyers</i> .....	370	175
<i>thereof clinical trial expenses</i> .....	83	64
<i>thereof costs for laboratory demand</i> .....	278	137
<i>thereof consulting, advisory and third-party services</i> .....	890	179
<i>thereof other manufacturing expenses for cartridges used in research and development</i> .....	123	154
<b>Total</b> .....	<b>4,683</b>	<b>3,161</b>

Research and development expenses increased by 48.1%, from €3,161 thousand in the six months ended 30 June 2017 to €4,683 thousand in the six months ended 30 June 2018, due mainly to the increase of personnel expenses in the first six months ended 30 June 2018 compared to the same period in 2017, which was due to the hiring of additional research employees.

Furthermore, other expenses increased significantly in the first six months of 2018 compared to the same period in 2017.

This was mainly due to:

- higher IP-fees and expenses for patent lawyers due to the filing of additional patents, especially in relation to the ARESdb-platform; and
- higher consulting expenses and higher costs for third party service providers, especially relating to the further development of the Unyvero A30 RQ system in the first six months of 2018.

#### *Other income*

Other income increased by 442%, from €50 thousand in the six months ended 30 June 2017 to €271 thousand in the six months ended 30 June 2018, mainly due to income from government grants for research and development projects amounting to €144 thousand received in the six months ended 30 June 2018, while no such income was recognized in the six months ended 30 June 2017. In addition, Curetis realized gains from the reversal of other current liabilities and other current financial liabilities amounting to €80 thousand in the six months ended 30 June 2018 compared to €9 thousand in the six months ended 30 June 2017 as a result of the lapse of previously incurred provisions and lower actual expenses than originally estimated.

#### *Operating loss*

As a result of the foregoing factors, operating loss increased from €9,262 thousand in the six months ended 30 June 2017 to €11,365 thousand in the six months ended 30 June 2018.

#### *Finance result – net*

In the six-months ended 30 June 2018, net finance result amounted to a loss of €222 thousand compared to a loss of €386 thousand for the six months ended 30 June 2017, arising primarily from an increase in finance income from €20 thousand in the six months ended 30 June 2017 to €274 thousand in the six months ended 30 June 2018 due to increased gains from exchange differences after Curetis purchased U.S. dollars to finance its U.S. commercial expansion and subsequently realized gains when the U.S. dollar strengthened. This increase in finance income was partially offset by an increase in finance costs from €406 thousand in the six months ended 30 June 2017 to €496 thousand in the six months ended 30 June 2018 due to accrued interest payable on €13,000 thousand in outstanding indebtedness under the first two tranches of the EIB Finance Contract, which were drawn down in April 2017 (€10,000 thousand) and June 2018 (€3,000 thousand).

### ***Comparison of the years ended 31 December 2017 and 2016***

#### *Revenues*

The following table sets forth a breakdown of Curetis' revenues in 2017 and 2016 based on the Annual Financial Statements:

	<b>For the year ended 31 December</b>	
	<b>(audited)</b>	
	<b>2017</b>	<b>2016</b>
	<i>(€thousand)</i>	
Sale of Unyvero Systems.....	448	690
Sales of Application Cartridges.....	736	573
Sales of Services .....	17	48
Discounts.....	(14)	(5)
<b>Total revenues.....</b>	<b>1,187</b>	<b>1,306</b>

The following table sets forth a breakdown of Curetis' revenues by geography for each of the periods presented based on the Annual Financial Statements:

	<b>For the year ended 31 December</b>	
	<b>(audited)</b>	
	<b>2017</b>	<b>2016</b>
	<i>(€thousand)</i>	
Germany, Austria, Switzerland .....	450	650
Western Europe <sup>(1)</sup> .....	28	178
Asia <sup>(2)</sup> .....	270	278
Rest of World <sup>(3)</sup> .....	439	200
<b>Total revenues</b> .....	<b>1,187</b>	<b>1,306</b>

Notes:

- (1) Including Belgium, Netherlands, Luxembourg, UK and France
- (2) Including Kuwait, Qatar, UAE, Singapore, China and Hong Kong
- (3) Including Italy, Russia, Romania, Spain, Greece and Bulgaria

Revenues decreased by 9.1%, from €1,306 thousand in 2016 to €1,187 thousand in 2017, due mainly to a 35.1% decline in the sale of Unyvero Systems, from €690 thousand in 2016 to €448 thousand in 2017, partly offset by an increase in the sale of Application Cartridges, from €573 thousand in 2016 to €736 thousand in 2017. The Company attributes the decline in revenues from the sale of Unyvero Systems to fewer Unyvero Systems sold in the markets where Curetis engages in direct sales. In 2016, Curetis had generated one-time revenues of €218 thousand through the sale of Unyvero Systems in those markets to a business partner, DiaMed. The increase in sales of Application Cartridges was due to higher utilisation of the installed base of Unyvero Systems as well as an increase in the number of Application Cartridge purchased by commercially converted accounts within the installed base.

Revenues in Germany, Austria and Switzerland and from other Western European markets declined significantly, from €650 thousand and €178 thousand, respectively, in 2016 to €450 thousand and €28 thousand in 2017, due to the one-time revenue impact of the large sale of Unyvero Systems in 2016 to DiaMed as well as by clinical studies in the UK which resulted in customers purchasing a larger amount of Application Cartridges in 2016 which did not recur in 2017. Sales in Asia over this period were flat. Revenue increased for the Rest of the World, from €200 thousand in 2016 to €439 thousand in 2017, driven mainly by the addition of a new distributor in Romania in 2017.

#### *Cost of sales*

Cost of sales increased 3.3%, from €1,596 thousand in 2016 to €1,649 thousand in 2017, despite the decline in revenue over the same period, due to higher write-downs on Unyvero Systems to reflect marketability discounts. The cost of sales for each individual Application Cartridge remained essentially flat over the period.

### *Gross loss*

As a result of the decline in revenue and increase in cost of sales, gross loss increased by 59.3%, from €290 thousand in 2016 to €462 thousand in 2017.

### *Distribution costs*

The following table sets forth a breakdown of distribution costs in 2017 and 2016.

	<b>For the year ended 31 December</b>	
	<b>(audited)</b>	
	<b>2017</b>	<b>2016</b>
	<i>(€thousand)</i>	
Personnel expenses .....	4,628	2,987
<i>thereof from share-based payments equity-settled</i> .....	566	295
Depreciation and amortisation .....	170	173
Other operating expenses.....	2,504	1,931
<i>thereof marketing expenses</i> .....	1,146	901
<i>thereof travel expenses</i> .....	520	407
<i>thereof consulting, advisory and third-party service</i> .....	431	353
<b>Total</b> .....	<b>7,302</b>	<b>5,091</b>

Distribution costs increased by 43.4%, from €5,091 thousand in 2016 to €7,302 thousand in 2017, due mainly to increases in personnel expenses. Personnel expenses increased from €2,987 thousand in 2016 to €4,628 thousand in 2017 as a result of the hiring of additional sales and marketing employees, mainly to strengthen the international direct sales organisation and in particular building up the US-based sales force in anticipation of the FDA clearance and commercial rollout of the Unyvero System and LRT Application Cartridge in the US. The average number of full time sales and marketing employees increased from 20.3 in 2016 to 27.6 in 2017.

The increase in other operating expenses, from €1,931 thousand in 2016 to €2,504 thousand in 2017, was due to expanded marketing activities in additional markets, driven in turn by increased employee numbers and an increase in commercial activities, events, and travel.

### *Administrative expenses*

The following table sets forth a breakdown of Curetis' administrative expenses in 2017 and 2016.

	<b>For the year ended 31 December</b>	
	<b>(audited)</b>	
	<b>2017</b>	<b>2016</b>
	<i>(€thousand)</i>	
Personnel expenses .....	1,603	1,215

	For the year ended 31 December	
	(audited)	
	2017	2016
	(€thousand)	
<i>thereof from share-based payments equity-settled</i> .....	312	195
Depreciation and amortisation .....	104	135
Other expenses.....	2,048	1,674
<i>thereof for remuneration of supervisory board</i> .....	310	213
<i>thereof from share-based payments equity-settled</i> .....	64	0
<i>thereof consulting, advisory and third-party service</i> .....	751	718
<b>Total</b> .....	<b>3,755</b>	<b>3,024</b>

Administrative expenses increased by 24.2%, from €3,024 thousand in 2016 to €3,755 thousand in 2017, due to the increase in personnel expenses and other expenses. The increase of personnel expenses from €1,215 thousand in 2016 to €1,603 thousand in 2017 was mainly due to (i) the hiring of additional employees in general and administrative departments, with the number of full time employees increasing from an average of 9.1 during 2016 to an average of 12.0 during 2017, and (ii) a higher number of equity stock options granted and correspondingly higher valuations.

The increase of other expenses from €1,674 thousand in 2016 to €2,048 thousand in 2017 was mainly due to an increase of supervisory board remuneration for additional supervisory board members in 2017 and additional remuneration with equity settled stock options that were granted in 2017 for supervisory board members and key employees in administrative departments.

#### *Research and development expenses*

The following table sets forth a breakdown of Curetis' research and development expenses in 2017 and 2016.

	For the year ended 31 December	
	(audited)	
	2017	2016
	(€thousand)	
Personnel expenses .....	3,665	3,147
<i>thereof from share-based payments equity-settled</i> .....	228	143
Depreciation and Amortisation .....	810	1,254
Material expenses.....	407	625
Other expenses.....	2,480	2,001
<i>thereof clinical trial expenses</i> .....	367	747
<i>thereof costs for laboratory demand</i> .....	303	290

	For the year ended 31 December	
	(audited)	
	2017	2016
	(€thousand)	
<i>thereof other manufacturing expenses for cartridges used in research and development</i> .....	395	401
<b>Total</b> .....	<b>7,362</b>	<b>7,027</b>

Curetis' research and development costs increased by 4.8%, from €7,027 thousand in 2016 to €7,362 thousand in 2017 due to increases in personnel expenses and other expenses, partly offset by decreases in depreciation and amortisation and material expenses. The increase of personnel expenses in 2017 was due to higher personnel expenses due to additional employees hired in research and development departments to accelerate development of products in the pipeline such as the Unyvero A30 RQ Analyzer and ARESdb/ARES Technology Platform related programmes. The number of full time research and development employees increased from an average of 20.2 during 2016 to an average of 26.4 during 2017. Other expenses also increased from 2016 to 2017, due to higher IP-related expenses arising from higher patent prosecution costs in 2017 than 2016. These costs increased as a result of growth in Curetis' patent portfolio in 2017 as a result of the acquisition of the GEAR database from Siemens in 2016 and the purchase of intellectual property in connection with the Unyvero A30 RQ. These increases were only partly offset by lower depreciation and amortisation expenses, attributable to the Unyvero Systems used in the FDA-clinical trial and lower depreciation and amortisation expenses due to a lower number of Application Cartridges delivered to clinical trial sites in the US. A majority of the installed base of Unyvero Systems on clinical trial sites are already fully depreciated (based on a useful life of three years),

#### *Other income*

Other income increased by 58.6%, from €198 thousand in 2016 to €314 thousand in 2017, mainly due to income from government grants for research and development projects amounting €109 thousand in 2017, compared to €86 thousand in 2016, and gains from the reversal of other current liabilities and other current financial liabilities amounting to €136 thousand in 2017 compared to €9 thousand in 2016 as a result of the lapse of previously incurred provisions and lower actual expenses than originally estimated.

#### *Operating loss*

As a result of the foregoing factors, operating loss increased by 21.9% from €15,234 thousand in 2016 to €18,567 thousand in 2017.

#### *Finance result – net*

Net finance result was equal to income of €71 thousand in 2016 and cost of €983 thousand in 2017, with the finance cost in 2017 arising primarily from accrued interest payable on €10,000 thousand in outstanding indebtedness under the first tranche of the EIB Finance Contract, which was drawn down in April 2017, and foreign currency (mainly US dollar) losses arising after Curetis purchased US dollars to finance its US commercial expansion and subsequently suffered losses when the US dollar weakened.

### *Income tax expenses*

Curetis has a double residency in Germany and the Netherlands for tax purposes. However, Curetis has elected to allocate the right of taxation to Germany only under the tax treaty between Germany and the Netherlands. In Germany the Company was subject to effective corporate income tax rate of 15.825% and a municipal trade tax of 12.05% in both 2016 and 2017. However, as a loss-making entity, Curetis' actual income tax liability over the period amounted to a tax expense of €10 thousand in non-German current income taxes in 2016 and tax income of €53 thousand resulting from deferred taxes on group consolidation in 2017.

### **Financial Position**

The following table presents the statement of financial position of Curetis as of 30 June 2018, which was taken from the Interim Financial Statements, and as of 31 December 2017 and 2016, which was taken from the Annual Financial Statements.

	<b>30 June (unaudited)</b>	<b>31 December (audited)</b>	
	<b>2018</b>	<b>2017</b>	<b>2016</b>
		<i>(€thousand)</i>	
<b>Assets</b>			
<b>Current assets</b> .....	20,348	24,009	30,272
Cash and cash equivalents .....	11,646	16,311	22,832
Trade receivables .....	250	200	101
Inventories .....	6,891	6,946	5,870
Other current assets .....	1,561	552	1,469
<b>Non-current assets</b> .....	11,156	11,506	12,514
Intangible assets.....	7,511	7,524	7,520
Property, plant and equipment .....	3,193	3,566	4,466
Other non-current assets .....	172	182	212
Other non-current financial assets.....	157	156	316
Deferred tax assets .....	123	78	-
<b>Total assets</b> .....	31,504	35,515	42,786
<b>Liabilities and equity</b>			
<b>Current liabilities</b> .....	3,180	2,926	2,384
Trade and other payables .....	447	928	721
Provisions current .....	54	124	51
Tax liabilities .....	26	24	10
Other current liabilities.....	1,442	1,226	1,120
Other current financial liabilities .....	1,211	624	482
Non-current liabilities .....	13,647	10,385	41
Provisions non-current .....	43	43	41

	30 June (unaudited)	31 December (audited)	
	2018	2017	2016
		(€thousand)	
Other non-current financial liabilities.....	13,604	10,342	-
<b>Total liabilities</b> .....	16,827	13,311	2,425
<b>Equity</b> .....	14,677	22,204	40,361
Share capital .....	164	155	155
Capital reserve .....	156,565	152,793	152,793
Other reserves .....	8,954	8,527	7,360
Currency translation differences .....	(30)	143	(29)
Retained earnings.....	(150,976)	(139,414)	(119,918)
<b>Total equity and liabilities</b> .....	31,504	35,515	42,786

***Comparison of the six months ended 30 June 2018 with the year ended 31 December 2017***

***Current assets***

***Cash and cash equivalents***

As of 30 June 2018, cash and cash equivalents, which consist of bank balances and cash on hand, amounted to €11,646 thousand compared to €16,311 thousand as of 31 December 2017. Cash and cash equivalents are unrestricted and may be freely utilized by Curetis.

The decrease in cash and cash equivalents was mainly due to a negative cash outflow from operating and investing activities of €11,692 thousand, which was only partly offset by positive cash inflows from financing activities from the net proceeds of the Company's equity offering in May 2018 and the second draw down under the EIB Finance Contract in June 2018, which collectively amounted to €6,780 thousand.

***Inventories***

Inventories amounted to €6,891 thousand as of 30 June 2018, compared to €6,946 thousand as of 31 December 2017.

The decrease in inventories for the six months ended 30 June 2018 compared to 31 December 2017 was due to the sale of Unyvero Systems to a business partner, as described in “*Key Factors Affecting the Results of Operations – Sale of Unyvero Systems to certain third parties*” and the applied marketability discounts for Unyvero Systems.

***Other current assets***

As of 30 June 2018, other current assets comprised VAT receivables amounting to €192 thousand, compared to €295 thousand at 31 December 2017. In addition, other current assets included prepaid expenses amounting to €1,252 thousand as of 30 June 2018 compared to €170 thousand as of 31 December 2017. Prepaid expenses mainly include lease payments, travel expenses, insurance fees, conference and exhibition fees, as well as deferred expenses in relation with future financing transactions. The decrease in VAT receivables was due to less purchased goods and services with invoiced VAT in June 2018 than in December 2017, whereas the increase in prepaid expenses was mainly due to higher fees and services in relation to the Offering.



## ***Non-current assets***

### ***Intangible assets***

Intangible assets, comprising mainly licences and patents, and in particular the GEAR database and platform assets acquired in 2016 and the Gyronimo assets acquired in 2016, amounted to €7,511 thousand as of 30 June 2018 compared to €7,524 thousand as of 31 December 2017. The small decrease resulted from the amortization of capitalized intangible assets, which was only partly offset by newly acquired intangible assets.

### ***Property, plant and equipment***

Property, plant and equipment, comprising mainly machines and technical equipment, amounted to €3,193 thousand as of 30 June 2018 compared to €3,566 thousand as of 31 December 2017. The decrease was mainly due to the depreciation of capitalized property, plant and equipment, which was only partly offset by newly acquired property, plant and equipment.

## ***Current liabilities***

### ***Trade and other payables***

The decrease in trade payables was due to higher study costs and higher research and development- expenses incurred during fiscal year 2017 and invoiced prior to 31 December 2017, but that were not yet due prior to 31 December 2017 and so were actually paid in the first half of 2018.

### ***Other current financial liabilities***

Other current financial liabilities amounted to €1,211 thousand as of 30 June 2018 compared to €624 thousand as of 31 December 2017. The increase was due to higher provision for product purchases and services rendered before 30 June 2018 from third party providers for research and development and financing transactions incurred but not yet invoiced.

## ***Non-current liabilities***

### ***Other non-current financial liabilities***

Other non-current financial liabilities increased from €10,342 thousand as of 31 December 2017 to €13,604 thousand as of 30 June 2018 as a result of a second draw down, of €3,000 thousand, under the EIB Finance Contract and increased deferred interest categorised as non-current relating to the Company's draw downs, in April 2017 (€10,000 thousand) and June 2018 (€3,000 thousand). See “- *Financial Indebtedness and Other Financial Liabilities*”.

### ***Equity***

Equity amounted to €14,677 thousand as of 30 June 2018 compared to €22,204 thousand as of 31 December 2017. The decrease was due to the negative total comprehensive loss for the six months ended 30 June 2018 which was only partly offset by an increase in the capital reserve and share capital due to net proceeds from an equity offering in May 2018 as well as an increase in the other reserves due to the higher evaluation of equity stock options.

## ***Comparison of the years ended 31 December 2017 and 2016***

### ***Current assets***

#### ***Cash and cash equivalents***

On 31 December 2017, cash and cash equivalents, comprising bank balances and cash on hand, amounted to €16,311 thousand, compared to €22,832 thousand on 31 December 2016. The decrease in cash and cash equivalents from 2016 to 2017 was mainly due to a negative cash outflow from operating and investing

activities of €16,102 thousand in 2017, with the decrease in cash and cash equivalents partly offset by a positive cash inflow of €9,952 thousand from the drawdown of €10,000 thousand under the first tranche of the EIB Finance Contract in April 2017.

#### *Inventories*

Inventories increased from €5,870 thousand as of 31 December 2016 to €6,946 thousand as of 31 December 2017 due to Curetis' purchase of a larger number of Unyvero Systems for future sales and demonstrations, as well as in anticipation of the commercial launch of the Unyvero System in the U.S. following the anticipated FDA clearance.

#### *Other current assets*

Other current assets decreased from €1,469 thousand as of 31 December 2016 to €552 thousand as of 31 December 2017 as a result of lower VAT receivables in 2017 due to VAT refund claims resulting from the acquisition of Gyronimo technology in December 2016 and no such corresponding projects in 2017.

#### *Non-current assets*

##### *Intangible assets*

Intangible assets, comprising mainly licences and patents, and in particular the GEAR database and platform assets acquired in 2016 and the Gyronimo assets acquired in 2016, remained flat at €7,520 thousand as of 31 December 2016 and €7,524 thousand as of 31 December 2017.

##### *Property, plant and equipment*

Property, plant and equipment, comprising mainly machines and technical equipment, decreased from €4,466 thousand as of 31 December 2016 to €3,566 thousand as of 31 December 2017 due mainly to depreciation only partly offset by new investments in property, plant and equipment.

#### *Current liabilities*

##### *Trade and other payables*

Trade and other payables increased by 28.7%, from €721 thousand as of 31 December 2016 to €928 thousand as of 31 December 2017, due to higher study costs and higher research and development expenses incurred by Curetis during 2017 but invoiced in December 2017 and not yet due at year end. The fair value of trade payables approximates their carrying amount.

##### *Other current financial liabilities*

Other current financial liabilities increased from €482 thousand as of 31 December 2016 to €624 thousand as of 31 December 2017 due to an increase in provisions for accrued interest in connection with outstanding indebtedness under the EIB Finance Contract.

#### *Non-current liabilities*

##### *Other non-current financial liabilities*

Other non-current financial liabilities increased from nil as of 31 December 2016 to €10,342 thousand as of 31 December 2017 as a result of the Company's draw down, in April 2017, of €10,000 thousand under the EIB Finance Contract, together with deferred interest categorised as non-current.

#### *Equity*

Equity declined from €40,361 thousand as of 31 December 2016 to €22,204 thousand as of 31 December 2017 due mainly to an increase in negative retained earnings from €119,918 thousand as of 31 December 2016 to €139,414 thousand as of 31 December 2017.

## Liquidity and Capital Resources

Curetis' liquidity requirements relate primarily to the funding of research and development expenses, marketing and distribution expenses, general and administrative expenses, capital expenditures, and working capital requirements. Curetis' primary goals when managing its capital are to ensure sufficient liquidity to meet these expenses and requirements and safeguard its ability to continue operating as a going concern.

Curetis' policy is to maintain a strong base in terms of equity capital and a sufficient cash balance in order to maintain investor and creditor confidence and to sustain the future development of its business. Since its listing and initial public offering in 2015, in which Curetis raised gross proceeds of €44,310 thousand, Curetis has relied for its working capital and other liquidity needs on the net proceeds from the IPO, a non-public equity offering to institutional investors in May 2018 and debt financing pursuant to the EIB Finance Contract. In April 2017 and June 2018, Curetis drew down €10,000 thousand and €3,000 thousand, respectively, under the EIB Finance Contract, and will have access to the remaining up to €12,000 thousand upon meeting certain pre-determined milestones. For more detail on Curetis' debt financing, see “— *Financial Indebtedness and Other Financial Liabilities*”.

The Company's cumulative net losses from the date of inception up to 30 June 2018 amounted to €150,976 thousand. The Company expects to continue incurring losses over the next few years.

As of 30 June 2018, 31 December 2017 and 31 December 2016, the Company held €11,646 thousand, €16,311 thousand and €22,832 thousand, respectively, in cash and cash equivalents.

For further detail on Curetis' working capital and liquidity position, see “*Capitalisation, Indebtedness and Working Capital*”.

## Cash Flow

The following table presents the statement of cash flows of Curetis for the six months ended 30 June 2018 and 2017, which was taken from the Interim Financial Statements, and for the years ended 31 December 2017 and 2016, which was taken from the Annual Financial Statements.

	30 June (unaudited)		31 December (audited)	
	2018	2017	2017	2016
	(€ thousand)			
Loss for the period .....	(11,561)	(9,662)	(19,498)	(15,172)
Adjustments for: .....				
Net finance income/cost .....	222	386	983	(71)
Depreciation, amortisation and impairments .....	618	694	1,327	1,744
Gain on disposal of fixed assets .....	—	—	2	2
Changes in provisions .....	(70)	35	75	23
Changes in equity settled stock options .....	427	822	1,167	767
Changes in the PSOP – liability .....	—	—	0	(367)
Net exchange differences .....	(249)	217	371	(30)
Changes in deferred tax assets and liabilities .....	(45)	0	(78)	0

	<b>30 June (unaudited)</b>		<b>31 December (audited)</b>	
	<b>2018</b>	<b>2017</b>	<b>2017</b>	<b>2016</b>
	<i>(€ thousand)</i>			
Changes in working capital relating to: .....				
Inventories.....	55	(336)	(1,076)	(3,083)
Trade receivables and other receivables .....	(1,050)	1,071	1,008	201
Trade payables and other payables.....	612	94	911	270
Effects of exchange rate differences not realised from consolidation.....	76	(100)	(199)	2
Income taxes received (paid) .....	(26)	(14)	(52)	0
Interest received (paid).....	(471)	(175)	(622)	(10)
<b>Net cash flows provided by (used in) operating activities .....</b>	<b>(11,462)</b>	<b>(6,969)</b>	<b>(15,681)</b>	<b>(15,724)</b>
Payments for intangible assets .....	(67)	(51)	(111)	(7,025)
Payments for property, plant and equipment.....	(163)	(152)	(320)	(456)
Interest received.....	0	6	10	51
<b>Net cash flow provided by (used in) investing activities .....</b>	<b>(230)</b>	<b>(197)</b>	<b>(421)</b>	<b>(7,430)</b>
Proceeds from other non-current financial liabilities.....	3,000	10,000	10,000	0
Payments for finance lease liabilities.....	0	(48)	(48)	(105)
Proceeds from issue of ordinary shares.....	4,100	—	—	—
Payments for financing costs for issue of ordinary shares.....	(320)	—	—	—
<b>Net cash flow provided by (used in) financing activities.....</b>	<b>6,780</b>	<b>9,952</b>	<b>9,952</b>	<b>(105)</b>
<b>Net decrease in cash and cash equivalents.....</b>	<b>(4,912)</b>	<b>2,786</b>	<b>(6,150)</b>	<b>(23,259)</b>
Net cash and cash equivalents at the beginning of the period.....	16,311	22,832	22,832	46,060
Net decrease in cash and cash equivalents..	(4,912)	2,786	(6,150)	(23,259)
Effects of exchange rate changes on cash and cash equivalents.....	247	(217)	(371)	30
<b>Net cash and cash equivalents at the end of the period .....</b>	<b>11,646</b>	<b>25,401</b>	<b>16,311</b>	<b>22,832</b>

### ***Comparison of the six months ended 30 June 2018 and 2017***

#### ***Net cash flows used in operating activities***

Net cash flows used in operating activities increased from €6,969 thousand in the six months ended 30 June 2017 to €11,462 thousand in the six months ended 30 June 2018. The increase was mainly due to (i) an increased loss after income tax which increased from €9,662 thousand in the six months ended 30 June 2017 to €11,561

thousand in the six months ended 30 June 2018, (ii) changes in the working capital related to trade receivables and other receivables which decreased from €1,071 thousand during the six months ended 30 June 2017 to (€1,050) thousand during the six months ended 30 June 2018 as the company received certain VAT refunds from November and December 2016 in early 2017 and (iii) higher interest paid in the six months ended 30 June 2018 under the EIB Finance Contract than in the six months ended 30 June 2017 as a result of drawdowns in April 2017 and June 2018.

#### *Net cash flows used in investing activities*

Net cash flows used in investing activities was relatively flat in the six months ended 30 June 2018 compared to the same period in 2017 and comprised mainly payments for software and licences in both periods.

#### *Net cash flows provided by financing activities*

Net cash flows provided by financing activities decreased from €9,952 thousand in the six months ended 30 June 2017 to €6,780 thousand in the six months ended 30 June 2018. This was due to the first draw down under the EIB Finance Contract of €10,000 thousand in April 2017, whereas the drawdown of the second tranche in June 2018 was only €3,000 thousand. In the six months ended 30 June 2018 Curetis also completed an equity offering with net proceeds of €3,780 thousand.

### **Comparison of the years ended 31 December 2017 and 2016**

#### *Net cash provided by (used in) operating activities*

Net cash used in operating activities was relatively flat from 2016 to 2017, amounting to an outflow of €15,724 thousand in 2016 and an outflow of €15,681 thousand in 2017. Losses for the period were €19,498 thousand in 2017 compared to €15,172 thousand in 2016. Net cash used in operating activities increased due to a decrease in trade and other receivables, driven by the cash-inflows from VAT receivables in 2017 and from an increase in trade and other payables due to a higher amount of invoices for services and deliveries in 2017 that were not yet due by the end of 2017, as well as accrued interest under the EIB Finance Contract in 2017, which was partly offset by negative cash effects from the investment in inventory in preparation for the U.S. commercial roll-out.

#### *Net cash provided by (used in) investing activities*

Net cash used in investing activities decreased from €7,430 thousand in 2016 to €421 thousand in 2017. This significant decline in investment was due mainly to the purchase of the GEAR database and the Unyvero A30 RQ technology in 2016.

#### *Net cash provided by (used in) financing activities*

Net cash provided by financing activities increased from an outflow of €105 thousand in 2016 to an inflow of €9,952 thousand in 2017 due to Curetis' draw down of €10,000 thousand in indebtedness under the EIB Finance Contract in April 2017.

### **Off-Balance Sheet Arrangements**

Except for the arrangements mentioned in “— *Other Financial Commitments / Contractual Obligations*”, Curetis had not entered in any off-balance sheet arrangements as of 30 June 2018.

### **Financial Indebtedness and Other Financial Liabilities**

#### ***EIB Finance Contract***

Curetis GmbH, as borrower, and the EIB, as lender, entered into the EIB Finance Contract, originally dated 12 December 2016, as amended by an amendment letter dated 20 April 2018, providing for two term loan tranches

in the aggregate principal amount of €25,000 thousand for the purpose of financing the development of novel test panels, e.g. for intra-abdominal infections and sepsis host response as well as urinary tract infection, cardiology associated infection and extended respiratory panels, as well as future panels on platforms such as the Unyvero platform, including the necessary clinical trials to obtain the relevant regulatory approvals for market authorization and reimbursement, and capex for manufacturing expansion. The loan amount is split into two tranches, a first tranche of €10,000 thousand which was drawn down in April 2017 and a second tranche of up to an additional €15,000 thousand, in respect of which a disbursement of €3,000 thousand was drawn down and received on 22 June 2018 following the fulfilment of the key condition in April 2018 that the FDA clear the Unyvero System and the LRT Application. Pursuant to the Amendment Letter, following the disbursement of €3,000 thousand as described above, the disbursement of the balance of the second tranche, with an aggregate commitment of up to €12,000 thousand, will be available for distribution as follows : (i) first, a disbursement of up to €5,000 thousand will become available subject to Curetis having raised cumulative new equity of at least €15,000 thousand, which was partly accomplished through the issuance of Shares raising €4,100 thousand in an equity offering in May 2018; and (ii) the remaining distribution amount of up to €7,000 thousand will become available subject to Curetis having installed 350 Unyvero Analyzers globally as well as Curetis' consolidated revenues being at least €10,000 thousand over the 12 months preceding the request for the loan disbursement. Subject to the relevant milestones being met, these amounts may be drawn until 12 December 2019.

The financing is backed by a guarantee from the European Fund for Strategic Investment. In addition, the granting of the loans is limited to the purpose of financing the development of novel test panels, e.g. for intra-abdominal infections and sepsis host response as well as urinary tract infection, cardiology associated infection and extended respiratory panels, as well as future panels on platforms such as the Unyvero Platform, including the necessary clinical trials to obtain the relevant regulatory approvals for market authorization and reimbursement, and capex for manufacturing expansion (together, the **"Financed Project"**), provided that the loans made available by EIB shall not exceed 50% of the total cost of the Financed Project.

Each loan under the EIB Finance Contract matures on the fifth anniversary of the disbursement of that loan and is to be repaid as a single installment on its maturity date. Each loan bears interest in the form of (i) a cash interest element at a floating rate of EURIBOR plus a cash pay margin and (ii) a deferred interest element of a fixed interest rate to be paid on the maturity date of the relevant loan. As of 30 June 2018, €13,000 thousand plus deferred interest in the amount of €684 thousand was outstanding under the EIB Finance Contract.

The obligations and liabilities of the borrower under the EIB Finance Contract are secured by a guarantee of Curetis as initial guarantor as well as guarantees by Ares Genetics and Curetis USA as additional guarantors

The EIB Finance Contract provides for compulsory prepayment events customary for such financing agreements, such as if (i) the credit granted by EIB exceeds 50% (fifty per cent) of the total cost of the Financed Project by the EIB Finance Contract, (ii) the borrower, any guarantor or other member of the Curetis group voluntarily prepays a part or the whole of any other financing arrangements, (iii) a change of control, defined as a person or group acting in concert gaining control of more than 50% of the equity (or gains the power to direct the management and policies) of the borrower, the guarantor or other member of the Curetis group or any of the foregoing entities engaging in certain merger transactions or selling all or substantially all of its assets, occurs, (iv) the borrower's or a guarantor's ability to perform its obligations under this EIB Finance Contract or the guarantees would be materially impaired due to a change in or amendment to law, rule or regulation or (v) it becomes unlawful for EIB to perform its obligations under the finance documents or to fund or maintain the loans.

The EIB Finance Contract contains undertakings on the part of the borrower to use the funds drawn down under the contract to finance the Financed Project and to maintain and insure the Financed Project, as well as certain restrictions, including restrictions on the borrower's ability to dispose of assets, engage in hedging activities,

violate applicable law, dispose of the shares of its material subsidiaries, engage in certain acquisitions, grant guarantees and security other than certain types of permitted guarantees and security, and incur additional financial indebtedness other than certain types of permitted indebtedness. The borrower is required to repay the loan together with accrued interest and any deferred interest upon demand by the EIB in the event of events of default, including payment defaults subject to a three-day grace period, certain insolvency or bankruptcy events, or the inability of the borrower or guarantor to fulfill its other obligations under the EIB Finance Contract or the guarantees.

### Other Financial Commitments / Contractual Obligations

Curetis leases its offices, production facility, logistics and warehouse space in Germany, Austria and California under non-cancellable operating lease agreements. The lease terms generally range from four to five years, with the exception of Ares Genetics' recent lease of laboratory space and additional office space in Vienna, Austria, which have lease terms of one year plus a three-year prolongation option, and the agreements are generally renewable at the end of the lease term.

Curetis also leases machinery, IT equipment and vehicles under non-cancellable operating leases agreements. The lease term is generally three years and the agreements are generally not renewable at the end of the lease term. The future aggregate minimum lease payments under non-cancellable operating leases and existing purchase commitments were as of 31 December 2017 and 2016 as follows:

	2017	2016
	(unaudited)	
	(€ thousand)	
No later than 1 year .....	4,956	5,581
Later than 1 year and no later than 5 years .....	631	1,134
Later than 5 years.....	—	—
<b>Total</b> .....	<b>5,587</b>	<b>6,715</b>

### Financial Liabilities

The following table sets forth a breakdown of Curetis' financial liabilities as of 31 December 2017 by remaining term:

	Up to 1 year	1-3 years	3-5 years	More than 5 years
		(€ thousand)		
Trade and other payables.....	928	—	—	—
Finance lease liabilities.....	—	—	—	—
Other financial liabilities .....	345	—	—	—
Loans.....	—	—	10,000	—
Interest accrued.....	400	800	3,800	—

The amounts disclosed are the contractual undiscounted cash flows.

## Capital Expenditures and Investments

Curetis' capital expenditures and investments for the six months ended 30 June 2018 and for the years ended 31 December 2017 and 2016 related primarily to the acquisitions of the GEAR database and the Unyvero A30 *RQ* platform, multi-cavity-tools for the molding of plastic parts, Unyvero Systems for internal use, manufacturing modules and other machinery. Curetis defines capital expenditure as its investments in property, plant and equipment and in intangible assets.

As noted in "Liquidity and Capital Resources", Curetis relies on the proceeds of debt financing, most recently the drawdown of €10,000 thousand in April 2017 and €3,000 thousand in June 2018, respectively, under the EIB Finance Contract, as well as from an equity offering in May 2018 to finance its liquidity needs including capital expenditures and similar investments.

The investments in intangible assets mainly relate to the acquisition of the GEAR database and the Unyvero A30 *RQ* platform in 2016 as well as licenses for Curetis' ERP-system and other standard software throughout all periods.

In the six months ended 30 June 2018, Curetis invested €54 thousand in multi cavity tools and €36 thousand in internally used Unyvero-Systems.

In the year ended 31 December 2017, Curetis invested €55 thousand in multi cavity tools; €35 thousand in other manufacturing machinery; €69 thousand in a laser welding machine and €32 thousand in internally used Unyvero-Systems.

In the year ended 31 December 2016, Curetis invested €7,000 thousand in the acquisition of the GEAR database and the Unyvero A30 *RQ* technology; €185 thousand in multi-cavity-tools and €38 thousand in Unyvero-Systems for internal use.

Curetis currently intends to plan an expansion of its production capacity for Application Cartridges once the utilization of the existing production capacity reaches 25% to 30% (corresponding to approximately 250 thousand to 300 thousand Application Cartridges per year). Curetis estimates that doubling the production capacity would require capital expenditures of €5,000 thousand to €6,000 thousand) payable over a period of approximately two years. Furthermore, in addition to the amounts paid up-front there are discrete milestone payments due under the asset acquisition contracts (Gyronimo and GEAR) and Curetis expects to pay the first CE-marking milestone to Carpegen and Systec once CE marking of the Unyvero A30 *RQ* System has been reached in late 2019. The FDA clearance milestone as well as GEAR / STA related milestones are not expected to be incurred in the coming 12 to 18 months, (although Ares Genetics may at any time make use of certain royalty buy-down options associated with one-time lump-sum payments if deemed economically beneficial).

## Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with IFRS requires the management of Curetis to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenue and expenses during the period. Actual results could differ from those estimates.

Significant areas requiring the use of management estimates relate to the determination of the useful lives of property, plant and equipment, inventories, valuation, provisions, discounted cash flows for impairment testing, the recognition of deferred tax assets and the determination of the fair value of certain financial instruments.



### ***Useful economic lives of intangible assets and property, plant and equipment***

The uniform determination of the useful economic life for intangible assets and property, plant and equipment of Curetis is subject to the estimations made by the management of Curetis. The Unyvero A30 RQ Analyzer has not been amortised since acquisition since the platform is not yet commercially available. The carrying amount of this intangible asset is reviewed at each reporting date for any indication of impairment. Impairment is recognised if the carrying amount of an asset or the cash-generating unit exceeds its estimated recoverable amount by using a discounted cash flow model.

### ***Inventories***

Inventories are valued at the lower value of acquisition and manufacturing cost and net realisable value. The net realisable value is determined by subtracting the costs incurred up to completion from the expected sales price of the end product. If assumptions regarding future share prices or end product market potentials are not appropriate, this may lead to a further need for write-offs. The obsolescence write-downs on inventories of Unyvero Systems are estimated considering the expected lifetime and usage of a Unyvero System. So far, Curetis has no reliable sales track record of such products, so write-downs are based on management's best estimate considering technical ageing and estimated sales prices for used systems.

### ***Provisions***

When accounting for provisions, management must make assumptions regarding the probability of certain business transactions resulting in an impending loss of commercial benefit for Curetis. Estimates regarding the amount and timing of possible economic outflows form the basis for the measurement of provisions. If the actual amount and timing differ from estimates made, then this may affect the results of Curetis. When measuring provisions for warranties, management makes forward-looking assumptions and estimates. The calculations are based on historical data but as Curetis is in an early commercial stage, these assumptions may change in the future.

### ***Impairments***

To test for impairment, the value in use is determined by means of the discounted cash flow method. Assumptions regarding future business developments and general underlying data are to be made for this purpose. If there are any changes in these input factors, the recognition of impairment may be necessary.

### ***Deferred tax assets***

The calculation of deferred tax assets requires assumptions to be made with regard to the level of future taxable income and the timing of recovery of deferred tax assets. These assumptions take account of forecast operating results and the impact on earnings of the reversal of taxable temporary differences. Since future business developments cannot be predicted with certainty and to some extent cannot be influenced by Curetis, the measurement of deferred tax assets is subject to risk and uncertainty.

### ***Contingent liabilities and contingent purchase commitments***

Certain of Curetis' future purchase prices for raw materials, goods and services are based on quantities and contractual periods. When valuing these contingent liabilities and commitments, the calculation is based on management's budgeted numbers and current assumptions of the future development of the business.

### **Recent Accounting Pronouncements**

IFRS 16, "Leases", a new accounting standard that will be effective from 1 January 2019, sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a lease agreement. Curetis is currently evaluating the potential future impact of IFRS 16. Curetis expects that (i) the outcome of the analysis will likely be that IFRS 16 would result in having additional assets on the balance sheet ("right-to-

use-assets”) and additional liabilities (the value of the remaining liability of the lease-contract), and (ii) there will not be any material impact on Curetis’ income or cash flow statements. The balance sheet expansion described in (i) above, resulting from the application of IFRS 16, could have an impact on some balance sheet related ratios, such as return on equity, in the future, although Curetis does not believe that the impact on such ratios will be material.

Please also refer to note 3 to the Annual Financial Statements and note 2.4 to the Interim Financial Statements.

## Qualitative and Quantitative Disclosure about Market Risk

Curetis’ activities expose the Company to a variety of financial and market risks. Curetis’ financial department relies on financial control instruments and tracks key metrics in order to identify and evaluate such risks in close co-operation with the Company’s operating units. See note 33 to the Annual Financial Statements incorporated in this Prospectus for additional information on Curetis’ exposure to market risk, foreign exchange risk, other market risk, credit risk and liquidity risk.

### 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 currently does not hold any securities available for sale and Curetis keeps all its liquidity in immediately available money market funds.

### Foreign exchange risk

Curetis is exposed to foreign currency risks primarily through its operating activities. Curetis identifies the main currency risk in US\$, because a significant proportion of its transactions are undertaken in US\$. The net exposure to exchange rate differences of the monetary assets (being cash and cash equivalents) of Curetis at the end of the reporting period is as follows:

	31 December 2017	31 December 2016
	(unaudited)	
	(€ thousand)	
USD .....	690	676
<b>Total</b> .....	<b>690</b>	<b>676</b>

If the US\$/€ exchange rate were to increase/decrease by 10%, compared to year-end 2017 exchange rates, this would have a negative/positive impact of €69 thousand. The Company considers a shift in the exchange rates of 10% as a realistic scenario.

### Other market risk

Curetis is not exposed to equity price risk or commodity price risk as it does not invest in these classes of investments.

### Credit risk

The Company’s finance department works in close co-operation with the other operating departments to identify credit risks related to account receivables balances. Curetis analyses the credit risk of each new client before standard payment and delivery terms and conditions are offered. Curetis has also implemented a well-organised dunning system. Curetis had write-downs on trade receivables of €2 thousand in 2017 compared to

€26 thousand in 2016. Curetis believes that the credit risk on the accounts receivables is limited because Curetis primarily sells to big laboratories, pharmaceutical companies and major public hospitals in Curetis' direct markets in Central and Western Europe, all of which, Curetis believes, have solid credit ratings. Outside of Europe Curetis works together with large and experienced distributors which Curetis believes are credit worthy. If Curetis were to expand its business to countries with higher credit risk profiles, Curetis would consider implementing a commercial credit insurance policy to cover the attendant risks.

Cash and cash equivalents as well as short-term deposits which are disclosed under other financial assets are invested in EURO-denominated money market funds with highly reputable banks. Curetis follows a decisive 'no-risk-policy' which means that Curetis has sight deposits at banks only, and sometimes time deposits with short runtimes.

### ***Liquidity risk***

Liquidity risk is the risk that Curetis might encounter difficulties in meeting the obligations associated with its financial liabilities, which are normally settled by delivering cash. Curetis' approach to managing liquidity is to ensure, as far as possible, that it will always have sufficient liquidity to meet its liabilities when due. Curetis 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.

With a cash and cash equivalents balance of €11,646 thousand at 30 June 2018, the Company estimates that Curetis had sufficient liquidity, as of 30 June 2018, to meet its liquidity needs until January 2019.

Curetis believes, however, that its operations will require additional cash resources of approximately €23 million assuming the execution of Curetis' current business plan to provide it with sufficient working capital for the next twelve months from the date of this Prospectus. If the Offering is completed and additional available funds of approximately €16.8 million are generated in the Offering (which would only be the case if the Company raises the Top-End Proceeds), these proceeds together with the €1.4 million in net proceeds expected to be received from the remainder of the first tranche under the Yorkville Agreement, an additional €5.0 million debt financing which is expected to be available from the EIB Finance Contract and Curetis' current cash resources will provide it with sufficient working capital for the next twelve months from the date of this Prospectus. The availability of the remainder of the first tranche of the Yorkville Agreement and the EIB Finance Contract are subject to certain conditions described below, including, in the case of the Yorkville Facility, the Yorkville Floor Price. For further detail on this subject, including the risk that Curetis may not be able to continue as a going concern if the Offering is not successful, see "*Capitalisation, Indebtedness and Working Capital*."

Even if Curetis is successful in acquiring sufficient liquidity and working capital for the next 12 months from the date of this Prospectus, Curetis will need additional funding in the future, which may not be available to it at all or not at acceptable or favourable terms. This could lead to a situation where Curetis would have to delay execution of parts of its business plans, which in turn could impair its ability to develop and commercialise its products and achieve profitability at some point in the future. Nor is it certain whether such funds if raised would be sufficient to allow Curetis to continue to execute its business plans and strategies long-term.

If Curetis were unable to raise additional equity or debt capital or otherwise generate non-dilutive funding for its operations, there would be a material risk of running out of cash unless operating costs were drastically reduced short term.

Curetis' future liquidity requirements will depend on many factors, some of which are beyond Curetis' control, including:

- the cost and timing of marketing or regulatory clearances, including FDA clearances for pipeline and future products and subsequent US commercial launch;
- market acceptance of Curetis' products;
- the cost and timing of establishing further sales, marketing and distribution capabilities;
- the cost of Curetis' research and development activities;
- the ability of healthcare providers to obtain coverage and adequate reimbursement by third-party payers for procedures using Curetis' products;
- the cost of goods associated with Curetis' products;
- the effect of competing technological and market developments; and
- the extent to which Curetis might decide to invest in third-party businesses, products and technologies, including entering into licensing or collaboration arrangements for products.

If Curetis were to miss its objectives or experienced material delays in one or more of these factors, additional funding would be required which may or may not be available at all or might be available only at rather unattractive terms and conditions. See *“Risk Factors — Risks Related to Business and Strategy — Curetis' cash position and operating cash flow may be insufficient to cover expected investment expenses, and Curetis may need to raise additional funds in the future”*.

## INDUSTRY

### Overview

Since the discovery of deoxyribonucleic acid (“DNA”) over 60 years ago, followed by the development of the sequencing and PCR 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 summarised under the term molecular diagnostics (“MDx”) and can also be used to identify microorganisms causing an infection.

The availability of methods to fast and reliably detect and characterise 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 personalised and more effective healthcare.

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.<sup>2</sup> The fast 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.<sup>3 4 5</sup>

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 personalised healthcare syndromic-based multiplexed MDx tests are becoming increasingly important.<sup>6 7</sup> 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 personalised approach to treatment with anti-infectious agents at the earliest stage of care.

### Size of the Molecular Diagnostics Market

The global molecular diagnostics market is projected to reach USD 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, haematology, (culture-based) microbiology, or coagulation. The MDx market is growing rapidly and it is expected to grow from USD 7.7 billion in 2018 with a CAGR of 8.4% globally to

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<sup>2</sup> WHO Factsheet: The Top 10 causes of death, WHO (2018). Link (17-May-2018): <http://www.who.int/en/news-room/fact-sheets/detail/the-top-10-causes-of-death>.

<sup>3</sup> Arias *et al.* (2009).

<sup>4</sup> WHO Global Action Plan on Antimicrobial Resistance (2015). Link (19-May-2018): [http://apps.who.int/iris/bitstream/handle/10665/193736/9789241509763\\_eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/193736/9789241509763_eng.pdf?sequence=1).

<sup>5</sup> Member states of the UN recommit to tackle AMR and implement WHO GAP (Declaration 2016). Link (9-May-2018): [https://www.un.org/pga/71/wp-content/uploads/sites/40/2016/09/DGACM\\_GAEAD\\_ESCAB-AMR-Draft-Political-Declaration-1616108E.pdf](https://www.un.org/pga/71/wp-content/uploads/sites/40/2016/09/DGACM_GAEAD_ESCAB-AMR-Draft-Political-Declaration-1616108E.pdf).

<sup>6</sup> Dincer C, *et al.* Multiplexed Point-of-Care Testing - xPOCT. Trends Biotechnol. 2017 Aug;35(8):728-742.

<sup>7</sup> J O’Neill, Rapid Diagnostics: Stopping unnecessary Use of Antibiotics, The review on Antimicrobial Resistance (2015); Link (14-May-2018): <https://amr-review.org/sites/default/files/Rapid%20Diagnostics%20-%20Stopping%20Unnecessary%20use%20of%20Antibiotics.pdf>.

USD 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.<sup>8</sup>

## **Molecular Diagnostics Market by Application**

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%).<sup>9</sup> Curetis products target the infectious disease market, projected to grow at 7.0% p.a. from USD 4.2 billion in 2018 to USD 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 USD 1 billion in 2023.<sup>10</sup> Curetis believes that there is a crucial need for multiplex MDx assay panels comprising for severe symptomatic infections in particular in hospitalised 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.

However, 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.<sup>11</sup> 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 globalised world facilitate the spread of pathogens, disease and antibiotic resistance.<sup>12</sup> Therefore, Curetis sets a clear focus on assays in severe infectious diseases in hospitalised patients capturing relevant microorganisms and antibiotic resistance markers.

Compared to traditional methods for the detection of microorganisms (microbiology cultures), modern and effective MDx tests aid in the earlier and more accurate detection of microorganisms.<sup>13</sup> Fast diagnostics can provide directions to selecting effective antimicrobial agents with greater likelihood of clinical efficacy and enable physicians to adjust empiric treatment at an earlier stage in the cycle of care.<sup>14</sup> Hence, a variety of fast sample-to-answer (sample-to-answer describes the process from patient sample drawings at bedside until test result are available for patient-treating physicians) molecular diagnostics test systems and new advanced pathogen and resistance biomarker assays have become available in recent years.<sup>15</sup> These fast multiplexed MDx assays can effectively complement conventional microbiology by providing timely and accurate information to tailor treatment to individual patients (personalised medicine). However, MDx is not expected to replace microbiology culture-based diagnostics as these traditional methods are an important confirmation of the MDx test results and still the backbone of epidemiological studies.

Such MDx tests may also aid in preventing the further spreading of antibiotic resistance by preventing misuse of scarce antibiotic resources. They further support the pharmaceutical industry in their clinical validation of new antibiotics by identifying suitable patients for enrolment into clinical trials faster, allowing for shorter and smaller trials and more targeted use of those antibiotics that make it to the market (companion diagnostics).<sup>16</sup>

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<sup>8</sup> Marketsandmarkets: Molecular Diagnostics Market (2018).

<sup>9</sup> Marketsandmarkets: Molecular Diagnostics Market (2018).

<sup>10</sup> Marketsandmarkets: Molecular Diagnostics Market (2018).

<sup>11</sup> IDSA (2011).

<sup>12</sup> Liang & Pong (2017); Leder *et al.* (2017); George (2018).

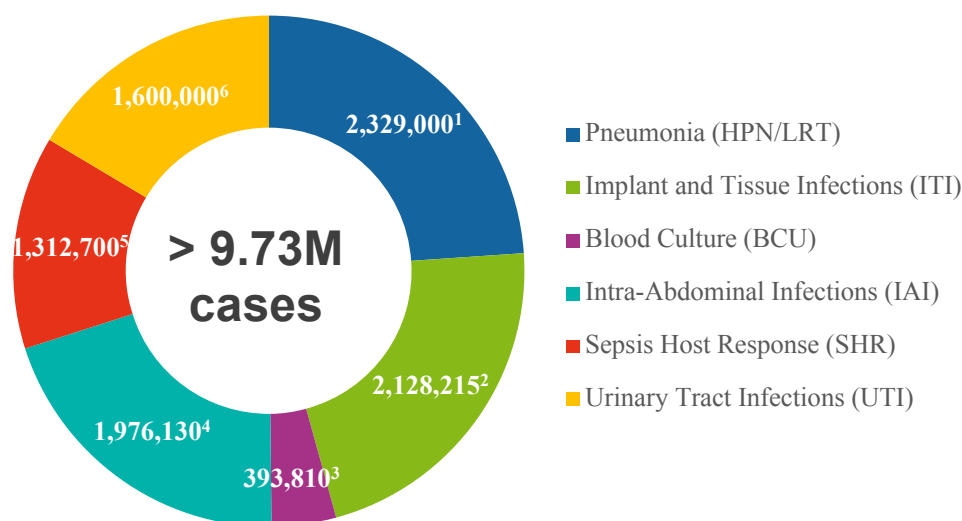
<sup>13</sup> Schulte *et al.* (2014); O'Neill (2015).

<sup>14</sup> O'Neill (2015); Ceccato *et al.* (2017).

<sup>15</sup> MarketsandMarkets (2014).

<sup>16</sup> European Commission (2013); Morel *et al.* (2016).

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 US and Europe spread across applications:



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> HCUP (2013a); CDC (2010) <sup>5</sup> Martin (2012); Statista (2015b) <sup>6</sup> ECDC (2013); Klevens *et al.* (2002).

## The Molecular Diagnostics Market by Customer

Molecular testing – which has traditionally been performed mostly by large specialised 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 US so-called reference laboratories, accounting for a combined 90% share of the global MDx market in 2013.<sup>17</sup> Of these, hospital laboratories account for 54.4% of the total market and are the largest end-user customer group.<sup>18</sup> 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 decentralised 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. For more information see “*Business — Marketing and Sales — Sales process*”.

<sup>17</sup> Marketsandmarkets: Molecular Diagnostics Market (2018).

<sup>18</sup> Marketsandmarkets: Molecular Diagnostics Market (2018).

## 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 (“**INAAT**”) and fluorescence in situ hybridization (“**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 parallelised 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.

## Molecular Diagnostics Market Dynamics

The following key trends are expected to drive the infectious disease MDx market growth through molecular assay menu expansion, molecular diagnostic technology development, and greater adoption of these technologies in medical practice:

- **Increase in ageing population:** According to the US Department of Health & Human Services, around 15% of the US population was older than 65 in 2016. The percentage is expected to grow to 21% by 2030.<sup>19</sup> As the population is ageing, the incidence rates of infections are increasing, a trend that is also reinforced by overuse of antibiotics in nursing homes.<sup>20</sup> Moreover, it is predicted that the elderly will more often require medical services – complicated by hospital-acquired infections (“**HAI**”) – than young adults. In summary, as the population ages, people become more prone to infectious diseases, thereby reinforcing the need for faster molecular-based diagnostics.<sup>21</sup>
- **Clinical applications for multiplexed MDx:** The commercial availability of assays targeting pathogens causative upper respiratory tract infections (“**URTI**”) is believed to be increasing current demand for multiplexed MDx testing as exemplified by bioMérieux’s molecular biology sales increasing year-on-year by approximately 40% largely driven by FilmArray sales constituting approximately 80% of such

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<sup>19</sup> Federal Interagency Forum on Aging-Related Statistics. Older Americans 2016: Key Indicators of Well-Being. Link (15-May-2018): <https://agingstats.gov/docs/LatestReport/Older-Americans-2016-Key-Indicators-of-WellBeing.pdf>.

<sup>20</sup> Sloane *et al.* (2016).

<sup>21</sup> MarketsandMarkets (2014); Marketsandmarkets: Molecular Diagnostics Market (2018); Mody *et al.* (2018).



molecular biology sales between 2015 and 2017.<sup>22</sup> Furthermore, as indicated by the product portfolios and product development pipelines of industry players such as Cepheid, bioMérieux/BioFire, Genmark, T2Biosystems, Luminex and Curetis further market growth is expected to result from the increasing commercial availability of multiplex tests addressing disease areas, like lower respiratory tract infections, implant and tissue infection, gastrointestinal tract infection, intra-abdominal infections, bloodstream infections and sepsis, and urinary tract infections and urosepsis CSN infections – all representing significant clinical needs.<sup>23</sup>

- **Antibiotic resistance – a global medical and economic burden:** According to the U.S. Centers for Disease Control and Prevention (“CDC”), 25,000 and more than 23,000 deaths per year in Europe and the U.S. respectively, are associated with antibiotic resistant<sup>24</sup> pathogens, which lead to annual treatment costs of €1.5 billion for the EU alone.<sup>25</sup> By 2050, experts predict that the number of global deaths related to drug resistant infections could possibly increase from the current total of 700,000 to 10 million deaths per year with significant losses in global production if no action is taken<sup>26</sup>. Anti-microbial resistance is expected to cause more deaths than cancer by 2050.<sup>27</sup> However, on a global scale, antibiotics consumption increased by 65% from 2000 to 2015, although 80 million antimicrobial drug prescriptions in the U.S. alone each year are unnecessary.<sup>28</sup> Therefore Curetis believes that the demand for fast and accurate tests for microorganism identification and genetic antibiotic resistance detection will increase.
- **Shortage of skilled labour in diagnostics:** an increase in the need for diagnostics is expected to result in increased demand for skilled workers to operate laboratories. However, a decrease in the number of laboratory training programs (25% since the 1990s)<sup>29</sup>, outflow of baby-boomers into retirement, and staff retention issues have all contributed to a shortage of qualified professionals in the diagnostics field. Curetis believes that innovative fully automated solutions with less hands-on time are likely to play an important role in resolving this issue.
- **Personalised medicine and companion diagnostics:** The trend towards personalised medicine, defined as therapeutic interventions being tailored to the individual patient based on their individual risk, prognosis and/or predicted response to such intervention as assessed by testing for biomarkers or biomarker signatures, which Curetis believes also includes the molecular identification of relevant microorganisms and their antibiotic resistance markers for an early informed choice of antibiotics for any given patient, is expected to increase the demand for molecular diagnostic tests.
- **Progress in biomarker discovery, allowing Curetis to address unmet clinical needs such as sepsis:** Curetis believes that new modern molecular biology techniques, particularly NGS, will contribute to progress in biomarker discovery and increasingly allow for the systematic identification and validation of biomarkers for diagnosing specific diseases. However, Curetis also believes that the results of such research will lead to the need for large biomarker panels to be tested in order to sufficiently capture

<sup>22</sup> See respective reports by bioMérieux. Links (09-Oct-2018): [https://www.biomerieux.com.tr/sites/subsidiary\\_tr/files/news-event-press-release/biomerieux\\_pr\\_2016\\_results.pdf](https://www.biomerieux.com.tr/sites/subsidiary_tr/files/news-event-press-release/biomerieux_pr_2016_results.pdf); [https://www.biomerieux.com/sites/corporate/files/doc/biomerieux\\_pr\\_sales\\_q4\\_2017\\_0.pdf](https://www.biomerieux.com/sites/corporate/files/doc/biomerieux_pr_sales_q4_2017_0.pdf)

<sup>23</sup> See respective corporate websites. Links (20-Aug-2018): bioMérieux/BioFire: <https://www.biofire.com/products/the-filmarray-panels/>; Cepheid: <http://www.cephheid.com/us/cephheid-solutions/clinical-ivd-tests/healthcare-associated-infections>; <https://www.genmarkdx.com/int/solutions/panels/eplex-panels/>; T2Biosystems: <https://www.t2biosystems.com/t2direct-diagnostics-eu/t2bacteria-panel-eu/>; Luminex: <https://www.luminexcorp.com/eu/respiratory-pathogens-flex-test/>;

<sup>24</sup> CDC (2018). Link (08-June-2018): [https://www.cdc.gov/globalhealth/infographics/antibiotic-resistance/antibiotic\\_resistance\\_global\\_threat.htm](https://www.cdc.gov/globalhealth/infographics/antibiotic-resistance/antibiotic_resistance_global_threat.htm).

<sup>25</sup> European Commission (2017); Link (08-June-2018): [http://europa.eu/rapid/press-release\\_MEMO-17-1723\\_en.htm#\\_ftn1](http://europa.eu/rapid/press-release_MEMO-17-1723_en.htm#_ftn1).

<sup>26</sup> O'Neill (2016).

<sup>27</sup> O'Neill (2014); O'Neill (2016).

<sup>28</sup> Klein (2018); CDC (2018), Link (08-June-2018): <https://www.cdc.gov/antibiotic-use/index.html>.

<sup>29</sup> <http://laboratory-manager.advanceweb.com/laboratory-personnel-shortages>

complex disease biology. Moving those complex biomarker panels into standard of care will require highly multiplexed molecular diagnostics platforms for routine testing.

- **Decentralisation of molecular testing - testing at point-of need:** Curetis believes that the need to have diagnostic test results as quickly as possible will lead to the development of near-patient testing and automated sample-to-answer diagnostic test solutions, which can be operated by non-specialist medical staff in a non-laboratory setting. The availability of near-patient solutions is also expected to make molecular diagnostics accessible to less developed and remote geographic areas. Curetis believes that both these trends will drive adoption of multiplex testing.
- **Reforms in reimbursement systems:** New regulations in the U.S. and some countries in Europe are expected to introduce new test-specific reimbursement codes for molecular testing. These new coding systems are intended to help ease the billing and payment process for MDx testing. In addition, more countries are expected to adopt reimbursement systems based on diagnosis related groups (“**DRG**”) that also cover diagnostic tests in a lump-sum payment. In Germany, multiplex PCR from 2019 onwards can be coded within the DRG system under the OPS code 1-931, creating more transparency on adoption of this technology in clinical microbiology. New incentives have been put in place to incentivise hospitals to optimise patients’ outcomes, such as Section 3025 of the ACA, which requires the Center for Medicare and Medicaid Services (“**CMS**”) to reduce payments to acute care hospitals with readmission rates in excess of certain specified rates. As a result, in 2017, 2,597 hospitals forfeited US\$564,000 thousand to the CMS. Of these, 769 were penalised for having high rates of infection. Curetis believes such reforms and incentives will have the potential to encourage hospitals to adopt molecular diagnostics technologies.
- **Need for cost efficient diagnostics:** Constrained healthcare budgets, a growing world population and higher life expectancy are expected to increase the need for more cost-effective approaches in healthcare. In order to achieve the best medical outcomes for patients, while saving money through optimised care cycles and avoidance of ineffective therapies, Curetis believes that healthcare providers around the world require timely and accurate test information enabling adequate treatment for infections, which in turn will drive demand for rapid multiplex infectious disease testing.
- **Consolidation:** Since 2015, several major diagnostic players have adopted external growth strategies and strengthened their presence in MDx through the acquisition of smaller, independent players. For example, Roche acquired Signature Diagnostics in February 2015, Luminex acquired Nanosphere in June 2016, Danaher acquired Cepheid in November 2016, Debiopharm acquired GenePOC in July 2016, Siemens Healthineers acquired Fast Track Diagnostics in December 2017 and Qiagen acquired STAT-DX in May 2018. Due to their financial strength and global presence, large multinational diagnostics providers have the capacity to accelerate the commercialisation of the acquired platforms as well as the development of new applications, which in turn should increase the adoption of MDx technologies in the healthcare market.

### **Considerations Regarding MDx Testing Solutions in Microbiology**

In the past, conventional molecular methods of microbiology involved many labour- and costly-intensive handling steps in the laboratory, which had to be performed by highly skilled and trained laboratory technicians. Such steps comprised sample preparation, isolation of DNA, its amplification, detection and as well as the final result interpretation. Smaller and mid-sized hospitals, therefore outsourced testing to independent laboratories, which required logistics providers to transport samples and increased the time to result for the physician ordering the test with potential delays in the initiation of adequate therapies.

Recently automated sample-to-answer platforms to perform a scalable volume of tests in shorter time with less hands-on time of moderately trained staff have been introduced to the market. Their high level of integration in fully contained systems limit the risk of contamination allowing performing the test outside a typical laboratory environment and even at the point of care. Based on Curetis' experience, the traditional MDx applications for the microbiology market are still dominated by either manual technologies or high throughput systems with different levels of automation and integration available, the sample-to-answer platform market is significantly growing.

Unfavourable working conditions in laboratories such as increased workloads connected to long working hours as well as exposure to dangerous chemicals and pathogens, make higher paid job opportunities in life science companies more attractive to lab technicians. The resulting shortage in skilled laboratory technicians required for is expected to conventional molecular testing in combination with the rapidly increasing demand for molecular information significantly increase the demand for simple and highly automated sample-to-answer solutions.

### Business models within the MDx Market

MDx is a fast moving and innovation driven market and is a rapidly growing and evolving segment within the IVD market.<sup>30</sup> There are numerous companies including large IVD players as well as small start-up companies active in the MDx field. Traditionally, the MDx market can be characterised as follows:

Category	Description	Main companies (instruments / services)
Large well established IVD companies offering MDx	<ul style="list-style-type: none"> <li>The MDx market has been traditionally dominated by large companies that have been present in this market for years focusing on continuously expanding their installed base of high-throughput platforms</li> <li>Most of the large companies offer high-throughput instruments targeting large laboratories that have to process high volumes of samples and have highly skilled staff at their disposal</li> <li>Typically, these companies focus on screening markets, i.e. systematically testing large patient populations for the presence or absence of individual pathogens, e.g. HIV or HCV</li> </ul>	<ul style="list-style-type: none"> <li>Roche</li> <li>Novartis (Chiron)</li> <li>Hologic (Panther)</li> <li>Qiagen</li> <li>Abbott Molecular</li> <li>Siemens Healthineers</li> </ul>
Market integrated, automatic, scalable and random-access sample-to-answer systems	<ul style="list-style-type: none"> <li>Focus on syndromic disease testing targeting different distinct clinical indications, like respiratory diseases or sepsis. In order to assess the</li> </ul>	<ul style="list-style-type: none"> <li>Danaher / Cepheid (GeneXpert™),</li> </ul>

<sup>30</sup> Kalorama Information (2014); Marketsandmarkets: Molecular Diagnostics Market (2018); Visiongain (2017).

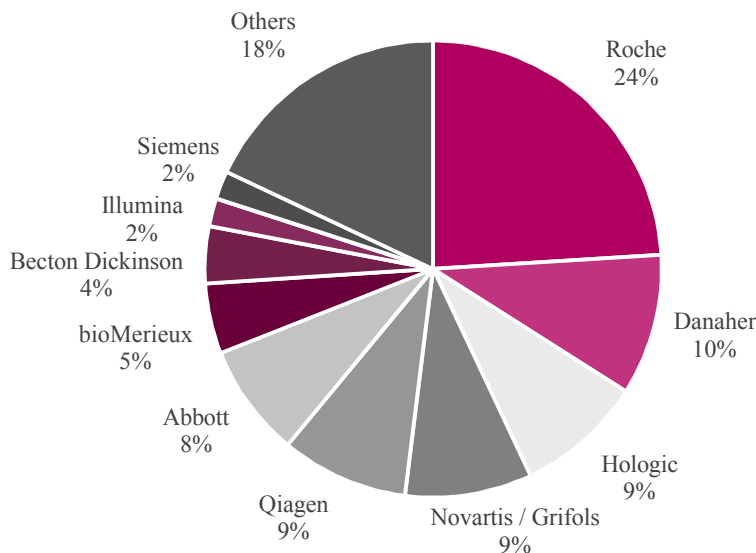
	<p>competitive situation in terms of assays a detailed distinction between panel composition and which kind of samples can be tested has to be made</p> <ul style="list-style-type: none"> <li>• Some screening applications in the low plex segment (such as Cepherd)</li> </ul>	<ul style="list-style-type: none"> <li>• GenMark (e-Plex™, launched in 2017),</li> <li>• bioMérieux (BioFire with FilmArray™),</li> <li>• T2 Biosystems Inc. (T2DX™),</li> <li>• Luminex / Nanoshphere (Verigene System™),</li> <li>• Roche (IQUUM with the Liat™),</li> <li>• Qiagen / Stat Diagnostica (DIAGcore™, CE-Mark in 2018)</li> <li>• Biocartis (Idylla™)</li> <li>• Bosch (Vivalytic)</li> </ul>
Sequencing or mass spectrometry based molecular diagnostics systems	<ul style="list-style-type: none"> <li>• Sequencing or mass spectrometry based molecular diagnostics systems, or automated culture-based technologies</li> </ul>	<ul style="list-style-type: none"> <li>• BGI Genomics/MGI Tech</li> <li>• Bruker Daltonic</li> <li>• bioMérieux</li> <li>• Beckman Coulter</li> <li>• Danaher</li> <li>• Copan</li> </ul>
MDx combined with functional testing for antimicrobial resistance	<ul style="list-style-type: none"> <li>• Use of MDx technologies such as FISH to identify pathogens combined with culture-based methods at a microscopic scale to measure the response to antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>• Accelerate Diagnostics (Accelerate ID/AST)</li> </ul>
Assays for MDx systems that are commercialised by other companies	<ul style="list-style-type: none"> <li>• Increases the attractiveness of an instrument by broadening the test menu</li> </ul>	<ul style="list-style-type: none"> <li>• Siemens Healthineers (Fast Track Diagnostics)</li> <li>• Genetic Signatures</li> </ul>
Laboratory Developed Tests (“LDTs”)	<ul style="list-style-type: none"> <li>• Design, validate and perform assays within their facilities. Often, the assays can be performed on a specific “open” instrument or manually by skilled personnel</li> <li>• LDTs are typically cheaper in terms of cost per test for end-users and faster to the market</li> <li>• Market penetration and commercial attractiveness is often limited due to regulatory constraints, the need for</li> </ul>	<ul style="list-style-type: none"> <li>• Quest</li> <li>• LabCorp</li> <li>• ARUP/IDbyDNA</li> </ul>

independent validation in each laboratory, and the need for skilled laboratory staff

Manual kits for microbiology or MDx labs

- Companies offering solutions to microbiology or Mdx laboratories such as: systems, software or consumables
- MobiDiag
- Seegene
- Genetic Signatures
- Siemens Healthineers (Fast Track Diagnostics)

Although the market remains fragmented, large MDx companies together account for over 82% market share.<sup>31</sup> The MDx market has been traditionally dominated by large companies that have been present in this market for years focusing on continuously expanding their installed base of high-throughput platforms:



## Competition

### *Unyvero System*

The Unyvero Platform is a sample-to-answer MDx solution. There are several other companies who develop and commercialise 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 Inc. (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 GenePOC Revogene™ system. Disease-related assays 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.

<sup>31</sup> Marketsandmarkets: Molecular Diagnostics Market (2018).

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 labour 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 capacity 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 commercialise their own infectious disease tests, Curetis believes that the variety and breadth of its menu of cartridges targeting different infection areas positions it favourably 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.

### ***Application Cartridges***

Considering its panel design, Curetis believes that there are currently no assays directly comparable to the Company's HPN / LRT, 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.

### ***HPN and LRT Application Cartridges***

Curetis believes that it currently has no direct competitor for its HPN and LRT Application Cartridges, as it is currently the only company offering an automated molecular HPN/LRT test. Other companies, such as bioMérieux, Luminex (formerly Nanosphere), GenMark, Seegene, Genomica, Miacom, PathoFinder, Fast-Track Diagnostics (recently acquired by Siemens Healthineers), Randox, ArcDia and Icube 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. However, according to publicly available sources, bioMérieux is in the process of developing a BioFire FilmArray application for lower respiratory tract infections and has recently submitted this panel for FDA approval. Accelerate Diagnostics is also believed to be in the process of developing an application for lower respiratory tract infections. Diatherix offers a manual test claiming to cover both upper and lower respiratory infections.

### *ITI Application Cartridges*

For the ITI Application Cartridge, Curetis believes that it currently has no direct competitor. In terms of pathogen panel composition, assays of competitors are very different and Curetis' ITI Application Cartridge covers the broadest range of antibiotic resistance markers. However, Diaxohit is developing a serological test for prosthetic joint infections, bioMérieux is also currently developing a test, while Diatherix is offering manual tests for skin and soft tissue infections and necrosis. For these tests, panel composition is not yet publicly known.

### *BCU Application Cartridges*

For Curetis' BCU Application Cartridge, GenMark, BioFire (bioMérieux) and Luminex (formerly Nanosphere) offer competing panels. However, compared to Curetis' BCU Application Cartridge, they are less comprehensive and in the case of GenMark and Luminex, the customer has to use two cartridges as Gram-positive and Gram-negative pathogens are split into different panels, which requires customers to perform a manual Gram staining procedure if they wish to use only one of the cartridges, while Curetis' BCU Application Cartridge targets both pathogen types at once. Compared to BioFire, Curetis believes that its Unyvero panel is more comprehensive and covers more resistance markers. Curetis believes it offers the most comprehensive panel for bloodstream-associated infections on the market.

### *IAI Application Cartridges*

Curetis believes that there is no other company taking a clear focus on severe intra-abdominal infections as addressed by Curetis' IAI Application Cartridge. These infections represent a high risk to patients, especially for those that are seriously ill, elderly or very young, immuno-compromised or in intensive care. BioFire (bioMérieux) has a medium-plexing solution for infectious diarrhea, Nanosphere has an enteric panel identifying common pathogenic enteric bacteria, viruses and genetic virulence markers, Cepheid has a clostridium difficile and norovirus infection panel and Illumina a multiplex gastrointestinal pathogen panel ("GPP") which is limited to one sample type. Even though there are other companies offering gastro-intestinal tests, Curetis believes it is offering the most comprehensive panel and is the only provider covering infections of the primary sterile intra-abdominal tract.

### *UTI Application Cartridges*

For the UTI Application Cartridge, Curetis believes that there is no direct competition commercialising molecular tests in the indication area of urinary tract infections. Diatherix offers laboratory services for UTI testing in the US, but its panel with 14 targets is limited and does not cover any antibiotic resistance markers. Rheonix offers a test for research use only, while other companies including ID Genomics, Spectromics, Minion Nanopore and Randox claim to have applications in development.

### *SHR Application Cartridges*

For the SHR Application Cartridge, which is being co-developed with Curetis' partner Acumen, there are several companies that are offering or developing tests for sepsis host response. Immunexpress' SeptiCytE LAB test for sepsis received 510(k) clearance from the FDA for use on a manual PCR instrument in February 2017. However, the tests address different utilities, with Unyvero SHR being able to distinguish between (a) presence and absence of bloodstream infections and (b) a sepsis in response to these infections, while Immunexpress' SeptiCytE test distinguishes between SIRS and Sepsis, with the complication that SIRS is not a commonly accepted concept anymore.

In January 2018, Biocartis and Immunexpress entered into a partnership agreement to co-develop and commercialise the Immunexpress SeptiCytE test for use on Biocartis' Idylla platform. Thermofisher Scientific offers a procalcitonin ("PCT") biomarker test for diagnosing and monitoring bacterial infections and Sepsis. Inflammatrix has validated its SepsisHR test. Abionic is commercialising the Pancreatic Stone Protein ("PSP") biomarker-based abioSCOPE PSP test for its AbioSCOPE platform. T2Bio states that its T2Sepsis Solution would

enable results with a sensitivity over 90% directly testing from whole blood samples and making results available within six hours. Bruker offers the MBT Sepsityper kit using positive blood culture samples promising that, once integrated into mass spectrometry identification workflow, this solution could shorten turn-around time by up to 24 hours by eliminating the step of culturing microorganisms.



## BUSINESS

### Overview

Curetis is a molecular diagnostics company that focuses on the development and commercialisation of reliable, fast and cost-effective products for diagnosing severe infectious diseases in hospitalised 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 commercialised 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 and Singapore), and is in the process of being rolled out commercially in the US following *De Novo* clearance of the Unyvero System and the LRT Application Cartridge by the FDA in April 2018. For a detailed description of the FDA's regulatory clearance procedures, including the *De Novo* clearance and other clearance processes that may be relevant for Curetis in the future, see "Regulation – United States."

Today, the diagnosis of infectious diseases in the hospital setting is still largely carried out through traditional culture-based microbiology methods. This process is labour-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<sup>32</sup>. 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.<sup>33</sup> 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 key EU countries, including Belgium, France, Germany, Luxembourg, the Netherlands, Switzerland and the UK, as well as the US, and distributors in selected European markets and the rest of the world. Curetis also intends to continue to expand internationally in certain additional ASEAN markets beyond Singapore (Indonesia, Malaysia, and Thailand) through its distribution agreement with Acumen and in Greater China through its distribution agreement with

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<sup>32</sup> Jamal *et al.* (2014), Personne *et al.* (2016), Prieto-Borja *et al.* (2016), Ozongwu *et al.* (2017), Papan *et al.* (2017), Lakbar *et al.* (2018), Mopuru *et al.* (2018), Pickens *et al.* (2018a, 2018b), Collins *et al.* (2018).

<sup>33</sup> Qi *et al.* (2017).

Beijing Clear Biotech, with the distribution rights for Hong Kong granted to Technomed (Hong Kong) Ltd. Curetis recently entered into distribution agreements with Future Horizons Scientific (FHS) in Egypt, Quimica Valaner S.A. de C.V. in Mexico and Biko S.A. in Uruguay for commercialization of the Unyvero Platform and Application Cartridges, subject to obtaining regulatory clearance for the products in the respective markets, which is expected in the fourth quarter of 2018.

As of 30 October 2018, Curetis' total installed base comprised 165 Unyvero A50 Analyzers. There are currently six commercially available Application Cartridges: 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 and is now being marketed in the US. The HPN and BCU Application Cartridges have also been approved by the Singaporean HSA.

To date, more than 90 clinical studies and evaluations with over 12,800 patient samples have been completed to validate these Application Cartridges and more than 40 clinical and scientific publications have been produced since the beginning of 2016. Additional trials with several thousand additional samples are ongoing or planned in the coming years. This includes clinical studies to obtain FDA clearance for the LRT Application Cartridge for use with the BAL specimen, in addition to the tracheal aspirate samples for which the Unyvero LRT Application Cartridge was cleared by the FDA in April 2018, and the IJI Application Cartridge, which addresses invasive joint infections, as well as CFDA trials for the Unyvero System and the HPN, ITI, and potentially other Application Cartridges.

In addition to the current Unyvero System, Curetis also plans to launch its Unyvero A30 *RQ* Analyzer module, subject to completion of development and regulatory clearance for CE-IVD-marking, in Europe in late 2019. Currently in the development stage, the Unyvero A30 *RQ* Analyzer has been 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) quantitative 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 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, addressing new markets and diversifying the product pipeline. 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.

Curetis is continuously updating and improving the content and performance of existing Application Cartridges to meet evolving market needs and reflect the dynamically changing pathogen and antibiotic resistance landscape. Curetis also 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 infectious disease testing.

Curetis' other core business is its ARES Technology Platform and its proprietary genetic database on AMR, *ARESdb*. The ARES Technology Platform and *ARESdb* build and expand upon the GEAR assets acquired from STA in 2016. Curetis believes GEAR is the world's most comprehensive database on the genetics of antibiotic resistance, which Curetis believes will enable it to enter into partnering deals and strategic collaborations with diagnostic companies, pharmaceutical companies and companies focused on public health and life science research. Curetis expects to increasingly utilise the proprietary biomarker content in its own assay and Unyvero Application Cartridge development, as well as to out-license it to partners and/or work with partners on the

development of solutions for microbiology relying on the database and/or the Ares Technology Platform. On 4 September, 2018, Curetis announced that Ares Genetics has initiated the development of its ARES<sup>Supa</sup> Universal Pathogenome Assay, which will be based on the ARES Technology Platform and ARES<sup>db</sup>. ARES<sup>Supa</sup> 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 laboratory workflow. Curetis 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.

## Strengths

- Commercial stage: 165 installed Unyvero A50 Analyzers as at 30 October 2018 in Europe, the Middle East, and recently launched in the US and the ASEAN region, with direct sales in the US and selected European countries.
- Targeting Large Market Opportunity: Curetis estimates that the addressable market for its current and nearer-term Unyvero Application Cartridges is more than 9.73 million cases eligible for testing per year in the EU and the US (see figure included in “Industry”— “Molecular Diagnostics Market by Application”)
- Comprehensive platform: processing numerous sample types and covering more microorganisms and resistance markers than competing platforms.
- Validated Unyvero Platform: extensive clinical studies (including US FDA trial for the LRT Application Cartridge) 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 integration of the Unyvero A30 RQ Analyzer as complementary analyzer module into Unyvero Systems at the same hospitals and accounts to complement the offering of Unyvero as a comprehensive solution in infectious disease testing.
- Set to become a broad solution provider in molecular microbiology with versatile and proprietary Unyvero platform and proprietary AMR content through ARES<sup>db</sup> for Unyvero and third-party platforms, for example in the NGS space.
- Expanding Unyvero menu: multiple clinical studies underway or planned to continue expanding the use of a number of available Application Cartridges.
- 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 commercialisation.
- Significant upside through partnering opportunities through the ARES Technology Platform and ARES<sup>db</sup> as well as the Unyvero Platform (in indications and market segments not directly target by with Curetis’ core business).

## Strategy

### ***Molecular Microbiology Leader***

Curetis' objective is to become a leading molecular microbiology solutions provider. To this end, Curetis' strategy builds on two assets: firstly, the Unyvero Platform – rapid, comprehensive, and versatile MDx diagnostic solutions for critical hospital infections – and secondly, Ares Genetics' ARES Technology Platform and ARESdb, which Curetis believes to be the world's most comprehensive database for antibiotic resistance markers. Through advancing its Unyvero Platform to an any-plex platform, Curetis aims to become a leading provider of reliable, comprehensive and fast infectious disease diagnostics, offering solutions for a range of multiplexing needs (high, medium and low). With ARESdb, which is intended to be continuously advanced and expanded by Ares Genetics and its partners, Curetis seeks to become a leader in antibiotic resistance data intelligence. To this end, the ARES Technology Platform, which includes advanced bioinformatics and deep learning algorithms and has the potential to expand into artificial intelligence concepts, leverages ARESdb for surveillance, prediction and diagnosis of antimicrobial resistance. It provides content and bioinformatics solutions for Curetis' Unyvero Platform and third-party platforms in the diagnostics and life science industries, as well as for supporting pharmaceutical companies in antimicrobial drug development.

### ***Rapid Syndromic Testing for Microbial Infections***

Curetis believes that in order to optimise the treatment of microbial infections, it is crucial to have timely access to relevant diagnostic information on pathogens and their antibiotic resistance markers.

With regards to infectious disease diagnostics, Curetis is convinced that optimised treatment can be achieved through comprehensive and reliable highly automated molecular diagnostic solutions. Therefore, Curetis has developed its innovative Unyvero System. With Unyvero, Curetis intends to make reliable and relevant diagnostic information available early in the patient treatment pathway, thereby allowing clinicians to adapt therapy at an earlier point in time in the care cycle. Curetis believes this will result in better patient outcomes through optimised and more targeted antibiotic treatment regimens, savings for healthcare providers through shorter ICU and hospital stays and reduced use of antibiotics, preserving antibiotics as effective weapons against bacterial pathogens.

### ***Data Intelligence in Antibiotic Resistance***

Ares Genetics combines the ARESdb, on the genetics of antimicrobial resistances with its ARES Technology Platform of proprietary data analysis workflows and interpretation applications into a comprehensive offering with specific molecular microbiology solutions for industry partners, clinicians, public health and life science research:

- Diagnostic companies: biomarker discovery and licensing, PCR and NGS assay development, and data interpretation solutions.
- Pharmaceutical companies: drug target selection, lead prioritisation and optimisation, pre-clinical solutions, clinical trial support, and companion diagnostics.
- Research and epidemiology: molecular epidemiology, outbreak monitoring, functional analysis, and antimicrobial stewardship.

ARESdb builds on and expands the GEAR database, acquired from STA in September 2016. Using the broad range of genetic and phenotypic antibiotic resistance data in ARESdb collected at more than 200 clinical sites on five continents over 30 years, Curetis aims to expand its leadership in genetic antibiotic resistance testing.

### ***Driving Corporate Value***

While Curetis' current corporate focus has been mainly on the Unyvero Platform, going forward revenue growth is expected to be increasingly generated by the Unyvero A30 *RQ* Analyzer family of products and ARESdb. The Unyvero A30 *RQ* Analyzer and its Application Cartridges will expand the menu of available Application Cartridges that customers can use with their existing Unyvero installations. As a result, Unyvero provides syndromic high-multiplex panels through the Unyvero A50 Analyzer but also, through the Unyvero A30 *RQ* Analyzer, is expected to address needs in areas that require the faster testing, quantitative testing, cheaper prices and different medium-plexing panels in infectious disease.

ARESdb is expected to become an increasingly important value driver as Curetis aims to enter into partnering deals and strategic collaborations that are expected to contribute to top-line revenue growth in the short and medium term. It also targets unique applications through proprietary content that can be used in product development for the Unyvero Platform over the mid to long term. Furthermore, Curetis believes that ARESdb will allow Curetis to become a key player in an emerging NGS-based molecular microbiology market through AMR data intelligence solutions in the long term.

### ***Driving Unyvero Adoption and Topline Growth***

With the exception of instrument manufacturing, Curetis is a fully integrated molecular diagnostics company, covering in-house Application Cartridge development and manufacturing as well as commercialisation and distribution of its products. Curetis' operational and financial objectives are to broadly install Unyvero Systems in hospitals in Europe, in other markets accepting the CE-IVD-mark as well as in the US, and – once regulatory clearance is obtained – in China and other key markets via its distributors. Curetis' objective is to increase its revenues by placing and/or selling Unyvero Systems in more hospitals and in more geographies and selling an increasing number of Application Cartridges for use with these systems.

To that end, Curetis follows a dual strategy of direct commercialisation in some key European markets and the US, and distribution partnerships in other territories, including the broader EMEA region and Asia. The progress in implementing this strategy is measured by tracking key metrics such as increase of installed base of Unyvero Systems, number of accounts covered either directly or via partners, and top-line revenue growth. Additional drivers of growth include the breadth of the Unyvero application menu and the geographic expansion of the sales territory.

## **History**

### ***2007-2009***

In 2007, a group of engineers, a physician and biologists from Philips Medizin Systeme Böblingen GmbH co-founded Curetis. This group includes today's Chief Technology Officer ("CTO") Andreas Boos, Chief Operating Officer ("COO") Johannes Bacher, Director Innovation, Technology & IP Dr. Gerd Lüdke and former Medical Director Dr. Anne Thews. In 2008, in addition to a capital increase by the founders and the management, aeris CAPITAL AG ("**aeris CAPITAL**"), a Swiss family office, also contributed to Curetis with a seed funding of €1,400 thousand. During this time the decision was made to focus on a lower respiratory tract Application Cartridge as a commercially attractive indication area. In November 2009, a €18,500 thousand series A financing round was successfully closed with a syndicate led by aeris CAPITAL and co-investors LSP, BioMed Invest and KfW.

### ***2010-2012***

In 2010, a first in-house validation testing of the P50 Application Cartridge with clinical samples was initiated. In April 2011, Oliver Schacht became the Chief Executive Officer ("CEO") of Curetis and under his leadership the company successfully extended its series A financing round by €15,600 thousand. In the autumn of 2011,

Curetis opened its manufacturing site for production of the Application Cartridges in Bodelshausen, Germany. Curetis officially launched its P50 Application Cartridge during the European Congress of Clinical Microbiology and Infectious Diseases (“ECCMID”) conference in April 2012 for commercialisation in Germany, Austria and Switzerland. The CE-IVD performance evaluation study for the Unyvero System and the P50 Application Cartridge was successfully completed in May 2012 and a multicentre prospective EU clinical trial clinical study was initiated. In the same year, Curetis entered into collaborations with Heraeus Medical GmbH (“**Heraeus Medical**”) and Cempra Pharmaceuticals Inc. (“**Cempra**”).

### **2013-2015**

In 2013, Curetis extended its commercial operations into Belgium, the Netherlands, Luxembourg, Russia, Eastern Europe and the Middle East. Concurrently, Curetis initiated an FDA clearance study for the LRT Application Cartridge at five initial clinical sites in the US. In April 2013, Curetis closed a €12,500 thousand series B financing round led by HBM and, in November 2014, it secured a €14,500 thousand extension of its series B financing round. In May 2014, Curetis officially launched in Europe its second Application Cartridge targeting implant and tissue infection (ITI Application Cartridge). This was followed by the next generation HPN Application Cartridge, which was successfully completed and introduced to the market in the second quarter of 2015. In June 2015, Curetis strengthened the executive team by appointing Dr. Achim Plum as its Chief Commercial Officer (“**CCO**”) and started expanding its direct sales effort in its key European markets (France, Belgium, the Netherlands, Luxembourg and the UK). On 11 November 2015 Curetis, following its corporate reorganisation, successfully completed its IPO on Euronext under the ticker symbol “**CURE**” and raised €44,300 thousand to further fund its growth.

### **2016-2018**

Since its IPO Curetis has launched five new Application Cartridges (a new ITI, BCU, IAI, UTI and LRT), added several new international distribution partnerships and expanded its direct sales and marketing teams and subsidiaries in the UK, France, the Netherlands, Switzerland and the US. Furthermore, Curetis raised up to €25,000 thousand through the EIB Finance Contract in 2016 (with the first €10,000 thousand tranche drawn down in April 2017) and completed an equity offering in May 2018, raising another €4,100 thousand in equity financing plus up to an additional US\$10,000 thousand in equity financing available over 36 months under the GCF Equity Facility. In October 2018, the Company entered into the Yorkville Agreement pursuant to which the Company has access to up to €20,000 thousand through the issue of Convertible Notes. At the same time, the Company issued €3,500 thousand in principal amount of Convertible Notes as part of the first tranche under the Yorkville Agreement, thereby raising a net proceeds amount of €3,220 thousand.

In September 2016, Curetis acquired the GEAR database from STA, and in December 2016, the Gyronimo platform (now Unyvero A30 RQ Analyzer) from Carpegen and Systec. The GEAR database is now part of Curetis’ proprietary ARES AMR Database, ARESdb.

Following the successful completion of the US trial for the LRT Application Cartridge in 2016 and subsequent FDA submission in January 2017, Curetis received the grant of its *De Novo* request for clearance of the Unyvero System and LRT Application Cartridge in the US from the FDA in April 2018. Curetis began launching the products in the US via its own direct sales, marketing and service organisation of which the core team was built over the last two years and the sales organisation was built during the second half of 2017 and the first quarter of 2018 in San Diego, US. Curetis has also initiated its second US FDA trial with the start of sample collection for retrospective specimens into its IJI study and expects to start patient sample enrolment later in 2018. Curetis chose the IJI Application Cartridge for its second US FDA trial because of its extensive experience with the development of the technically similar ITI Application Cartridge for the European market, as well as market research suggesting that it, like the LRT Application Cartridge, would be a first-in-class product in the US.

In addition, to focus on further development and commercialisation of ARESdb and the ARES Technology Platform assets and BioIT capabilities and offerings, Ares Genetics was founded in 2017 as a wholly-owned subsidiary in Vienna, Austria. Ares Genetics has won several competitive non-dilutive grant financings for a total project volume of approximately €1.7 million with an overall funding rate of approximately 38% as well as entering into several strategic collaboration projects with MGI/BGI (China).

## **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 US, 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 and System Components***

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 approved 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 hybridisation 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 Master Mix tube cap, sample pre-treatment tool and Unyvero**

### *Workflow*

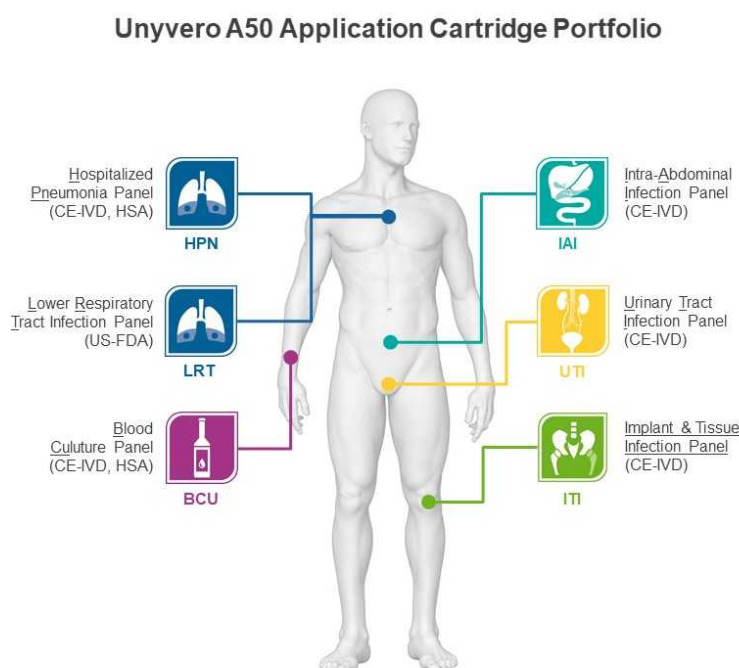
The Unyvero Platform is a modular, flexible easy-to-use platform which substantially reduces turnaround time from up to 24 hours or even weeks for traditional microbiology culture-based tests to around four to five hours. This allows physicians to adjust treatment at a much earlier stage than with the 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. The Unyvero workflow consists of five steps:

- Step 1: The native patient sample is transferred into the Unyvero sample tube and is sealed with the Unyvero sample tube cap.
- Step 2: By selecting an application and indication on the Unyvero C8 Cockpit and scanning the sample tube or alternatively manual entry of sample information using the on-screen keyboard, the Unyvero L4 Lysator automatically opens. The sealed Unyvero sample tube is loaded into the Unyvero L4 Lysator where the lysis is carried out fully automatically for 30 minutes.
- Step 3: After lysis, the Unyvero sample tube and Master Mix tube are plugged into the Application Cartridge.
- Step 4: After scanning the preloaded Application Cartridge, it is inserted into the analyzer for further fully automatic processing.
- Step 5: Comprehensive results are available in approximately four to five hours and will be displayed on the Unyvero C8 Cockpit screen without any further operator interaction. Results include a quick overview of positively identified pathogens and resistance markers, a more detailed result screen for all pathogens and all resistance markers tested for, as well as relevant test-log information. After the test has been completed, the Application Cartridge is simply taken out of the analyzer and can be discharged into hospital waste.

### *Unyvero Application Cartridges*

With eight parallel and fully independent multiplex endpoint PCR chambers, the single-use, disposable and sealed Application Cartridges facilitate the identification of a broad range of disease relevant microorganisms and antibiotic resistance markers within a single closed system, enabling syndromic infectious disease testing. All Application Cartridges have the same physical design and format and contain a DNA extraction and purification column with silica membrane, all required reagents and buffers, a mixing vessel for PCR set-up, a waste chamber and eight fully independent PCR chambers with integrated multiplex end-point PCR amplification and array-based detection.

The various Application Cartridges differ only in the primer composition in the eight PCR chambers, in the detection probes on the specific detection arrays in each PCR chamber and in the indication and sample selection protocols (software), execution protocols and labelling. Each Application Cartridge has two specific loading slots: one for the sealed Unyvero sample tube, containing the lysed patient sample, and the other for the sealed Unyvero Master Mix tube. All Application Cartridges are prefilled with all required reagents except for the PCR Master Mix and have a self-contained fluidic system. Curetis believes that this closed fluidic system significantly reduces the contamination risk. After being used, the single-use Application Cartridge can be handled as standard waste in hospitals. Curetis' product portfolio of Application Cartridges currently comprises the following Application Cartridges:



**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 hospitalised patients.

The HPN Application Cartridge targets severe cases of pneumonia in hospitalised patients who are mostly in intensive care and have a high mortality rate. It has a total sample-to-answer time of around four to five hours, with a hands-on time of about five minutes. In the small cohort using native clinical samples, the HPN Application Cartridge achieved an overall sensitivity of 89% and an overall specificity of 98% for pathogen identification. Moreover, it detected six additional pathogens not discovered by routine microbiological culture. The resistance markers showed an overall sensitivity of 87% at an overall specificity of 97%. The HPN Application Cartridge has been clinically validated in more than 5,000 of pneumonia patient samples.

Pneumonia is a severe, life-threatening acute infection of the lower respiratory tract. It results from various causes, most commonly bacteria. The current diagnosis process and treatment of pneumonia is imprecise. It is a fast progressing disease associated with high treatment costs, mortality rates of up to 29.3% and a hospital stay of between around eight and 23 days.<sup>34</sup> Pneumonia is classified in community-acquired pneumonia (“CAP”), healthcare-associated pneumonia (“HCAP”) and hospital-acquired pneumonia (“HAP”) with its subclass ventilator-associated pneumonia (“VAP”).<sup>35</sup> A CAP is acquired in the community without a history of medical intervention and is mostly caused by viruses. Patients with a CAP usually follow a mild course, however about 20% of them need to be hospitalised.<sup>36</sup> Such hospitalisation cases are classified as severe community-acquired pneumonia (“sCAP”). In 50% of all healthcare associated infections (“HAI”) cases antibiotics are prescribed HAP constitutes 22% of all HAI and up to 25% of ICU infections.<sup>37</sup> Because hospitalised individuals are exposed to more dangerous, often drug-resistant bacteria, such HAP tends to be deadlier than CAP. Antibiotics administered for HAP are often given intravenously, are expensive, may produce greater side effects and may be used in combination. Empirically based initial regimen is inadequate in 10% to 73% of cases,<sup>38</sup> however, adequate initial treatment can significantly reduce both mortality and length of stay<sup>39</sup>, with potential cost savings of several thousand euros per patient. For VAP, the length of stay (“LOS”) in intensive care is increased by a mean of six days<sup>40</sup> and additional costs are as high as US\$40,000 per patient.<sup>41</sup> Those VAPs, a subset of HAP associated with mechanical ventilation, have an incidence of 11% and a mortality of 29%.<sup>42</sup> Whilst VAP is specifically difficult to diagnose, patients with ventilation-associated complications spend more time on mechanical ventilation, more days in intensive care and consume more broad spectrum antibiotics.<sup>43</sup>

The underlying cause in pneumonia cases is usually diagnosed through a microbiology culture from a respiratory sample. Results from microbiology cultures typically take 24 to 72 hours or even weeks. Therefore, clinicians must almost always begin treatment before lab results are available to validate their treatment selection. In addition, antibiotic resistances complicate the difficulty of therapy selection. Antibiotic resistances have risen steadily in the last several decades due to inadequate antibiotic treatment.<sup>44</sup> Clinical studies have

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<sup>34</sup> Kollef *et al.* (2005), Torio *et al.* (2016).

<sup>35</sup> Kollef *et al.* (2005), Torres *et al.* (2016).

<sup>36</sup> Jain *et al.* (2015).

<sup>37</sup> Torres *et al.* (2010), Magill *et al.* (2014).

<sup>38</sup> Piskin *et al.* (2012).

<sup>39</sup> Livermore and Wain (2013).

<sup>40</sup> Rello (2011).

<sup>41</sup> Borgatta & Rello (2014).

<sup>42</sup> Kollef *et al.* (2005).

<sup>43</sup> Hayashi *et al.* (2013).

<sup>44</sup> Kollef *et al.* (1999), O’Neill (2014).

demonstrated that adequate initial antibiotic treatment for most severe acute infections significantly improves medical outcome.<sup>45</sup> In addition, appropriate and early antibiotic selection limits the risk of increasing antibiotic resistance in the population as a whole.

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 clinical 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; and
- 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:

- $\beta$ -Lactam resistance, including ESBL;
- kpc resistance;
- macrolide resistance;
- quinolone resistance; and
- multi-drug resistance.

The LRT Application Cartridge was launched in the US 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 8 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 *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. On a weighted average sensitivity and specificity basis as presented at ASM Microbe in summer 2017 by Matt Sims<sup>46</sup>, the LRT Application Cartridge demonstrated 91.4% sensitivity at 99.5% specificity (and 99.8% after discrepant result resolution) in the study including BAL as well as tracheal aspirate samples. The sensitivity for aspirate samples only was indeed significantly higher at 96.1% compared to BAL of 86.9%. The test is much faster than microbiology culture and identifies many pathogens that are overlooked in microbiology cultures.<sup>47</sup>

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<sup>45</sup> Kollef *et al.* (1999), Livermore and Wain (2013).

<sup>46</sup> Qi *et al.* (2017).

<sup>47</sup> Mopuru *et al.* (2018), Pickens *et al.* (2018a, 2018b), Collins *et al.* (2018).

Of 87,337 patients surveyed by the ECDC staying in an ICU in Europe in 2014 for more than two days, 6,995 (8.0%) patients presented with at least one HAI. Of all such 87,337 patients staying in an ICU for more than two days, 5.5% presented with pneumonia, 3.5% with bloodstream infection (BSI) and 2.6% with urinary tract infection (UTI) with some patients presenting with more than one HAI.<sup>48</sup> The overwhelming majority (98%) of pneumonia episodes were associated with intubation, 48% of BSI episodes were catheter-related, and 98% of UTI episodes were associated with presence of a urinary catheter.<sup>49</sup> The incidence for hospitalised sCAPs for Europe is estimated at approximately 1 million cases annually.<sup>50</sup> The U.S. CDC's official 2010 US hospital statistics reported 1,128,000 discharges because of pneumonia.<sup>51</sup> In 2015, 544,000 patients visiting hospital emergency departments were diagnosed with pneumonia as their primary condition.<sup>52</sup> Curetis estimates the total potentially available market for severe pneumonia in the EU and US is 2.3 million cases.<sup>53</sup>

### *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 by Heraeus Medical, a worldwide market leader in orthopaedic bone cement which offers comprehensive infection management solutions. Curetis pays a customer referral commission to Heraeus Medical, but has retained full control on product commercialisation.

Implant and tissue infections represent a significant risk factor during the healing process after surgery or trauma and can significantly influence or delay the recovery process, making early and reliable identification of the causative pathogens just as necessary as an adequate antimicrobial treatment. Some of the most common occurring infections are: prosthetic joint infections (“PJI”), surgical site infections (“SSI”), diabetic foot ulcers, catheter-associated infections, deep skin and tissue infections, cardiology-related infections, other implant infections and burn-wound infections. The number of patients requiring joint replacement or internal fixation devices increases due to prosthetic joint infections<sup>54</sup>. After initial hip replacement surgery, an infection rate of less than 1% is to be expected, while for a knee replacement an infection rate of less than 2% is to be expected.<sup>55</sup> A much higher incidence of infection occurs in revision surgery patients. It can reach up to 40% after primary replacement. The numbers of revisions done for reasons of an infection are rising, although periprosthetic hip infections appear to now be plateauing at around 13%.<sup>56</sup> Patients receiving a fixation of open fractures are

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<sup>48</sup> ECDC (2016)

<sup>49</sup> ECDC (2016).

<sup>50</sup> Chalmers, J.D. *et al.* (2014).

<sup>51</sup> CDC (2010).

<sup>52</sup> CDC (2018).

<sup>53</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); Kleven *et al.* (2007) in Jhung (2009); Geffers (2011); Brun-Buisson (2001); Michelotti *et al.* (2012); Sunderlin (2006).

<sup>54</sup> Otto-Lambertz *et al.* (2017).

<sup>55</sup> Otto-Lambertz *et al.* (2017).

<sup>56</sup> Perfetti *et al.* (2017).

estimated to have a 20% risk of infection.<sup>57</sup> Costs concerning ITIs pose a significant burden for the healthcare system. For example, the average cost difference between an aseptic and a septic hip replacement is US\$8,893 and can be attributed to an incremental length of stay of 24 days.<sup>58</sup>

SSIs are the most common and costly of all HAIs, accounting for 20 percent of all HAIs. They occur in an estimated 2 percent to 5 percent of patients undergoing inpatient surgery. The estimated annual incidence of SSIs in the U.S. ranges from 160,000 to 300,000, and the estimated annual cost ranges from \$3.5 billion to \$10 billion. On average, a surgical site infection increases the hospital length of stay by 9.7 days, according to studies cited in the guidelines.<sup>59</sup> These infections vary in severity; some are limited to skin and subcutaneous tissue while other more aggressive forms involve deep soft tissues, such as muscles and fascia. SSIs have a major impact on patients' life quality. Infected surgical patients are more likely to die, spend more time in intensive care units and have a higher likelihood to be readmitted to hospitals after discharge.<sup>60</sup> In the US about 9,000 deaths can be associated with SSIs per year.<sup>61</sup>

Diabetic foot infections (“**DFIs**”) are high incidence clinical problems and represent the most common cause of diabetes-related admission to hospital. The continued rise in incidence of diabetes in developed and less developed countries, the increasing body weight of many diabetic patients, and their greater longevity all contribute to the growth of the problem. The rise of DFIs are associated with potentially serious sequelae, and are in fact accepted as the leading causes of non-trauma lower extremity amputations in the developed world.<sup>62</sup> In Germany, DFIs accounted for approximately 64% of all amputations in 2014.<sup>63</sup> When properly managed, most patients can be cured. Adherence to diagnosis and treatment guidelines is essential to prevent patients needlessly undergoing amputations.<sup>64</sup> DFIs usually begin with a diabetic foot wound, most often a neuropathic ulceration. Acute ulcers are usually colonised by a single pathogen, while chronic ulcers have a more diverse microbiome.<sup>65</sup> The care costs for diabetic patients with foot ulcers are very high, at up to US\$17,000 per patient, doubling those of diabetic patients without ulcers.<sup>66</sup>

Catheter related bloodstream infections account for 10% of all HAIs and constitute therefore an important issue in hospital settings. Device-associated infections (central lines, urinary catheters and VAP) make up 25% HAI.<sup>67</sup> In the US, around 17 to 19% of patients admitted to hospitals will use a catheter during their hospital stay<sup>68</sup> and 57% of hospitalized patients with HAI have a central catheter.<sup>69</sup> Catheter associated infections can pose a huge cost burden on the healthcare system, with estimated additional €24,700 thousand per year in Germany alone.<sup>70</sup>

Conventional diagnosis of implant and tissue infections – encompassing orthopaedic implant infections and SSIs but also diabetic foot infections, catheter-associated infections, deep skin and tissue infections and cardiology related infections – has shown low accuracy and is problematic. Physicians usually have to wait up to two weeks for diagnostic results from the different clinically relevant sample types in the case of certain PJIs.

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<sup>57</sup> Guerra *et al.* (2017).

<sup>58</sup> Assmann *et al.* (2014).

<sup>59</sup> Ban *et al.* (2017).

<sup>60</sup> ECDC (2017).

<sup>61</sup> Awad (2012).

<sup>62</sup> Lipsky *et al.* (2016).

<sup>63</sup> Kröger *et al.* (2017).

<sup>64</sup> Lipsky *et al.* (2016).

<sup>65</sup> Lipsky *et al.* (2016).

<sup>66</sup> Rice *et al.* (2013).

<sup>67</sup> Magill *et al.* (2014), Magill *et al.* (2017).

<sup>68</sup> Magill *et al.* (2014), Magill *et al.* (2017).

<sup>69</sup> Magill *et al.* (2014).

<sup>70</sup> Leistner *et al.* (2014).

Therefore, treatment is initiated before diagnostic results are available. As in other severe infections, physicians generally believe that rapid and accurate detection of the disease-causing pathogens and drug resistance markers, followed by the implementation of appropriate antibiotic therapy, hold the potential to significantly reduce patient mortality rates, length of stay and costs.

Curetis estimates that the addressable market for the ITI Application Cartridge is approximately 2.1 million cases eligible for testing per year in the EU and the US, (see table 1 below).<sup>71</sup>

**Table 1: Estimated ITI Application Cartridge market potential**

<b>Total Implant and Tissue Infections by indication</b>	<b>Incidence</b>
Diabetic Foot Ulcer Infections	355,320
Decubitus Ulcer Infections	31,338
Burn Wound Infections	38,409
SSIs	582,012
Orthopaedics /PJIs	607,834
Catheter-associated Bloodstream Infections	501,400
Cardiology-related Infections	11,902
All indications	2,128,215

Source: 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); Kleven *et al.* (2007) in Jhung (2009); Geffers (2011); Brun-Buisson (2001); Michelotti *et al.* (2012); Sunderlin (2006).

#### *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.

Bloodstream infections can lead to sepsis, which was recently redefined as life-threatening organ dysfunction caused by a dysregulated host response to an infection.<sup>72</sup> According to Critical Care Company GmbH statistics, sepsis is the leading cause of non-cardiac deaths in ICUs.<sup>73</sup> Of the total hospitalized adult sepsis cases in the U.S., estimated to be 1.7 million in 2014, about 270,000 died, representing a mortality rate of around 16%.<sup>74</sup> In Germany, 279,530 cases of sepsis were reported in German hospitals in 2013, of whom 67,849 died, representing a mortality rate of 24.3%. Of these 279,530 cases, 115,421 were cases of severe sepsis, with a

<sup>71</sup> See Footnote 43.

<sup>72</sup> Singer (2016).

<sup>73</sup> Society of Critical Care Medicine (2018).

<sup>74</sup> Rhee *et al.* (2017).

mortality rate of 43.6%, amounting to 50,349 deaths in 2013.<sup>75 76</sup> The CDC estimates that one in three patients who die in a hospital have sepsis.<sup>77</sup>

Sepsis is also an expensive illness to treat. In the US, sepsis has a higher incidence than common cancer types and heart failure and was the most expensive condition treated in US hospital stays in 2013, at an aggregate cost of US\$23.7 billion for nearly 1.3 million hospitalisations.<sup>78</sup> Early diagnosis is necessary to properly manage sepsis, as initiation of directed therapy is of key importance to reducing mortality.<sup>79</sup> Within the first three hours of suspected sepsis, diagnostics should obtain appropriate cultures before starting antibiotics. However, with conventional methods pathogen identification in the blood is successful in only about 30%-40% of cases.<sup>80</sup> A retrospective study by Kumar et al. showed that administration of an effective antimicrobial therapy within the first hour was associated with a survival rate of 79.9%, however each hour of delay in antimicrobial administration over the ensuing six hours was associated with an average decrease in survival of 7.6%.<sup>81</sup> Time required to test positivity by the traditional microbiological culture method is around 15 hours, but individual bottles may turn positive between a few hours and several days<sup>82</sup> with positive rates in around 30%-40% depending on literature.<sup>83</sup> Therefore, Curetis believes there is a great medical need for its BCU Application Cartridge in the management of sepsis.

The global blood culture (“BC”) test market was estimated to be worth U.S.\$ 3.2 billion in 2016, and is expected to grow at a compound annual growth rate of 8.6% to US\$ 6.6 by 2025.<sup>84</sup> Based on a BC positivity rate of 30%<sup>85</sup>, which Curetis considers a conservative assumption, and incidence estimates for blood stream infections in Europe and the U.S.<sup>86</sup>, Curetis estimates that the addressable market for the BCU Application Cartridge is approximately 600,000 cases eligible for testing per year in the EU and the US. The following table 2 summarises the described market potential for the BCU Application Cartridge.

**Table 2: Estimated market potential for BCU Application Cartridge**

	EU (market size)	US (market size)	Total potential available market
<b>Variables for incidence of sepsis and positive blood cultures</b>			
Incidence Bloodstream Infections	1,200,000 <sup>(1)</sup>	600,000 <sup>(1)</sup>	1,800,000
BC positivity rate	30% <sup>(2)</sup>	30% <sup>(2)</sup>	30% <sup>(2)</sup>
BC positive cases / estimated market potential for BCU	400,000	200,000 <sup>(2)</sup>	600,000

<sup>75</sup> Fleischmann *et al.* (2016).

<sup>76</sup> Thee *et al.* (2017).

<sup>77</sup> CDC (2014).

<sup>78</sup> Torio *et al.* (2016).

<sup>79</sup> Seymore *et al.* (2017).

<sup>80</sup> Afshari *et al.* (2012).

<sup>81</sup> Kumar *et al.* (2006).

<sup>82</sup> Peralta *et al.* (2006).

<sup>83</sup> Afshari *et al.* (2012).

<sup>84</sup> Grand View Research (2017).

<sup>85</sup> Afshari *et al.* (2012).

<sup>86</sup> Goto & Al-Hasan (2013).



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Notes:

- (1) Goto & Al-Hasan (2013);
- (2) Dellinger *et al.* (2013).

### *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.

Infections of the digestive tract have a variety of etiologies, involve different part of this system and show variability in their cause, some being mild and self-limiting, others being life-threatening with the need for rapid diagnosis and intervention. They involve different organs, such as appendices, pancreas or peritoneum and include a wide spectrum of pathological conditions, ranging from uncomplicated appendicitis to faecal peritonitis. In the event of complicated IAIs, the infection proceeds beyond a singularly affected organ and causes either localised peritonitis (intra-abdominal abscesses) or diffuse peritonitis. Effectively treating patients with complicated intra-abdominal infections involves both source control and antimicrobial therapy.<sup>87</sup> However, antimicrobial resistance has become a major challenge complicating the treatment and management of intra-abdominal infections.<sup>88</sup> In line with Curetis' overall strategy, the focus is on severe digestive tract infections, which represent a high risk to patients, especially those that are seriously ill, elderly or very young, immunocompromised or in intensive care. All targeted indications present a significant burden in terms of patient morbidity and mortality and are associated with significant costs to health services around the world.

Complicated intra-abdominal infections – community or healthcare acquired – are a common problem, with appendicitis alone affecting approximately 300,000 people per year and consuming more than 1 million hospital days in the US. Intra-abdominal infections cause higher mortality (29%) than other infections in the intensive care unit.<sup>89</sup> and complicated intra-abdominal infections result in an overall mortality of 9.2%.<sup>90</sup> Most frequent source of complicated intra-abdominal infection is acute appendicitis, accounting for 34% of infections.<sup>91</sup> In the US, in 2009, acute pancreatitis was the most common gastroenterology discharge diagnosis with a cost of US\$2.6 billion.<sup>92</sup>

For IAI, diagnostics should always be obtained for patients with HAIs as well as for patients with CAIs who are known to be at risk for drug-resistant bacteria. In these patients, causative pathogens and resistance patterns are unpredictable and always require sampling from the site of infection. In many clinical laboratories, species identification and susceptibility testing of anaerobic isolates, frequent in IAI, are not routinely performed. In addition, antimicrobial resistance (e.g.; ESBL-producing *Enterobacteriaceae*) has become a major challenge complicating the treatment and management of intra-abdominal infections. Therefore, the IAI Application Cartridge addresses a high unmet medical need, where faster, more comprehensive diagnostic results will have an impact on medical and economic outcomes.

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<sup>87</sup> Vogelmann & Ebert (2014).

<sup>88</sup> Vogelmann & Ebert (2014).

<sup>89</sup> De Waele *et al.* (2014).

<sup>90</sup> Sartelli *et al.* (2015).

<sup>91</sup> Sartelli *et al.* (2015).

<sup>92</sup> Peery *et al.* (2012).

Curetis' initial estimated target market in the EU and US accounts for about 2 million cases per year, as shown in table 3, based on the estimated total potential available for an IAI Application Cartridge across EU and US. The total available market was estimated by the number of hospital discharges per disease in the US focusing on severe indications: infectious enteritis and diarrhoea<sup>93</sup> plus those related to intra-abdominal infections such as appendicitis, gastritis/duodenitis, as well as diverticulitis.<sup>94</sup> As the incidence of pancreatitis and peritonitis is relatively low, those are not taken into account. EU calculations are based on US numbers with the assumption of the same incidence rates as in the US population.<sup>95</sup>

**Table 3: Estimated market potential for IAI Application Cartridge**

	US (market size)	EU <sup>(2)</sup> (market size)	Total potential available market
<b>Variables for incidences of IAI</b>			
Appendicitis <sup>(1)</sup> .....	311,000	492,368	803,368
Gastritis/Duodenitis <sup>(1)</sup> .....	138,000	218,478	356,478
Diverticulitis <sup>(1)</sup> .....	316,000	500,284	816,284
Total Sum of IAI .....	765,000 <sup>(3)</sup>	1,211,130 <sup>(3)</sup>	1,976,130 <sup>(3)</sup>

Notes:

(1) CDC (2007);

(2) Statista (2015b);

(3) Initial estimated target market for IAI considers only severe IAI incidences.

### *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 US.

The prospective, multi-center clinical performance evaluation study for CE-IVD-marking was conducted at Curetis and three clinical centres in France and Germany. The study, which analysed a total of 443 patient samples, demonstrated that the overall weighted average sensitivity for the pathogens specifically targeted by the test panel was 95.6% at an overall weighted average specificity of 99.3%.

Urinary tract infections (“**UTI**”) are the most common hospital acquired infections. According to the ECDC, healthcare-associated UTIs (“**HAUTI**”) account for about 25% of all HAIs.<sup>96</sup> Hospital-acquired UTIs

<sup>93</sup> HCUP (2013a).

<sup>94</sup> CDC (2007).

<sup>95</sup> Statista (2015b).

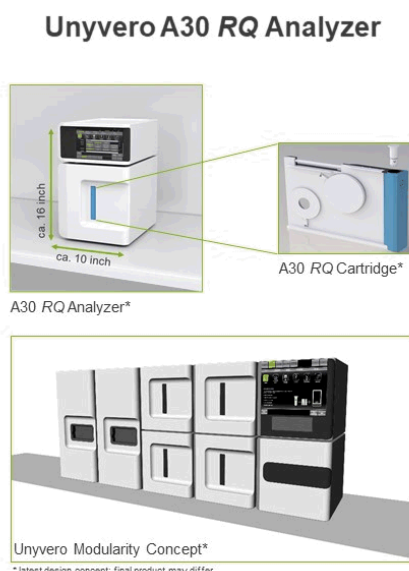
<sup>96</sup> Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals 2011–2012. Link (21.08.2018): <https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/healthcare-associated-infections-antimicrobial-use-PPS.pdf>

(NAUTIs) are in 70% of cases associated with the use of urinary catheters.<sup>97</sup> In severe cases, UTIs can result in sepsis (“**Urosepsis**”) and it is estimated that about 25% of all sepsis case originate from UTIs with mortality rates reported to be in the 25-60% range.<sup>98</sup> Timely appropriate antibiotic therapy is an important survival factor in this indication.<sup>99</sup> However, antimicrobial resistance to one or more antibiotics is frequent complication in the treatment of UTIs.<sup>100</sup> With HAUTI leading to an extra length of hospital stay of four days, early adequate treatment in Curetis’ opinion has the potential to provide health-economic benefits.<sup>101</sup> HAUTIs are estimated to account for about one million cases per year in Europe<sup>102</sup> and about 600,000 cases per year in the U.S.<sup>103</sup>

### ***Future Product Pipeline***

The following discussion assumes that the Company raises the Top-End Proceeds in the Offering. If the Offering should be withdrawn or otherwise not completed, or if the additional available funds generated from the Offering fall below €16.6 million, needed to provide Curetis, together with the remainder of the first Yorkville tranche and the additional EIB debt financing, with €23 million of additional cash resources, or if Curetis’ cash burn is higher than expected, then Curetis will implement an action plan to control and potentially reduce costs. This could in turn result in changes to its business plan, including scaling back its future product pipeline. For more detail on this subject, see “*Capitalisation, Indebtedness and Working Capital – Working Capital Statement*”.

### ***The Unyvero A30 RQ Analyzer***



**Figure 4: latest design concept of Unyvero A30 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

<sup>97</sup> Magill *et al.* (2014)

<sup>98</sup> Peach *et al.* (2016)

<sup>99</sup> Peach *et al.* (2016)

<sup>100</sup> Perletti *et al.* (2018)

<sup>101</sup> Mitchell *et al.* (2016)

<sup>102</sup> Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals 2011–2012. Link (21.08.2018): <https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/healthcare-associated-infections-antimicrobial-use-PPS.pdf>

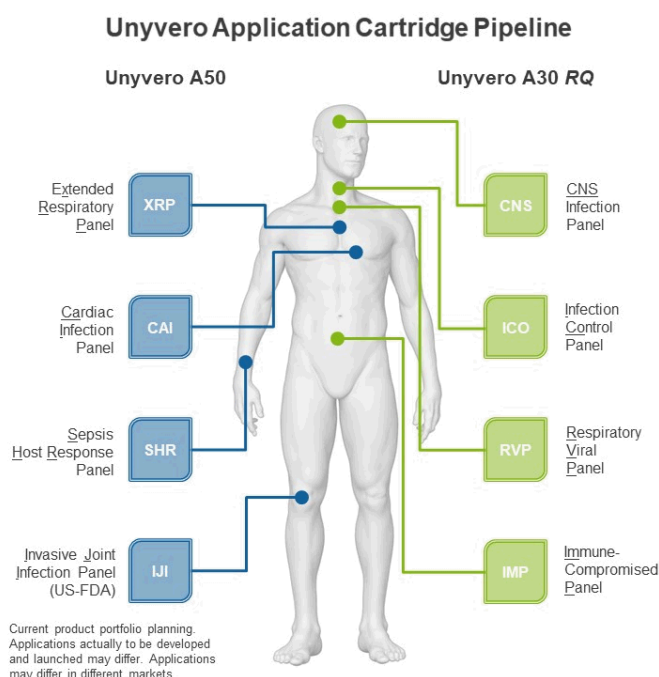
<sup>103</sup> Klevens *et al.* (2002)

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. Curetis expects completion of development by the end of 2018 with potential CE-IVD-marking of the system and the first Application Cartridge in late 2019.

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.

Over the course of 2018, Curetis expects to complete the IVD development and industrialisation as well as arranging for third party manufacturing of the Unyvero A30 *RQ* Analyzer, develop the first Unyvero A30 *RQ* Analyzer Application Cartridges and establish in-house Application Cartridge production.

#### *Unyvero A50 and Unyvero A30 RQ Application Cartridge Pipelines*



**Figure 5: Planned Application Cartridges**

Going forward, Curetis plans to continuously improve its existing Application Cartridges and advance the development of new Application Cartridges for both its Unyvero A50 Analyzer and the Unyvero A30 *RQ*

Analyzer. Curetis plans to accelerate its Application Cartridge development pipeline and over time introduce at least two new or improved Application Cartridges per year.

Pipeline products in development include Application Cartridges targeting IJI, which application is currently the subject of a new FDA clearance study, and XRP, CAI and SHR. Further, the Company intends to extend the label claim of the current LRT Application Cartridge for the US market to also include BAL as an additional sample type and one further pathogen and selected further resistance markers. In addition, the Unyvero A30 *RQ* Analyzer modules are expected to further broaden Curetis' Application Cartridge pipeline by extending it to indications that require low- to medium-level multiplexing such as infection control tests, CNS infections, respiratory viral panels (“**RVP**”), tests for immune-compromised patients or potentially other third-party partner content that might get developed for use on the Unyvero A30 *RQ* Analyzer system. Other indication areas such as oncology, companion diagnostics, transplant medicine and veterinary, food safety or environmental testing may also be future indication areas for the Unyvero Platform, e.g. on the Unyvero A30 *RQ* Analyzer in collaboration with strategic partners.

With regard to software development, Curetis will strive to implement further features and functionality as required by customers, for example connectivity to the hospital and laboratory IT infrastructure as well as various levels of server solutions.

#### *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 numbers discussed in the BCU Application Cartridge regarding market potential, around 2.3 million<sup>104</sup> patients would be eligible for a SHR test representing a total available market in the US und EU of several hundred million Euros depending on price points and with a potential further market potential by applying the Application Cartridge in emergency rooms (see table 4). As Sepsis Host Response testing is a complementary application, major cannibalisation of the BCU Application Cartridge is not anticipated at the outset.

**Table 4: Estimated market potential for the Sepsis Host Response Application Cartridge**

	US (market size)	EU (market size)	Total potential available market
<b>Variables for incidences of IAI</b>			
Incidence sepsis .....	1,500,000 <sup>(1)</sup>	808,000 <sup>(2)</sup>	2,308,000

<sup>104</sup> CDC (2018), ECDC (2008).

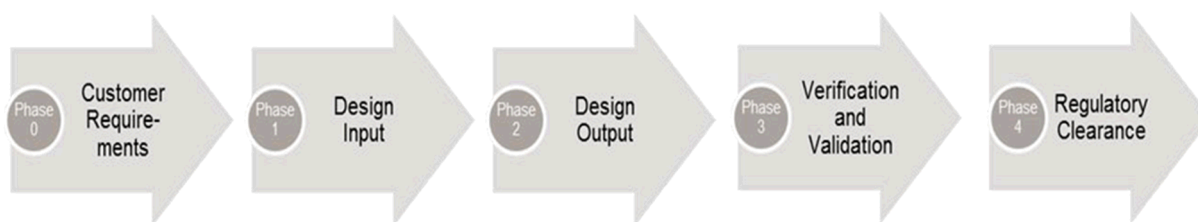
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Notes:

- (1) CDC (2018);
- (2) ECDC (2008).

### ***Product development phases***

Curetis' product development follows a systematic stage-gated process, as shown in figure 6 below, of five phases under its ISO 13485 certified Quality Management System:



**Figure 6: Curetis product development process**

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 (see “*Risk Factors — Risks Related to Business and Strategy — Curetis’ business could be significantly and negatively affected by current or new governmental regulations and clearance, approval and post-approval requirements, particularly in the EU and the US*”).

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.

Curetis’ commitment to clinical evaluation is reflected in several additional clinical projects targeting a total of several thousand patient samples, which are either currently enrolling or in preparation:

- additional FDA clearance study for the LRT Application Cartridge targeting label claim extension to BAL specimen;
- a new FDA clearance study for the IJI Application Cartridge;
- geographic expansion of studies into France, the UK, China, the ASEAN region and other countries;
- companion diagnostic clinical trial with Biotest AG (“**Biotest**”) for PEPPER Pentaglobin® trial;
- a systematic evaluation of the properties and effects of Curetis’ Unyvero System, also known as a health technology assessment (“**HTA**”) in the UK; and
- an interventional multi-center study using the HPN Application Cartridge in Switzerland (Basel, FLAGSHIP Study).

## Partnerships and Collaboration Agreements

### *Acumen*

For a description of the Acumen agreement, see “— Material Contracts — Strategic Partnerships and Collaboration Agreements— Acumen”.

### *Beijing Clear Biotech*

For a description of the Beijing Clear Biotech agreement, see “— Material Contracts — Strategic Partnerships and Collaboration Agreements — Beijing Clear Biotech”.

### *Collaboration Agreements with Pharmaceutical Companies*

Curetis has entered into four collaboration projects (see table 5) where the partner is a pharmaceutical company typically using the Unyvero Platform in a clinical trial of a novel antibiotic. Of these four collaborations, one is currently still ongoing. Agreements can range from a simple research and development collaboration and service agreement where Curetis acts as central reference lab for a clinical trial (e.g. in the Cempra phase III oral solithromycin trial in community-acquired bacterial pneumonia) 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. This latter model was currently pursued under the phase III Amikacin trial and was also the model of choice in a former Sanofi Pasteur phase IIb trial. The most recent pharmaceutical collaboration project is the Biotest PEPPER study for Pentaglobin® where IAI Application Cartridges are being used to test two matched samples from 100 patients (one ascites and one positively flagged blood culture specimen amounting to 200 samples in total). The first patients were enrolled into this study by Biotest in 2017 and Curetis expects to receive the first batch of samples to be tested in-house by Curetis using the IAI Application Cartridge during the second half of 2018.

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.

**Table 5: Curetis’ projects with pharmaceutical partners**

<b>Pharmaceutical Partner</b>	<b>Study Phase</b>	<b>Drug Compound</b>	<b>Status</b>
Sanofi Pasteur (SP)	Phase IIb	KB001-A Project	Terminated upon return of drug from SP to Kalobios
Cempra	Phase III	Oral solithromycin in Community Acquired Pneumonia	Completed
Large Pharmaceutical Company	Phase III	Amikacin in VAP	Completed
Biotest	Phase IIb	PEPPER Pentaglobin® trial	Ongoing

Economics in these collaborations range from a simple “each party bears their own cost and owns their own data” (Cempra) to outright purchases of the Unyvero System, Unyvero software and Application Cartridges (e.g. Sanofi) with added full-time equivalent (“FTE”) based services provided by Curetis upon request such as installation, trainings, on-going service and support. However, none of these agreements include any licences

being granted by Curetis to any of the partners and hence there are also no milestones nor royalties on future product sales to be expected. The upside potential lies in the ability to broaden and expand the installed base of the Unyvero Platforms at the expense of pharmaceutical partners and their trials.

### ***MGI***

For a description of the MGI agreement, see “— Material Contracts — Strategic Partnerships and Collaboration Agreements — MGI”.

### **Production**

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 US FDA inspections and manufacturing standards.

So far, no decision has been made on the selection of the OEM provider for the series production of the Unyvero A30 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.

Up to 1,900 Application Cartridges can be manufactured per week with a single eight-hour shift for five days a week, following an increase in manufacturing capacity in the second quarter in 2018. The current output can be increased by extending the manufacturing shifts up to a 24/7 manufacturing operation and by undertaking small changes and moderate incremental investment in the production line. The current Application Cartridge assembly line is highly automated and complies with ISO 13485 requirements (and is also expected to be 21 CFR 820 compliant for the manufacturing of the LRT Application Cartridges and consumables) and is operated in three ISO 8 and ISO 7 cleanrooms. Throughout the manufacturing process, each Application Cartridge and its components are validated by a suite of in-process quality control measurements in order to ensure consistent, stable and reliable product quality with a high first-pass yield. Finally, every batch of Application Cartridges produced is subject to final Quality Control (“QC”) release testing with well-defined negative as well as positive control materials.



Curetis expects future Application Cartridges to be used with the Unyvero A30 *RQ* Analyzer 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.

## Marketing and Sales

### *Customers*

In 2016, Curetis' commissioned an EU commercial team of direct sales, marketing and customer service personnel to market the Unyvero System. Additionally, in the US, Curetis hired an executive core team in 2016 and between the second half of 2017 and the second quarter of 2018 has built out its commercial organisation to a total of 25 staff by 30 June 2018. Both commercial organisations were responsible for initially vetting market research that had been done starting in 2009 through to the present.

Curetis' commercial teams have identified several stakeholder groups: treating clinicians, doctors of pharmacy (PharmDs), antibiotic stewardship programmes, 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 hospitalised 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. Table 6 below presents Curetis' key stakeholders and key messages relating to the Unyvero Platform's selling proposition:

**Table 6: Curetis' key stakeholders and key messages relating to the Unyvero Platform**

Key Stakeholder	Key Messages
Treating clinicians	<ul style="list-style-type: none"> <li>fast and accurate</li> </ul>
Doctors of pharmacy (PharmDs)	<ul style="list-style-type: none"> <li>understandable and useful information</li> </ul>
Antibiotic Stewardship Programmes	<ul style="list-style-type: none"> <li>In EU can be operated in different hospital wards, particularly relevant in ICUs where 24/7 access is key</li> <li>PharmDs as part of and in conjunction with, antibiotic stewardship programmes, can be instrumental in developing, changing and implementing hospital algorithms for treatment pathways for hospitalised patients as well as potential economic impact of new technologies</li> </ul>
Microbiologists	<ul style="list-style-type: none"> <li>ease of use</li> <li>minimal hands-on time</li> <li>on-demand random-access</li> <li>full automation, walk away</li> <li>fast and accurate</li> </ul>
Molecular biologists / laboratory managers	<ul style="list-style-type: none"> <li>ease of use</li> </ul>

#### Hospital administration

- minimal hands-on time
- full transparent total cost of ownership
- integration, automation
- health economics arguments such as reduced length of stay, more prudent use of antibiotics, disaster prevention in multidrug resistant outbreaks, identifying additional DRG codes that can be applied to certain patients to allow for optimised margins

### ***Sales Process***

Curetis' 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 optimising 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 US, the Unyvero System will be placed in the core laboratory, In the EU and the 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 six to nine months, based on the experience of competitors and peer companies, in the US and around nine to 12 months 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. In the IVD market, hospitals with more than 500 beds generate approximately 80% of the Curetis' revenues but represent only 20% of the Curetis' customer base in any given period. Therefore, the Curetis 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 orthopaedics wards depending on the particular Application Cartridge being promoted.

Accordingly, Curetis focuses direct sales activities on university or teaching hospitals and hospital chains with more than 300 beds and greater in the US. In the US, Curetis intends to target 700-1,000 relevant hospitals. In its direct sales region in Europe (as defined below) Curetis currently aims to address more than 714 relevant

target hospitals with 500 beds and greater. Furthermore, Curetis has identified approximately 1,200 target hospitals in sales regions where Curetis is currently engaged in indirect sales via a distributor or is striving for future indirect channels. Curetis' 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 aims to optimise the utilisation of each placed hardware unit rather than solely maximising the installed base of instruments. Therefore, Curetis, with its tests primarily targeting in-patients (hospitalised) with severe infections, is focusing its sales and commercialisation efforts on laboratories in hospitals and independent laboratories serving larger hospitals. Customer segmentation relies on the size of the hospital defined by the number of beds per institution (see table 7). In addition to the relevant target hospitals Curetis estimates that there are more than 2,810 self-administered MDx labs in Europe and more than 2,000 of these laboratories are present in the US. Furthermore, 1,399 target hospitals in China and 56 target hospitals in certain ASEAN markets have been identified by Curetis (see table 8).

**Table 7: Estimated hospitals by country and size as of August 2018**

		Small	Medium	Large
	Total number of hospitals	(up to 199 beds)	(200 to 499 beds)	(>499 beds)
<b>Hospitals by country and size</b>				
Austria.....	280 <sup>(3)</sup>	180 <sup>(3)</sup>	65 <sup>(3)</sup>	30 <sup>(3)</sup>
Germany.....	1,800 <sup>(1)</sup>	900 <sup>(1)</sup>	670 <sup>(1)</sup>	250 <sup>(1)</sup>
Switzerland.....	300 <sup>(1)</sup>	250 <sup>(1)</sup>	40 <sup>(1)</sup>	15 <sup>(1)</sup>
Italy.....	1,400 <sup>(1)</sup>	930 <sup>(1)</sup>	330 <sup>(1)</sup>	130 <sup>(1)</sup>
France.....	1,950 <sup>(1)</sup>	1,100 <sup>(1)</sup>	600 <sup>(1)</sup>	250 <sup>(1)</sup>
UK.....	950 <sup>(1)</sup>	630 <sup>(1)</sup>	180 <sup>(1)</sup>	170 <sup>(1)</sup>
Spain.....	800 <sup>(1)</sup>	520 <sup>(1)</sup>	200 <sup>(1)</sup>	100 <sup>(1)</sup>
Sweden.....	80 <sup>(1)</sup>	40 <sup>(1)</sup>	20 <sup>(1)</sup>	15 <sup>(1)</sup>
Netherlands.....	90 <sup>(1)</sup>	10 <sup>(1)</sup>	60 <sup>(1)</sup>	30 <sup>(1)</sup>
Germany, Austria and Switzerland.....	2,380 <sup>(1) (3)</sup>	1,330 <sup>(1) (3)</sup>	775 <sup>(1) (3)</sup>	295 <sup>(1) (3)</sup>
Europe (incl. countries listed above).....	7,650 <sup>(1) (3)</sup>	4,560 <sup>(1) (3)</sup>	2,165 <sup>(1) (3)</sup>	990 <sup>(1) (3)</sup>
US.....	5,700 <sup>(1)</sup>	3,350 <sup>(2)</sup>	1,600 <sup>(2)</sup>	730 <sup>(2)</sup>

Notes:

(1) Data information intelligence GmbH (2015);

(2) Hospital size numbers extrapolated based on shares in the EU CDC (2011);

(3) Bundesministerium für Gesundheit (2014).

**Table 8: Estimated number of Hospitals in China, Indonesia, Thailand, Malaysia and Singapore as of August 2018**

Hospitals by country	Total number of hospitals	Total number of potential target hospitals >500 beds[*] > 800 beds[**]
China	760,000 <sup>(1)</sup>	1,400 <sup>(1)</sup> (>500 beds) 700 <sup>(2)</sup> (>800 beds)
Indonesia	2,200 <sup>(3)</sup>	10 <sup>(2)</sup> (>800 beds)
Thailand	1,300 <sup>(4)</sup>	20 <sup>(2)</sup> (>800 beds)
Malaysia	400 <sup>(5)</sup>	26 <sup>(2)</sup> (>800 beds)
Singapore	260 <sup>(6)</sup>	10 <sup>(6)</sup>

Notes:

- (1) Novumed (2013a);
- (2) Novumed (2013b);
- (3) Exim Bank Malaysia (2014);
- (4) Asia Pacific Observatory on Health Systems and Policies (2015);
- (5) REFSA (2015);
- (6) Ministry of Health Singapore (2014).

Curetis will also face certain market entry barriers mostly related to upfront investments for the implementation of its new technology, as most laboratories and microbiology centres are cost centres, 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 will pursue a sales strategy whereby it will offer 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).

### ***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 US. 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.

It is not uncommon for clinicians not to be fully trained with respect to the underlying microbiology of infectious diseases and antibiotic treatment schemes, or on MDx approaches. In particular, genotypic antibiotic resistance markers, their interpretation and correlation to phenotypic resistance profiles are not common knowledge.

Therefore, Curetis' marketing in addition focuses on medical education of physicians through its team of clinical application specialists, participation in scientific conferences, organising scientific sessions and symposia, and by publications in peer-reviewed journals. The conference schedule primarily focuses on well selected scientific congresses e.g. ECCMID, American Association for Clinical Chemistry ("AACC"), Interscience Conference on Antimicrobial Agents and Chemotherapy ("ICAAC"), Deutsche Gesellschaft für Hygiene und Mikrobiologie ("DGHM"), Österreichische Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin ("ÖGHM"), Schweizer Gesellschaft für Mikrobiologie ("SGM"), American Society for Microbiology ("ASM"), Association for Molecular Pathology ("AMP"), Clinical Virology Symposium ("CVS") and ID Week and others, if appropriate.

Curetis also creates awareness of its products through marketing materials produced for the Curetis sales team and its third-party partners that helps the sales team convey the message regarding the required investment in Curetis products based on medical outcome improvements and streamlining laboratory processes.

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 US. Both advisory boards are comprised of key opinion leaders. In addition, follow-on research and clinical studies are conducted at 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; and
- 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.

Strong KOLs can help to shape the adoption curve as lead users may turn into first clients and can become high volume end-users. Initial usage by some of these KOL driven sites, such as Essen, Basel, London / Norwich, and Nantes in Europe and the University of North Carolina, National Children's Hospital, Columbia University and the Mayo Clinic in the US, can range up to several hundred Application Cartridges per year as part of clinical evaluation studies (partly or fully sponsored by Curetis) and can eventually, assuming adoption of the Unyvero Platform, also result in commercial purchase of several hundred Application Cartridges per year thereafter.

### ***Distribution Channels***

To distribute the Unyvero System and the Application Cartridges, Curetis has adopted a dual approach combining direct sales in the home markets of Germany, Austria and Switzerland (although Switzerland may be covered from Germany in the future), and other key markets such as the UK, France and Benelux with indirect sales through specialised distributors in other European countries such as 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 US (together the "RoW"). While it is currently beyond the means of Curetis to adopt a direct sales model in all

geographies, the company considers it of utmost importance to directly sell the Unyvero Platform in many relevant key markets right from the start to obtain direct customer feedback and further develop its product portfolio according to market needs.

In addition, Curetis is addressing the US through its own dedicated sales and marketing organisation.

The choice between direct sales and indirect sales distribution is based on 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 therefore 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***

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. Curetis' sales team for this region and its other direct sales markets in Europe is currently headed by Riwat Lim as Director Commercial Operations EMEA, and is comprised of five key account managers with backgrounds in instrument placements and consumable sales into the hospital market and considerable experience in the IVD market. The team combines expertise in microbiology with expertise in hospital IVD sales, instrument business, and consumable sales. Since its IPO in 2015, Curetis has 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 30 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.

The initial US launch commenced following the FDA clearance, which was granted on 3 April 2018. See “—*US Market*” below for further details.

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), minimising downtime for the customer as well as reducing the need for a costly service organisation. 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.

Curetis plans to further develop this commercial organisation in line with the market adoption of the Unyvero System and its growing product portfolio. This is expected to result in additional incremental recruiting for Germany and Western European Markets direct sales teams as well as for corresponding application specialist support. As of 30 October 2018, Curetis' installed base via direct sales efforts comprised 87 Unyvero A50 Analyzers.

### ***Indirect Sales Markets***

In addition to the direct sales initiative of Curetis' commercial team, as of the date of the Prospectus there are several distribution agreements in place for the following European countries:

- Austria, Czech Republic, Slovakia, Slovenia and Croatia: Axon Lab;
- Spain, Portugal: Diagnostics and Research Products; Laboratorios LETI, S.L.U;
- Italy: Arrow Diagnostics;
- Romania: Synttergy Consult LTD;
- Bulgaria: SGP Bio Dynamics Ltd;
- Greece: Helix Squared P.C; and

In the RoW markets, Curetis currently plans to commercialise 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. As of 30 October 2018, Curetis' installed base via distributors comprised 52 Unyvero Systems.

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

- Russia, Ukraine, Kazakhstan: BioLine LLC;
- Belarus: BioLine BS LLC;
- Qatar & UAE: Al Zahrawi;
- Kuwait: ATOC;
- Singapore, Malaysia, Indonesia and Thailand: Acumen;
- China, Taiwan and Hong Kong: Beijing Clear Biotech/ Technomed (Hong Kong) Ltd.;
- Israel: Eldan;
- Egypt Future Horizons Scientific;
- Mexico: Quimica Valaner; and
- 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 Beijing Clear Biotech's commitment, which applies over an eight year period

following CFDA approval and 1,533,264 Application Cartridges (HPN, ITI, BCU, IAI, UTI) of which approximately 1,500,000 are part of Beijing Clear Biotech's commitment) in the period between 2018 and 2027, subject to extension in certain events (for example, regulatory delays in the case of China). Investors should note that the failure of distributors to reach minimum purchase quantities does not normally lead to a "forced" purchase of the minimum quantities, but to a termination of the distribution agreements or termination of exclusivity in territories for such distributor. The above minimum purchase requirements do not guarantee any certain minimum future levels of revenues.

### ***US 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 5th 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 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.

Curetis markets and sells the Unyvero Platform and will market any future cleared Application Cartridges directly in the US through its own US-based commercial organisation 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, US, shortly after trial enrolment was completed. A core leadership team of five were hired over the next six months. The 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 US employees to 25 as of the date of the Prospectus.

Using the proceeds from this Offering, Curetis intends to continue to develop commercial teams in the US based on market demand and growth initiatives. Curetis USA spent the last half of 2017 and early 2018 preparing for the US launch which included surveying and testing the market in the areas of pricing, messaging and positioning. Since the launch of the Unyvero System and LRT Application Cartridge in the U.S., Curetis' U.S. commercial team has initially qualified more than 140 accounts as potential first buyers of Unyvero Systems out of a total approximately 1,000 hospitals identified by Curetis to be initial targets for the Unyvero LRT Application Cartridge. Of those qualified accounts, more than 60 have been thoroughly vetted by Curetis and many are expected to be converted to commercial accounts over the next several quarters with approximately ten accounts constituting near term opportunities currently at the contract negotiation stage. These initial ten accounts on average are expected to have Unyvero LRT Application Cartridge volumes of 700 to 800 annually once they become commercial customers. The estimated Unyvero LRT Cartridge volume potential for the more than 60 accounts in advanced stages of qualification range from approximately 250 to over 1,600 per year.

Curetis plans to further develop this US subsidiary and commercial organisation in line with the market adoption of the Unyvero Platform and its growing product portfolio. See "*Operating and Financial Review and Prospects -- Recent Developments and Outlook*".

### **Pricing and Reimbursement**

#### ***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 programmes, 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-patients 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 analysed existing reimbursement schemes in Germany, Austria and Switzerland, as well as other European countries and the US, where hospitalised in-patients with severe infections are typically covered under the DRG system. With DRG, hospitals receive a lump-sum payment, e.g. up to €22 thousand in Germany for a life-threatening case of VAP treated in intensive care.<sup>105</sup> Therefore, Curetis has taken the strategic direction to target hospitalised 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 favourable in some countries, such as the US, 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 favourable 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.

### ***Outcomes research and health economics***

Curetis' management believes that outcomes-based research which demonstrates actual medical and economic benefits upon implementing the Unyvero Platform, and health economic modelling proving the medical and economic value of the Unyvero will considerably support the commercial sales and backing-up the Application Cartridges sales price, particularly in areas where no reimbursement is currently available.

The ongoing and planned clinical studies are expected to demonstrate:

- diagnostic value for labs/microbiologists/clinicians;
- clinical utility/medical outcome improvement to clinicians (e.g. reduction in length of stay or reduced antibiotics usage or shorter time to adequate antibiotic therapy selection); and
- economic outcome improvement to hospital administration/payers (for details see below).

In cooperation with external experts, Curetis has created an internal health economic app conducting a health economic model utilising VAP patients to demonstrate the potential value of the HPN Application Cartridge compared against today's standard, microbial culture. This economic modelling app 'Impact of Faster Pneumonia Testing with the HPN Application Cartridge' (internally named BaseCase app) provides clinical evidence and estimates health outcome costs related to the utilisation of the Unyvero Platform specific to a hospital. The model is evidence based, relies on scientific publications about its input and output variables. Those include: number of ICU beds in the hospital, number of cases suspicious for VAP, average age of death, overall life expectancy, inadequate treatment rate, mortality rate among patients with inadequate initial therapy, LOS, and cost of standard of care, with respect to Unyvero testing. The data and assumptions in the model are based on comprehensive US and EU studies showing that initial inadequate treatment results in higher mortality

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<sup>105</sup> Universitätsklinikum Münster (2015).

and an average longer LOS in the ICU, compared to patients with initial adequate treatment.<sup>106</sup> Indeed, 10%-73% of VAP treatment is reported to be inadequate.<sup>107</sup> Regarding LOS, the ICU stay is increased by six days to a total length of 32.8 days in ICU for inadequate treatment, while for an adequate treatment a LOS in the ICU of 26.3 days has been identified.<sup>108</sup> A mortality rate of 35% for adequate treatment of VAP rises to 48%, if VAP is treated inadequately.<sup>109</sup> Of US hospitalized patients with pneumonia, those with VAP have the highest costs (around \$64,000 for cases hospitalized between January 1, 2008 and March 31, 2015) and longest LOS (21 days).<sup>110</sup> In a study shorter LOS translates into an overall cost reduction ranging from approximately of US\$6 thousand per VAP patient.<sup>111</sup> As Unyvero does not intend to replace microbiology, but rather complement it, its implementation will of course add costs to the laboratory.

### **Pricing**

Curetis has implemented a pricing strategy similar to a classic razor/razor-blade business model with covering only full-costs, or very low margins for hardware, but with substantial margins for the consumables. In its initial market assessment, Curetis assessed pricing based on total process and process flow cost of standard of care, as well as of using competitive products. Curetis research on infectious disease tests confirmed that target prices should be set at least at a similar level to the total cost of ownership of currently marketed manual or semi-automated tests. The modular concept of the Unyvero Platform not only meets various throughput needs, but also allows set-up of a minimal configuration at reasonable total cost of ownership which can be easily expanded with growing test demand. This approach has been independently validated in some customer settings where other MDx kits have been replaced by HPN Application Cartridges at near full list prices.

Most of the currently available low-complexity molecular tests on the market are in the price range of €15 to €25 for centralised testing and €30 to €40 for decentralised testing. Higher complexity molecular infectious disease tests (more than 10 parameters) are in the price range of €90 to €205. Curetis believes that the advanced features of the Unyvero Platform, such as faster time-to-answer with the potential to improve patient management, justify a pricing premium and thus the company is pursuing a value-added pricing strategy. Such pricing is based on the modelled health economic savings overall and a certain proportion of these savings to be allocated to the Application Cartridge prices with the remainder benefiting the hospital budgets and ultimately the healthcare system at large.

Therefore, Curetis sets end-customer list-prices for its CE-IVD-marked Application Cartridges in the EU direct sales markets in the range of €192 (HPN Application Cartridge) to €262 (ITI Application Cartridge) and the currently offered discount structure also reflects this pricing premium. In the US, US\$245 is the current list price of the LRT Application Cartridge. This pricing strategy is supported by an estimation of the perceived value of Unyvero products through customer feedback and accounts for the simultaneous test of between 40 (HPN) via 102 (ITI), 103 (BCU and UTI) all the way up to 130 (IAI) analytes in Europe and 29 in the US with the LRT Application Cartridge) as well as for the sample preparation fully integrated in the Unyvero Platform. Lastly, the initially targeted customers are early innovators and fast adopters, which Curetis believes are typically less price-sensitive.

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<sup>106</sup> Kollef *et al.* (2006), Rello (2011).

<sup>107</sup> Piskin *et al.* (2012).

<sup>108</sup> Rello (2011).

<sup>109</sup> Rello *et al.* (2012).

<sup>110</sup> Sun *et al.* (2016).

<sup>111</sup> Ost *et al.* (2003).

## Intellectual Property

It is essential for Curetis to achieve and ensure a sustainable and reliable protection of the intellectual property rights related to the Unyvero Platform products and the underlying proprietary technology and manufacturing processes. To this end, Curetis have sought and will continue to seek to obtain and maintain patents and other applicable forms of protection for inventions, know-how, as well as proprietary technology and manufacturing processes of commercial relevance.

Curetis utilises different methods to achieve the desired protection, including patents (see table 9.1, 9.2 and 9.3 below), design registrations (see table 10 below), trademarks (see table 11 below), copyrights and trade secrets. Where necessary, Curetis may also rely on third parties to develop, complement and maintain its proprietary position. Curetis' success will furthermore depend on its ability to defend and enforce its intellectual property rights, to maintain its licences, to use third-party intellectual property rights, to preserve the confidentiality of its trade secrets and to operate without infringing the valid and enforceable patents and other proprietary rights of third parties.

### *Patents*

Curetis' granted and filed patents focus on protecting critical elements of the instrumentation of the Unyvero Platform and the proprietary Application Cartridges, specifically related to sample preparation and homogenisation and to DNA amplification and detection. All patent inventors are Curetis' employees or members of its Management Board.

- The patent titled “Universally Applicable Lysis Buffer and Processing Methods for the Lysis of Bodily Samples” relates to sample preparation and homogenisation (patent belongs to patent family 1). The patent has been issued (in Singapore grant date 13 May 2015), has been granted in Australia (term: twenty years from 9 May 2011), has been issued in the US (21 Mar 2017), has been granted in Japan (3 Mar 2017), has been granted in EP (grant date: 12 Jul 2017, nationalized in CH, DE, ES, FR, GB, IT and NL), has been granted in Hong Kong and is pending in Canada and India. An opposition has been filed anonymously on 10 Apr 2018 against the EP patent. As a result of the opposition, the patent may remain in force in its granted form, may require amendment of the claims or may be revoked completely. Even in the case of revocation of the patent, Curetis believes that the sample handling procedure for the Unyvero Platform may still be protected by the patent application entitled “Apparatus and Method for a Lysis of a Sample, in particular for an Automated and/or Controlled lysis of a Sample” as described below, if this opposition proceeds in Europe. The time limit for response to the communication has been extended to 2 November 2018 to allow presentation of additional data.
- The patent titled “Reaction Vessel For PCR Device and Method of Performing PCR”, relating to the Unyvero PCR Chamber, describes a method to perform an integrated PCR and detection in one integrated reaction vessel (patent belongs to patent family 2). The patent has been filed and has been granted in Australia (term: 20 years from 19 May 2011), has been granted in the US (14 Mar 2017), has been granted in China (19 Aug 2015), has been granted in Japan (26 Aug 2016), has been granted in Canada (24 Apr 2018) has been granted in Singapore (25 Sep 2015) and is pending in the EU, Hong Kong and India. For details, see table 9.1 below.
- The patent titled “Apparatus and Method for a Lysis of a Sample, in particular for an Automated and/or Controlled Lysis of a Sample”, relating to the instrumentation for and sample preparation and homogenisation (patent belongs to patent family 3). The patent has been filed and has been granted in Australia (16 Jun 2016), has been granted in the US (8 May 2018), has been granted in China (30 Jun 2017), has been granted in Japan (21 Apr 2017) and is pending in the EU and Canada. For details, see table 9.1 below.

**Table 9.1: Curetis' inventor and patent overview**

Application number	Country	Title	Application date	Publication date	Publication number	Issue date	Patent number	Status
2011254936	Australia	Universally Applicable Lysis Buffer And Processing Methods For The Lysis Of Bodily Samples (Patent Family 1)	09.05.2011	20.12.2012	AU 2011254936 A1	11.06.2015	2011254936	In force
2,799,599	Canada		09.05.2011	24.11.2011	CA 2799599 A1			Pending / Notice of Allowance
11 718 666.8	European patent		09.05.2011	27.03.2013	2 571 976	12.07.2017	2 571 976	In force / Opposition
11 718 666.8	Switzerland		09.05.2011			12.07.2017	2 571 976	In force
11 718 666.8	Germany		09.05.2011			12.07.2017	2 571 976	In force
11 718 666.8	Spain		09.05.2011	13.10.2017	ES 2637589 T3	12.07.2017	2 571 976	In force
11 718 666.8	France		09.05.2011			12.07.2017	2 571 976	In force
11 718 666.8	UK		09.05.2011			12.07.2017	2 571 976	In force
11 718 666.8	Hong Kong		09.05.2011	01.11.2013	1181071A	21.09.2018	HK1181071	In force
11 718 666.8	Italy		09.05.2011			12.07.2017	2 571 976	In force
11 718 666.8	Netherlands		09.05.2011			12.07.2017	2 571 976	In force
9666/DELNP/2012	India		09.05.2011					Pending
2013-510514	Japan		09.05.2011	24.06.2013	2013-526284	03.03.2017	6100162	In force
201208221-0	Singapore		09.05.2011	28.12.2012	SG185466 A1	13.05.2015	185466	In force
13/698,216	US		09.05.2011	14.03.2013	US-2013-0065223-A1	21.03.2017	9,598,721	In force

Application number	Country	Title	Application date	Publication date	Publication number	Issue date/Registration date	Patent number/Registration number	Status
PCT/EP2011/003770	WO	Apparatus and Method for a Lysis of a Sample, in particular for an Automated and/or Controlled Lysis of a Sample (Patent family 3)	27.07.2011	31.01.2013	WO 2013/013687			Pending
2011373961	Australia		27.07.2011			16.06.2016	2011373961	In force
2,839,951	Canada		27.07.2011					Pending
2011800726 24.9	China		27.07.2011	09.04.2014	CN103718012A	30.06.2017	ZL 2011800726 24.9	In force
11 743 026.4	European patent		27.07.2011	04.06.2014	2 737 294			Pending
JP 2014-521955	Japan		27.07.2011	25.09.2014	2014-525041	21.04.2017	6130831	In force
14/232,391	US		27.07.2011	28.08.2014	US-2014-0242678-A1	08.05.2018	9,963,670	In force
15/942,702	US		27.07.2011					Pending
PCT/EP2011/002507	WO	Reaction Vessel For PCR Device And Method Of Performing PCR (Patent family 2)	19.05.2011	24.11.2011	WO 2011/144345			Pending
2011254887	Australia		19.05.2011			17.07.2014	2011254887	In force
2,799,676	Canada		19.05.2011			24.04.2018	2,799,676	In force
2011800244 84.8	China		19.05.2011	13.02.2013	CN 102933300A	19.08.2015	ZL 2011800244 84.8	In force
11 720 402.4	European patent		19.05.2011	27.03.2013	2 571 617			Pending
13110773.7	Hong Kong		19.05.2011	27.12.2013	1183460A			Pending
9813/DELNP/2012	India		19.05.2011	29.01.2016	05/2016			Pending
2013-510521	Japan		19.05.2011	27.06.2013	2013-526867	26.08.2016	5992904	In force
201208222-8	Singapore		19.05.2011			25.09.2015	185467	In force
13/698,805	US		19.05.2011	23.05.2013	US-2013-0130267-A1	14.03.2017	9,592,511	In force

Legend: "Pending": The patent application has been received by the respective patent office; "In Force": patent has been granted by the respective patent office. "Published": Publication date; WO = World Organisation for Intellectual Property.

Patent Family 1 relates to the initial sample lysis and liquefaction process; Patent Family 2 relates to instrumentation when used in conjunction with the described reaction vessel for PCR device within a dependent claim; Patent Family 3 relates to the instrumentation for the lysis process and is not protecting the Unyvero Application Cartridge, but the instrumentation.

Patents of the type mentioned above are typically granted between two and seven years upon filing. Any granted patents will expire 20 years after filing.

With the acquisition of the Gyronimo asset, four additional patents have been acquired. All inventors of these patents are outside of Curetis.

**Table 9.2: Gyronimo (now Unyvero A30 RQ) inventor and patent overview**

Application number	Country	Title	Application date	Publication date	Publication number	Issue date/Registration date	Patent number/Registration number	Status
PCT/EP2009/005031	WO	Device for analysing a chemical or biological sample	10.07.2009	14.01.2010	WO 2010/003690	—	—	Pending
PI0915736-0	Brazil		10.07.2009	—	—	—	—	Pending
2,729,875	Canada		10.07.2009	—	—	05.07.2016	2,729,875	In Force
2009801269 12.0	China		10.07.2009	08.06.2011	102089080A	29.04.2015	ZL200980126912.0	In Force
09 793 891.4	European patent		10.07.2009	20.04.2011	2 310 128	05.04.2017	2 310 128	In Force
09 793 891.4	Switzerland		10.07.2009	20.04.2011	2 310 128	05.04.2017	2 310 128	In Force
09 793 891.4	Germany		10.07.2009	20.04.2011	2 310 128	05.04.2017	2 310 128	In Force
09 793 891.4	Spain		10.07.2009	20.04.2011	2 310 128	05.04.2017	2 310 128	In Force
09 793 891.4	France		10.07.2009	20.04.2011	2 310 128	05.04.2017	2 310 128	In Force
09 793 891.4	UK		10.07.2009	20.04.2011	2 310 128	05.04.2017	2 310 128	In Force
09 793 891.4	Italy		10.07.2009	20.04.2011	2 310 128	05.04.2017	2 310 128	In Force
09 793 891.4	Netherlands		10.07.2009	20.04.2011	2 310 128	05.04.2017	2 310 128	In Force
816/CHENP/2011	India		10.07.2009	02.12.2011	48/2011	—	—	Pending
13/003,016	US		10.07.2009	03.11.2011	US 2011/026913 5	21.04.2015	9,011,796	In Force
14/663,471	US		10.07.2009	09.07.2015	US 2015/019081 2	01.12.2015	9,199,238	In Force
PCT/EP2015/001681	WO	Device for separating bubbles from a fluid	14.08.2015	18.02.2016	WO 2016/023637	—	—	Pending
2,957,824	Canada		14.08.2015	—	—	—	—	Pending
2015800438 50.2	China		14.08.2015	31.05.2017	CN 106794396A	—	—	Pending
15 757 133.2	European patent		14.08.2015	21.06.2017	3 180 099	—	—	Pending
17107282.3	Hong Kong		14.08.2015	02.02.2018	1233574A	—	—	Pending
2017-508526	Japan		14.08.2015	17.08.2017	2017-523435	—	—	Pending
15/503,821	US		14.08.2015	28.09.2017	US 2017-0274379	—	—	Pending
PCT/EP2015/073382	WO	Hose pump and Device for analysing a Chemical or Biological Sample	09.10.2015	21.04.2016	WO 2016/058926	—	—	Pending
2,962,128	Canada		09.10.2015	—	—	—	—	Pending
2015800552 39.1	China		09.10.2015	18.08.2017	CN 107076136A	—	—	Pending
15 790 845.0	European patent		09.10.2015	23.08.2017	3 207 252	—	—	Pending

With the acquisition of the GEAR asset, the following patents have been acquired.

**Table 9.3: ARES Genetics patent overview**

Application number	Country	Title	Application date	Publication date	Publication number	Issue date/Registration date	Patent number/Registration number	Status
17 201 102.5	European patent	Methods for the Comprehensive Identification of Antimicrobial Resistance Markers	10.11.2017	—	—	—	—	Claiming priority only
20148004015 4.1	China	Method and System for Determining a Bacterial Resistance to an Antibiotic Drug	25.06.2014	18.05.2016	CN 105593865 A	—	—	Pending
14/905,014	US		25.06.2014	09.06.2016	US 2016/016263 5	—	—	Pending
20158001470 3.2	China	Genetic resistance testing	30.01.2015	22.02.2017	CN 106460039 A	—	—	Pending
15 702 733.5	European patent		30.01.2015	07.12.2016	3 099 813	—	—	Pending
15/115,322	US		30.01.2015	12.01.2017	US 2017/000927 7	—	—	Pending
PCT/EP2015/066658	WO	Genetic testing for predicting resistance of Gram-negative Proteus against antimicrobial agents	21.07.2015	26.01.2017	WO 2017/012653	—	—	Pending
PCT/EP2016/067440	WO		21.07.2016	26.01.2017	WO 2017/013219	—	—	Pending
2016295176	Australia		21.07.2016	—	—	—	—	Pending
2,991,090	Canada		21.07.2016	—	—	—	—	Pending
16 753 587.1	China		21.07.2016	10.07.2018	CN 108271398 A	—	—	Pending
16 753 587.1	European patent		21.07.2016	30.05.2018	3 325 659	—	—	Pending
15/745,253	US		21.07.2016	—	—	—	—	Pending
2,961,266	Canada		06.08.2015	—	—	—	—	Pending
20158006331 0.0	China	Genetic testing for predicting resistance of klebsiella species against antimicrobial agents	06.08.2015	08.06.2018	CN 108138219A	—	—	Pending
15 750 681.7	European patent		06.08.2015	02.08.2017	3 198 025	—	—	Pending
15/512,166	US		06.08.2015	05.10.2017	US 2017-0283862	—	—	Pending
PCT/EP2015/062202	WO	Genetic Testing for Predicting Resistance of Shigella Species Against Antimicrobial Agents	02.06.2015	08.12.2016	WO 2016/192772	—	—	Pending
PCT/EP2016/062379	WO		01.06.2016	08.12.2016	WO 2016/193306	—	—	Pending
2016273220	Australia		01.06.2016	—	—	—	—	Pending
2,987,866	Canada		01.06.2016	—	—	—	—	Pending
20168003252 7.X	China		01.06.2016	20.04.2018	CN 107949644 A	—	—	Pending
16 727 451.3	European patent		01.06.2016	11.04.2018	3 303 617	—	—	Pending
15/578,333	US		01.06.2016	31.05.2018	US 2018/014876 2	—	—	Pending
PCT/EP2015/065971	WO		13.07.2015	19.01.2017	WO 2017/008835	—	—	Pending
PCT/EP2016/066628	WO	Genetic Testing for Predicting Resistance of Acinetobacter Species Against Antimicrobial Agents	13.07.2016	19.01.2017	WO 2017/009374	—	—	Pending
2016293027	Australia		13.07.2016	—	—	—	—	Pending
2,991,085	Canada		13.07.2016	—	—	—	—	Pending
20168003959 6.3	China		13.07.2016	10.07.2018	CN 108271397 A	—	—	Pending
16 741 589.2	European patent		13.07.2016	23.05.2018	3 322 818	—	—	Pending
15/743,926	US		13.07.2016	19.07.2018	US 2018/020197 9	—	—	Pending
PCT/EP2015/066711	WO		22.07.2015	26.01.2017	WO 2017/012659	—	—	Pending
PCT/EP2016/067437	WO		21.07.2016	26.01.2017	WO 2017/013217	—	—	Pending
2016295174	Australia	Genetic Testing for Predicting Resistance of Salmonella Species Against	21.07.2016	—	—	—	—	Pending
2,990,894	Canada		21.07.2016	—	—	—	—	Pending

20168003854 0.6	China	Antimicrobial Agents	21.07.2016	10.07.2018	CN 108271394 A	—	—	Pending
16 745 656.5	European patent		21.07.2016	30.05.2018	3 325 656	—	—	Pending
15/745,330	US		21.07.2016	—	—	—	—	Pending
PCT/EP2015/ 066773	WO	Genetic Testing for Predicting Resistance of Pseudomona s Species Against Antimicrobial Agents	22.07.2015	26.01.2017	WO 2017/012661	—	—	Pending
PCT/EP2016/ 067406	WO		21.07.2016	26.01.2017	WO 2017/013204	—	—	Pending
2016295122	Australia		21.07.2016	—	—	—	—	Pending
2,990,908	Canada		21.07.2016	—	—	—	—	Pending
20168003853 9.3	China		21.07.2016	07.09.2018	CN 108513589 A	—	—	Pending
16 745 655.7	European patent		21.07.2016	30.05.2018	3 325 655	—	—	Pending
15/745,633	US		21.07.2016	20.09.2018	US 2018/026591 3	—	—	Pending
PCT/EP2015/ 067382	WO	Genetic testing for predicting resistance of Enterobacter species against antimicrobial agents	29.07.2015	02.02.2017	WO 2017/016600	—	—	Pending
PCT/EP2016/ 067610	WO		25.07.2016	02.02.2017	WO 2017/017044	—	—	Pending
2016299327	Australia		25.07.2016	—	—	—	—	Pending
2,991,670	Canada		25.07.2016	—	—	—	—	Pending
20168004223 6.9	China		25.07.2016	10.07.2018	CN 108271400 A	—	—	Pending
16 745 674.8	European patent		25.07.2016	06.06.2018	3 329 008	—	—	Pending
15/747,046	US		25.07.2016	—	—	—	—	Pending
PCT/EP2015/ 066762	WO	Genetic testing for predicting resistance of Serratia species against antimicrobial agents	22.07.2015	26.01.2017	WO 2017/012660	—	—	Pending
PCT/EP2016/ 067442	WO		21.07.2016	26.01.2017	WO 2017/013220	—	—	Pending
2016295177	Australia		21.07.2016	—	—	—	—	Pending
2,991,673	Canada		21.07.2016	—	—	—	—	Pending
20168004201 9.X	China		21.07.2016	10.07.2018	CN 108271399 A	—	—	Pending
16 745 657.3	European patent		21.07.2016	30.05.2018	3 325 657	—	—	Pending
15/745,645	US		21.07.2016	—	—	—	—	Pending
PCT/EP2015/ 066699	WO	Genetic testing for predicting resistance of Morganella species against antimicrobial agents	22.07.2015	26.01.2017	WO 2017/012658	—	—	Pending
PCT/EP2016/ 067446	WO		21.07.2016	26.01.2017	WO 2017/013223	—	—	Pending
2016296900	Australia		21.07.2016	—	—	—	—	Pending
2,991,666	Canada		21.07.2016	—	—	—	—	Pending
20168003875 8.1	China		21.07.2016	10.07.2018	CN 108271395 A	—	—	Pending
16 745 658.1	European patent		21.07.2016	30.05.2018	3 325 658	—	—	Pending
15/745,935	US		21.07.2016	09.08.2018	US 2018/022333 6 A1	—	—	Pending
PCT/EP2015/ 067413	WO	Genetic testing for predicting resistance of Stenotropho monas species against antimicrobial agents	29.07.2015	02.02.2017	WO 2017/016602	—	—	Pending
PCT/EP2016/ 067611	WO		25.07.2016	02.02.2017	WO 2017/017045	—	—	Pending
2016299328	Australia		25.07.2016	—	—	—	—	Pending
2,991,671	Canada		25.07.2016	—	—	—	—	Pending
20168003946 9.3	China		25.07.2016	10.07.2018	CN 108271396 A	—	—	Pending
16 745 675.5	European patent		25.07.2016	06.06.2018	3 329 009	—	—	Pending
15/747,295	US		25.07.2016	02.08.2018	US 2018/021616 7 A1	—	—	Pending
PCT/EP2015/ 068188	WO	Genetic testing for alignment- free predicting resistance of microorganis ms against antimicrobial agents	06.08.2015	09.02.2017	WO 2017/020967	—	—	Pending
2015404958	Australia		06.08.2015	—	—	—	—	Pending
2,992,795	Canada		06.08.2015	—	—	—	—	Pending
20158008224 6.0	China		06.08.2015	10.07.2018	CN 108271393 A	—	—	Pending
15 750 348.3	European patent		06.08.2015	13.06.2018	3 332 023	—	—	Pending

15/748,969	US		06.08.2015	—	—	—	—	Pending
PCT/EP2016/068731	WO	Genetic Resistance Prediction Against Antimicrobial Drugs in Microorganism Using Structural Changes in the Genome	05.08.2016	09.02.2017	WO 2017/021529	—	—	Pending
2016301963	Australia		05.08.2016	—	—	—	—	Pending
2,992,828	Canada		05.08.2016	—	—	—	—	Pending
20168004478 0.7	China		05.08.2016	10.07.2018	CN 108271392 A	—	—	Pending
16 751 551.9	European patent		05.08.2016	13.06.2018	3 332 028	—	—	Pending
15/749,384	US		05.08.2016	—	—	—	—	Pending
16 159 205.0	European patent	Combination of structural variations and single nucleotide changes in one statistical model for improved therapy selection	08.03.2016	13.09.2017	3 216 873	—	—	Pending
PCT/EP2017/058866	WO	Using the full repertoire of genetic information from bacterial genomes and plasmids for improved genetic resistance tests	12.04.2017	19.10.2017	WO 2017/178558	—	—	Pending
PCT/EP2017/061445	WO	Stable pan-genomes and their use	12.05.2017	16.11.2017	WO 2017/194732	—	—	Pending
PCT/EP2017/072757	WO	Combination of structural variations and single nucleotide changes in one statistical model for improved therapy selection	11.09.2017	—	—	—	—	Pending

## Designs

Curetis has registered designs for certain shapes of its products such as the Column Adaptor or the sample handling tool, as well as the design of the Unyvero C8 Cockpit, Unyvero L4 Lysator and the Unyvero A50 Analyzer, as set out in Table 10 below.

- Registered Design “Column Adaptor” has been published in the EU, Japan, US, Switzerland
- Registered Design “Sample Handling Tool” has been published in the EU, US, Switzerland
- Registered Design for “Unyvero System”, “Unyvero L4 Lysator”, “Unyvero A50 Analyzer” and “Unyvero C8 Cockpit” has been published in the EU.

**Table 10: Curetis’ design registration**

Application number	Country	Title	Application date	Priority	Registration date	Registration number	Status
2012-00413	Switzerland	Teil von Analysegerät	21.05.2012	EU 21.12.2011 001 966 433	11.07.2012	138 957	Registered
001 966 433	EU	Column Adaptor	21.12.2011	—	21.12.2011	001 966 433	Registered
2012-013717	Japan	Column Adaptor	08.06.2012	EU 21.12.2011 001 966 433	02.11.2012	1456898	Registered



29/409,184	US	Column Adapter	21.12.2011	—	21.05.2013	D683,044	Registered
002070441	EU	Sample Handling Tool	09.07.2012	—	09.07.2012	002070441	Registered
2012-00580	Switzerland	Sample Handling Tool	20.07.2012	EU 09.07.2012 002 070 441	28.08.2012	139 083	Registered
29/433,060	US	Sample Handling Tool	25.09.2012	EU 09.07.2012 002 070 441	24.02.2015	D723,180	Registered
002210401-0001, -0002, -0003, -0004	EU	Komponenten des Unyvero Systems	27.03.2013	—	27.03.2013	002210401-0001, -0002, -0003, -0004	Registered
001197560	EU	Column Adapter	24.02.2010	—	24.02.2010	001197560-0001	Registered

### ***Licences in and supplier agreements***

Curetis collaborates with several external patent attorneys across the globe to assess, evaluate and implement its intellectual property protection strategy. Curetis does not own the intellectual property for reagents and markers and their use, including the spin column, the PCR Master Mix and the fluorophore labels. These are used for pre-lysis, sample preparation, amplification, detection and quality control purposes. The detailed reagent composition is not disclosed by the suppliers. A licence is required to become a legitimate user for some of the reagents. Under its existing supplier agreement with the supplier for the reagents and the spin column used for sample preparation and the PCR Master Mix, Curetis has been granted the worldwide distribution rights for the sample preparation reagents. For the PCR Master Mix reagents, distribution rights cover all countries where Curetis is planning to become commercially active including the US.

Supplier agreements have furthermore been concluded for the supply of labelled primers and probes, including the necessary licence governing the use of fluorophore dyes that are incorporated in the Unyvero products.

The markers selected by Curetis for incorporation into the current Unyvero Platform are either in the public domain, are no longer protected by a patent or have been newly developed by Curetis. In the future, Curetis may decide to obtain a licence for one or more targets to complement Application Cartridge coverage with one or more specific markers that are protected.

Furthermore, as the functionality of future products has not yet been defined, it is not yet clear whether Curetis might need any other licences for one or more of the functions, methods, reagents or processing steps of such future products.

Standard software licences are required for the Unyvero instruments, including but not limited to a Microsoft operating system, image processing, database driver and other proprietary driver libraries. Certain open source software used in the Unyvero product requires publishing a corresponding disclaimer notice.

### ***Proprietary Rights and Processes***

In addition to the filed patents and registered designs, Curetis relies on proprietary technology and processes (including trade secrets) to protect the Unyvero products and technology. All full-time and temporary employees, scientific advisers, contractors and consultants working for Curetis who have access to confidential information of Curetis are therefore required to execute confidentiality agreements in order to safeguard Curetis' proprietary technologies, methods, processes, know-how, and trade secrets. This is complemented by preserving the integrity and confidentiality of Curetis' proprietary technology and processes by maintaining physical security of Curetis' premises and physical and electronic security of its information technology systems. All its full-time and temporary employees and where applicable, Curetis' independent contractors, manufacturing partners and consultants, are also bound by invention assignment obligations, pursuant to which rights to all inventions and other types of intellectual property conceived by them during the course of their employment are assigned and licensed to Curetis.

### ***Trademarks and domain names***

Curetis has secured trademark protection for its corporate name “Curetis” and its product platform “Unyvero” in Germany, Switzerland, the EU and the US. Both trademarks have been filed and published in China. Curetis has also obtained trademark protection for the marks “Univero” and “Trovero” in Germany, Switzerland and the EU and for the trademarks “IGENTIFYER” and “ANYLYSER” in Germany and the trademark “Gyronimo” in the EU.

Curetis has also obtained trademark protection for the “ARES Genetics” trademark in Switzerland, the EU and the US and has filed applications to register the “ARES Genetics” trademark in China and the “ARES” trademark in the US and the EU, which are currently pending.

**Table 11: Curetis’ trademark registrations**

Application number	Country	Title	Application date	Publication date	Publication number	Registration date	Registration number	Status
62910/2010	Switzerland	Univero	25.11.2010			21.03.2011	613 202	Registered
009 531 831	EU	Univero	18.11.2010	27.01.2011	009 531 831	24.05.2011	009 531 831	Registered
30 2010 032 715.4/01	Germany	Unyvero	31.05.2010	10.12.2010	30 2010 032 715	09.11.2010	30 2010 032 715	Registered
16871251	China	Unyvero	05.05.2015	27.03.2016	16871251	28.06.2016	16871251	Registered
16871250	China	Unyvero	05.05.2015	27.03.2016	16871250	28.06.2016	16871250	Registered
62908/2010	Switzerland	Unyvero	25.11.2010			21.03.2011	613 203	Registered
16871252	China	Unyvero	05.05.2015	27.03.2016	16871252	28.06.2016	16871252	Registered
009 532 029	EU	Unyvero	18.11.2010	27.01.2011	009 532 029	06.05.2011	009 532 029	Registered
017881436	EU	ARES	29.03.2018					Pending
85/068,577	US	Unyvero	22.06.2010	17.05.2011	85/068,577	26.03.2013	4,309,449	Registered
87/855,784	US	ARES	29.03.2018					Pending
30 2010 034 450.4/42	Germany	Trovero	09.06.2010	30.07.2010	30 2010 034 450	30.06.2010	30 2010 034 450	Registered
57614/2010	Switzerland	Trovero	21.07.2010			18.10.2010	606651	Registered
009 259 607	EU	Trovero	20.07.2010	20.09.2010	009 259 607	03.01.2011	009 259 607	Registered
30 2010 036 814.4/01	Germany	IGENTIFYER	18.06.2010	10.12.2010	30 2010 036 814	05.11.2010	30 2010 036 814	Registered
30 2010 036 815.2/01	Germany	ANYLYSER	18.06.2010	10.12.2010	30 2010 036 815	05.11.2010	30 2010 036 815	Registered
30 2010 041 752.8/10	Germany	Anylyser	13.07.2010	11.02.2011	30 2010 041 752	11.01.2011	30 2010 041 752	Registered
011257722	EU	Gyronimo	11.10.2012	12.06.2013	011257722	19.09.2013	011257722	Registered
26586711	China	ARES GENETICS	25.09.2017					To be lapsed
26586712	China	ARES GENETICS	25.09.2017					To be lapsed
26586713	China	ARES GENETICS	25.09.2017					To be lapsed
26586714	China	ARES GENETICS	25.09.2017					To be lapsed
61438/2017	Switzerland	ARES GENETICS	14.09.2017			05.03.2018	713 586	Registered
26586715	China	ARES GENETICS	25.09.2017					Pending
016553331	EU	ARES GENETICS	05.04.2017	15.09.2017	16553331	13.09.2017	016553331	Registered
87/517,605	US	ARES GENETICS	06.07.2017	10.04.2018	87/517,605	26.06.2018	5,500,858	Registered
30 2010 032 714.6/01	Germany	Univero	31.05.2010	10.12.2010	30 2010 032 714	09.11.2010	30 2010 032 714	Registered
51184/2010	Switzerland	Curetis	05.02.2010	27.07.2010	603 237	27.07.2010	603 237	Registered
007 160 955	EU	Curetis	14.08.2008	14.08.2008	007 160 955	28.05.2009	007 160 955	Registered
30 2008 010 146.6/44	Germany	Curetis	15.02.2008	22.08.2008	30 2008 010 146	22.08.2008	30 2008 010 146	Registered
16871248	China	Curetis	05.05.2015	27.03.2016	16871248	28.06.2016	16871248	Registered
16871246	China	Curetis	05.05.2015	27.03.2016	16871246	28.06.2016	16871246	Registered
16871249	China	Curetis	05.05.2015	27.03.2016	16871249	28.06.2016	16871249	Registered
77/930,558	US	Curetis	08.02.2010	07.12.2010	77/930,558	19.03.2013	4,305,553	Registered

Curetis currently has 11 registered domain names for the “Curetis” family of domains and 10 domain names for the “Unyvero” family of domains.

## Employees

Since it was founded in 2007, Curetis has grown from six employees to a total full-time equivalent headcount of 112.50 as of 30 June 2018 (not including marginal employment (*mini-jobs*)).

**Table 12: Curetis’ employment overview**

	Headcount as of		
	31 Dec 2016	31 Dec 2017	30 June 2018
Research & Development (incl. <i>RQ</i> ).....	32	41	44
Manufacturing .....	12	12	14
Marketing & Sales .....	26	33	42
G&A.....	12	14	16
<b>Total</b> .....	82	100	116
FTE .....	79.74	95.89	112.50

Approximately 20% of Curetis’ employees have a Ph.D. and around 45% of employees hold a Master’s degree or equivalent. Curetis’ team members have many years of relevant industry experience and have worked in a regulated industry.

Curetis’ key technical staff consists of the CTO, the COO, its Director IVD Development, Director Innovation, Technology and IP, Senior Scientists Director of Software Development, Head of Quality and Regulatory Affairs, Head of Manufacturing and Senior Engineers for firmware and hardware. The key technical staff’s relevant collective expertise and experience encompasses product development for MDx including hardware, software, assay design and Application Cartridge development, manufacturing, scientific affairs and clinical trial operations, all regulatory aspects of IVD development in the EU and US, quality management under ISO 13485, as well as a relevant background for working in the medical device and diagnostics industry.

None of Curetis’ employees are subject to any collective bargaining agreement.

## Scientific Advisory Boards

Curetis has established an EU Scientific Advisory Board consisting of four persons and a US Scientific Advisory Board consisting of five persons (together, 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.

## Material Contracts

### *Strategic Partnerships and Collaboration Agreements*

#### *Acumen*

On 5 October 2015, Curetis and Acumen entered into two separate collaboration agreements. First, a non-exclusive patent licence and research collaboration agreement, under which Curetis has obtained a limited,

royalty-bearing, non-exclusive, non-transferrable, non-sublicensable licence 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 licence and Curetis is expected to develop products based on such technology and develop a novel sepsis host response Application Cartridge which 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). 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.

Secondly, 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. Transfer prices for the Unyvero Systems and Application Cartridges are defined and reflect typical MDx industry 30% to 40% distributor margins on the consumable sales. 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*

On 25 September 2015, Curetis and Beijing Clear Biotech entered into an exclusive international distributor agreement for initially five years following CFDA approval of the Unyvero System and a first Application Cartridge. On 11 October 2018, the agreement with Beijing Clear Biotech was amended, extending the initial term of the agreement from five to eight years following CFDA 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 (such agreement as amended, the "agreement"). The agreement appoints Beijing Clear Biotech as the exclusive distributor of Unyvero Systems and HPN and ITI Application Cartridges in Greater China.

Under the agreement Beijing Clear Biotech shall be responsible for conducting and implementing, as well as fully funding, comprehensive CFDA clinical trials of the Unyvero System and the HPN and ITI Application Cartridges according to CFDA guidelines. Beijing Clear Biotech shall act as direct contact for the Beijing CFDA and is obligated to file the Unyvero Platform CFDA registration as Curetis' Chinese representative. Curetis is obligated to fully support Beijing Clear Biotech for obtaining CFDA clearance by providing its expert knowledge. Further, Curetis shall compensate Beijing Clear Biotech for certain milestone achievements, consisting of (1) initiation of up to three clinical trial sites as marked by first patient enrolment and (2) regulatory approval by CFDA of the Unyvero System and the HPN and ITI Application Cartridges. Curetis shall be responsible for the labelling of instruments and consumables according to the requirements of the CFDA during the clinical trial and after the approval.

Beijing Clear Biotech will become the exclusive distributor for Unyvero Systems and HPN and ITI Application Cartridges in Greater China. Beijing Clear Biotech 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 Beijing Clear Biotech'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. Beijing Clear Biotech 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 30% to 40% 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 Beijing Clear Biotech 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 Beijing Clear Biotech's territorial exclusivity.

With effect of 1 April 2016, Technomed (Hong Kong) Ltd assumed the role of Beijing Clear Biotech as Curetis' distributor in Hong Kong.

Under the agreement, Beijing Clear Biotech 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 €30,000 thousand annually in years six to eight of commercialization in China in addition to potential cumulative revenues of more than €60,000 thousand 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 Beijing Clear Biotech, 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 CFDA of the Unyvero System and the HPN and ITI Application Cartridges. These waivers represent a total savings to Curetis of €600 thousand over the next one to three years.

#### *MGI*

On 12 September 2017, Curetis and MGI, a fully-owned subsidiary of BGI Group, one of the world's leading genome sequencing centres 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 agreement, 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 *ARESdb*. Ares Genetics will also develop a data interpretation application that automates the bioinformatics analysis of the NGS data and supports the interpretation and visualisation 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.

In September 2017, Curetis and MGI entered also into a first collaboration agreement under the MoU to assess the feasibility of using MGISEq sequencing data with the *ARESdb* and ARES Technology Platform. In January 2018, Curetis entered into a supply and authorisation agreement as well as a further research and development collaboration and service 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 will reimburse 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***

In December 2016, Curetis acquired the real-time qPCR-based Gyronimo platform from joint owners Carpegen and Systec. Integrating Gyronimo into the Unyvero Platform for infectious disease testing allows Curetis to significantly expand its product portfolio into novel application areas such as infection control, viral testing and central nervous system infections, as well as applications for immunocompromised patients. 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 US, Canada and China, and allowed in Europe. Curetis obtained exclusive licence to Gyronimo know-how and a non-exclusive licence 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 €5,000 thousand. 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, totalling up to €2,500 thousand. 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 €9,000 thousand.

### ***GEAR asset acquisition agreement with the STA***

In September 2016, Curetis GmbH as acquirer entered into an asset acquisition agreement with 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. By 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 expanded GEAR through its wholly owned subsidiary, Ares Genetics, to the ARESdb.

## ***Manufacturing Agreements***

### ***Zollner***

On 27 May 2009, Curetis and Zollner entered into a framework agreement, pursuant to which Zollner shall perform 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 will receive a non-exclusive, non-transferable, world-wide, royalty free, irrevocable perpetual licence (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.

Over the course of the collaboration, 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 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 moulding 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 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 moulding 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 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 moulds 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 moulds, Curetis subsequently commissioned a series of multi-cavity injection moulds (owned by Curetis yet stored and used on site at Scholz) under a strategic lease agreement with Scholz for all injection moulded plastics parts entered into on 28 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.

#### *Contexo*

On 30 April 2010, Curetis and Contexo entered into a collaboration and contract manufacturing agreement for the manufacturing of a pilot line and the automated Application Cartridge manufacturing line modules. Under the terms of the agreement, Curetis receives drawings as well as comprehensive documentation of the automated manufacturing line modules and components. Curetis has acquired ownership in all of the construction documents of the pilot line whereas the copyright rights and all rights related to the Contexo index machine base technologies ("**Rundtakt- und Längstakt-Basistechnologien**") remain with Contexo.

### ***Supply Agreements***

#### *PCR Master Mix Supply Agreement*

Effective as of 19 October 2017, Curetis entered into a supply agreement, updating the previous supply agreement between the parties dated 1 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.

### ***Distribution Agreements***

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.

As at 30 October 2018, Curetis has entered into distribution agreements with 17 distributors covering 29 countries. In Europe, Curetis has for example entered into a distribution agreement with Axon Lab covering Austria, Croatia, the Czech Republic, Slovakia and Slovenia in May 2016 and with Arrow Diagnostics in Italy. In line with its strategic objectives, Curetis entered into distribution agreements with Acumen for certain ASEAN markets (Indonesia, Malaysia, Thailand and Singapore), where its HPN Application Cartridge and the BCU Application Cartridge were approved by the Singapore HSA and Beijing Clear Biotech for Greater China. In the Middle East, Curetis recently entered into distribution agreements with Future Horizons Scientific (FHS) in Egypt, Quimica Valaner S.A. de C.V. in Mexico and Biko S.A. in Uruguay for commercialization of the Unyvero Platform and Application Cartridges, subject to obtaining regulatory clearance for the products in the respective markets, which is expected in the fourth quarter of 2018. Each of the three new distribution partners intends to commercialize all five Unyvero Application Cartridges that are currently CE-IVD marked, namely HPN, ITI, BCU, IAI and UTI. These three partners have in total committed to purchase a minimum of 45 Unyvero Systems at Curetis' standard distributor transfer prices over the respective three-year contractual terms. In addition, they have committed to minimum purchases of several thousand Application Cartridges over the terms of the agreements. For a description of the distribution agreement with Beijing Clear Biotech covering China, Taiwan and Hong Kong, see “— *Material Contracts — Strategic Partnerships and Collaboration Agreements — Beijing Clear Biotech*” and for a description of the distribution agreement with Acumen covering Singapore, Malaysia, Indonesia and Thailand, see “— *Material Contracts — Strategic Partnerships and Collaboration Agreements — Acumen*”. In addition, the Curetis entered into a distribution agreement with Eldan in Israel in January 2017 and also into a distribution agreement with ATC for Kuwait, and with Al Zahrawi covering UAE and Qatar in 2012 and 2015, respectively.

### ***Financing Arrangements***

#### ***EIB Finance Contract***

For a description of the EIB Finance Contract, see “*Operating and Financial Review and Prospects — Liquidity and Capital Resources*” and “*Operating and Financial Review Prospects — Financial Indebtedness and Other Liabilities*”.



### *GCF Equity Facility*

On 26 April 2018, Curetis entered into the USD 10,000 thousand GCF Equity Facility with GCF. Under the GCF Equity Facility, the Company may from time to time require GCF to subscribe for Shares up to an aggregate subscription amount of USD 10,000 thousand over a three-year period beginning on the date of the agreement at a subscription price per share equal to 95% of the volume weighted average price of the Shares on Euronext in Amsterdam over the five trading days following Curetis' notice to GCF of a required subscription (such notice, a "**Sales Notice**"). GCF is however not under an obligation to subscribe for Shares if the Company is in breach of material obligations under the GCF Equity Facility, there is a reasonable allegation of fraud committed by the Company or its officers, the Company undergoes a change of control, defined as one person or more persons acting in concert acquiring direct or indirect control over more than 50% of the total voting rights in Curetis' equity or gaining the ability to appoint a majority of Curetis' management board, or the Shares cease to be listed or trading in the Shares is suspended continuously for more than five days on which Euronext in Amsterdam is open, or if the subscription price falls below a floor price to be set by Curetis in each Sales Notice (which floor price shall not be lower than €4.50 unless otherwise agreed between Curetis and GCF), subject to adjustments to reflect variations to the share capital of the Company. As at 30 October 2018, the share price of the Company quoted on Euronext was less than the GCF Floor Price and the Company therefore will, unless otherwise agreed with GCF, not have been permitted to make any drawings under the GCF Equity Facility until the subscription price per share exceeds the GCF Floor Price. In addition, the full US\$10,000 thousand is not accessible by the Company at one time, but rather only in US\$ 500,000 tranches which the Company is restricted from initiating, pursuant to a Sales Notice, more than one time in any three-week period unless previously agreed with GCF. The Shares to be subscribed for by GCF are not subject to any lock-up undertakings.

### *Yorkville Financing*

On October 2, 2018, the Company entered into the Yorkville Agreement. Under the terms of the Yorkville Agreement, Yorkville has committed to subscribe for up to 2,000 Convertible Notes with a principal amount of €10,000 per note, divided into multiple tranches, over a period of 36 months from the date of the agreement. Share subscription warrants (the "**Warrants**") are to be issued with each tranche of Convertible Notes, except for the first tranche of 500 Convertible Notes with an aggregate principal amount of €5,000 thousand. As of October 2, 2018, Curetis had issued €3,500 thousand in principal amount of Convertible Notes as part of the first tranche under the Yorkville Agreement, thereby raising a net proceeds amount of €3,220 thousand, and intends to issue the remaining €1,500 thousand in principal amount of Convertible Notes of the first tranche within 90 trading days thereafter, subject to certain conditions being met, as described below. The Company plans to use the proceeds of this first tranche of Convertible Notes to continue to finance its commercial execution and research and development efforts.

The principal amount of subsequent tranches of Convertible Notes will be equal to the lower of either (a) €5,000 thousand and (b) 10 times the combined average daily value of the Shares traded on Euronext in Amsterdam and Euronext in Brussels during the 10 days preceding the Company's tranche request (up to a maximum of €5,000 thousand). The Company is restricted from submitting a request to fund a subsequent tranche of Convertible Notes under the Yorkville Agreement until after the tenth calendar day following the conversion into Shares and/or redemption of all the outstanding Convertible Notes issued under the previous tranches. The commitment by Yorkville under the Yorkville Agreement to subscribe for subsequent tranches of the Convertible Notes is subject to certain conditions, described below.

Under the Yorkville Agreement, the number of Warrants issued with subsequent tranches of Convertible Notes shall be equal to 25% of the aggregate principal amount of such Convertible Notes divided by the relevant Warrant exercise price, as described below. Each Warrant entitles the holder to one share of the Company at the specified exercise price. Accordingly, if all Warrants issued with a tranche of Convertible Notes are exercised,

the aggregate proceeds of such Warrants would be equal to approximately 25% of the aggregate principal value of the related Convertible Notes.

The key terms of the Convertible Notes and Warrants under the Yorkville Agreement are described below, as well as conditions to the funding of a tranche of Convertible Notes, information about certain undertakings made by Yorkville, and certain other information.

#### *Convertible Notes*

The Convertible Notes are issuable at a subscription price per note equal to 96% of their principal amount. A commitment fee of 4% of the aggregate principal amount of the relevant Convertible Notes is payable to Yorkville by deducting such fee from the aggregate subscription price of those notes.

Each Convertible Note shall have a maturity of 12 months from its date of issuance. Curetis has the right to extend such maturity by an additional 12-month period, while paying a cash fee equal to 5% of the principal amount of the relevant Convertible Notes. The maturity period can be extended up to four times, provided that the resulting extended maturity date shall exceed the maturity of the indebtedness of the Company under the EIB Finance Contract and the extension fee is paid. See “*Operating and Financial Review and Prospects — Liquidity and Capital Resources — EIB Finance Contract*”

The Convertible Notes shall not accrue interest, except in the case of an event of default under the notes, in which case the Convertible Notes shall accrue default interest at a rate of 15% per annum until the earlier of the date that the event of default is cured or the date on which the Convertible Notes have been fully converted or redeemed.

Convertible Notes may be converted at any time until they are fully redeemed. Conversion rights are limited to the number of Shares that are authorized, available and approved for issuance during the period from the moment it has insufficient Shares authorized, available and approved for issuance for one time coverage for the conversion or exercise of the outstanding Notes and Warrants until the extraordinary General Meeting at which the additional authorizations to issue Shares are requested. Upon conversion of one or more Convertible Notes into Shares, the number of Shares will be calculated by dividing the aggregate principal amount of the relevant Convertible Notes by 93% of the lowest daily volume weighted average price of the Shares on Euronext in Amsterdam over the 10 trading days prior to the conversion date. The number of Shares to be issued upon a conversion of Convertible Notes is subject to a maximum specified by the Company in its request to Yorkville for the disbursement of the tranche of such Convertible Notes. Any excess entitlement on the basis of the conversion ratio will be settled in cash unless the Company elects to settle such excess in Shares.

Convertible Notes may be freely transferred, except to retail investors, and subject to compliance with applicable securities laws. The Convertible Notes contain anti-dilution protection, which protects the holder of the security from equity dilution resulting from later issues of shares at a lower price or value than that provided for in the security. The protection in the Convertible Notes takes the form of tying the conversion price of the Convertible Notes to the prevailing market price of the underlying Shares, as described above, so that changes to the Share price due to Share issuances, Share splits or other potentially dilutive events will result in a corresponding change in the number of Shares issuable upon conversion of a Convertible Note.

The Convertible Notes will not be listed or admitted to trading on any financial market.

#### *Warrants*

As noted above, Convertible Notes (with the exception of the €5,000 thousand first tranche) shall be issued with a number of Warrants equal to 25% of the aggregate principal amount of such Convertible Notes divided by the relevant Warrant exercise price. The exercise price of the Warrants shall be equal to 135% of the lowest

daily volume weighted average price of the Shares on Euronext in Amsterdam over the 10 trading days prior to the date of the request by the Company for disbursement of a tranche.

Warrants can be exercised for a period of three years from their respective issue date. During such period, each Warrant will give its holder the right to subscribe to one Share, provided that the number of Shares to be issued upon an exercise of Warrants is subject to a maximum specified by the Company in its request to Yorkville for the disbursement of a tranche of Convertible Notes. Any excess entitlement on the basis of the Warrant exercise ratio will be settled in cash unless the Company elects to settle such excess in Shares.

Warrants may be freely transferred, except to retail investors, subject to compliance with applicable securities laws, and shall include customary provisions and protections, including full anti-dilution protection. As the value of the Warrants could be adversely affected if there is an increase in the total number of Shares outstanding, diluting the holder of the Warrant, the Warrants include protections that provide for an adjustment of the exercise price of the Warrant pursuant to a formula in the event of further share issuances (at a lower price than the Share price when the Convertible Notes were issued) or a Share split. The adjustment feature therefore has the effect of ensuring that the holder of the Warrant is not diluted. The Warrants will not be admitted to trading on any financial market.

#### *Conditions to the issue of a tranche of Convertible Notes*

The issuance of a tranche of Convertible Notes is subject to certain conditions:

- no material adverse change shall have occurred in the assets or financial or trading position of the Company with a net adverse impact of €5,000 thousand;
- no event of default or event or circumstance constituting an event of default if not cured within the applicable cure period is in existence;
- no suspension of trading of the Shares on Euronext in Amsterdam shall have occurred during the 90 days preceding the request for the disbursement of a tranche;
- the closing price of the Shares on the day prior to it sending the request for the disbursement of a tranche shall be €3.00 per Share or greater;
- the combined average daily value of the Shares on Euronext in Amsterdam and Euronext in Brussels during the week prior to the request for the disbursement of a tranche shall be €150 thousand or greater;
- upon each disbursement request, the Company shall have at least (a) two times coverage of Shares authorized, available and approved for issuance upon conversion of the maximum amount of Convertible Notes of the tranche to be issued and any other outstanding Convertible Notes (calculated as if the conversion occurred on the date of the request for disbursement of the tranche); and (b) one time coverage of Shares authorized, available and approved for issuance upon exercise of the maximum number of Warrants to be issued.

A holder of Convertible Notes may require the Company to redeem all or any of its notes if the Company fails to issue new Shares in accordance with the terms of the Yorkville Agreement or if an event of default, as described below, occurs which has not been cured within 10 calendar days. Unless converted or previously redeemed, Convertible Notes will be redeemed at 100% of their principal amount plus interest, if any, on their maturity date.

#### *Restrictions*

The Yorkville Agreement provides for certain covenants applicable to Curetis, including most importantly in relation to: (i) compliance with applicable law, (ii) the maintenance of corporate existence, insurance of assets and payment of taxes, (iii) not engaging in mergers whereby the Company is the disappearing entity without

prior approval, (iv) not effecting major asset disposals, (v) not declaring dividends, (vi) not granting security for indebtedness (subject to certain exceptions) when Convertible Notes are outstanding, (vii) incurring further indebtedness (subject to certain exceptions, including for incurring indebtedness under the EIB Finance Contract), (viii) participating in variable rate equity financing transactions (such as an issue of Shares under the GCF Equity Facility) from 30 days prior to the request for the disbursement of a tranche of convertible notes until the 20th business day following the redemption or conversion of such convertible notes.

#### *Events of default*

The Yorkville Agreement further provides for certain events of default in respect of Curetis, including most importantly in relation to: (i) failure to repay principal under the Convertible Notes when due; (ii) failure to comply with the covenants, (iii) failure to pay for the cash settlement of Warrants when due, (iv) the impossibility for any Convertible Notes to be converted, (v) the delisting or suspension of the Shares from Euronext in Amsterdam (except for temporary suspensions); (vi) representations or warranties of the Company (to the effect that it is in compliance with applicable money laundering, sanctions, anti-bribery and similar laws, is not in violation of its contractual obligations or its by-laws, that its financial statements give a true and fair view of its financial position, and similar matters) being materially incorrect or misleading, (vii) failure to pay other indebtedness when due, (viii) voluntary discontinuance or liquidation of the business or insolvency proceedings being instituted, (ix) the failure to comply with judgements for the payment of money and (x) failure to issue Shares upon conversion of Convertible Notes when due under the Yorkville Agreement.

#### *Investor's commitments*

Pursuant to the Yorkville Agreement, from the date of the agreement until the full conversion and / or redemption of all outstanding Convertible Notes, Yorkville covenants and undertakes:

- not to request any seat on the Company's management board or the Company's supervisory board;
- either alone or acting in concert, not to hold at any time a number of shares higher than 4.99% of the outstanding number of shares of the Company; and
- not to send any conversion notice or exercise notice for any Convertible Notes or Warrants if a prospectus would be required for the admission to listing and trading of the shares to be issued upon such conversion or exercise, until such prospectus has been approved by the Dutch Authority for the Financial Markets.

#### *New Shares*

The number of Shares to be issued upon the conversion of all Convertible Notes of the first tranche of €5,000 thousand shall not exceed 2.75 million Shares.

The new Shares to be issued upon the conversion of Convertible Notes or the exercise of Warrants from time to time (any and all such Shares, the "**Conversion Shares**") shall carry the same rights as the existing Shares and will be admitted to trading on the regulated market of Euronext in Amsterdam and Euronext in Brussels.

The Company will maintain on its website a table of the number of outstanding Convertible Notes, Warrants and shares issued upon a conversion of Convertible Notes or exercise of Warrants.

#### *Lease Agreements*

##### *Schneider GmbH & Co. KG, Lease Agreement Holzgerlingen*

Curetis' headquarters are located at Holzgerlingen, Germany, where it leases approximately 1,500 sqm of office space pursuant to a lease agreement most recently amended on 27 September 2013. Pursuant to the exercise of an extension option in November / December 2017, the term of the lease has been extended until 31 August

2021. After that term, the lease agreement is automatically extended for an indefinite period of time unless terminated with nine months' prior notice by either lessor or lessee.

*Joma-Polytec, Lease Agreement Bodelshausen*

On 18 February 2010 Curetis and Joma-Polytec entered into a leasing agreement for about 1,600 sqm of manufacturing, office and logistics space. Based on an amendment of the leasing agreement from June 2010 the leasing period did not commence until 1 September 2010. According to the amended leasing agreement the leasing term ends on 30 June 2020 and can be extended by an additional five year term at the request of Curetis. Otherwise it shall be automatically extended for an additional one-year period, provided that it is not terminated by one of the parties at least six months prior to expiration.

*Lease Agreements San Diego, USA*

Curetis USA has entered into a lease agreement originally dated 10 March 2017 originally with Fenway X as landlord and assumed by PRH XVI, LP in July 2017 for 465 sqm of office. Pursuant to the terms of the lease agreement the term ends on 31 May 2022, unless sooner terminated pursuant to any applicable provision of the lease agreement. In addition, Curetis USA has entered into a warehouse storage agreement with TTL, which includes not only storing, but also transportation from Los Angeles Airport (LAX) to either TTL's warehouse or Curetis' offices in San Diego, USA.

*Marx Realitäten, Lease Agreement Vienna, Austria*

In March 2017, Ares Genetics, and Marx Realitäten entered into a main lease agreement and in March 2018 into an additional lease agreement for together approximately 153 sqm office space in Vienna, Austria. The term of the main lease agreement ends on 31 March 2022, with a general option to extend the term for three additional years upon agreement by the parties.

*Allcyte GmbH, Lease Agreement Vienna, Austria*

In July 2018, Ares Genetics and Allcyte GmbH entered into a lease agreement for approximately 97 sqm of laboratory space in Vienna, Austria. The term of the lease agreement ends on 31 December 2020.

(See “Risk Factors — Risks Related to Business and Strategy — Curetis has entered into lease agreements for its headquarters, for a manufacturing plant in which its laboratory facilities are located, as well as other lease agreements in the US and Austria. The unexpected termination or non-renewal of this lease agreement could have a significant adverse effect on Curetis' business, results of operations, financial position, cash flows and prospects.”).

## **Insurance**

Curetis maintains insurance to cover its potential exposure for a number of claims and losses, including public liability, product liability, transportation and business interruption insurance.

In addition, Curetis has obtained directors' and officers' liability insurance, which covers expenses, capped at a certain amount, that Curetis' board members may incur in connection with their conduct as members of Curetis' board of directors. Management believes that the insurance coverage Curetis has is adequate in light of the risks Curetis faces.

## **Legal Proceedings**

There are no and there have been no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which Curetis is aware), during the previous 12 months which

may have, or have had in the recent past, significant effects on Curetis and/or Curetis' financial position or profitability.

## REGULATION

In each of the countries in which Curetis markets its products, it must comply with local regulations affecting, among other things, design and product standards, packaging and labelling requirements and clinical validation. A summary of the most important regulations is set out below.

### European Union

In the EU, Curetis is currently required to comply with the local rules and regulations which implement the IVD Directive. The IVD Directive provides the regulatory framework for manufacturers who place IVD devices on the EU market. Each member state of the EU (each, a “**Member State**”) is required to implement the IVD Directive into its national legislation.

Additional European Directives, Regulations and local rules have to be followed to be in compliance with the regulations. This includes the Directive Waste Electrical and Electronic Equipment (WEEE 2012/19/EC), the Directive on Packaging and Waste (2013/2/EC), Regulation of Registration, Evaluation and Restriction of Chemicals (REACH 1907/2006) and others.

### **CE Conformity Mark**

In order to demonstrate compliance with the essential requirements of the IVD Directive and to obtain the right to bear the CE-conformity mark (without which Curetis’ products could not be marketed as IVDs in Europe), each of Curetis’ products must undergo a conformity assessment procedure, which procedure varies according to the type of device and its classification. For IVD devices not intended for self-testing and not covered in Annex II of the IVD Directive, the conformity procedure involves the manufacturer issuing an EC Declaration of Conformity (a “**Conformity Declaration**”) based on a self-assessment of the conformity of its products with the relevant essential requirements of the IVD Directive and registering such Conformity Declaration with the governmental or regulatory body that is responsible for regulating medical devices in the relevant Member State (the “**Competent Authority**”). The relevant Member State is usually the manufacturer’s place of incorporation. For IVD devices covered in Annex II of the IVD Directive, a conformity assessment procedure requires notification to a Notified Body in the relevant Member State who must audit and examine the quality system of the manufacturer, and, in case of an IVD device covered by Annex II List A, also an examination of the design and validation of the device before approving the manufacturer’s issuing of a certification demonstrating compliance with the relevant essential requirements of the IVD Directive.

Curetis’ Unyvero Platform and all Unyvero Application Cartridges therefore were eligible for CE-IVD self-certification by Curetis. The only application which required a notification of Curetis’ Notified Body (mdc medical device certification GmbH, Stuttgart) was the HPN Application Cartridge, as it includes *Chlamydomydia pneumonia*, an Annex II List B organism. Based on a self-assessment of the conformity of these products with the relevant essential requirements of the IVD Directive, Curetis issued the respective Conformity Declarations and has registered its products with the German Competent Authority (DIMDI; German Institute for Medical Documentation and Information) as CE-IVD-marked IVDs for distribution in the EU over time, starting with the Unyvero Platform and the P50 Application Cartridge back in May 2012. With its ISO 13485 certification in good standing, Curetis is therefore entitled to bear the CE-conformity mark to the Unyvero Platform and the Unyvero Application Cartridges, which allows Curetis to market these products in the EU, as well as in additional countries recognising CE-IVD-marked IVD devices (for further information, see “— *Customers, marketing and sales — Channels to market*”). As part of its strategy, Curetis intends, in general, to seek CE-IVD-mark status for each of its assays so that they can be marketed in the EU and the key countries where the CE-IVD-mark is accepted.

The IVD Regulation entered into force on 25 May 2017 and will replace the IVD Directive after a transition period of five years after entry into force. CE-IVD-marking of Curetis products will remain valid until the end of this transitional period, after which both new and existing devices will need to comply with the requirements of the IVD Regulation. This also includes new clinical evidence requirements specific to the IVD sector which are also expected with respect to the way a device works to provide a diagnosis. Curetis quality management system (for further information, see “*Quality management system*”) has already taken these requirements into account in its development process in principle, and Curetis therefore believes it is unlikely that the additional requirements for clinical evidence would significantly impact the Unyvero Platform or Curetis’ Application Cartridges which are currently on the market or under development other than with a likely increase in time and resources needed to bring a product to market in the EU.

Under the IVD Regulation, all of Curetis’ Application Cartridges products will require a conformity assessment by its Notified Body, as they are not considered a low risk class A device. The IVD Regulation also includes new labelling requirements, such as the deployment of unique device identification (UDI) labelling to allow and improve traceability of devices, e.g. to enhance the effectiveness of post-market safety related activities. As UDI labelling has already been implemented for the commercial launch of the Unyvero System and the LRT Application Cartridge in the US, management believes that these new labelling requirements will have minimal impact on Curetis’ other products.

As a manufacturer of CE-IVD-marked medical devices sold on the European market, Curetis must also maintain a vigilance system that enables it to notify relevant regulatory authorities of incidents which may lead to (or may have led to) death or serious injury/health consequences for individuals, or a recall of the relevant product. This includes obligations to submit reports to the relevant national Competent Authority (or Authorities) for recording and evaluation when incidents (comprising any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health) occur, for the dissemination of information which could be used to prevent a recurrence of the incident or to alleviate the consequences of such incidents, and where appropriate, by the implementation of a “Field Safety Corrective Action” to reduce the risk of death or serious injury associated with the use of the device (such as a product recall).

### ***Research Use and Clinical Investigations***

In the EU, subject to certain restrictions set out in the Active Implantable Medical Devices Directive (Directive 90/385/EC), the Medical Devices Directive (Directive 93/42/EC), the In-Vitro Diagnostic Medical Devices (Directive 98/79/EC) and its successor, on in-vitro diagnostic medical devices (Regulation (EU) 2017/746), respectively, and the local laws and regulations implementing these Directives in each Member State, devices without the CE-conformity mark may be used for clinical investigations, for example for the purposes of determining whether the particular device will meet the requirements of the IVD Directive (and when applicable the IVD Regulation) and the Medical Devices Directive.

### **United States**

In the US, IVDs are medical devices as defined in section 201(h) of the Federal Food, Drug and Cosmetic Act 1938, as amended, and may also be biological products subject to section 351 of the Public Health Service Act 1944. Like other medical devices, IVDs are subject to premarket and post market controls as defined in the US Code of Federal Regulations, including 21CFR820, Quality System Regulation. Clinical laboratories running IVDs are subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA).



### ***Requirement for Premarket Notification or Approval***

IVDs are classified in one of three classes (Class I, II or III) depending on risk and the extent of controls the FDA determines are necessary to reasonably ensure their safety and efficacy. The classification of an IVD determines the appropriate premarket process.

- Class I: general controls, such as registration, listing, labelling and adherence to quality system regulations; generally, exempt from the premarket notification (510(k)) requirement;
- Class II: general controls, and special controls such as performance standards, patient registries and/or post-market surveillance; generally subject to 510(k) requirements; and
- Class III: general controls; generally subject to PMA requirements.

Pursuant to the 510(k) process, a person who wants to market certain Class I, most Class II (or some Class III) devices intended for human use in the US must submit a 510(k)-premarket notification to the FDA at least 90 days before marketing the device (unless the device is exempt from the 510(k) requirements). The FDA will then review the 510(k) premarket notification and determine whether the proposed device is “substantially equivalent” to a previously cleared 510(k) device, a device which has been reclassified from Class III to Class II or I, or a device that was in commercial distribution before 28 May 1976, for which the FDA has not yet called for the submission of PMA applications, referred to as a “predicate” device. The type of studies required to demonstrate substantial equivalence may include the following:

- in the majority of cases, analytical studies using clinical samples (sometimes supplemented by carefully selected artificial samples) will suffice;
- for some IVDs, the link between analytical performance and clinical performance is not well defined. In these circumstances, clinical information may be required. Where clinical information is required, the producer must (unless a relevant exemption applies) apply for an investigational device exemption (“**IDE**”), which would allow the investigational device to be used in a clinical study in order to collect safety and effectiveness data; and
- for microbiological multiplexed PCR based tests like the LRT application, the FDA issued a guidance document on 27 August 2014 (Guidance for Industry and Food and Drug Administration Staff: Highly Multiplexed Microbiological / Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices). Following this guidance, the sample set for the Curetis LRT application requires at least 1,500 prospective clinical patient samples to determine specificity.

In making its determination, the FDA compares the proposed device to the predicate device. If the two devices have the same intended use and the same technological characteristics, or the same intended use and different technological characteristics, but the information submitted to FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the predicate, the device may be cleared for marketing. 510(k) Submissions generally include, among other things, a description of the device, its intended use and its manufacturing, device labelling, medical devices to which the device is substantially equivalent, safety and biocompatibility information and the results of performance testing. Marketing may commence only when the FDA issues a clearance letter finding the proposed device to be substantially equivalent to the predicate. If the device is not found to be substantially equivalent, a reclassification process could be requested by the applicant. After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or any product modification that would constitute a significant change in intended use, requires a new 510(k) clearance or PMA. If the FDA determines that the non-exempt product does not qualify for 510(k) clearance the FDA must approve a PMA before the product can be marketed in the United States.

The FDA has implemented more stringent clinical investigation and PMA requirements for devices that are classified as Class III. Pursuant to the PMA process, the relevant person who wants to market the device in the US would be required to provide clinical and laboratory data that establishes that the new device is safe and effective using clinical outcome measures rather than proving substantial equivalence to another legally marketed product or pre-amendment device. Information about the device and its components, device design, manufacturing and labelling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will inspect the device manufacturer's facilities for compliance with quality system regulation, or QSR, requirements, which govern design, testing, control, documentation and other aspects of quality assurance with respect to manufacturing. The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The PMA can include post-approval conditions including, among other things, restrictions on labelling, promotion, sale and distribution, or requirements to do additional clinical studies post approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorise certain modifications to the device, its labelling or its manufacturing process. After a device is cleared, or approved for marketing by the FDA, numerous and pervasive regulatory requirements continue to apply. These include compliance with, but are not limited to:

- regulation on registration of the manufacturer and listing of the IVD devices in the FDA database when starting commercial distribution;
- the QSR, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over and document manufacturing of their products;
- Part 11 compliance with FDA required e-records of documents in the manufacturer's quality system defined as "in scope";
- labelling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labelling;
- advertising and promotion in accordance with the requirements of the FD&C Act and its implementing regulations and FDA guidance, including FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- Medical Device Reporting regulation, which requires reporting to the FDA certain adverse experiences associated with the use of the product;
- complaint handling regulations designed to track, monitor and resolve complaints related to the Company's products;
- in some cases, on-going monitoring of the Company's products' performance and periodic reporting to the FDA of such performance results; and
- the federal Physician Sunshine Payment Act and various state laws on reporting remunerative relationships with healthcare customers.

If a relevant person wants to market a device in the US and wants to test it in a clinical study in the US prior to obtaining 510(k) or PMA approval, that person will have to obtain an approved IDE unless the device is exempt. An approved IDE allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data to support a PMA or 510(k) clearance application.

As new devices not equivalent to existing Class I or II devices will be classified into Class III regardless of risk, the FDCA was modified to establish the so called *De Novo* classification process for those cases where no suitable predicate device is available.

After submission of the *De Novo* request for classification, this process allows FDA to decide whether such new device should be classified as Class I, Class II without requiring a prior 510(k) submission. In case the FDA determines there is a suitable predicate device, or that the device falls under Class III and thus a PMA is required, the *De Novo* request will be declined and the submitting entity may subsequently submit a 510(k) or a PMA. If not, and if FDA comes to the conclusion that the new device meets the requirements for a Class I or Class II product with general or with special controls, it will then grant the *De Novo*, informing about the regulatory class, regulation name and product code, and the device may be legally marketed.

The FDA has granted Curetis' *De Novo* request for the Unyvero System and the Unyvero LRT Application on 3 April 2018 as a Class II device under product code QBH as a "Device to detect and identify microorganisms and associated resistance marker nucleic acids directly in respiratory specimens".

Curetis expects that future additional Unyvero Application Cartridges may be filed with the FDA as 510(k) submissions, however FDA may also require additional *De Novo* requests for new Application Cartridges. Although Curetis considers it unlikely, it cannot be excluded that future products have to undergo PMA approval processes. The FDA makes such determinations on a case-by-case basis. Curetis intends to request pre-submission meetings for future submissions if needed to, for example, discuss the appropriate regulatory pathway or clinical study details with the FDA.

#### ***Research Use Only in the United States ("RUO")***

In the US, certain IVD products may also be sold (subject to certain restrictions) as research use only (RUO) products, without 510(k) clearance or PMA approval. Producers selling RUO IVD products must prominently label them: *For Research Use Only. Not for use in diagnostic procedures.*

#### ***Investigational Use Only ("IUO")***

In the US, certain IVD products may also be sold (subject to certain restrictions) as IUO products, without 510(k) clearance or PMA approval. Certain IUO-labelled products are exempt from the IDE regulation. Any IUO product that is being shipped or delivered for product testing prior to full commercial marketing must be prominently labelled: *"For Investigational Use Only. The performance characteristics of this product have not been established."*

#### ***Emergency Use Authorisation (EUA)***

Under section 564 of the FD&C Act, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological and nuclear (CBRN) threat agents when there are no adequate, approved, and available alternatives.

#### ***Clinical Laboratory Improvement Amendments of 1988 ("CLIA")***

CLIA establishes quality standards for laboratory testing and a certification programme for clinical laboratories in the US. CLIA requirements vary according to the technical complexity in the testing process and risk of harm in reporting erroneous results. These regulations established three categories of testing on the basis of the complexity of the testing methodology:

- waived tests (these are tests that can be operated outside of specialised, dedicated laboratory environments and without the need for technically specialised and highly trained staff);
- tests of moderate complexity, and
- tests of high complexity.

Producers of IVDs apply for CLIA categorisation of their IVDs during the premarket process. Under CLIA, laboratories performing only waived tests are subject to less regulation, whereas laboratories performing moderate or high complexity tests are subject to more stringent laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections, among other requirements.

Effective on 13 April 2018, FDA has categorised the LRT Application Cartridges as test of moderate complexity.

### **Other Territories**

In accordance with Curetis' commercialisation strategy, Curetis will develop a country specific regulatory strategy for countries outside of the EU and the US (including but not limited to China, Hong Kong, Taiwan, Singapore, Thailand, Indonesia, Malaysia, Russia, and the Middle East as well as potential further RoW markets going forward). Some of these target countries require samples from their local population to be included in clinical studies used to support product registration applications. Curetis with potential future collaboration and distributors, therefore, intends to conduct either individual national or even multinational clinical studies (which look at samples from each of the target countries, where possible) and multi-country regulatory auditing to gain maximum efficiency in product registrations in countries outside of the EU and the US.

### **Regulation of End Users**

In general, users of any diagnostic platform are required to respect local laws and regulations when providing healthcare services, including performing diagnostic activities. For example, in a number of jurisdictions an ISO15189 accreditation needs to be obtained on a test-by-test basis to qualify for reimbursement. The norm requires laboratories to have a Quality Management System. As most laboratories have a Quality Management System in place, the amount of work to obtain ISO15189 accreditation for Unyvero is considered limited given the sample-to-result nature of the platform. However, Curetis will provide guidelines to customers to allow them to be able to comply with the internal and external laboratory standards based on the feedback by the German Medical association.

## MANAGEMENT, EMPLOYEES AND CORPORATE GOVERNANCE

### General

Set out below is a summary of certain information concerning the Management Board, the Supervisory Board, Curetis' employees and corporate governance. It is based on relevant provisions of Dutch law as in effect on the date of this Prospectus, the Articles of Association, the Management Board Rules, the Supervisory Board Rules and the Terms of Reference (all as defined below).

This summary does not purport 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 and the Articles of Association, the Management Board Rules, the Supervisory Board Rules and the Terms of Reference, in each case as in force on the date of this Prospectus. The Articles of Association in the governing Dutch language and in an unofficial English translation thereof as well as the Management Board Rules, the Supervisory Board Rules and the Terms of Reference in the English language are available on the Company's website (<http://www.curetis.com/en/investors/share-information/offering.html>).

### Management Structure

The Company 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 the Company's objectives. The Supervisory Board supervises and advises the Management Board.

### 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, defining and attaining the Company's objectives, determining the Company's strategy and risk management policy, and day-to-day management of the Company's operations. The Management Board may perform all acts necessary or useful for achieving the Company's 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 the Company and the business connected with it, taking into consideration the interests of all the stakeholders of Curetis (which includes but is not limited to its customers, its employees, its business partners and the Shareholders).

The Management Board shall timely provide the Supervisory Board with all information necessary for the exercise of the duties of the Supervisory Board. The Management Board is required to notify the Supervisory Board in writing of the main features of the Company's strategic policy, 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 authorised to represent the Company. Each Managing Director, acting jointly with another Managing Director, has the authority to represent the Company. In addition, pursuant to the Articles of Association, the Management Board is

authorised to appoint proxy holders (*procuratiehouders*) who are authorised to represent the Company within the limits of the specific delegated powers provided to them in the proxy.

### ***Management board rules***

Pursuant to the Articles of Association, the Management Board has adopted rules of procedure that regulate internal matters concerning its functioning and internal organisation (the “**Management Board Rules**”).

### ***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. At the date of this Prospectus, the Management Board consists of four Managing Directors.

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 there is a tie in the votes of the Supervisory Board on the nomination, 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 the Company’s issued share capital.

The General Meeting may at any time, 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 the Company’s 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.

### ***Term of appointment***

The Managing Directors shall be appointed for a term of not more than four years. A Managing Director may be reappointed for a term of not more than 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*”.

### ***Meetings and decision-making***

Pursuant to the Management Board Rules, the Managing Directors shall endeavour to achieve that resolutions are as much as possible adopted unanimously. 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:

- the issue and acquisition of any of the Company's shares or debt instruments, or of debt instruments issued by a limited partnership or general partnership of which the Company is a fully liable partner;
- the application or the withdrawal for quotation in the listing on any stock exchange of the Company's shares or debt instruments, or of debt instruments issued by a limited partnership or general partnership of which the Company is a fully liable partner;
- the entry into or termination of a long-term cooperation of the Company 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 the Company;
- 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 the Company 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 the Company's 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*) the Company;
- 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 the Company 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 the Company 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 the Company's 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 the Company's 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 the Company; 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 the Company according to the Company's 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 the Company.

### ***Conflict of interest***

The laws of the Netherlands provide that a managing director of a Dutch public company with limited liability (*naamloze vennootschap*), such as the Company, 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. Such a conflict of interest only exists if in the situation at hand the Managing Director is deemed to be unable to serve the Company's 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 interests with Managing Directors will be agreed on terms that are customary in the sector concerned and disclosed in the Company's management report, together with a statement that best practice provisions 2.7.3 and 2.7.4 of the Dutch Corporate Governance Code have been complied with.

The existence of a (potential) personal conflict of interest does not affect the authority to represent the Company, as described under “— *Responsibilities, powers and functioning*”.

### ***Managing directors***

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

<b>Name</b>	<b>Age</b>	<b>Position</b>	<b>Date of (re-) appointment</b>	<b>Term</b>
Oliver Schacht, PhD	48	Chief Executive Officer	21 June 2018	until 31 December 2021
Johannes Bacher	49	Chief Operating Officer	8 October 2015	until 30 June 2019
Dr. Achim Plum	50	Chief Business Officer	21 June 2018	until 31 December 2021

The Company's registered address, Max-Eyth-Straße 42, 71088 Holzgerlingen, Germany, serves as the business address for the Managing Directors.



#### *Oliver Schacht*

Mr. Oliver Schacht, a corporate finance professional and expert in the molecular diagnostics industry, has been CEO of the Company 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, US). 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 treasurer and on the Supervisory Board of Protagen AG (Dortmund, Germany). 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 PhD 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-organisation in the pharmaceutical, biotechnology and other industries. He has co-founded several start-up companies in biotech, IT and education in Europe and the US.

#### *Johannes Bacher*

Mr. Johannes Bacher combines over 20 years of research and development and managerial experience with extensive expertise in research and development, clinical trials, international project management, finance, human resources, operations legal affairs. Hence, the Company's co-founder is ideally suited to managing the general research and development operations and Clinical Trial Operations of the Company. He was responsible for managing all clinical trial operations for the prospective multi-center FDA trial for the Unyvero Platform and LRT Cartridge including managing all relevant teams during the FDA submission and FDA review process throughout. Mr. Bacher also oversees all research and development teams and functions from hardware to software, IVD development as well as lab operations and innovation, technology and IP.

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 the Company 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 managing the GEAR bioinformatics efforts. Dr. Plum also serves as Managing Director in all of Curetis' international commercial subsidiaries. As of 2018, 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 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 US, negotiated strategic commercial agreements with leading diagnostics industry players and led Epigenomics' corporate communications and compliance functions. 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 the Company 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 the Company and its business enterprise, taking into account the interests of Curetis' stakeholders (which include but are not limited to Curetis' employees and the 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 will therefore request any information from the Management Board, the internal audit function and/or the external auditor it deems necessary. The Supervisory Board may, at the Company's expense, seek the advice which it deems desirable for the correct performance of its duties.

The Supervisory Board will draw 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 has adopted rules of procedure concerning the division of its duties and its working methods (the "**Supervisory Board Rules**") and that of its committees as described below.

### ***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. At the date of this Prospectus, the Supervisory Board consists of six members. Only natural persons may be appointed as Supervisory Director.

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 there is a tie in the votes of the Supervisory Board on the nomination; 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 the Company's 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 the Company's 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 term of four years and may thereafter be reappointed for one period of four years. Supervisory Directors may thereafter be reappointed for one period of not more than two years, which period may be extended by a period of not more than two years. The Supervisory Directors must retire periodically in accordance with a rotation plan to be drawn up by 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 is 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 the Company 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 Directors or Managing Directors. The Managing Directors shall attend the meetings of the Supervisory Board, if invited to do so, 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 favour of a specific proposal. The Supervisory Board Rules contain such a provision.

Pursuant to the Supervisory Board Rules, the Supervisory Directors shall endeavour 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.

### ***Conflict of interest***

Similar to the rules that apply to the Managing Directors as described above, Dutch law also provides that a supervisory director of a Dutch public company with limited liability, such as the Company, 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 Board 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 the Company's management report, together with a statement that best practice provisions 2.7.3 and 2.7.4 of the Dutch Corporate Governance Code have been complied with.

### ***Supervisory directors***

At the date of this Prospectus, the Supervisory Board consists of the following six Supervisory Directors:

<b>Name</b>	<b>Age</b>	<b>Position</b>	<b>Date of (re-) appointment</b>	<b>Term</b>
Mr. William E. Rhodes, III	64	Chairman of the Supervisory Board and Chairman of the Remuneration Committee	10 November 2015	End of annual General Meeting in 2019
Mr. Mario Crovetto	64	Member of the Supervisory Board and Chairman of the Audit Committee	10 November 2015	End of annual General Meeting in 2019
Dr. Werner Schaefer	70	Vice-Chairman of the Supervisory Board	21 June 2018	End of annual General Meeting in 2020
Ms. Prabhavathi Fernandes, Ph.D.	69	Member of the Supervisory Board	16 June 2016	End of annual General Meeting in 2019
Dr. Rudy Dekeyser	56	Member of the Supervisory Board	21 June 2018	End of annual General Meeting in 2019
Dr. Nils Clausnitzer	49	Member of the Supervisory Board	23 June 2017	End of annual General Meeting in 2020

The Company's registered address, Max-Eyth-Straße 42, 71088 Holzgerlingen, Germany, serves as the business address for all Supervisory Directors.

#### ***William E. Rhodes, III***

Mr. William E. Rhodes, III, has served as Chairman of the Supervisory Board since 10 November 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., Collector 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 serves 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 US 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 on 10 November 2015. Mr. Crovetto has been working as an independent adviser 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 on 10 November 2015. 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 research and development 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 the Company (previously Curetis AG – since 2014). Dr. Schaefer holds a PhD in Chemistry from Philipps University Marburg.

#### *Prabhavathi Fernandes, Ph.D.*

Dr. 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, Dr. 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. In 2017, she was appointed to the Board of the National Preparedness Response Science Advisory Board (NPRSB) in the Health and Human Services department of the US government.

#### *Dr. Rudy Dekeyser*

Dr. Rudy Dekeyser is a Supervisory Director of the Company. 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 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 the Company. Dr. Dekeyser holds a Ph.D. in Molecular Biology from Ghent University.

#### *Dr. Nils Clausnitzer*

Dr. Nils Clausnitzer was elected to the Company's Supervisory Board in June 2017. Dr. Clausnitzer is Executive VP Europe of Avantor/VWR International llc./ VWR GmbH, Germany, and has profound knowledge in sales and marketing of diagnostics and medical products. Prior to VWR International, he was President and Head of Commercial Operations, EMEA, at Qiagen and General Manager for Olympus Germany. He also worked as Managing Director for Abbott Diagnostics Germany.

#### ***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 terms of reference on each Supervisory Board committee's role, responsibilities and functioning (the "**Terms of Reference**"). At the date of this Prospectus, 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.

#### ***Remuneration committee***

The Remuneration Committee advises the Supervisory Board on the exercise of its duties regarding the remuneration policy of the Managing Directors within Curetis', including analysing developments of the Code, and preparing proposals for the Supervisory Board on these subjects. The duties of the Remuneration Committee include the preparation of proposals of the Supervisory Board on the remuneration policy for the Managing Directors to be adopted by the General Meeting, and on the remuneration of the individual Managing Directors to be determined by the Supervisory Board. The Remuneration Committee also prepares a remuneration report on the execution of the remuneration policy for the Management Board during the respective year to be adopted by the Supervisory Board. The Remuneration Committee meets at least three times every year.

The Remuneration Committee consists of Mr. William E. Rhodes (chairman), Prabhavathi Fernandes, Ph.D. and Dr. Rudy Dekeyser.

#### ***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 the Company's internal risk management and control systems. The Audit Committee advises the Supervisory Board on the exercise of certain of its duties and prepares nominations and reviews for the Supervisory Board in this regard. The Audit Committee also supervises the submission of financial information by the Company, the compliance with recommendations of internal and external accountants, the Company's policy on tax planning, the Company's financing arrangements, assists the Supervisory Board with the Company's information and communications technology. It furthermore maintains regular contact with and supervises the external accountant and it prepares the nomination of an external accountant for appointment by the General Meeting. The Audit Committee also issues preliminary advice to the Supervisory Board regarding the approval of the annual accounts and the annual budget and major capital expenditures. The Audit Committee meets at least four times a year.

The Audit Committee consists of Mr. Mario Crovetto (chairman), Dr. Nils Clausnitzer and Dr. Rudy Dekeyser.

#### ***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 duties of the Nomination and Appointment Committee include preparing the selection criteria and appointment procedures for Managing Directors and Supervisory Directors, and proposing the profile for the Supervisory Board. It also periodically assesses the scope and composition of the Management Board and the Supervisory Board, and the functioning of the individual directors. The Nomination and Appointment Committee also proposes on appointments and reappointments. It supervises the Management Board's policy on selection criteria and appointment procedures for the Management Board. The Nomination and Appointment Committee meets at least once every year.

The Nomination and Appointment Committee consists of Dr. Werner Schaefer (chairman), Prabhavathi Fernandes, Ph.D. and Dr. Nils Clausnitzer.

#### **Senior Management**

In addition to the three Managing Directors, Mr. Chris Emery, age 46, forms part of the Company's senior management. Mr. Chris Emery was appointed as President and CEO of Curetis USA, Inc. as of 1 September 2018 and combines over 20 years of healthcare experience and 10 years in executive leadership roles in the laboratory diagnostics, medical device and pharmaceuticals industries. Most recently, he acted as Chief Commercial Officer – North America for Menarini Silicon Biosystems, where he directed U.S. sales and business development activities. Prior to Menarini Silicon Biosystems, Mr. Emery was General Manager for Abbott's cancer diagnostics laboratory division. He also held senior level management roles as Chief Operating Officer at CombiMatrix, VP Sales & Marketing at Response Genetics, and National Sales & Marketing Manager at US LABS, prior to its acquisition by LabCorp.

Mr. Emery obtained his MBA from Pepperdine University and his BA in Communications Studies from University of California - San Diego and started his career in healthcare at Johnson & Johnson.

Mr. Emery's business address is 10525 Vista Sorrento Parkway, CA 92121, San Diego, United States.

## Diversity and Limitation of Supervisory Positions

As the Company does not qualify as a “large company” within the meaning of Dutch legislation requiring large Dutch companies to pursue a policy of having at least 30% of the seats on both the management board and the supervisory board to be held by men and at least 30% to be held by women, these requirements do not apply to the Company. For the same reason, the Dutch legislation limiting the number of supervisory positions to be occupied by managing directors or supervisory directors is not applicable to the Company.

Although the requirements of Dutch legislation limiting the number of supervisory positions to be occupied by male Supervisory Directors are not applicable on the Company, 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. In the recruitment procedure for possible future appointments of Managing and Supervisory Directors, sincere efforts will be made to find candidates which are suitable according to the Company’s diversity policy and are best qualified for the position at that time.

## Remuneration and Equity Holdings

The Supervisory Board establishes the remuneration of the individual members of the Management Board in accordance with the principles laid down in the Management Board remuneration policy as adopted by the General Meeting on 21 June 2018.

The Supervisory Board presents to the General Meeting for approval any proposal providing for the remuneration of the members of the Management Board in the form of shares or options. This proposal must include the number of shares and/or options that may be granted to the Management Board and which criteria apply to a grant or modification. An equity-based incentive plan has been established by the General Meeting in 2016 (see “— *Curetis’ Equity Settled Stock Option Plan 2016 (ESOP 2016)*”).

The Company’s current remuneration policy provides for competitive compensation so as to enable the Company 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 the Company 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;
- when the overall remuneration is fixed, its impact on pay differentials within the Company shall be taken into account;
- 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 the Company 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 to balance short-term operational performance by reference to, among other things, including the results, the share price performance and other non-financial indicators, with the long-term objective of creating sustainable value whilst becoming one of the leaders in the area of molecular microbiology, leveraging the Unyvero Platform



and suite of fast and comprehensive molecular infectious disease tests to help save lives of hospitalized patients with life-threatening infectious diseases, and taking into account the interests of all stakeholders that are relevant to the Company's long-term value creation; and

- 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 the Company.

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

### ***Profit Sharing Bonus***

Managing Directors are 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 the Company 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 2017, the Supervisory Board established a set of corporate goals (e.g. revenue, cash burn, corporate growth, FDA review and clearance) which made up 50% of each Managing Director's potential bonus and for each Managing Director a series of personal goals were defined which made up the other 50% of the potential bonus.

### ***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 the Company if certain circumstances apply. The Supervisory Board may adjust the 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).

In addition, Dutch law prescribes that, in case the value of the Shares or rights to subscribe for such Shares granted by the Company to the respective Managing Directors as part of their remuneration increases during a period in which a public takeover bid is made for the Shares, the remuneration of that respective Managing Director will be reduced by the amount by which the value of the Shares or rights to subscribe for such Shares so granted by the Company to such member has increased. To the extent the increase in value exceeds the remuneration of the respective Managing Director, the Company shall have a claim against the respective Managing Director for such excess. Similar provisions apply in the situation of an intended legal merger or demerger, or if the Company intends to enter into certain transactions that are of such significance to the Company that the Management Board requires the approval of the General Meeting pursuant to Dutch law (i.e., transactions that fall within the scope of Section 2:107a Dutch Civil Code).

### ***Remuneration of the Management Board***

An overview of the remuneration received by the Management Board for the year ended 31 December 2017 is shown in the table below.

Name	Base salary	Annual bonus <sup>(1)</sup>	Other benefits	Share based payments and other incentives	Total remuneration
Mr. Johannes Bacher .....	€200,000	€32,000	0	€196,000 <sup>(2)</sup>	€428,000
Dr. Achim Plum.....	€200,000	€30,000	€5,000 <sup>(3)</sup>	€196,000 <sup>(2)</sup>	€431,000
Mr. Oliver Schacht, Ph.D.....	€240,000	€45,000	0	€196,000 <sup>(2)</sup>	€481,000

Notes:

- (1) Refers to the bonus for the year 2017 which was paid in 2018;
- (2) Expense recognized for granted stock options;
- (3) Company car reimbursement.

At the date of this Prospectus, there are no amounts reserved or accrued by the Company or its subsidiaries to provide pension, benefit, retirement or similar benefits for current members of the Management Board.

### ***Remuneration of the Supervisory Board***

The table below shows the fixed annual remuneration of the Supervisory Board at the date of this Prospectus as well as additional remuneration for committee chairing roles as well as per meeting and per telephone conference fees earned in 2017.

Name	Max. fixed remuneration in 2017	Committee chairing fees	Meeting & Telco fees	Stock Option Expense in 2017	Total remuneration paid in 2017
William E. Rhodes, III (chairman and chair of Remuneration Committee) .....	€60,000	€10,000	€14,000	€10,627	€94,627
Dr. Werner Schäfer (vice chairman and chair of Nomination & Appointment Committee) .....	€40,000	€10,000	€14,000	€10,627	€74,627
Mario Crovetto (chair of Audit Committee) .....	€20,000	€10,000	€14,000	€10,627	€54,627
Dr. Rudy Dekeyser .....	Waived	n.a.	Waived	0	Waived
Prabhavathi Fernandes, Ph.D.....	€20,000	n.a.	€14,000	€10,627	€44,627
Dr. Nils Clausnitzer (since 23 June 2017).....	€10,833	n.a.	€9,000	€10,627	€30,460

The Remuneration Policy for the Supervisory Board was proposed to and approved by the General Meeting on 23 June 2017. Each of the Supervisory Directors also received a grant of 15,000 options under the ESOP 2016 (as defined below) in 2017 as well as another grant of 10,000 options as of 1 July 2018, see “— *Equity holdings*”. All Supervisory Board members accepted the grants with the exception of Dr. Rudy Dekeyser who waived the grant under LSP fund policies.

### ***Curetis' Equity Settled Stock Option Plan 2016 (ESOP 2016)***

In 2016, the General Meeting adopted the ESOP 2016. The purpose of the ESOP 2016 is the retention of current and attraction of new key employees, Managing Directors and Supervisory Directors, spare liquidity, reduce

employee turnover, align the interests of employees, directors and shareholders and increase the interest of the capital markets in the Company by a shareholder value orientated compensation model.

Under the ESOP 2016, Managing Directors, Supervisory Directors and key employees are eligible to be granted options. The aggregate number of Shares for which options may be granted on any grant date plus (i) the aggregate number of Shares for which options are outstanding under the ESOP; plus (ii) the aggregate number of Shares issued upon exercise of options granted under the ESOP 2016, may not exceed 10% of the number of issued Shares immediately prior to the date of grant. Options granted under the ESOP 2016 vest over a three year period with the first third of the options granted vesting on first anniversary of the grant date and the remaining two thirds of the options granted vesting in monthly increments over the following 24 months. Options granted under the ESOP 2016 may not be exercised prior to the third anniversary of the grant date. The strike price for options granted under the ESOP 2016 is the volume weighted average closing Share price during the five trading days prior to and including the day the option is granted.

Pursuant to the current remuneration policy for Managing Directors, the number of Shares for which stock options may be granted shall not exceed 200,000 and the aggregate number of Shares for which options may be granted to Managing Directors shall not exceed 50% of the total number of options available under the ESOP 2016.

### ***Equity holdings***

The number of Shares held by the Managing and Supervisory Directors at the date of this Prospectus are as follows:

<b>Name</b>	<b>Number of Shares</b>	<b>Right to receive Shares<sup>(1)</sup></b>
Mr. Johannes Bacher .....	107,865	65,075
Dr. Achim Plum .....	0	65,075
Mr. Oliver Schacht, Ph.D.....	23,541	172,389
Dr. Werner Schäfer.....	2,702	—

Note:

- (1) This relates to the Shares to which these persons are entitled pursuant to the PSOP Roll-Over Agreements. See “Reasons for the Offering and Use of Proceeds”.

The below table reflects the options granted to Managing Directors under the ESOP 2016 as of the date of this Prospectus.

<b>Beneficiary</b>	<b>Options granted in 2016</b>	<b>Strike Price</b>	<b>Options granted in 2017</b>	<b>Strike Price</b>	<b>Options Vested in 2017</b>	<b>Options Exercisable as of 31 December 2017</b>	<b>Options Exercised in 2017</b>	<b>Options forfeited in 2017</b>
Johannes Bacher .....	100,000	€6.45	0	—	50,000	0	0	0
Dr. Achim Plum.....	100,000	€6.45	0	—	50,000	0	0	0
Oliver Schacht, Ph.D. ...	100,000	€6.45	0	—	50,000	0	0	0

Furthermore, as of the date of this Prospectus, Mr. Chris Emery holds 100,000 options granted to him on 1 October 2018 under the ESOP 2016 at a strike price of €3.29, which vest three years after the grant. As of the date of this Prospectus, Mr. Emery did not hold any Shares.

The below table reflects the options granted to Supervisory Directors under the ESOP 2016 as of the date of this Prospectus.

Name	Stock Options granted in 2018	Strike Price	Stock Options granted in 2017	Strike Price	Options Vested in 2017	Options Exercised in 2017	Options Forfeited in 2017
William E. Rhodes, III..	10,000	€4.62	15,000	€4.93	0	0	0
Dr. Werner Schäfer .....	10,000	€4.62	15,000	€4.93	0	0	0
Mario Crovetto .....	10,000	€4.62	15,000	€4.93	0	0	0
Dr. Rudy Dekeyser .....	Waived		Waived	—	—	—	—
Prabhavathi Fernandes, Ph.D.....	10,000	€4.62	15,000	€4.93	0	0	0
Dr. Nils Clausnitzer .....	10,000	€4.62	15,000	€4.93	0	0	0

## Employment, Service and Severance Agreements

At the date of this Prospectus, the current members of the Management Board have a service agreement with the Company. None of the members of the Management Board are entitled to any severance payment upon termination of their service agreement. In the event a person or persons acting in concert acquire 51% or more of the Shares, a Managing Director may terminate his service agreement with three months' notice and will be entitled to his contractual fixed remuneration for a period of six months following such termination or the remaining period of his service agreement, whichever period is shorter.

At the date of this Prospectus, the Supervisory Directors do not have an employment, service or severance contract with the Company.

## Potential Conflicts of Interest and Other Information

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

Dr. Werner Schaefer, who is a Supervisory Director, had received a certain number of shares from certain existing Shareholders under a Carve Out Agreement (as disclosed in the IPO Prospectus in 2015). the date of this Prospectus, he holds 2,702 Shares, see “— *Equity holdings*”. This subjects him to a potential conflict of interest as a Shareholder on the one hand and his duties as a Supervisory Director on the other.

In addition, the Managing Directors Johannes Bacher and Oliver Schacht hold a minority stake in the Company, see “— *Equity holdings*”. Johannes Bacher, Oliver Schacht and Dr. Achim Plum, are also entitled to be delivered Shares under the PSOP Roll-Over Agreements and have been granted options for Shares under the ESOP 2016, see “— *Equity holdings*”.

Other than these circumstances, the Company is not aware of any potential conflicts between the personal interests or other duties of Supervisory Directors, Managing Directors or Mr. Emery and their respective relatives on the one hand and the interests of the Company on the other hand. There is no family relationship between any Managing Director, any Supervisory Director and Mr. Emery. 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, Supervisory Directors or Mr. Emery:

- has been convicted of fraudulent offenses;
- has served as a director or officer of any entity subject to bankruptcy proceedings, receivership or liquidation; or
- 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, the Company is not aware of any arrangement or understanding with major Shareholders, suppliers, customers or others pursuant to which any Managing Director, Supervisory Director or Mr. Emery was selected as a member of such management or supervisory bodies.

There was no transaction up to the date of this Prospectus between the Company and legal or natural persons who hold at least ten percent of the shares in the Company. Best practice provision 2.7.5 of the Dutch Corporate Governance Code was complied with.

## **Liability of Managing Directors and Supervisory Directors**

Under the laws of the Netherlands, the Managing Directors and Supervisory Directors may be liable towards the Company for damages in the event of improper or negligent performance of their duties. They may be jointly and severally liable for damages towards the Company 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.

## **Insurance**

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

## **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 defence 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 the Company's 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 characterised as wilful (*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.

## **Employees**

For an overview of the total numbers of employees of Curetis, subdivided per operating segment, see “*Business — Employees*”. Curetis GmbH is not required to install a works council under German Law. The Company is not required to install a works council in the Netherlands since the Company has no employees in the Netherlands.

## **Dutch Corporate Governance Code**

The current revised Dutch Corporate Governance Code was published on 8 December 2016, and became effective on 1 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 Board and Supervisory Board, shareholders and General Meetings, financial reporting, auditors, disclosure, compliance and enforcement standards, and is based on a “comply or explain” principle. Accordingly, the Company 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 the Company does not apply a certain provision, to explain the reason why.

The Company 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. The Company complies with the Dutch Corporate Governance Code, however, the Company does not (yet) fully comply with or deviates from the best practice provisions with the following rationale and explanation provided below.

- Best practice provision 1.3.3 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 has interactions with all three named parties and does his auditing on an ongoing basis in constant consultation with them.
- Whilst the Company has appointed an internal auditor, due to its size and resource constraints, this function is 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 has full access to all information needed, to the Audit Committee and the external auditors. The Audit Committee evaluates the need for an independent or bigger internal audit function on a regular basis and may make a recommendation to the Management Board 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. At the date of this Prospectus, 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, the Company 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 largest shareholders, being LSP Curetis Pooling B.V. (holding more than 10% of the issued and outstanding share capital of the Company). 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 2018).
- Mr. Rhodes shall not formally be deemed to be 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 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 November 2015, and with an overall fee of USD 2,000 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.
- 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.
- The Company does not yet comply with best practice provision 2.4.5, which requires that the Supervisory Directors will follow an introductory program. The Company's Supervisory Directors all have extensive relevant experience in the field the Company operates in, and/or have substantial experience with the Company 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 the Company, the Company will re-evaluate 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 is the case with the exception of the roll-over shares which will be held by the Managing Directors pursuant to the restructuring of the PSOP. See note 4.20 in the notes to the Company's consolidated financial statements for the year ended 31 December 2017). After the expiry

of the lock up period, the beneficiaries under the PSOP, amongst which the Managing Directors, shall be allotted shares as a step of the equity settlement of the PSOP. As part of the expected future settlement of the PSOP, one or several transactions are expected to be consummated in order to generate the funds that will enable the beneficiaries to pay the German income taxes that will become due as a result of the roll-up and settlement of the former PSOP.

- 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 Supervisory Directors (except for Dr. Rudy Dekeyser who waived these grants under LSP fund policies) have been granted stock options under the ESOP 2016 as set out above under “— *Equity holdings*”. Under this plan, stock options may be granted to Supervisory Directors on an annual basis subject to approval by the General Meeting. The Company believes that being able to grant stock options to Supervisory Directors shall contribute in finding and binding competent Supervisory Directors. The number of stock options to be granted to Supervisory Directors is limited to 15,000 per year.
- Best practice provision 4.2.3 provides that the Company 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, the Company complies with this rule for major investor conferences only. The Company 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 the Company’s resources. The Company will make sure that all presentations shall be posted on the website of the Company as soon practically possible.



## MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

### Major Shareholders

The public register of the AFM identifies the following investors holding a substantial interest of 3% or more in the Company's share capital and/or voting rights on 30 October 2018.

Shareholder	Number of Shares	Percentage of share capital and voting rights <sup>(1)</sup>
LSP Curetis Pooling B.V. ....	2,822,780	18.68%
C Partners Holding GmbH <sup>(2)</sup> .....	2,329,378	14.99%
Forbion Capital Fund II Coöperatief U.A.....	1,387,059	9.10%
HBM BioCapital II Management Ltd. <sup>(3)</sup> .....	1,309,676	8.67%
Aviva plc <sup>(4)</sup> .....	1,125,000	7.45%
Milaya Invest NV.....	1,091,000	6.66%
Roche Finanz AG.....	966,018	6.39%
Federal Republic of Germany <sup>(5)</sup> .....	926,930	6.14%

Notes:

- (1) Actual interests may differ as the holder of a substantial interest is only obliged to notify the AFM of any change in the percentage of share capital and/or voting rights if such holder, directly or indirectly, reaches, exceeds or falls below any of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%;
- (2) Held indirectly through aeris CAPITAL Archer, L.P.;
- (3) Held indirectly through HBM BioCapital II L.P. and HBM BioCapital II Invest S.à r.l.;
- (4) Held indirectly, as follows: (i) 6,570 Shares are directly held by Aviva France SA, investment managed by Aviva Investors Global Services Limited, (ii) 1,096,611 Shares are directly held by Aviva Life & Pensions UK Limited, investment managed by Aviva Investors Global Services Limited and (iii) 21,819 Shares are directly held by RBS Collective Investment Funds Limited, investment managed by Aviva Investors Global Services Limited;
- (5) Held indirectly through KfW.

All Shares have the same voting rights. None of the above shareholders will hold voting rights which are different from those held by other Shareholders and there will not be any shareholdings that carry special rights relating to control of the Company.

### Related Party Transactions

For a description of related party transactions, please see Note 35 to the Annual Financial Statements.

## DESCRIPTION OF SHARE CAPITAL

The following paragraphs summarise certain information concerning the Company's share capital and certain material provisions of the Articles of Association and applicable laws of the Netherlands.

This summary does not purport 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 the laws of the Netherlands, the Articles of Association, the Management Board Rules and the Supervisory Board Rules, in each case as in effect on the date of this Prospectus. The Articles of Association in the governing Dutch language and in an unofficial English translation thereof as well as the Management Board Rules and the Supervisory Board Rules in the English language are available on the Company's website (<http://www.curetis.com/en/investors/share-information/offering.html>). See also "*Management, Employees and Corporate Governance*" for a summary of certain material provisions of the Articles of Association, Management Board Rules, Supervisory Board Rules, Terms of Reference and the laws of the Netherlands relating to the Management Board and the Supervisory Board.

### General

The Company was incorporated as a private limited liability company (*besloten vennootschap met beperkte aansprakelijkheid*) under the laws of the Netherlands on 8 October 2015. The Company is domiciled in Holzgerlingen, Germany. The Company was converted to a public company with limited liability (*naamloze vennootschap*) on 10 November 2015. The statutory seat of the Company is in Amsterdam, The Netherlands, and its principal place of business is at Holzgerlingen, Germany. The Company is registered in the Commercial Register of the Chamber of Commerce (*Handelsregister van de Kamer van Koophandel*) under number 64302679. The Company's commercial name is Curetis N.V. and its phone number is 0049 (0)70314919510.

### Corporate Purpose

Pursuant to article 3 of the Articles of Association, the corporate objectives of the Company are:

- (a) to develop, to produce and to sell products and solutions for molecular diagnostics (MDx) combating infectious diseases and other diseases;
- (b) to participate in, to take an interest in any other way in and to conduct the management of other business enterprises, of whatever nature;
- (c) to finance companies or enterprises with which it is affiliated in a group and to give security, to give guarantees and to bind itself in any other manner for debts of companies or enterprises with which it is affiliated in a group;
- (d) to borrow, and to raise funds, including the issue of bonds, debt instruments and other securities, to lend funds to companies or enterprises with which it is affiliated in a group, as well as to enter into agreements in connection therewith;
- (e) to render advice and services to other persons;
- (f) to acquire, manage, exploit and dispose of immovables and other registered properties;
- (g) to develop, exploit and trade in patents, trademarks, licenses, know-how, copyrights, database rights and other intellectual property rights;
- (h) to perform all activities of an industrial, financial or commercial nature,

as well as all activities which are incidental to or which may be conducive to any of the foregoing in the broadest sense.

In pursuing its objectives, the Company shall also take into account the interests of the legal entities and companies with which it forms a group.

## **Share Capital**

### ***Authorised and issued share capital of the Company***

The authorised capital of the Company amounts to €550,000 and consists of 55,000,000 Shares with a nominal value of €0.01 each and the issued share capital consists of 16,458,802 Shares. As of the date of this Prospectus, no Shares are held by the Company. The Shares are fully paid-up and are subject to, and have been created under, the laws of the Netherlands.

### ***History of share capital***

In addition to the Share issued upon the Company's incorporation, the Company has issued the following Shares:

- 11,107,378 Shares on 10 November 2015;
- 4,000,000 Shares on 13 November 2015;
- 431,033 Shares on 7 December 2015;
- 854,166 Shares on 2 May 2018; and
- 66,225 Shares on 9 October 2018.

### ***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.

The Company's 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 pre-emptive 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 authorised, 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. The Company may not subscribe for its own Shares on issue.

The General Meeting has designated the Management Board as the corporate body authorised, subject to approval of the Supervisory Board, to issue Shares and grant rights to subscribe for Shares and to restrict or exclude statutory pre-emptive rights relating thereto. This designation of the Management Board ends on 21 December 2019 and is limited to (i) up to 10% of the total number of Shares issued on 21 June 2018, the date on which the designation was provided, plus (ii) up to an additional 10% of the total number of Shares issued on such date, which additional authorisation may be used in relation to mergers and acquisitions or strategic alliances involving any one or more of the Company and its group companies, plus (iii) up to an additional 1,639,257 Shares which may be used for ESOP 2016. The General Meeting has designated the Supervisory Board as the corporate body authorised to grant options for up to 60,000 Shares to Mr. Oliver Schacht, Ph. D. and options for up to 40,000 Shares to Dr. Achim Plum effective per 1 January 2019. In addition, the General Meeting has designated the Management Board as the corporate body authorised, subject to approval of the Supervisory Board, to issue Shares or grant rights to subscribe for Shares and to restrict or exclude statutory pre-emptive rights relating thereto. This designation of the Management Board ends on 21 December 2019 and is limited to 50% of the issued share capital of the Company on 21 June 2018, the date on which the designation was provided, and may be used to raise additional capital to support the execution of the Company's strategy and the development of its business. The Management Board, with the approval from the Supervisory Board, intends to issue the Offer Shares and exclude the statutory pre-emptive rights relating thereto pursuant to these authorisations. The relevant management and supervisory board resolutions shall be adopted prior to Settlement.

### ***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 the Company 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 the Company is present or represented at the General Meeting.

The Management Board is authorised, 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 has designated the Management Board as the corporate body authorised, subject to approval of the Supervisory Board, to issue Shares and grant rights to subscribe for Shares and to restrict or exclude statutory pre-emptive rights relating thereto. This designation of the Management Board ends on 21 December 2019 and is limited to (i) up to 10% of the total number of Shares issued on 21 June 2018, the date on which the designation was provided, plus (ii) up to an additional 10% of the total number of Shares issued on such date, which authorisation may be used in relation to mergers and acquisitions or strategic alliances involving any one or more of the Company and its group companies, plus (iii) up to an additional 1,639,257 Shares which may be used for ESOP 2016. In addition, the General Meeting has designated the Management Board as the corporate body authorised, subject to approval of the Supervisory Board, to issue Shares or grant rights to subscribe for Shares and to restrict or exclude statutory pre-emptive rights relating thereto. This designation of the Management Board ends on 21 December 2019 and is limited to 50% of the issued share capital of the Company on 21 June 2018, the date on which the designation was provided, and may be used to raise additional capital to support the execution of the Company's strategy and the development of its business. The Management Board, with the approval from the Supervisory Board, intends to issue the Offer Shares and exclude the statutory pre-emptive rights relating thereto pursuant to these authorisations. The relevant management and supervisory board resolutions shall be adopted prior to Settlement.

#### ***Acquisition of Shares by the Company***

The Company 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 the Company 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 authorised by the General Meeting to repurchase Shares, which authorisation 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 authorisation is valid for a specific period not exceeding 18 months. As part of the authorisation, 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 authorisation 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.

The Company 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 the Company in its own capital shall not be included. The Management Board is authorised, subject to approval of the Supervisory Board, to dispose of the Company's own Shares held by it.

The General Meeting designated the Management Board for a period which ends on 21 December 2019, as the corporate body authorised to, subject to approval of the Supervisory Board, cause the Company to acquire its own fully paid-up shares, through a stock exchange or in a different manner up to a maximum of (i) 10% of the total number of Shares issued and outstanding on 21 June 2018, plus (ii) any and all of the Shares issued pursuant to the exercise of the options granted under PSOP Roll-Over Agreements, 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%.

### ***Transfer of Shares***

A transfer of a Share or a restricted right thereto (*beperkt recht*) requires a deed of transfer and the acknowledgment by the Company of the transfer in writing. Such acknowledgement is not required if the Company itself is a party to the transfer.

A Share becomes a deposit share by transfer or issuance to Euroclear Nederland or to an intermediary, recording in writing that it is a deposit share. The deposit share shall be recorded in the Company's shareholders register in the name of Euroclear Nederland or the relevant intermediary, stating in writing that it is a deposit share. Deposit Shareholders are not recorded in the Company's shareholders register. Deposit shares can only be delivered from a collective depot or giro depot with due observance of the related provisions of the Dutch Securities Giro Transfers Act and with the approval of the Management Board. The transfer by a deposit shareholder of its book-entry rights representing deposit shares shall be effected in accordance with the provisions of the Dutch Securities Giro Transfers Act. The same applies to the establishment of a right of pledge and the establishment or transfer of a usufruct on these book-entry rights.

### ***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 the Company 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.

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. Certain aspects of taxation of a reduction of share capital are described in the section "*Taxation*" of this Prospectus.

## **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. The Company 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. See the section "*Dividends and Dividend Policy*" for a more detailed description regarding dividends.

### ***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.

### ***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 annual 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 authorised 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 the Company 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 the Company. 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 the Company's annual accounts, the discussion of any substantial change in the Company's 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 Dutch law (which as of the date of this Prospectus 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 the Company 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 €250,000, may request the Company to disseminate information that is prepared by them in connection with an agenda item for a General Meeting. The Company 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 or misleading signal or if, in light of the nature of the information, the Company 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 the Company 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 the Company.

### ***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 the Company for the inspection of every Shareholder until the end of the General Meeting.

### ***Dissolution and Liquidation***

Under the Articles of Association, the Company may be dissolved by a resolution of the General Meeting, subject to a proposal by the Management Board which has been approved by the Supervisory Board.

In the event of dissolution, the Company's business will be liquidated in accordance with Dutch law and the Articles of Association and the liquidation shall be arranged by the Management Board under supervision of the Supervisory Board, unless the General Meeting has designated other liquidators. During liquidation, the provisions of the Articles of Association will remain in force as far as possible.

The balance of the Company's remaining equity after payments of debts and liquidation costs will be distributed to holders of the Shares, in proportion to the aggregate nominal value of the Shares held by them.

### ***Annual Accounts, Semi-Annual Accounts and Interim Management Statements***

Annually, within four months after the end of the financial year, the Management Board must prepare the annual accounts. The annual accounts must be accompanied by an independent auditor's statement, a management report and certain other information required under Dutch law. Annually, the Supervisory Board must prepare a report, which will be enclosed with the annual accounts and the management report. All Managing Directors and Supervisory Directors must sign the annual accounts. If the signature of one or more of them is missing, this will be stated and reasons for this omission will be given. The annual accounts must be adopted by the general meeting. The annual accounts, the annual report and other information required under Dutch law must be made available at the offices of the Company to the shareholders and other persons entitled to attend and address the general meetings from the date of the notice convening the annual general meeting.



The annual accounts, the annual report, the management report and other information required under Dutch law must be filed with the AFM within five days following adoption.

Within three months after the end of the first six months of each financial year, the Management Board must prepare semi-annual financial statements and make them publicly available. If the semi-annual financial statements are audited or reviewed, the independent auditor's report must be made publicly available together with the semi-annual financial statements.

### ***Dutch Financial Reporting Supervision Act***

On the basis of the Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*) (the “**FRSA**”), the AFM supervises the application of financial reporting standards by, among others, companies whose corporate seat is in the Netherlands and whose securities are listed on a regulated Dutch or foreign stock exchange, such as the Company.

Pursuant to the FRSA, the AFM has an independent right to (i) request an explanation from the Company regarding its application of the applicable financial reporting standards and (ii) recommend the Company to make available further explanations. If the Company does not comply with such a request or recommendation, the AFM may request that the enterprise chamber of the court of appeal in Amsterdam (*Ondernemingskamer van het Gerechtshof te Amsterdam*) (the “**Enterprise Chamber**”) orders the Company to (i) provide an explanation of the way the Company has applied the applicable financial reporting standards to its financial reports or (ii) prepare its financial reports in accordance with the Enterprise Chamber's instructions.

### **Rules Governing Obligations of Shareholders to Make a Public Takeover Bid**

Pursuant to the Dutch Financial Supervision Act and in accordance with European Directive 2004/25/EC, also known as the takeover directive, the obligation to make a public takeover bid for all issued and outstanding shares or depositary receipts for shares in the share capital of a Dutch listed company arises when a party, by itself or together with parties with whom it is acting in concert, directly or indirectly acquires ‘predominant control’ in such listed company. ‘Predominant control’ is defined as being able to cast, alone or acting in concert, at least 30% of the votes at the general meeting of such listed company.

Under the Dutch Financial Supervision Act, “persons with whom a party is acting in concert” has been defined as natural persons, legal persons or companies collaborating under a contract with the aim to acquire predominant control in a Dutch listed company or, if the target company is one of the collaborators, to frustrate the success of an announced public takeover bid for that company. The following categories of natural persons, legal persons or companies are deemed in any case to act in concert: (i) legal persons or companies which together form part of a group as referred to in Section 2:24b of the Dutch Civil Code; and (ii) natural persons, legal persons or companies and the undertakings controlled by these persons or companies.

No obligation to launch a public takeover bid exists if an exemption applies, including if a party has decreased its shareholding to below 30% within a period of 30 days, unless the loss of predominant control is the result of a transfer of shares to a natural person, legal person or company that may invoke an exemption from the requirement to make a public takeover bid or if the controlling party has made use of its voting rights during that period.

In addition, it is prohibited to launch a public takeover bid for shares of a listed company, such as the Offer Shares, unless an offer document has been approved by the AFM. A public takeover bid may only be launched by way of publication of an approved offer document unless a company makes an offer for its shares. The public takeover bid rules are intended to ensure that in the event of a public takeover bid, among others, sufficient information will be made available to the holders of the shares, the holders of the shares will be treated equally, that there will be no abuse of inside information and that there will be a proper and timely offer period.

### ***Squeeze-out Proceedings***

Pursuant to Section 2:92a of the Dutch Civil Code, a shareholder who for his or her own account contributes at least 95% of a Dutch company's issued share capital may institute proceedings against such company's minority shareholders jointly for the transfer of their shares to him or her. The proceedings are held before the Enterprise Chamber and can be instituted by means of a writ of summons served upon each of the minority shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). The Enterprise Chamber may grant the claim for squeeze-out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the minority shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the shares shall give written notice of the date and place of payment and the price to the holders of the shares to be acquired whose addresses are known to him. Unless the addresses of all of them are known to him, he is required to publish the same in a daily newspaper with nationwide circulation.

The offeror under a public takeover bid is also entitled to start squeeze-out proceedings if, following the public takeover bid, the offeror contributes at least 95% of the outstanding share capital and represents at least 95% of the total voting rights. The claim of a takeover squeeze-out needs to be filed with the Enterprise Chamber within three months following the expiry of the acceptance period of the offer. The Enterprise Chamber may grant the claim for squeeze-out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the minority shareholders. In principle, the offer price is considered reasonable if the offer was a mandatory offer or if at least 90% of the shares to which the offer related were received by way of voluntary offer.

The Dutch takeover provisions of the Dutch Financial Supervision Act also entitle those minority shareholders that have not previously tendered their shares under an offer to transfer their shares to the offeror, provided that the offeror has acquired at least 95% of the outstanding share capital and represents at least 95% of the total voting rights. In regard to price, the same procedure as for takeover squeeze-out proceedings initiated by an offeror applies. The claim also needs to be filed with the Enterprise Chamber within three months following the expiry of the acceptance period of the offer.

### **Obligations to Disclose Holdings**

Holders of the Shares may be subject to notification obligations under the Dutch Financial Supervision Act. Shareholders are advised to seek professional advice on these obligations.

### ***Shareholders***

Pursuant to the Dutch Financial Supervision Act, any person who, directly or indirectly, acquires or disposes of an actual or potential interest in the capital or voting rights of the Company must immediately notify the AFM by means of a standard form, if, as a result of such acquisition or disposal, the percentage of capital interest or voting rights held by such person in the Company reaches, exceeds or falls below any of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%.

A notification requirement also applies if a person's capital interest or voting rights reaches, exceeds or falls below the abovementioned thresholds as a result of a change in the Company's total outstanding share capital or voting rights. Such notification has to be made no later than the fourth trading day after the AFM has published the Company's notification of the change in its outstanding share capital.

The Company is required to notify the AFM immediately of the changes to its total share capital or voting rights if its issued share capital or voting rights changes by 1% or more since the Company's previous notification.

The Company must furthermore notify the AFM within eight days after each quarter, in the event its share capital or voting rights changed by less than 1% in that relevant quarter since the Company's previous notification.

In addition, every holder of 3% or more of the Company's share capital or voting rights who, in relation to its previous notification, reaches, exceeds or falls below any of the abovementioned thresholds as a consequence of a different composition by means of an exchange or conversion into shares or the exercise of rights pursuant to an agreement to acquire voting rights, shall notify the AFM at the latest within four trading days.

Controlled entities, within the meaning of the Dutch Financial Supervision Act, do not have notification obligations under the Dutch Financial Supervision Act, as their direct and indirect interests are attributed to their (ultimate) parent. Any person may qualify as a parent for purposes of the Dutch Financial Supervision Act, including a natural person. A person who has a 3% or larger interest in the Company's share capital or voting rights and who ceases to be a controlled entity for these purposes must immediately notify the AFM. As of that moment, all notification obligations under the Dutch Financial Supervision Act will become applicable to the former controlled entity.

For the purpose of calculating the percentage of capital interest or voting rights, the following interests must, *inter alia*, be taken into account: (i) shares and voting rights directly held (or acquired or disposed of) by any person; (ii) shares and voting rights held (or acquired or disposed of) by such person's controlled entity or by a third party for such person's account or by a third party with whom such person has concluded an oral or written voting agreement; (iii) voting rights acquired pursuant to an agreement providing for a temporary transfer of voting rights against a payment; (iv) shares which such person (directly or indirectly) or third party referred to above, may acquire pursuant to any option or other right to acquire shares; (v) shares which determine the value of certain cash settled financial instruments such as contracts for difference and total return swaps; (vi) shares that must be acquired upon exercise of a put option by a counterparty; and (vii) shares that are the subject of another contract creating an economic position similar to a direct or indirect holding in those shares. Special attribution rules apply to shares and voting rights which are part of the property of a partnership or other community of property. A holder of a pledge or right of usufruct in respect of shares can also be subject to the reporting obligations, if such person has, or can acquire, the right to vote on the shares. The acquisition of (conditional) voting rights by a pledgee or beneficial owner may also trigger the reporting obligations as if the pledgee or beneficial owner were the legal holder of the shares.

For the purpose of the notification obligation, the following instruments qualify as "shares": (i) shares; (ii) depositary receipts for shares (or negotiable instruments similar to such receipts); (iii) negotiable instruments for acquiring the instruments under (i) or (ii) (such as convertible bonds); and (iv) options for acquiring the instruments under (i) or (ii).

### ***Notification of short positions***

Each person holding a gross short position in relation to the issued share capital of a Dutch listed company that reaches, exceeds or falls below any one of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%, must immediately give written notice to the AFM. If a person's gross short position reaches, exceeds or falls below one of the above-mentioned thresholds as a result of a change in the Company's issued share capital, such person must make a notification not later than the fourth trading day after the AFM has published the Company's notification in the public register of the AFM. Shareholders are advised to consult with their own legal advisers to determine whether the gross short selling notification obligation applies to them. In addition, pursuant to Regulation (EU) No. 236/2012, each person holding a net short position attaining 0.2% of the issued share capital of a Dutch listed company is required to notify such position to the AFM. Each subsequent increase of this position by 0.1% above 0.2% must also be notified. Each net short position equal to 0.5% of the issued share capital of a Dutch listed company and any subsequent increase of that position by 0.1%

will be made public via the AFM short selling register. To calculate whether a natural person or legal person has a net short position, their short positions and long positions must be set-off. A short transaction in a Share can only be contracted if a reasonable case can be made that the Shares sold can actually be delivered, which requires confirmation of a third party that the Shares have been located.

### ***Management***

Pursuant to the Dutch Financial Supervision Act, each Managing Director and Supervisory Director must notify the AFM: (a) immediately following the admission to trading and listing of the Shares of the number of Shares he/she holds and the number of votes he/she is entitled to cast in respect of the Company's issued share capital, and (b) subsequently of each change in the number of Shares he/she holds and of each change in the number of votes he/she is entitled to cast in respect of the Company's issued share capital, immediately after the relevant change. If a Managing Director or Supervisory Director has notified a transaction to the AFM under the Dutch Financial Markets Supervision Act as described under “— *Shareholders*”, such notification is sufficient for purposes of the Dutch Financial Markets Supervision Act as described in this paragraph.

Furthermore, pursuant to the Market Abuse Regulation ((EU) No. 596/2014), persons discharging managerial responsibilities must notify the AFM and the Company of any transactions conducted for his or her own account relating to Shares or any debt instruments of the Company or to derivatives or other financial instruments linked thereto. Persons discharging managerial responsibilities within the meaning of the Market Abuse Regulation include: (a) Managing Directors and Supervisory Directors; or (b) members of the senior management who have regular access to inside information relating directly or indirectly to that entity and the authority to take managerial decisions affecting the future developments and business prospects of the Company.

In addition, pursuant to the Market Abuse Regulation and the regulations promulgated thereunder, certain persons who are closely associated with persons discharging managerial responsibilities, are also required to notify the AFM and the Company of any transactions conducted for their own account relating to Shares or any debt instruments of the Company or to derivatives or other financial instruments linked thereto. The Market Abuse Regulation and the regulations promulgated thereunder cover, *inter alia*, the following categories of persons: (i) the spouse or any partner considered by national law as equivalent to the spouse; (ii) dependent children; (iii) other relatives who have shared the same household for at least one year at the relevant transaction date; and (iv) any legal person, trust or partnership, the managerial responsibilities of which are discharged by a person discharging managerial responsibilities or by a person referred to under (i), (ii) or (iii) above, which is directly or indirectly controlled by such a person, which is set up for the benefit of such a person, or the economic interest of which are substantially equivalent to those of such a person.

These notification obligations under the Market Abuse Regulation apply when the total amount of the transactions conducted by a person discharging managerial responsibilities or a person closely associated to a person discharging managerial responsibilities reaches or exceeds the threshold of €5,000 within a calendar year (calculated without netting). When calculating whether the threshold is reached or exceeded, persons discharging managerial responsibilities must add any transactions conducted by persons closely associated with them to their own transactions and vice versa. The first transaction reaching or exceeding the threshold must be notified as set forth above. The notifications pursuant to the Market Abuse Regulation described above must be made to the AFM and the Company no later than the third business day following the relevant transaction date.

### ***Non-compliance***

Non-compliance with the notification obligations under the Dutch Financial Supervision Act and the Market Abuse Regulation set out in the paragraphs above is an economic offence (*economisch delict*) and could lead to the imposition of criminal fines, administrative fines, imprisonment or other sanctions. The AFM may impose administrative penalties or a cease-and-desist order under penalty for non-compliance. If criminal charges are pressed, the AFM is no longer allowed to impose administrative penalties and vice versa, the AFM is no longer

allowed to seek criminal prosecution if administrative penalties have been imposed. In addition, non-compliance with some of the notification obligations set out in the paragraphs above may lead to civil sanctions, including suspension of the voting rights relating to the shares held by the offender for a period of not more than three years, voiding of a resolution adopted by the general meeting in certain circumstances and ordering the person violating the disclosure obligations to refrain, during a period of up to five years, from acquiring shares and/or voting rights in shares.

### ***Public registry***

The AFM does not issue separate public announcements of these notifications. It does, however, keep a public register of all notifications under the Dutch Financial Supervision Act on its website ([www.afm.nl](http://www.afm.nl)). Third parties can request to be notified automatically by e-mail of changes to the public register in relation to a particular company's shares or a particular notifying party.

### ***Identity of Shareholders***

The Company may in accordance with Chapter 3A of the Dutch Securities Giro Transfers Act request Euroclear Nederland, admitted institutions, intermediaries, institutions abroad, and managers of investment institutions, to provide certain information on the identity of the Shareholders. Such request may only be made during a period of 60 days up to the day on which the General Meeting will be held. No information will be given on Shareholders with an interest of less than 0.5% of the issued share capital. A Shareholder who, individually or together with other Shareholders, holds an interest of at least 10% of the issued share capital may request the Company to establish the identity of the Shareholders. This request may only be made during a period of 60 days until (and not including) the 42<sup>nd</sup> day before the day on which the General Meeting will be held.

### **Market Abuse Regime**

The regulatory framework on market abuse is laid down in the Market Abuse Directive (2014/57/EU) as implemented in Dutch law and the Market Abuse Regulation (No. 596/2014) which is directly applicable in the Netherlands.

### ***Prohibitions***

Pursuant to the Market Abuse Regulation, no natural or legal person is permitted to: (a) engage or attempt to engage in insider dealing in financial instruments listed on a regulated market or for which a listing has been requested, such as the Shares, (b) recommend that another person engages in insider dealing or induce another person to engage in insider dealing or (c) unlawfully disclose inside information relating to the Shares or the Company. Furthermore, no person may engage in or attempt to engage in market manipulation.

### ***Publication of inside information***

The Company is required to inform the public as soon as possible and in a manner that enables fast access and complete, correct and timely assessment of the information, of inside information which directly concerns the Company. Pursuant to the Market Abuse Regulation, inside information is knowledge of concrete information directly or indirectly relating to the issuer or the trade in its securities which has not yet been made public and publication of which could significantly affect the trading price of the securities (i.e. information a reasonable investor would be likely to use as part of the basis of his or her investment decision). An intermediate step in a protracted process can also be deemed to be inside information. The Company is required to post and maintain on its website all inside information for a period of at least five years. Under certain circumstances, the disclosure of inside information may be delayed, which needs to be notified to the AFM after the disclosure has been made. Upon request of the AFM, a written explanation needs to be provided setting out why a delay of the publication was considered permitted.

***Closed periods***

A person discharging managerial responsibilities is not permitted to (directly or indirectly) conduct any transactions on its own account or for the account of a third party, relating to Shares or debt instruments of the Company or other financial instruments linked thereto, during a closed period of 30 calendar days before the announcement of a half-yearly report or an annual report of the Company.

***Non-compliance with Market Abuse Rules***

In accordance with the Market Abuse Regulation, the AFM has the power to take appropriate administrative sanctions, such as fines, and/or other administrative measures in relation to possible infringements. Non-compliance with the market abuse rules set out above could also constitute an economic offense and/or a crime (*misdrift*) and could lead to the imposition of administrative fines by the AFM. The public prosecutor could press criminal charges resulting in fines or imprisonment. If criminal charges are pressed, it is no longer allowed to impose administrative penalties and vice versa.

The AFM shall in principle also publish any decision imposing an administrative sanction or measure in relation to an infringement of the Market Abuse Regulation. The Company has adopted a policy on insider trading in respect of the reporting and regulation of transactions in the Company's securities by Managing Directors and Supervisory Directors and the Company's employees. The Company and any person acting on its behalf or on its account is obligated to draw up an insiders' list, to promptly update the insider list and provide the insider list to the AFM upon its request. The Company and any person acting on its behalf or on its account is obligated to take all reasonable steps to ensure that any person on the insider list acknowledges in writing the legal and regulatory duties entailed and is aware of the sanctions applicable to insider dealing and unlawful disclosure of inside information.

**Transparency Directive**

The Netherlands is the Company's home member state for the purposes of Directive 2004/109/EC (as amended by Directive 2013/50/EU) as a consequence of which the Company will be subject to the Dutch Financial Supervision Act in respect of certain on-going transparency and disclosure obligations.

## THE OFFERING

### Introduction

The Company is offering up to 7,428,349 Offer Shares. The Management Board, with the approval from the Supervisory Board, intends to issue the Offer Shares and exclude the statutory pre-emptive rights relating thereto pursuant to the authorisations to issue Shares and limit or exclude pre-emptive rights in relation thereto under the authorisations granted to it during the annual General Meeting held on 21 June 2018. The relevant management and supervisory board resolutions shall be adopted prior to Settlement. The Offer Shares will constitute not more than approximately 45.13% of the issued Shares.

The Offering solely consists of private placements to certain institutional investors in various jurisdictions. The Offer Shares are being offered: (a) within the United States, to QIBs as defined in Rule 144A under the US Securities Act, pursuant to Rule 144A or another applicable exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act and applicable state securities laws, and (b) outside the United States in offshore transactions as defined in, and in accordance with Regulation S.

The Offer Shares have not been and will not be registered under the US Securities Act. The Offering is made only in those jurisdictions in which, and only to those persons to whom, the Offering may be lawfully made.

### Timetable

Subject to acceleration or extension of the timetable for, or withdrawal of, the Offering, the timetable below lists certain expected key dates for the Offering:

Event	Time (CET) and date
Start of Offer Period.....	09:00 on 2 November 2018
End of Offer Period for institutional investors.....	15:00 on 7 November 2018
Expected pricing and allocation.....	7 November 2018
First day of trading after close of the Offer Period.....	8 November 2018
Settlement Date.....	9 November 2018

The Company, after consultation with the Managers, may adjust the dates, times and periods given in the timetable and throughout this Prospectus. Should such adjustment be decided on, then the Company will make this public through a press release, which will also be posted on the Company's website. Any other material alterations will be published through a press release that will also be posted on the Company's website and in a supplement to this Prospectus (if required) that is subject to the approval of the AFM.

Any extension of the timetable for the Offering will be published in a press release at least three hours before the end of the original Offer Period, provided that any extension will be for a minimum of one full day. Any acceleration of the timetable for the Offering will be published in a press release at least three hours before the proposed end of the accelerated Offer Period.

### Offer Period

Subject to acceleration or extension of the timetable for the Offering, prospective investors may subscribe for Offer Shares during the period commencing at 09:00 CET on 2 November 2018 and ending at 15:00 CET on 7 November 2018. In the event of an acceleration or extension of the Offer Period, pricing, allocation, admission

and first trading of the Offer Shares, as well as payment (in euro) for, and delivery of, the Offer Shares may be advanced or extended accordingly.

If a significant new factor, material mistake or inaccuracy relating to the information included in this Prospectus, which is capable of affecting the assessment of the Offer Shares, arises or is noted before the end of the Offer Period, a supplement to this Prospectus will be published and the Offer Period will be extended, if so required by the Dutch Financial Supervision Act or the rules promulgated thereunder. A supplement to this Prospectus is subject to AFM approval.

### **Offer Price and Number of Offer Shares**

As at the date of this Prospectus, the Offer Price is expected to be in the range of €2.00 to €2.60 (inclusive) per Offer Share. The Offer Price Range is an indicative price range. The Offer Price, which may be higher or lower than the initial Offer Price Range, and the exact number of Offer Shares will be determined on the basis of a book-building process. The Offer Price and the exact number of Offer Shares offered in the Offering will be determined and agreed upon by the Company and the Managers after the end of the Offer Period, including any acceleration or extension, on the basis of a book-building process and taking into account the quoted Share price, economic and market conditions, a qualitative and quantitative assessment of demand for the Offer Shares, and other factors deemed appropriate.

The Offer Price and the exact number of Offer Shares offered in the Offering will be set out in the Pricing Statement that will be deposited with the AFM and published through a press release by the Company, which will also be posted on the Company's website. Printed copies of the Pricing Statement will be made available at the Company's registered office address. The number of Offer Shares being offered may be increased or decreased. See "*— Change of the Number of Offer Shares or Offer Price Range*".

A number of factors will be considered in determining the Offer Price, the number of Offer Shares sold, the proceeds of the Offering and the basis for allocation. Unless required to do so by law or regulation, the Company does not envisage publishing any supplementary prospectus or, until announcement of the Offer Price, a pricing statement.

### **Change of the Number of Offer Shares or Offer Price Range**

The Company, in consultation with the Managers, reserves the right to change the Offer Price Range and/or increase or decrease the number of Offer Shares being offered prior to Allocation. Any such change in the Offer Price Range and/or the number of Offer Shares being offered will be published in a press release that will also be posted on the Company's website.

### **Subscription and Allocation**

Allocation is expected to take place after the end of the Offer Period, on or about 7 November 2018, subject to acceleration or extension of the timetable for the Offering. Allocation to investors who applied to subscribe for Offer Shares will be determined by the Company, after consultation with the Managers, and full discretion will be exercised as to whether or not and how to allot the Offer Shares. There is no maximum or minimum number of Offer Shares for which prospective investors may subscribe and multiple (applications for) subscriptions are permitted. In the event that the Offering is over-subscribed, investors may receive fewer Offer Shares than they applied to subscribe for. The Company and the Managers may, at their own discretion and without stating the grounds therefore, reject any subscriptions wholly or partly. Any monies received in respect of subscriptions which are not accepted in whole or in part will be returned to the investors without interest and at the investor's risk.



Investors participating in the Offering will be deemed to have checked and confirmed that they meet the selling and transfer restrictions described in “*Selling and Transfer Restrictions*”. Each investor should consult his or her own advisers as to the legal, tax, business, financial and related aspects of a purchase of Offer Shares.

The Managers will notify investors or the relevant financial intermediary of any allocation of Offer Shares to them on the date of, or immediately following the date of, Allocation.

## **Payment**

Payment in euro for and delivery of the Offer Shares will take place on the Settlement Date. Taxes and expenses, if any, must be borne by the investor (for more information, see “*Taxation*”). The Offer Price must be paid in immediately available funds in full in euro on or before the Settlement Date (or earlier in the case of an early closing of the Offer Period and consequent acceleration of pricing, Allocation, first trading and payment and delivery) and is exclusive of any taxes and expenses, if any, which must be borne by the investor.

## **Delivery, Clearing and Settlement**

The Offer Shares will be delivered in book-entry form through the facilities of Euroclear Nederland. Application has been made for the Shares to be accepted for clearance through the book-entry facilities of Euroclear Nederland. Euroclear Nederland is located at Herengracht 459-469, 1017 BS Amsterdam, the Netherlands.

Delivery of the Offer Shares is expected to take place on the Settlement Date through the book-entry facilities of Euroclear Nederland, in accordance with its normal settlement procedures applicable to equity securities and against payment (in euro) for the Offer Shares in immediately available funds.

The Shares, excluding the Offer Shares, are currently listed and trading under the symbol “CURE” on Euronext in Amsterdam and Euronext in Brussels. The ISIN code of the Shares is NL0011509294. Application has been made to list the Offer Shares on Euronext in Amsterdam and Euronext in Brussels under the same symbol and with the same ISIN code.

Closing of the Offering may not take place on the Settlement Date or at all if certain conditions or events referred to in the Underwriting Agreement are not satisfied or waived or occur on or prior to such date. See “*Plan of Distribution — Underwriting Arrangements*”. If Settlement does not take place on the Settlement Date as planned or at all, the Offering may be withdrawn, in which case all subscriptions for Offer Shares will be disregarded, any allotments made will be deemed not to have been made and any subscription payments made will be returned without interest or other compensation. Any dealings in Offer Shares prior to Settlement are at the sole risk of the parties concerned. None of the Company, the Managers, the Listing Agent or Euronext accepts any responsibility or liability for any loss incurred by any person as a result of a withdrawal of the Offering or the related annulment of any transactions in Shares on Euronext in Amsterdam and Euronext in Brussels. Should the anticipated gross proceeds of the Offering (excluding the PSOP Proceeds) fall below €8 million, the Offering will in any event be withdrawn, no Shares will be issued and any applications to subscribe for Offer Shares will be disregarded.

## **Dilution**

The voting interest of the existing Shareholders will be diluted as a result of the issuance of the Offer Shares. The maximum dilution for the existing Shareholders not participating in the Offering pursuant to the issuance of the Offer Shares would be 31.1%, assuming the issuance of the maximum number of Offer Shares.

## **Voting Rights**

Each Share confers the right to cast one vote in the General Meeting, see “*Description of Share Capital — General Meetings and Voting Rights — Voting rights*”. All Shareholders have the same voting rights.

## **Ranking and Dividends**

The Offer Shares rank equally in all respects. The Offer Shares will carry dividend rights as of the date of issue. See “*Dividends and Dividend Policy*”.

## **Sole Global Coordinator, Sole Bookrunner and Sole Underwriter**

Baader Bank is acting as sole global coordinator, sole bookrunner and sole underwriter for the Offering.

## **Placement Agent and Co-Manager**

goetzpartners is acting as placement agent and co-manager for the Offering.

Baader Bank and goetzpartners are together acting as managers for the Offering.

## **Listing Agent**

ABN AMRO Bank N.V. is acting as listing agent with respect to the listing of Shares on Euronext in Amsterdam and Euronext in Brussels and is also acting as paying agent for the Shares in the Netherlands.

## **Liquidity Provider**

Bank DeGroof Petercam is liquidity provider for the Shares on Euronext in Amsterdam and Euronext in Brussels.

## PLAN OF DISTRIBUTION

### Underwriting Arrangements

The Company and the Managers entered into the Underwriting Agreement on 2 November 2018 with respect to the issue of the Offer Shares in connection with the Offering. The material terms and conditions of the Underwriting Agreement are set out below.

After entering into the pricing agreement between the Company and the Managers (the “**Pricing Agreement**”) (when the Offer Price is determined), which is a condition for the obligations of the Managers under the Underwriting Agreement, and on the terms and subject to the conditions set forth in the Underwriting Agreement, the Company will agree to issue the number the Offer Shares at the Offer Price, as specified in the Pricing Agreement, to subscribers procured for by the Managers and the Managers will severally but not jointly agree to procure subscribers for, or failing subscription by such procured subscribers to subscribe themselves for, such number of Offer Shares at the Offer Price.

Subject to the satisfaction of these conditions precedent, the proportion of Offer Shares that each Underwriter may severally be required to subscribe for is indicated below.

<b>Managers</b>	<b>Underwriting Commitment of Offer Shares</b>
Baader Bank AG .....	100%
goetzpartners securities Limited .....	nil%
<b>Total</b> .....	<b>100%</b>

In the Underwriting Agreement, the Company makes certain representations and warranties. In addition, the Company will indemnify the Managers against liabilities in connection with the Offering. The Underwriting Agreement provides that the obligations of the Managers to procure subscribers for, or failing subscription by such procured subscribers to subscribe themselves for, the Offer Shares are subject to, among other things, the following conditions: (i) the approval of this Prospectus by the AFM being in full force and effect, (ii) receipt at closing of opinions on certain legal matters from counsel, (iii) receipt of customary officers’ certificates, (iv) the absence of a material adverse change in respect of the business, financial position, results of operations or prospects of Curetis or in financial markets since the date of the Underwriting Agreement, (v) the admission of the Offer Shares to listing on Euronext in Amsterdam and Euronext in Brussels occurring no later than 09:00 a.m. CET on the Settlement Date and (vi) certain other customary conditions, most notably in respect of the accuracy of certain representations and warranties by the Company, required disclosure by the Company having been made and the Company having complied with the terms of the Underwriting Agreement.

Upon the occurrence of certain specific events, such as the occurrence of (i) a material adverse change in respect of the business, financial position, results of operations or prospects of the Company and its subsidiaries taken as a whole or in financial markets since the date of the Underwriting Agreement, (ii) a material breach of the Underwriting Agreement or (iii) a statement in this Prospectus, the Pricing Statement or any amendment or supplement to this Prospectus being untrue, inaccurate or misleading, the Sole Global Coordinator (acting on behalf of the Managers) may elect to terminate the Underwriting Agreement at any time prior to the Settlement Date.

In consideration of the agreement by the Managers to procure subscribers for or, failing subscription by such procured subscribers to subscribe themselves for, the Offer Shares at the Offer Price and subject to the Offer

Shares being issued in accordance with the Underwriting Agreement, the Company has agreed to pay the Managers an aggregate commission of 4.5% of the gross proceeds of the Offering and the Sole Global Coordinator an additional commission of 0.5% of the gross proceeds of the Offering. This does not include an incentive commission of up to 1% of the gross proceeds of the Offering, which may be paid to the Managers at the discretion of the Company. Notwithstanding the commissions payable but still subject to the Offer Shares being issued in accordance with the Underwriting Agreement, pursuant to the Underwriting Agreement the Company has agreed to pay a minimum amount of €500,000 to the Sole Global Coordinator and €375,000 to the Co-Manager. The Company has also agreed to reimburse the Managers for certain expenses incurred by them in connection with the Offering.

The Offer Shares have not been and will not be registered under the US Securities Act or the applicable securities laws of any state or other jurisdiction of the US and may not be offered, sold, pledged or transferred within the US, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act. The Offer Shares may be offered and sold: (i) in the US only to QIBs in reliance on Rule 144A; and (ii) outside the US in compliance with Regulation S. Any offer or sale of Offer Shares in reliance on Rule 144A will be made by broker dealers who are registered as such under the Exchange Act. Terms used in this paragraph have the meanings given to them by Regulation S and Rule 144A.

### **Lock-up Arrangements**

The restrictions of the lock-up arrangement described below, including those on sales, issues or transfers of Shares, may be waived by the Managers, in their sole discretion and at any time. If the consent of the Sole Global Coordinator (acting on behalf of the Managers) in respect of a waiver of the lock-up arrangements is requested as described below, the Sole Global Coordinator (acting on behalf of the Managers) shall not unreasonably withhold its consent and may give its consent conditionally.

Pursuant to the Underwriting Agreement, the Company has agreed with the Managers that, for a period from the date of the Underwriting Agreement until 180 days from the Settlement Date (the company lockup period), it will not, except as set forth below, without the prior consent of the Managers, (i) directly or indirectly, issue, offer, pledge, sell, contract to sell, sell or grant any option, right, warrant or contract to purchase, exercise any option to sell, purchase any option or contract to sell, or lend or otherwise transfer or dispose of any Shares or other shares of the Company or any securities convertible into or exercisable or exchangeable for Shares or other shares of the Company or file any registration statement under the US Securities Act or any similar document with any other securities regulator, stock exchange or listing authority with respect to any of the foregoing; (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of any Shares or other shares of the Company, whether any such transaction is to be settled by delivery of Shares or such other securities, in cash or otherwise; (iii) publicly announce such an intention to effect any transaction referred to in (i) or (ii) above; or (iv) submit to its Shareholders or any other body of the Company a proposal to effect any of the foregoing.

The foregoing shall not apply to: (a) the issue and offer by or on behalf of the Company of the Offer Shares, (b) the Company's obligations pursuant to the Yorkville Agreement and (c) the granting of awards in options or Shares by the Company or the issuance of Shares upon exercise of options granted by the Company pursuant to employee incentive schemes disclosed in, and as such grant or issue is disclosed in, the Prospectus (including, for the avoidance of doubt, the issuance of Shares in connection with and pursuant to the PSOP Roll-Over Agreements).

## **Potential conflicts of interests**

The Managers are acting exclusively for the Company and for no one else and will not regard any other person (whether or not a recipient of this Prospectus) as their respective clients in relation to the Offering and will not be responsible to anyone other than to the Company for giving advice in relation to the Offering and for the listing and trading of the Shares and/or any other transaction or arrangement referred to in this Prospectus.

Certain of the Managers and/or their respective affiliates have in the past been engaged, and may in the future, from time to time, engage in commercial banking, investment banking and financial advisory and ancillary activities in the ordinary course of their business with the Company or any parties related to it, in respect of which they have received, and may in the future receive, customary fees and commissions.

In connection with the Offering, each of the Managers and any of their respective affiliates, acting as an investor for its own account, may take up Offer Shares in the Offering and in that capacity may retain, purchase or sell for its own account such securities and any Offer Shares or related investments and may offer or sell such Offer Shares or other investments otherwise than in connection with the Offering. Accordingly, references in this Prospectus to Offer Shares being issued should be read as including any issuance of Offer Shares to any of the Managers or any of their respective affiliates acting in such capacity. None of the Managers intends to disclose the extent of any such investment or transactions otherwise than pursuant to any legal or regulatory obligation to do so. In addition, certain of the Managers or their affiliates may enter into financing arrangements (including swaps) with investors in connection with which such Managers (or their affiliates) may from time to time acquire, hold or dispose of Offer Shares.

As a result of acting in the capacities described above, the Managers may have interests that may not be aligned, or could potentially conflict, with the interests of investors and the Company.

## SELLING AND TRANSFER RESTRICTIONS

### General

The offering of the Offer Shares to persons resident in, or who are citizens of, a particular jurisdiction may be affected by the laws of that jurisdiction. Investors should consult their professional adviser as to whether they require any governmental or any other consent or need to observe any other formalities to enable the investor to accept, sell or purchase Offer Shares.

No action has been or will be taken to permit a public offering of the Offer Shares in any jurisdiction outside the Netherlands and Germany. Receipt of this Prospectus will not constitute an offer in those jurisdictions in which it would be illegal to make an offer and, in those circumstances, this Prospectus will be sent for informational purposes only and should not be copied or redistributed.

If an investor receives a copy of this Prospectus in any territory other than the Netherlands and Germany, the investor may not treat this Prospectus as constituting an invitation or offer to the investor of the Offer Shares, unless, in the relevant jurisdiction, such an offer could lawfully be made to the investor, or the Offer Shares could lawfully be dealt in without contravention of any unfulfilled registration or other legal requirements. Accordingly, if the investor receives a copy of this Prospectus or any other offering materials or advertisements, the investor should not distribute the same to any person in or into any jurisdiction where to do so would or may contravene local securities laws or regulations.

If an investor forwards this Prospectus or any other offering materials or advertisements into any such territories (whether under a contractual or legal obligation or otherwise) the investor should draw the recipient's attention to the contents of this "*Selling and Transfer Restrictions*" section.

Subject to the specific restrictions described below, if investors (including, without limitation, any investor's nominees and trustees) are outside the Netherlands or Germany and wish to accept, sell or purchase Offer Shares, they must satisfy themselves as to full observance of the applicable laws of any relevant territory including obtaining any requisite governmental or other consents, observing any other requisite formalities and paying any issue, transfer or other taxes due in such territories.

The information set out in this "*Selling and Transfer Restrictions*" section is intended as a general guideline only. Investors that are in any doubt as to whether they are eligible to purchase Offer Shares should consult their professional adviser without delay.

### Selling Restrictions

#### *United States*

The Offer Shares have not been and will not be registered under the US Securities Act, or with any securities regulatory authority of any state or other jurisdiction in the United States, and may not be offered, sold, subscribed for, pledged or otherwise transferred within the United States, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act. Accordingly, the Offer Shares may be offered or sold: (i) within the United States to QIBs as defined in Rule 144A in reliance on Rule 144A or pursuant to another exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act, and (ii) outside the United States in offshore transactions in reliance on Regulation S under the US Securities Act. Any offer or sale of the Offer Shares in the United States will be made through US broker-dealer affiliates of the Managers. Transfers of the Offer Shares will be restricted and each purchaser will be deemed to have made acknowledgements, representations and agreements, as described in the section "*— Transfer Restrictions*".

In addition, until the end of the 40th calendar day after the commencement of the Offering, an offer or sale of the Offer Shares within the United States by a dealer (whether or not participating in the Offering) may violate the registration requirements of the US Securities Act if such offer or sale is made otherwise than in accordance with Rule 144A or another exemption from registration under the US Securities Act.

### ***European Economic Area***

In relation to each Relevant EEA Member State, no Offer Shares have been offered or will be offered pursuant to the Offering to the public in that Relevant EEA Member State, except to legal entities which are qualified investors as defined in the Prospectus Directive, provided that no such offer of Offer Shares shall result in a requirement for the publication of a prospectus pursuant to Article 3 of the Prospectus Directive or any measure implementing the Prospectus Directive in a Relevant EEA Member State or publish a supplement to the prospectus pursuant to Article 16 of the Prospectus Directive or any measure implementing the Prospectus Directive in a Relevant EEA Member State.

For the purpose hereof, the expression an ‘offer of any shares to the public’ in relation to any Offer Shares in any Relevant EEA Member State means a communication to persons in any form and by any means presenting sufficient information on the terms of the Offering and the Offer Shares to be offered, so as to enable an investor to decide to acquire any Offer Shares, as that definition may be varied in that Relevant EEA Member State by any measure implementing the Prospectus Directive in that Relevant EEA Member State.

Each person in a Relevant EEA Member State who receives any communication in respect of, or who acquires any Offer Shares under, the Offering contemplated hereby will be deemed to have represented, warranted and agreed to and with each of the Managers and us that:

- (i) it is a qualified investor within the meaning of Article 2(1)(e) of the Prospectus Directive; and
- (ii) in the case of any Offer Shares acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, the Offer Shares acquired by it in the Offering have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant EEA Member State other than qualified investors, as that term is defined in the Prospectus Directive.

The Company, the Managers and their affiliates, and others will rely upon the truth and accuracy of the foregoing representation, acknowledgement and agreement. Notwithstanding the above, a person who is not a qualified investor and who has notified the Managers of such fact in writing may, with the prior consent of the Managers, be permitted to acquire Offer Shares in the Offering.

### ***United Kingdom***

This Prospectus and any other material in relation to the Offer Shares described herein is directed at and for distribution in the United Kingdom only to persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospective Directive that are also (i) persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Promotion Order, or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Financial Promotion Order (all such persons being together referred to as “relevant persons”). The Offer Shares are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such Offer Shares will be engaged in only with, relevant persons. Any person in the United Kingdom who is not a relevant person should not act or rely on this Prospectus or any of its contents. Any investment or investment activity to which this Prospectus relates is available only to relevant persons and will be engaged in only with relevant persons. This Prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other person in the United Kingdom.

Furthermore, the Managers have warranted that they (i) have only invited or will only invite participation in investment activities in connection with the offering or the sale of the Offer Shares within the meaning of Section 21 of the FSMA, and have only initiated or will only initiate such investment activities to the extent that Section 21(1) of the FSMA does not apply to the Company; and (ii) have complied and will comply with all applicable provisions of FSMA with respect to all activities already undertaken by each of them or will undertake in the future in relation to the Offer Shares in, from, or otherwise involving the United Kingdom.

### ***Switzerland***

This document as well as any other material relating to the Offer Shares which are the subject of the offering contemplated by this Prospectus does not constitute an issue prospectus pursuant to Articles 652a and/or 1156 of the Swiss Code of Obligations. The Offer Shares will not be listed on the SIX Swiss Exchange and, therefore, the documents relating to the Offer Shares including, but not limited to, this document, do not claim to comply with the disclosure standards of the listing rules of the SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange.

The Offer Shares are being offered in Switzerland by way of a private placement, i.e., to a small number of selected investors only, without any public offer and only to investors who do not purchase the Offer Shares with the intention to distribute them to the public. The investors will be individually approached by the Company from time to time.

This document as well as any other material relating to the Offer Shares is personal and confidential and does not constitute an offer to any other person. This document may only be used by those investors to whom it has been handed out in connection with the Offering described herein and may neither directly nor indirectly be distributed or made available to other persons without the express consent of the Company. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in (or from) Switzerland.

### ***Israel***

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the “**Israeli Securities Law**”), and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the Offer Shares is directed only (i) at a limited number of persons in accordance with Section 15A(a)(1) of the Israeli Securities Law or (ii) to investors listed in the first schedule to the Israeli Securities Law (the “**Schedule**”), consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and qualified individuals, each as described in the Schedule (as it may be amended from time to time), collectively referred to as “qualified investors” (in each case purchasing for their own account or, where permitted under the Schedule, for the accounts of their clients who are investors listed in the Schedule). Qualified investors will be required to submit written confirmation that they fall within the scope of the Schedule.

### **Transfer Restrictions**

The Offer Shares have not been and will not be registered under the US Securities Act or the applicable securities laws of any state or other jurisdiction of the United States and may not be offered, sold, pledged or otherwise transferred within the United States, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act and applicable state securities laws.



### ***Outside the United States***

Each investor of the Offer Shares outside the United States will, pursuant to Regulation S, be deemed to have represented and agreed that it has received a copy of this Prospectus and such other information as it deems necessary to make an informed investment decision and that:

- (i) the investor acknowledges that the Offer Shares have not been and will not be registered under the US Securities Act, or with any securities regulatory authority of any state of the United States, and are subject to significant restrictions on transfer;
- (ii) the investor and the person, if any, for whose account or benefit the investor is acquiring the Offer Shares, were located outside the United States at the time the buy order for such Offer Shares was originated and continue to be located outside the United States and has not purchased the Offer Shares for the benefit of any person in the United States or entered into any arrangement for the transfer of the Offer Shares to any person in the United States;
- (iii) the investor is aware of the restrictions on the offer and sale of the Offer Shares pursuant to Regulation S as described in this Prospectus; and
- (iv) the Offer Shares have not been offered to it by means of any “directed selling efforts” as defined in Regulation S.

### ***Within the United States***

Each investor of Offer Shares in reliance on Rule 144A, by accepting delivery of this Prospectus, will be deemed to have represented, agreed and acknowledged as follows (terms used in the following paragraphs that are defined in Rule 144A have the respective meanings given to them in Rule 144A):

- (i) the investor is (a) a QIB, (b) acquiring the Shares for its own account or for the account of one or more QIBs, (c) not formed for the purpose of investing in the Offer Shares or the Company, and (d) is aware, and each beneficial owner of such Offer Shares has been advised, that the sale of the Offer Shares to it is being made in reliance on Rule 144A or in reliance on another exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act;
- (ii) the investor understands that (1) the Offer Shares have not been, and will not be, registered under the United States Securities Act or with the securities regulatory authority of any state or other jurisdiction of the United States, and may not be offered, sold, pledged or otherwise transferred except (a) in accordance with Rule 144A to a person that it, and any person acting on its behalf, reasonably believes is a QIB purchasing for its own account or for the account of one or more QIBs, (b) in an offshore transaction in accordance with Rule 903 or Rule 904 of regulation S under the US Securities Act, (c) pursuant to an exemption from registration under the US Securities Act provided by Rule 144 thereunder (if available), (d) pursuant to an effective registration statement under the US Securities Act, or (e) to the Company or any of their respective affiliates, in each case in accordance with any applicable securities laws of any State of the United States, and (2) it will, and each subsequent holder of the Offer Shares is required to, notify any investor of the Offer Shares from it of the resale restrictions applicable to the Offer Shares;
- (iii) the investor understands that the Offer Shares (to the extent they are in certificated form) will bear a legend to the following effect, unless Curetis determine otherwise in accordance with applicable law:

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN, AND WILL NOT BE, REGISTERED UNDER THE UNITED STATES SECURITIES ACT OF 1933, AS AMENDED (THE “US SECURITIES ACT”) OR ANY SECURITIES LAW OF ANY STATE OR OTHER JURISDICTION OF THE UNITED STATES. THE HOLDER HEREOF, BY PURCHASING THE SECURITIES REPRESENTED HEREBY,

AGREES THAT THE SECURITIES REPRESENTED HEREBY MAY BE REOFFERED, RESOLD, PLEDGED OR OTHERWISE TRANSFERRED ONLY IN COMPLIANCE WITH THE SECURITIES ACT AND OTHER APPLICABLE LAWS AND ONLY (1) PURSUANT TO RULE 144A UNDER THE SECURITIES ACT TO A PERSON THAT THE HOLDER REASONABLY BELIEVES IS A QUALIFIED INSTITUTIONAL BUYER WITHIN THE MEANING OF RULE 144A PURCHASING FOR ITS OWN ACCOUNT OR A PERSON PURCHASING FOR THE ACCOUNT OF A QUALIFIED INSTITUTIONAL BUYER WHOM THE HOLDER HAS INFORMED, IN EACH CASE, THAT THE REOFFER, RESALE, PLEDGE OR OTHER TRANSFER IS BEING MADE IN RELIANCE ON RULE 144A, (2) IN AN OFFSHORE TRANSACTION IN ACCORDANCE WITH RULE 903 OR 904 OF REGULATION S UNDER THE SECURITIES ACT OR (3) PURSUANT TO AN EXEMPTION FROM REGISTRATION PROVIDED BY RULE 144 UNDER THE SECURITIES ACT (IF AVAILABLE), IN EACH CASE IN ACCORDANCE WITH ANY APPLICABLE SECURITIES LAWS OF ANY STATE OF THE UNITED STATES. NO REPRESENTATION CAN BE MADE AS TO THE AVAILABILITY OF THE EXEMPTION PROVIDED BY RULE 144 UNDER THE SECURITIES ACT FOR REALES OF THIS SECURITY. NOTWITHSTANDING ANYTHING TO THE CONTRARY OR FOREGOING, THE SECURITIES REPRESENTED HEREBY ARE “RESTRICTED SECURITIES” WITHIN THE MEANING OF 144(A) (3) UNDER THE SECURITIES ACT AND FOR SO LONG AS SUCH SECURITIES ARE “RESTRICTED SECURITIES” (AS SO DEFINED) THE SECURITIES MAY NOT BE DEPOSITED INTO ANY UNRESTRICTED DEPOSITORY RECEIPT FACILITY IN RESPECT OF THE SECURITIES ESTABLISHED OR MAINTAINED BY A DEPOSITORY BANK. EACH HOLDER, BY ITS ACCEPTANCE OF THIS SECURITY, REPRESENTS THAT IT UNDERSTANDS AND AGREES TO THE FOREGOING RESTRICTIONS.

- (iv) if it is acquiring any Shares for the account of one or more QIBs, the investor represents that it has sole investment discretion with respect to each such account and that it has full power to make the foregoing acknowledgements, representations and agreements on behalf of each such account; and
- (v) the investor understands that the Company, the Managers and their affiliates and others will rely upon the truth and accuracy of the foregoing acknowledgements, representations and agreements.

Prospective investors that are QIBs are hereby notified that sellers of the Offer Shares may be relying on the exemption from the provisions of Section 5 of the US Securities Act provided by Rule 144A.

## TAXATION

### Dutch Tax Considerations

The following summary of certain Dutch taxation matters is based on the laws and practice in force as of the date of this Prospectus and is subject to any changes in law and the interpretation and application thereof, which changes could be made with retroactive effect. The following summary does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to acquire, hold or dispose of a Share, and does not purport to deal with the tax consequences applicable to all categories of investors.

Except for the section “— *Withholding tax*”, this summary does not describe the Dutch tax consequences for:

- (i) An individual or non-resident entity holding a Share which individual or non-resident entity has or will have a substantial interest or a deemed substantial interest in the Company.
- (ii) Generally speaking, an individual holding a Share has a substantial interest in the Company if (a) such individual, either alone or together with his partner, directly or indirectly has, or (b) certain relatives of such individual or his partner, directly or indirectly have, (i) the ownership of, a right to acquire the ownership of, or certain rights over, shares representing 5% or more of either the total issued and outstanding capital of the Company or the issued and outstanding capital of any class of shares of the Company, or (ii) the ownership of, or certain rights over, profit participating certificates (*winstbewijzen*) that relate to 5% or more of either the annual profit or the liquidation proceeds of the Company. Also, an individual holding a Share has a substantial interest in the Company if his partner has, or if certain relatives of the individual or his partner have, a deemed substantial interest in the Company. Generally, an individual holding a Share, or his partner or relevant relative, has a deemed substantial interest in the Company if either (a) such person or his predecessor has disposed of or is deemed to have disposed of all or part of a substantial interest or (b) such person has transferred an enterprise in exchange for shares in the Company, on a non-recognition basis. In the event an individual holding a Share has a substantial interest in the Company, all classes of shares and / or any profit participating certificates are deemed to be part of this substantial interest
- (iii) Generally speaking, a non-resident entity holding a Share has a substantial interest in the Company if such entity, directly or indirectly has (i) the ownership of, a right to acquire the ownership of, or certain rights over shares representing 5% or more of either the total issued and outstanding capital of the Company or the issued and outstanding capital of any class of shares of the Company, or (ii) the ownership of, or certain rights over, profit participating certificates (*winstbewijzen*) that relate to 5% or more of either the annual profit or the liquidation proceeds of the Company. Generally, an entity holding a Share has a deemed substantial interest in the Company if such entity has disposed of or is deemed to have disposed of all or part of a substantial interest on a non-recognition basis. The above is applicable in the event the substantial interest is held with the main purpose or one of the main purposes of avoiding Dutch income tax (*inkomstenbelasting*) of another person and there is an arrangement or a series of arrangements that have not been put into place for valid commercial reasons reflecting economic reality
- (iv) An individual to whom a Share or the benefits derived therefrom is attributable to employment activities which are taxed as employment income in the Netherlands
- (v) Entities which are a resident of Aruba, Curaçao or Sint Maarten that have an enterprise which is carried on through a permanent establishment or a permanent representative on Bonaire, Sint Eustatius or Saba and the Share is attributable to such permanent establishment or permanent representative
- (vi) A holder of a Share which is not considered the beneficial owner (*uiteindelijk gerechtigde*) of this Share or the benefits derived from or realized in respect of such Share

For the purpose of this summary, the term entity means a corporation as well as any other person that is taxable as a corporation for Dutch corporate income tax purposes as defined under the Dutch corporate income tax act (*Wet op de vennootschapsbelasting 1969*). Hence, this summary is not applicable for corporations which are exempt from Dutch corporate income tax or are subject to a special tax regime.

Where this summary refers to a holder of a Share, an individual holding a Share or an entity holding a Share, such reference is restricted to an individual or entity holding legal title to as well as an economic interest in such Share or otherwise being regarded as owning a Share for Dutch tax purposes. It is noted that for purposes of Dutch income, corporate, gift and inheritance tax, assets legally owned by a third party such as a trustee, foundation or similar entity, may be treated as assets owned by the (deemed) settlor, grantor or similar originator or the beneficiaries in proportion to their interest in such arrangement.

Where the summary refers to “the Netherlands” or “Dutch” it refers only to the European part of the Kingdom of the Netherlands.

Investors are advised to consult their professional advisers as to the tax consequences of purchase, ownership and disposition of a Share.

### ***Withholding tax***

In general, the Company must withhold Dutch tax (dividend withholding tax) from dividends distributed on the Shares at the rate of 15%.

Dividends include, without limitation:

- (i) distributions of profits (including paid-in capital not recognised for dividend withholding tax purposes) in cash or in kind, including deemed and constructive dividends;
- (ii) liquidation distributions and, generally, proceeds realised upon a repurchase of Shares by the Company or upon the transfer of Shares to the Company’s direct or indirect subsidiary, in excess of the average paid-in capital recognised for dividend withholding tax purposes;
- (iii) the nominal value of Shares issued or any increase in the nominal value of Shares, except where such (increase in) the nominal value of Shares is funded out of the Company’s paid-in capital recognised for dividend withholding tax purposes; and
- (iv) repayments of paid-in capital recognised for dividend withholding tax purposes up to the amount of the Company’s profits (*zuivere winst*) unless the Company’s General Meeting has resolved in advance that the Company shall make such repayments and the nominal value of the Shares concerned has been reduced by a corresponding amount through an amendment of the Articles of Association.

A holder of a Share which is, or is deemed to be, resident in the Netherlands for Dutch tax purposes is generally entitled to credit the dividend withholding tax withheld against such holder’s liability to Dutch tax on income and capital gains or, in certain cases, to apply for a full refund of the dividend withholding tax withheld or apply for a complete exemption of dividend withholding tax.

A holder of a Share which is not, and is not deemed to be, resident in the Netherlands for Dutch tax purposes may be eligible for a partial or complete exemption or refund of all or a portion of the dividend withholding tax under an income tax convention in effect between the Netherlands and the holder’s country of residence.

Under the terms of Dutch domestic anti-dividend stripping rules, a recipient of dividends distributed on a Share will not be entitled to an exemption from, reduction, refund, or credit of dividend tax if the recipient is not the beneficial owner of such dividends as meant in those rules.

Under the Convention between the Kingdom of the Netherlands and the Federal Republic of Germany for the avoidance of double taxation and the prevention of fiscal evasion with respect to taxes on income (the “**DTT-GER/NL**”), a holder of Shares will not be subject to Netherlands dividend withholding tax on dividends distributed by the Company, irrespective of the nature or form of such dividend and irrespective of such holder’s place of residence (unless such holder is tax resident in the Netherlands), if and for as long as the Company is tax resident solely in Germany for the purpose of the DTT-GER/NL. The Company intends to be tax resident solely in Germany for the purposes of the DTT-GER/NL. See “— *German Withholding Tax Considerations*” below for a brief discussion of German withholding tax.

### ***Taxes on income and capital gains***

#### ***Resident entities***

An entity holding a Share which is, or is deemed to be, resident in the Netherlands for Dutch tax purposes and which is not tax exempt, will generally be subject to corporate income tax in the Netherlands in respect of income or a capital gain derived from such Share at the prevailing statutory rates, unless the holder has the benefit of the participation exemption (*deelnemingsvrijstelling*) with respect to such Share. Generally speaking, the holder of a Share will have the benefit of the participation exemption if the holder owns at least 5% of the nominally paid-up share capital of the Company. In the event the participation exemption is applicable, a capital loss derived from such Share and costs related to the acquisition or disposal of such Share are not deductible for Dutch corporate income tax purposes.

#### ***Resident individuals***

An individual holding a Share who is, or is deemed to be, resident in the Netherlands for Dutch tax purposes will be subject to income tax in the Netherlands in respect of income or a capital gain derived from such Share at rates up to 51.95% if:

- (i) the holder has an enterprise or an interest in an enterprise to which the Share is attributable; or
- (ii) the income or capital gain qualifies as income from miscellaneous activities (*belastbaar resultaat uit overige werkzaamheden*) as defined in the Income Tax Act (*Wet inkomstenbelasting 2001*).

If neither condition (i) nor condition (ii) applies, such individual will be subject to income tax on the basis of a deemed return on the holder’s yield basis (*rendementsgrondslag*) at the beginning of the calendar year insofar as the yield basis exceeds a €30,000 threshold (*heffingvrij vermogen*), regardless of any actual income or capital gain derived from a Share. Such yield basis is determined as the fair market value of certain qualifying assets held by the holder of the Share, less the fair market value of certain qualifying liabilities at the beginning of the calendar year. The fair market value of the Share will be included as an asset in the holder’s yield basis. The holder’s yield basis is allocated to up to three brackets for which different deemed returns apply. The first bracket includes amounts up to and including €70,800, which amount will be split into a 67% low-return part and a 33 % high-return part. The second bracket includes amounts in excess of €70,800 and up to and including €978,000, which amount will be split into a 21% low-return part and a 79% high-return part. The third bracket includes amounts in excess of €978,000, which will be considered high-return in full. For 2018 the deemed return on the low-return parts is 0.36% and on the high-return parts is 5.38%. The deemed return percentages will be reassessed every year. The deemed return on the holder’s yield basis is taxed at a rate of 30%.

#### ***Non-residents***

A holder of a Share which is not and is not deemed to be resident in the Netherlands for Dutch tax purposes will not be subject to taxation in the Netherlands on income or a capital gain derived from a Share unless:

- (i) such income or capital gain is attributable to an enterprise or part thereof which is either effectively managed in the Netherlands or carried on through a permanent establishment (*vaste inrichting*) or permanent representative (*vaste vertegenwoordiger*) taxable in the Netherlands; or
- (ii) the holder is an individual and such income or capital gain qualifies as income from miscellaneous activities (*belastbaar resultaat uit overige werkzaamheden*) in the Netherlands as defined in the Income Tax Act (*Wet inkomstenbelasting 2001*).

#### ***Gift and inheritance tax***

Dutch gift or inheritance taxes will not be levied on the occasion of the transfer of a Share by way of gift by, or on the death of, a holder, unless:

- (i) the holder is or is deemed to be resident in the Netherlands for the purpose of the relevant provisions; or
- (ii) the transfer is construed as an inheritance or gift made by, or on behalf of, a person who, at the time of the gift or death, is or is deemed to be resident in the Netherlands for the purpose of the relevant provisions.

#### ***Value added tax***

No value added tax will be due in the Netherlands in respect of payments in consideration for the issuance of a Share, payments on Share, or payments made upon a transfer of a Share.

#### ***Other taxes and duties***

There is no registration tax, capital tax, customs duty, transfer tax, stamp duty, or any other similar tax or duty payable in the Netherlands in respect of or in connection with the subscription, issue, placement, allotment, delivery or transfer of a Share.

#### ***Residence***

A holder of a Share will not be, or deemed to be, resident in the Netherlands or will not have, or deemed to have, a permanent establishment (*vaste inrichting*) in the Netherlands for Dutch tax purposes, by reason only of acquiring, holding or disposing of a Share.

#### ***German withholding tax considerations***

In the case of dividends the Company is required to deduct German withholding tax at a rate of 25% plus solidarity surcharge of 5.5% on the withholding tax, resulting in an aggregate rate of 26.375%. The basis for the withholding tax is the dividend approved for distribution by the Company's general shareholder meeting. German withholding tax is generally withheld regardless of whether and to what extent the dividend is exempt from tax at the level of the Shareholder and whether the Shareholder is a person residing in Germany or in a foreign country.

Subject to the individual qualification of a shareholder it needs to claim a withholding tax certificate from the Company for its own tax purposes (for example a non-German shareholder, who wants to claim a (partial) withholding tax refund under a double taxation treaty). Investors need to consult with their own tax advisor on the relevant rules in Germany or elsewhere on the taxation of a dividend distribution at the level of such Investor.

Special rules apply if a distribution is sourced from the so-called "tax contribution account" (*steuerliches Einlagekonto*).

#### ***Belgian Tax Considerations***

The paragraphs below are a summary of certain material Belgian federal income tax consequences of the ownership and disposal of Shares by an investor that acquires such Shares in connection with this Offering. The

summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this Prospectus, all of which are subject to change, including changes that could have retroactive effect.

Investors should appreciate that, as a result of evolutions in law or practice, the eventual tax consequences may be different from what is stated below.

This summary does not purport to address all tax consequences of the investment in, ownership of and disposal of Shares, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. In particular, this summary does not address the tax treatment of investors who are subject to special rules, such as financial institutions, insurance companies, collective investment undertakings, dealers in securities or currencies or persons who hold, or will hold, the Shares as a position in a straddle, share-repurchase transactions, conversion transactions, a synthetic security or other integrated financial transaction.

For purposes of this summary, a Belgian resident is an individual subject to Belgian personal income tax (i.e. an individual who is domiciled in Belgium or has his seat of wealth in Belgium or a person assimilated to a resident for purposes of Belgian tax law), a company subject to ordinary Belgian corporate income tax (i.e. a corporate entity that has its statutory seat, its main establishment, its administrative seat or seat of management in Belgium), an Organisation for Financing Pensions subject to Belgian corporate income tax (i.e. a Belgian pension fund incorporated under the form of an Organisation for Financing Pensions), or a legal entity subject to Belgian income tax on legal entities (i.e. a legal entity other than a company subject to Belgian corporate income tax, that has its statutory seat, its main establishment, its administrative seat or seat of management in Belgium). A Belgian non-resident is any person that is not a Belgian resident.

Investors should note that the Belgian federal parliament adopted tax reform legislation on 25 December 2017 which was amended by a repair bill of 30 July 2018. This tax reform legislation is expected to be further amended by a second repair bill which is currently available. Once adopted and entered into force, this second repair legislation may impact the Belgian taxation regime as described in this section.

This summary does not address the tax regime applicable to Shares held by Belgian tax residents through a fixed basis or a permanent establishment situated outside Belgium.

Investors should consult their own advisers regarding the tax consequences of an investment in Shares in the light of their particular circumstances, including the effect of any state, local or other national laws, treaties and regulatory interpretations thereof.

### ***Taxation of dividends on Shares***

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to the Shares is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with the relevant company law provisions applicable to the Company is not treated as a dividend distribution to the extent that such repayment is imputed to the fiscal capital. This fiscal capital includes, in principle, the actual paid-up statutory share capital and, subject to certain conditions, the paid-up issuance premiums and the cash amounts subscribed to at the time of the issue of profit sharing certificates.

Note that as of 2018 (i.e. financial years starting on or after 1 January 2018), any reduction of fiscal capital is deemed to be paid out on a pro rata basis of the fiscal capital and certain reserves (i.e. and in the following order: the taxed reserves incorporated in the statutory capital, the taxed reserves not incorporated in the statutory capital and the tax-exempt reserves incorporated in the statutory capital). Only the part of the capital reduction that is deemed to be paid out of the fiscal capital will, for Belgian income tax purposes, not be considered as a dividend distribution provided such repayment is carried out in accordance with the relevant company law provisions applicable to the Company.

A Belgian withholding tax of 30% is normally levied on dividends, subject to such relief as may be available under applicable domestic or double tax treaty provisions.

Upon redemption of the Shares, the redemption distribution (after deduction of the portion of the fiscal capital represented by the redeemed Shares) will be treated as a dividend subject to a Belgian withholding tax of 30%, subject to such relief as may be available under applicable domestic or double tax treaty provisions. No withholding tax will be triggered if this redemption is carried out on a stock exchange and meets certain conditions.

In the event of liquidation of the Company, any amounts distributed in excess of the fiscal capital will in principle be subject to a 30% withholding tax, subject to such relief as may be available under applicable domestic or double tax treaty provisions.

Non-Belgian dividend withholding tax, if any, will neither be creditable against any Belgian income tax due nor reimbursable to the extent that it exceeds Belgian income tax due.

#### *Belgian resident individuals*

For Belgian resident individuals who acquire and hold the Shares as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. These Belgian resident individuals may nevertheless elect to report the dividends in their personal income tax return, or even need to report them if no intermediary established in Belgium was in any way involved in the processing of the payment of the non-Belgian sourced dividends, or even if an intermediary established in Belgium was in any way involved in the processing of the payment of the dividends but such intermediary did not withhold the Belgian dividend withholding tax due. Belgian resident individuals who report the dividends in their personal income tax return will normally be taxable at the lower of the generally applicable 30% Belgian withholding tax rate on dividends or at the progressive personal income tax rates applicable to their overall declared income. If the Belgian resident individual reports the dividends, any income tax due on such dividends will not be increased by communal surcharges. In addition, if the dividends are reported, any Belgian dividend withholding tax levied at source may, in both cases, be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on the Shares. This condition is not applicable if the individual can demonstrate that he has held the Shares in full legal ownership for an uninterrupted period of 12 months prior to the payment or attribution of the dividends. Provided the dividends are reported in the personal income tax return, they will in principle be eligible for the newly introduced tax exemption with respect to ordinary dividends up to an amount of €640 (amount applicable for income year 2018) per year Article 21, first subsection, 14°, of the Belgian Income Tax Code 1992 ("ITC"). The indexed amount for income year 2019 will be €800. For the avoidance of doubt, all reported dividends (not only dividends distributed on the Shares) are taken into account to assess whether said maximum amount is reached.

For Belgian resident individuals who acquire and hold the Shares for professional purposes, the Belgian withholding tax does not fully discharge their Belgian personal income tax liability. Dividends received must be reported by the investor and will, in such case, be taxable at the investor's personal income tax rate increased with communal surcharges. Any Belgian withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, subject to two conditions: (i) the taxpayer must own the Shares in full legal ownership at the time the dividends are paid or attributed and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable if the investor can demonstrate that he has held the full legal ownership of Shares for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.



## *Belgian resident companies*

### Corporate income tax

For Belgian resident companies, the dividend income (after deduction of any non-Belgian withholding tax but including any Belgian withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 29.58% (i.e. for financial years 2018 and 2019) (including the 2% crisis surcharge) and 25% as of 2020 (i.e. for financial years starting on or after 1 January 2020). Subject to certain conditions, a reduced corporate income tax rate of 20.4% (including the 2% crisis surcharge) and 20% as of 2020 (i.e. for financial years starting on or after 1 January 2020) applies for Small and Medium Sized Enterprises (as defined by article 15, §1 to §6 of the Belgian Companies Code) on the first €100,000 of taxable profits.

Belgian resident companies can under certain conditions deduct 100% of gross dividends received from their taxable income (“dividend received deduction”), provided that at the time of a dividend payment or attribution: (i) the Belgian resident company holds Shares representing at least 10% of the share capital of the Company or a participation in the Company with an acquisition value of at least €2,500,000 (it being understood that only one out of the two tests must be satisfied); (ii) the Shares have been held or will be held in full ownership for an uninterrupted period of at least one year; and (iii) the conditions relating to the taxation of the underlying distributed income, as described in article 203 ITC (the “**Article 203 ITC Taxation Condition**”) are met (together, the “**Conditions for the Belgian Application**”).

Under certain circumstances the conditions referred to under (i) and (ii) do not need to be fulfilled in order for the dividend received deduction to apply.

The Conditions for the Belgian Application depend on a factual analysis, upon each distribution, and for this reason the availability of this regime should be verified upon each distribution.

Any Belgian dividend withholding tax levied at source may be credited against the Belgian corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due, subject to two conditions: (i) the taxpayer must own the Shares in full legal ownership at the time the dividends are paid or attributed and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable: (i) if the company can demonstrate that it has held the Shares in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) if, during that period, the Shares never belonged to a taxpayer other than a Belgian resident company or a non-resident company which has, in an uninterrupted manner, invested the Shares in a Belgian establishment.

### Withholding tax

Dividends received by Belgian resident companies are exempt from Belgian withholding tax provided that the investor satisfies the identification requirements in article 117, par. 11 of the Royal Decree implementing the ITC.

## *Belgian resident organisations for financing pensions*

For organisations for financing pensions (“**OFPs**”), i.e. Belgian pension funds incorporated under the form of an OFP (“*organismes de financement de pensions*”) within the meaning of article 8 of the Belgian Act of 27 October 2006, the dividend income is generally tax exempt. Although there is no specific exemption from Belgian dividend withholding tax at source for dividends paid or attributed to OFPs, subject to certain limitations, any Belgian dividend withholding tax can be credited against the OFPs’ corporate income tax due and is reimbursable to the extent it exceeds the corporate income tax due.

#### *Other Belgian resident legal entities subject to Belgian legal entities tax*

To the extent that an intermediary established in Belgium was in any way involved in the processing of the payment of the non-Belgian sourced dividends, and such intermediary did withhold the Belgian dividend withholding tax due, the Belgian dividend withholding tax should have normally been withheld by this intermediary.

To the extent that the dividends were collected without the intervention of such intermediary, or, even if an intermediary established in Belgium was in any way involved in the processing of the payment of the dividends, but such intermediary did not withhold the Belgian dividend withholding tax due, the Belgian resident legal entity subject to Belgian legal entities tax will be liable to pay the Belgian dividend withholding tax and file the withholding tax return.

In both cases, the Belgian dividend withholding tax in principle fully discharges their income tax liability.

#### *Belgian non-resident individuals or non-resident companies*

If the Shares are acquired by a Belgian non-resident individual or a non-resident company without any connection to a business in Belgium, no Belgian dividend withholding tax will be due, assuming that, in such case, no intermediary established in Belgium will in any way be involved in the processing of the payment of the non-Belgian sourced dividends.

If the Shares are acquired by a Belgian non-resident in connection with a business in Belgium, the investor must report any dividends received, which will be taxable at the applicable Belgian non-resident personal or corporate income tax rate, as appropriate. Any Belgian withholding tax levied at source may be credited against the Belgian non-resident personal or corporate income tax and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own Shares in full legal ownership at the time the dividends are paid or attributed and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable if (i) the non-resident individual or the non-resident company can demonstrate that the Shares were held in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) with regard to non-resident companies only, if, during the said period, the Shares have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested Shares in a Belgian establishment.

Dividends paid or attributed as of 1 January 2018 to Belgian non-resident individuals who do not use the Shares in the exercise of a professional activity, may be exempt from Belgian non-resident individual income tax up to the amount of €640 (for income year 2018 – €800 for income year 2019). Consequently, if Belgian withholding tax has been levied on dividends paid or attributed to the Shares, such Belgian non-resident may request in his or her Belgian non-resident income tax return that any Belgian withholding tax levied on dividends up to the amount of €640 (for income year 2018 – €800 for income year 2019) be credited and, as the case may be, reimbursed. However, if no Belgian non-resident income tax return has to be filed by the Belgian non-resident individual, any Belgian withholding tax levied on dividends up to such an amount could in principle be reclaimed by filing a request thereto addressed to the tax official to be appointed in a Royal Decree. Such a request has to be made at the latest on 31 of December of the calendar year following the calendar year in which the relevant dividend(s) have been received, together with an affidavit confirming the Belgian non-resident individual status and certain other formalities which are still to be determined in a Royal Decree. For the avoidance of doubt, all dividends paid or attributed to the Belgian non-resident individual are taken into account to assess whether the maximum amount of €640 (for income year 2018 – €800 for income year 2019) is reached (and hence not only the amount of dividends paid or attributed on the Shares).

Belgian non-resident companies whose Shares are invested in a Belgian establishment may deduct 100% of the gross dividends received from their taxable income if, at the date the dividends are paid or attributed, the

Conditions for the Belgian Application are met. Application of the dividend received deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

### ***Belgian taxation of capital gains and losses on Shares***

#### ***Belgian resident individuals***

In principle, Belgian resident individuals acquiring the Shares as a private investment should not be subject to Belgian capital gains tax on the disposal of the Shares and capital losses will not be tax deductible.

However, capital gains realised by a Belgian resident individual on the disposal of the Shares are taxable at 33% (plus local surcharges) if the capital gain on the Shares is deemed to be speculative or realised outside the scope of the normal management of the individual's private estate. Capital losses are, however, not tax deductible in such event.

Moreover, capital gains realised by Belgian resident individuals on the disposal of the Shares for consideration, outside the exercise of a professional activity, to a non-resident company (or body constituted in a similar legal form), to a foreign State (or one of its political subdivisions or local authorities) or to a non-resident legal entity, each time established outside the European Economic Area, are in principle taxable at a rate of 16.5% (plus local surcharges) if, at any time during the five years preceding the sale, the Belgian resident individual has owned, directly or indirectly, alone or with his or her spouse or with certain relatives, a substantial shareholding in the Company (i.e., a shareholding of more than 25% in the Company). Capital losses are, however, not tax deductible.

Belgian resident individuals who hold the Shares for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realised upon the disposal of the Shares, except for the Shares held for more than five years, which are taxable at a separate rate of 16.5% (plus local surcharges). Capital losses on the Shares incurred by Belgian resident individuals who hold the Shares for professional purposes are in principle tax deductible.

Capital gains realised by Belgian resident individuals upon redemption of the Shares or upon liquidation of the Company will generally be taxable as a dividend (see above).

#### ***Belgian resident companies***

Belgian resident companies are not subject to Belgian capital gains taxation on gains realised upon the disposal of Shares in the Company provided that: (i) the Belgian resident company holds Shares representing at least 10 % of the share capital of the Company or a participation in the Company with an acquisition value of at least €2,500,000 (it being understood that only one out of the two tests must be satisfied); (ii) the article 203 ITC Taxation Condition is satisfied and (iii) the Shares have been held in full legal ownership for an uninterrupted period of at least one year.

If all of the above conditions except condition (iii) (i.e. the one-year minimum holding condition) are satisfied, the capital gains realised upon the disposal of Shares in the Company by a Belgian resident company are taxable at a separate corporate income tax rate of 25.5% (including the 2% crisis surcharge) and, as of 2020 (i.e. financial years starting on or after 1 January 2020) at the ordinary corporate income tax rate of 25%.

If the conditions (i) and/or (ii) above are not met, the capital gains realised upon the disposal of Shares in the Company by a Belgian resident company will be taxable at the ordinary corporate income tax rate as applicable in the relevant financial year.

Capital losses on Shares incurred by Belgian resident companies are as a general rule not tax deductible.

Capital gains realised by Belgian resident companies upon redemption of the Shares or upon liquidation of the Company will, in principle, be subject to the same taxation regime as dividends (see above).

Shares held in the trading portfolios of qualifying credit institutions, investment enterprises and management companies of collective investment undertakings are subject to a different regime. The capital gains realised by these investors will be subject to the corporate income tax at the general rates and the capital losses on such Shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realisation.

#### *Belgian resident organisations for financing pensions*

OFPs are, in principle, not subject to Belgian capital gains taxation realised upon the disposal of Shares and capital losses are not tax deductible.

#### *Other Belgian resident legal entities subject to Belgian legal entities tax*

Belgian resident legal entities subject to the legal entities income tax are in principle not subject to Belgian capital gains taxation. Capital gains realised upon disposal of (part of) a substantial participation in a Belgian company (i.e. a participation representing more than 25% of the share capital of the Company at any time during the last five years prior to the disposal) may, however, under certain circumstances be subject to income tax in Belgium at a rate of 16.83%.

Capital gains realised by Belgian resident legal entities upon redemption of the Shares or upon liquidation of the Company will, in principle, be subject to the same taxation regime as dividends.

Capital losses on Shares incurred by Belgian resident legal entities are not tax deductible.

#### *Belgian non-residents individuals or non-resident companies*

##### Belgian non-resident individuals

Capital gains realised on the Shares by a Belgian non-resident individual that has not acquired the Shares in connection with a business conducted in Belgium through a fixed base in Belgium or a Belgian establishment are in principle not subject to taxation in Belgium, unless the gains are deemed to be realised outside the scope of the normal management of the individual's private estate, and are obtained or received in Belgium. In such case, the capital gains are subject to a final professional withholding tax of 30.28% (to the extent that Articles 90,1° and 248 ITC are applicable). However, Belgium has concluded tax treaties with more than 95 countries which generally provide for a full exemption from Belgian capital gains taxation on such gains realised by residents of those countries. Capital losses are generally not tax deductible.

Capital gains realised by Belgian non-resident individuals upon the redemption of Shares or upon the liquidation of the Company will generally be taxable as a dividend (see above).

##### Belgian non-resident Companies or Entities

Capital gains realised on the Shares by Belgian non-resident companies or non-resident entities that have not acquired the Shares in connection with a business conducted in Belgium through a Belgian establishment are in principle not subject to taxation and losses are not tax deductible.

Capital gains realised by Belgian non-resident companies or other non-resident entities that hold the Shares through a Belgian establishment are generally subject to the same regime as Belgian resident companies.

#### ***Tax on stock exchange transactions***

No tax on stock exchange transactions is due upon subscription to Shares (primary market transactions).

The purchase and the sale and any other acquisition or transfer for consideration of existing Shares (secondary market transactions) in Belgium through a professional intermediary is subject to the tax on stock exchange

transactions (*taks op de beursverrichtingen/taxe sur les opérations de bourse*) of 0.35 % of the purchase price, capped at €1,600 per transaction and per party.

Following the Law of 25 December 2016, the scope of application of the tax on the stock exchange transactions has been extended as of 1 January 2017 to secondary market transactions of which the order is, directly or indirectly, made to a professional intermediary established outside of Belgium by (i) a private individual with habitual residence in Belgium or (ii) a legal entity for the account of its seat or establishment in Belgium (both referred to as a “**Belgian Investor**”). In such a scenario, the tax on the stock exchange transactions is due by the Belgian Investor, unless the Belgian Investor can demonstrate that the tax on the stock exchange transactions due has already been paid by the professional intermediary established outside of Belgium. In the latter case, the foreign professional intermediary also has to provide each client (which gives such intermediary an order) with a qualifying order statement (*bordereau/borderel*), at the latest on the business day after the day the transaction concerned was realised. Alternatively, professional intermediaries established outside of Belgium could appoint a stock exchange tax representative in Belgium, subject to certain conditions and formalities (the “**Stock Exchange Tax Representative**”). Such Stock Exchange Tax Representative will then be liable towards the Belgian Treasury for the tax on stock exchange transactions due and for complying with reporting obligations and the obligations relating to the order statement in that respect. If such a Stock Exchange Tax Representative would have paid the tax on stock exchange transactions due, the Belgian Investor will, as per the above, no longer be the debtor of the tax on stock exchange transactions.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in article 2, 9° and 10° of the Belgian Law of 2 August 2002 on the supervision of the financial sector and financial services; (ii) insurance companies described in article 2, § 1 of the Belgian Law of 9 July 1975 on the supervision of insurance companies; (iii) pension institutions referred to in article 2, 1° of the Belgian Law of 27 October 2006 concerning the supervision of pension institutions; (iv) collective investment institutions; (v) regulated real estate companies; and (vi) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

On 14 February 2013 the EU Commission adopted the Draft Directive on a financial transaction tax (the “**Financial Transaction Tax**”). The Draft Directive currently stipulates that once the Financial Transaction Tax enters into effect, the Participating Member States shall not maintain or introduce any taxes on financial transactions other than the Financial Transaction Tax (or VAT as provided in the Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the Financial Transaction Tax enters into effect. The Draft Directive is still subject to negotiation between the Participating Member States and may, therefore, be further amended at any time.

### ***Belgian tax on securities accounts***

Pursuant to the law of 7 February 2018 introducing a tax on securities accounts, a tax of 0.15% will be levied on the share of Belgian resident and non-resident individuals in the average value of the qualifying financial instruments (including but not limited to shares, notes and units of undertakings for collective investment) held on one or more securities accounts during a reference period of twelve consecutive months starting on 1 October and ending on 30 September of the subsequent year (the “**Belgian Tax on Securities Accounts**”). The first reference period starts on the day of entry into effect of the law (i.e. 10 March 2018) and ends on 30 September 2018.

No Belgian Tax on Securities Accounts will be due provided the holder’s share in the average value of the qualifying financial instruments on those accounts amounts to less than €500,000. If, however, the holder’s share in the average value of the qualifying financial instruments on those accounts amounts to €500,000 or

more, the Belgian Tax on Securities Accounts will be due on the entire share of the holder in the average value of the qualifying financial instruments on those accounts (and, hence, not only on the part which exceeds the €500,000 threshold).

Qualifying financial instruments held by Belgian non-resident individuals only fall within the scope of the Belgian Tax on Securities Accounts provided they are held on securities accounts with a financial intermediary established or located in Belgium. Note that pursuant to certain double tax treaties, Belgium has no right to tax capital. Hence, to the extent the Belgian Tax on Securities Accounts is viewed as a tax on capital within the meaning of these double tax treaties, treaty protection may, subject to certain conditions, be claimed.

A financial intermediary is defined as (i) a credit institution or a stockbroking firm as defined by article 1, §2 and §3 of the Law of 25 April 2014 on the status and supervision of credit institutions and investment companies and (ii) the investment companies as defined by article 3, §1 of the Law of 25 October 2016 on access to the activity of investment services and on the legal status and supervision of portfolio management and investment advice companies, which are, pursuant to national law, admitted to hold financial instruments for the account of customers.

The Belgian Tax on Securities Accounts is in principle due by the financial intermediary established or located in Belgium if (i) the holder's share in the average value of the qualifying financial instruments held on one or more securities accounts with said intermediary amounts to €500,000 or more or (ii) the holder instructed the financial intermediary to levy the Belgian Tax on Securities Accounts due (e.g. in case such holder holds qualifying financial instruments on several securities accounts held with multiple intermediaries of which the average value does not amount to €500,000 or more, but of which the holder's share in the total average value of these accounts amounts to at least €500,000). Otherwise, the Belgian Tax on Securities Accounts would have to be declared and would be due by the holder itself unless the holder provides evidence that the Belgian Tax on Securities Accounts has already been withheld, declared and paid by an intermediary which is not established or located in Belgium. In that respect, intermediaries located or established outside of Belgium could appoint a Tax on the Securities Accounts representative in Belgium, subject to certain conditions and formalities. Such a Tax on the Securities Accounts representative will then be liable towards the Belgian Treasury for the Tax on the Securities Accounts due and for complying with certain reporting obligations in that respect.

Belgian resident individuals will have to report in their annual income tax return various securities accounts held with one or more financial intermediaries of which they are considered as a holder within the meaning of the Belgian Tax on Securities Accounts. Belgian non-resident individuals have to report in their annual Belgian non-resident income tax return various securities accounts held with one or more financial intermediaries established or located in Belgium of which they are considered as a holder within the meaning of the Belgian Tax on Securities Accounts.

Prospective investors are strongly advised to seek their own professional advice in relation to the Belgian Tax on Securities Accounts.

## **US Federal Income Tax Considerations**

*The following is a description of certain US federal income tax consequences that may be relevant with respect to the acquisition, ownership, and disposition of Offer Shares by a US Holder (as defined below).*

*This summary deals only with initial purchasers of Offer Shares in this Offering who are US Holders (as defined below) and will hold the Offer Shares as capital assets.*

*This description does not purport to address all material US tax consequences of the acquisition, ownership, and disposition of Offer Shares and does not address aspects of US federal income taxation that may be applicable to investors that are subject to special tax rules such as:*

- *certain financial institutions;*
- *dealers or certain traders in securities;*
- *persons holding Offer Shares as part of a straddle, wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the Offer Shares;*
- *persons whose functional currency for US federal income tax purposes is not the US Dollar;*
- *persons who are resident in or have a permanent establishment in Germany or the Netherlands;*
- *certain US expatriates;*
- *“dual resident” corporations;*
- *persons that own or are deemed to own 5% or more of the Company’s stock (by vote or value);*
- *regulated investment companies;*
- *insurance companies;*
- *tax-exempt investors; or*
- *persons holding Offer Shares in connection with a trade or business outside the United States.*

*Further, this description does not address state, local, non-US, or other tax laws, nor does it address the Medicare tax on net investment income, the alternative minimum tax, or the US federal gift and estate tax consequences of the acquisition, ownership, and disposition of Offer Shares.*

*This summary is based on the Internal Revenue Code of 1986, as amended, the Treasury Regulations promulgated under the Internal Revenue Code 1986, as amended, administrative and judicial interpretations, as well as on the income tax treaty between the United States and the Netherlands (the “**Treaty**”). These income tax laws, regulations and interpretations, however, may change at any time, possibly with retroactive effect.*

*The Company has not requested, and does not intend to request, a ruling from the US Internal Revenue Service (the “**IRS**”) with respect to matters addressed herein.*

*As used herein, a “US Holder” means a beneficial owner of the Offer Shares that is, for US federal income tax purposes:*

- *an individual citizen or resident of the United States;*
- *a corporation created or organised in or under the laws of the United States, any state therein or the District of Columbia;*
- *an estate, the income of which is subject to US federal income taxation regardless of its source; or*
- *a trust if (i) a court within the United States is able to exercise primary supervision over its administration and one or more US persons have the authority to control all of the substantial decisions*

*of such trust, or (ii) such trust has a valid election in effect to be treated as a US person for US federal income tax purposes.*

*If a partnership (or any other entity or arrangement treated as a partnership for US federal income tax purposes) holds Offer Shares, the tax treatment of the partnership and a partner in such partnership will generally depend on the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax adviser as to the US federal income tax consequences of acquiring, holding, or disposing of the Offer Shares.*

*The summary of US federal income tax consequences set out below is for general information only. All prospective purchasers should consult their tax advisers as to the particular tax consequences to them of owning Offer Shares, including the applicability and effect of state, local, non-US and other tax laws and possible changes in tax law.*

### ***Taxation of distributions***

Subject to the PFIC rules discussed below, distributions paid on Offer Shares (including the amount of any Dutch taxes withheld) will be treated as dividends to the extent paid out of the Company's current or accumulated earnings and profits, as determined under US federal income tax principles. Distributions in excess of current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of a US Holder's basis in its Offer Shares and thereafter as capital gain. Because the Company does not maintain calculations of its earnings and profits under US federal income tax principles, it is expected that distributions generally will be reported to you as ordinary dividend income. For US federal income tax purposes, US Holders will be treated as having received the amount of Dutch taxes withheld by the Company, and as then having paid over the withheld taxes to the Dutch taxing authorities. As a result of this rule, the amount of dividend income included in gross income for US federal income tax purposes by a US Holder with respect to a payment of dividends may be greater than the amount of cash actually received (or receivable) by the US Holder from the Company with respect to the payment.

Subject to applicable limitations, if you are a non-corporate US Holder, dividends paid to you may be eligible for taxation as "qualified dividend income" and therefore may be taxable at favourable rates. Dividends will be treated as qualified dividends if (a) certain holding period requirements are satisfied, (b) the Company is eligible for the benefits of the Treaty, which the Company expects will be the case provided that its Offer Shares are regularly traded on the regulated market of Euronext in Amsterdam, and (c) the Company was not a PFIC in the year prior to the year in which the dividend was paid, and is not a PFIC in the year in which the dividend is paid. You should consult your tax adviser regarding the availability of the reduced tax rate on qualified dividends.

Dividends will generally be included in your income on the date of receipt. Dividends will not be eligible for the dividends-received deduction generally available to US corporations under the Code. The amount of any dividend income paid in euro will be the US Dollar amount calculated by reference to the spot rate in effect on the date of receipt, regardless of whether the payment is in fact converted into US dollars. If the dividend is converted into US dollars on the date of receipt, you should not be required to recognise foreign currency gain or loss in respect of the amount received. You may have foreign currency gain or loss if the dividend is converted into US dollars after the date of receipt, and any such gain or loss will be US-source ordinary income or loss.

Dividends paid by the Company generally will constitute income from sources outside the United States for US foreign tax credit limitation purposes and will be categorised as "passive income" for US foreign tax credit purposes. Subject to applicable limitations, some of which vary depending upon your circumstances, Dutch income taxes withheld from dividend payments on Offer Shares at a rate not exceeding the applicable Treaty



rate will be creditable against your US federal income tax liability. Dutch income taxes withheld in excess of the applicable Treaty rate will not be eligible for credit against your US federal income tax liability.

The rules governing foreign tax credits are complex, and you should consult your tax adviser regarding the creditability of foreign taxes in your particular circumstances. In lieu of claiming a foreign tax credit, you may elect to deduct foreign taxes, including any Dutch taxes, in computing your taxable income, subject to applicable limitations. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the relevant taxable year.

### ***Sale or other taxable disposition of Shares***

Subject to the PFIC rules discussed below, you generally will recognise taxable gain or loss on a sale or other taxable disposition of Offer Shares equal to the difference between the amount realised on the sale or disposition and your adjusted tax basis in Offer Shares, each as determined in US dollars. This gain or loss will generally be capital gain or loss, and will be long-term capital gain or loss if at the time of sale or disposition the Offer Shares have been held for more than one year. Any gain or loss will generally be US-source for foreign tax credit purposes. The deductibility of capital losses is subject to limitations. A US Holder's adjusted tax basis in an Offer Share generally will be its US dollar cost.

US Holders should consult their own tax advisors about how to account for payments made or received in a currency other than the US dollar.

### ***Passive foreign investment company rules***

A non-US corporation will be classified as a "passive foreign investment company", or a PFIC, for US federal income tax purposes in any taxable year in which, after applying certain look through rules, either:

- at least 75% of its gross income is "passive income"; or
- at least 50% of the quarterly average value of its gross assets is attributable to assets that produce "passive income" or are held for the production of passive income.

Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. In determining whether a non-US corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

The determination of PFIC status is a factual determination that must be made annually at the close of each taxable year and, therefore; there can be no certainty as to the Company's status in this regard until the close of the current or any future taxable year. Based on Curetis' current income and assets and the expected value of the Offer Shares, it is possible that we could be a PFIC for the current taxable year and/or in future taxable years. The Company's status could change depending, among other things, upon a decrease in the trading price of Offer Shares, changes in the composition and relative values of its assets, and the sources of its income.

If the Company were a PFIC in any year during a US Holder's holding period for Offer Shares, the Company would ordinarily continue to be treated as a PFIC for each subsequent year during which the US Holder owned the Offer Shares. If the Company were a PFIC for a taxable year during a US Holder's holding period for the Offer Shares, US Holders generally would be subject to additional taxes (including taxation at ordinary income rates and an interest charge) on any "excess distributions" received from the Company and on any gain realised from a sale or other disposition of Offer Shares. A US Holder would have an excess distribution to the extent that distributions on Offer Shares during a taxable year exceed 125% of the average amount received during the three preceding taxable years (or, if shorter, the US Holder's holding period). To compute the tax on excess distributions or any gain, (i) the excess distribution or gain would be allocated rateably over the US Holder's

holding period, (ii) amounts allocated to the current taxable year and any year before the Company became a PFIC would be taxed as ordinary income in the current year and (iii) amounts allocated to other taxable years would be taxed at the highest applicable marginal rate in effect for each such year (i.e., at ordinary income tax rates) and (iv) an interest charge would be imposed to recover the deemed benefit from the deferred payment of the tax attributable to each year described in (iii). Gain on the disposition of Offer Shares will be subject to taxation in the same manner as an excess distribution, described immediately above.

If the Company were a PFIC in any year during which you hold Offer Shares, you would not be able to avoid the tax consequences described above by electing to treat the Company as a qualified electing fund (“QEF”), because the Company does not intend to provide US Holders with the information that would be necessary to make a QEF election with respect to Offer Shares. However, in the event the Company were a PFIC, a US Holder may be able to avoid some of the adverse effects of the PFIC rules described above with respect to Offer Shares by electing to mark the Offer Shares to market annually. The election is available only if Offer Shares are regularly traded in more than de minimis quantities on Euronext in Amsterdam. Any gain from marking the Offer Shares to market or from disposing of them would be ordinary income. Any loss from marking the Offer Shares to market would be recognised only to the extent of un-reversed gains previously included in income. Loss from marking the Offer Shares to market would be ordinary, but loss on disposing of them would be capital loss except to the extent of mark to market gains previously included in income. A US Holder’s adjusted tax basis in Offer Shares would be adjusted to reflect any income or loss resulting from the mark-to-market election.

Because, as a technical matter, a mark-to-market election cannot be made for any lower-tier PFICs that the Company may own, a US Holder would generally continue to be subject to the general PFIC rules described above with respect to such US Holder’s indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. Each US Holder should ask its own tax adviser whether a mark to market election is available or desirable. A valid mark to market election cannot be revoked without the consent of the IRS unless the Offer Shares cease to be marketable.

If you own the Company’s Shares during any year in which the Company is a PFIC, you must file IRS Form 8621 with respect to the Company, generally with your federal income tax return for that year.

You should consult your tax adviser regarding whether the Company is a PFIC and the potential application of the PFIC rules to your ownership of Offer Shares for any taxable year.

### ***Backup withholding and information reporting***

Payments of dividends and sales proceeds that are made within the United States or through US or certain US related intermediaries will generally be subject to information reporting and backup withholding, unless (i) you are an exempt recipient or (ii) in the case of backup withholding, you provide a correct taxpayer identification number and certify that you are not subject to backup withholding. Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against your US federal income tax liability, provided that the required information is timely furnished to the IRS. You may be required to report information relating to non-US accounts through which Offer Shares are held (or information regarding the Shares if the Shares are not held through any financial institution). You should consult your tax adviser regarding these rules, including and any other reporting obligations that may apply to the ownership or disposition of Offer Shares.

Certain non-corporate US Holders are required to report information relating to an interest in Offer Shares, subject to certain exceptions (including an exception for Offer Shares held in accounts maintained at US financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. US Holders are urged to consult their tax advisers regarding their information reporting obligations, if any, with respect to their ownership and disposition of the Shares.

## GENERAL INFORMATION

### Significant Change in the Company's Financial or Trading Position

As at the date of this Prospectus, there have been no significant changes in the Company's financial or trading position since 30 June 2018 other than:

- the decrease in cash and cash equivalents to €6,689 thousand as at 30 October 2018 (which, disregarding the net proceeds of €3,220 thousand from the issuance of Convertible Notes to Yorkville, represents a decrease of €8,177 thousand in the period since 30 June 2018), as a result of the Company's regular and expected cash burn that the Company experiences as a result of its stage of development. See "*Operating and Financial Review and Prospects – Key Factors Affecting the Results of Operation – Cash Burn*"; and
- the issue of €3,500 thousand in principal amount of Convertible Notes as part of the first tranche under the Yorkville Agreement, thereby raising a net proceeds amount of €3,220 thousand. See "*Business – Material Contracts – Financing Arrangements – Yorkville Financing*".

### Expenses of the Offering

The expenses related to the Offering are estimated at approximately €2,500 thousand (assuming that the Mid-Point Proceeds are raised and the PSOP Offer Shares are issued and sold as part of the Offering) and include, among other things, the fees due to the AFM and Euronext, the commission for the Managers and legal and administrative expenses, as well as publication costs and applicable taxes, if any. See also "*Reasons for the Offering and Use of Proceeds*".

### Documents on Display

The following documents (or copies thereof) will be available for inspection free of charge on the website of the Company (<http://www.curetis.com/en/investors/share-information/offering.html>) for as long as this Prospectus is valid:

- this Prospectus;
- the Articles of Association;
- the Pricing Statement;
- the Management Board Rules;
- the Supervisory Board Rules;
- the Terms of Reference for the Audit Committee;
- the Terms of Reference for the Nomination and Appointment Committee;
- the Terms of Reference for the Remuneration Committee;
- the Annual Financial Statements; and
- the Interim Financial Statements.

This Prospectus will also be available free of charge from the Company's registered address at Max-Eyth-Straße 42, 71088 Holzgerlingen, Germany.

## GLOSSARY

“AACC”	American Association for Clinical Chemistry
“ACA”	Affordable Care Act
“Acumen”	Acumen Research Laboratories Pte Ltd.
“aeris CAPITAL”	aeris CAPITAL AG
“AFM”	the Dutch Authority for the Financial Markets ( <i>Stichting Autoriteit Financiële Markten</i> )
“AIA”	Leahy-Smith America Invents Act
“Al Zahrawi”	Al Zahrawi Medical LLC
“Allocation”	the allocation of Offer Shares
“Amendment Letter”	the amendment letter dated 20 April 2018, amending EIB Finance Contract originally dated 12 December 2016
“AMP”	Association for Molecular Pathology
“Annual Financial Statements”	the audited consolidated financial statements of the Company as of and for the financial years ended 31 December 2017 and 2016, prepared in accordance with IFRS
“Application Cartridges”	the application-specific cartridges used in connection with the Unyvero System
“Ares Genetics”	Ares Genetics GmbH
“ARES Technology Platform”	Ares Genetics’ Bioinformatics, Biostatistics, and Artificial Intelligence technology platform building on and expanding upon the GEAR bioinformatics platform
“ARESdb”	Curetis’ ARES AMR Database building on and expanding on the GEAR database.
“Arrow Diagnostics”	Arrow Diagnostics Srl
“Article 203 ITC Taxation Condition”	the conditions relating to the taxation of the underlying distributed income, as described in article 203 ITC
“Articles of Association”	the Company’s articles of association ( <i>statuten</i> )
“ASEAN”	Association of Southeast Asian Nations
“ASM”	American Society for Microbiology
“ATC”	Advanced Technology Company
“Baader Bank”	Baader Bank AG
“BAL”	bronchoalveolar lavage
“BC”	global blood culture
“BCU”	blood cultures
“Beijing Clear Biotech”	Beijing Clear Biotech Co., Ltd
“Belgian Investor”	(i) a private individual with habitual residence in Belgium or (ii) a legal entity for the account of its seat or establishment in Belgium

<b>“Biotest”</b>	Biotest AG
<b>“CAGR”</b>	compounded annual growth rate
<b>“CAI”</b>	cardiology-associated infections
<b>“CAIO”</b>	complicated intra-abdominal infections observational
<b>“CAP”</b>	community-acquired pneumonia
<b>“Carpegen”</b>	Carpegen GmbH
<b>“CCO”</b>	Chief Commercial Officer
<b>“CE”</b>	Conformité Européenne
<b>“Cempra”</b>	Cempra Pharmaceuticals Inc.
<b>“CEO”</b>	Chief Executive Officer
<b>“CET”</b>	Central European Time
<b>“CFDA”</b>	China Food and Drug Administration
<b>“CLFS”</b>	Clinical Laboratory Fee Schedule
<b>“CLIA”</b>	Clinical Laboratory Improvement Amendments of 1988
<b>“CMS”</b>	Center for Medicare and Medicaid Services
<b>“Committee Rules”</b>	the rules on each Supervisory Board committee’s role, responsibilities and functioning
<b>“Company”</b>	Curetis N.V.
<b>“Competent Authority”</b>	the governmental or regulatory body that is responsible for regulating medical devices in the relevant Member State
<b>“Conditions for the Belgian Application”</b>	(i) the Belgian resident company holds Shares representing at least 10% of the share capital of the Company or a participation in the Company with an acquisition value of at least €2,500,000 (it being understood that only one out of the two tests must be satisfied); (ii) the Shares have been held or will be held in full ownership for an uninterrupted period of at least one year; and (iii) the Article 203 ITC Taxation Condition
<b>“Conformity Declaration”</b>	EC declaration of conformity based on a self-assessment of the conformity of its products with the relevant essential requirements of the IVD Directive
<b>“Contexo”</b>	Contexo GmbH
<b>“Convertible Notes”</b>	notes convertible into Shares issued under the Yorkville Agreement
<b>“Conversion Shares”</b>	Any and all Shares that may be issued upon the conversion of Convertible Notes and/or exercise of Warrants from time to time
<b>“COO”</b>	Chief Operating Officer
<b>“CTO”</b>	Chief Technology Officer
<b>“Curetis”</b>	Curetis N.V. and its consolidated subsidiaries
<b>“Curetis USA”</b>	Curetis USA Inc
<b>“CVS”</b>	Clinical Virology Symposium
<b>“DACH”</b>	Germany, Austria and Switzerland

<b>“DFIs”</b>	Diabetic foot infections
<b>“DGHM”</b>	Deutsche Gesellschaft für Hygiene und Mikrobiologie
<b>“DiaMed Care”</b>	DiaMed Care GmbH
<b>“DNA”</b>	deoxyribonucleic acid
<b>“Draft Directive”</b>	a proposal for a Council Directive adopted by the European Commission on 14 February 2013
<b>“DRG”</b>	Diagnosis Related Group
<b>“DTT-GER/NL”</b>	Convention between the Kingdom of the Netherlands and the Federal Republic of Germany for the avoidance of double taxation and the prevention of fiscal evasion with respect to taxes on income
<b>“Dutch Corporate Governance Code”</b>	the Dutch corporate governance code published on 8 December 2016 and effective as of 1 January 2017
<b>“Dutch Civil Code”</b>	the Dutch Civil Code ( <i>Burgerlijk Wetboek</i> )
<b>“Dutch Code of Civil Procedure”</b>	the Dutch Code of Civil Procedure ( <i>Wetboek van Burgerlijke Rechtsvordering</i> )
<b>“Dutch Financial Supervision Act”</b>	the Dutch Financial Supervision Act ( <i>Wet op het financieel toezicht</i> )
<b>“Dutch Securities Giro Transfers Act”</b>	the Dutch Securities Giro Transfers Act ( <i>Wet giraal effectenverkeer</i> )
<b>“ECCMID”</b>	European Congress of Clinical Microbiology and Infectious Diseases
<b>“ECDC”</b>	European Centre for Disease Prevention Control
<b>“EEA”</b>	European Economic Area
<b>“EFS”</b>	European Fund for Strategic Investment
<b>“EGFF”</b>	European Growth Finance Facility
<b>“EIB”</b>	European Investment Bank
<b>“EIB Finance Contract”</b>	the loan agreement with the EIB originally dated 12 December 2016, as amended by the Amendment Letter
<b>“Eldan”</b>	Eldan Electronic Instruments Ltd.
<b>“EMEA”</b>	Europe, the Middle East and Africa
<b>“EMS”</b>	Electronic Manufacturing Services
<b>“Enterprise Chamber”</b>	the enterprise chamber of the Amsterdam court of appeal ( <i>Ondernemingskamer van het Gerechtshof te Amsterdam</i> )
<b>“ESOP 2016”</b>	Curetis’ Equity Settled Option Plan 2016
<b>“EU”</b>	European Union
<b>“euro” or “€”</b>	lawful currency of the European Union
<b>“Euroclear Nederland”</b>	Nederlands Centraal Instituut voor Giraal Effectenverkeer B.V.
<b>“Euronext”</b>	Euronext Amsterdam and Euronext Brussels
<b>“Euronext Amsterdam”</b>	Euronext Amsterdam N.V.
<b>“Euronext Brussels”</b>	Euronext Brussels NV/SA
<b>“Euronext in Amsterdam”</b>	a regulated market of Euronext Amsterdam

<b>“Euronext in Brussels”</b>	a regulated market of Euronext Brussels
<b>“FDA”</b>	US Food and Drug Administration
<b>“FDCA”</b>	Federal Food, Drug and Cosmetic Act
<b>“Financed Project”</b>	the development of novel test panels, e.g. for intra-abdominal infections and sepsis host response as well as urinary tract infection, cardiology associated infection and extended respiratory panels, as well as future panels on platforms such as the Unyvero platform, including the necessary clinical trials to obtain the relevant regulatory approvals for market authorization and reimbursement, and capex for manufacturing expansion to which the granting of the loans under the EIB Finance Contract is limited to.
<b>“Financial Promotion Order”</b>	the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended
<b>“Financial Reporting Supervision Reporting Act”</b>	the Dutch Financial Reporting Supervision Act ( <i>Wet toezicht financiële verslaggeving</i> )
<b>“Financial Transaction Tax”</b>	a common financial transaction tax as proposed in the Draft Directive
<b>“FISH”</b>	fluorescence in situ hybridization
<b>“FRSA”</b>	Dutch Financial Reporting Supervision Act ( <i>Wet toezicht financiële verslaggeving</i> )
<b>“FSMA 2000”</b>	the Financial Services and Markets Act 2000, as amended
<b>“FSMA”</b>	the Belgian Financial Services and Markets Authority ( <i>Autorité des services et marchés financiers</i> )
<b>“FTE”</b>	full time equivalent
<b>“GAAP”</b>	German Generally Accepted Accounting Principles
<b>“GCF”</b>	Global Corporate Finance
<b>“GEAR”</b>	Genetic Antibiotic Resistance and susceptibility Database and bioinformatics platform
<b>“General Data Protection Regulation”</b>	Regulation 2016/679/EU of the European Parliament and of the Council of April 27, 2016
<b>“General Meeting”</b>	any general meeting ( <i>algemene vergadering</i> ), being the corporate body or, where the context so requires, the physical meeting of Shareholders
<b>“Germany”</b>	Federal Republic of Germany ( <i>Bundesrepublik Deutschland</i> )
<b>“goetzpartners”</b>	goetzpartners securities Limited
<b>“GPP”</b>	gastrointestinal pathogen panel
<b>“Greater China”</b>	China, Taiwan and Hong Kong
<b>“Gyronimo Acquisition”</b>	the acquisition of the real-time qPCR-based Gyronimo platform, a prototype version of the Unyvero A30 <i>RQ</i> Analyzer, from Carpegen and Systec in December 2016
<b>“HAI”</b>	hospital-acquired infections
<b>“HAP”</b>	hospital-acquired pneumonia
<b>“HCAP”</b>	healthcare-associated pneumonia

<b>“Heraeus Medical”</b>	Heraeus Medical GmbH
<b>“HPN”</b>	Hospitalised pneumonia
<b>“HSA”</b>	Singapore Health Services Authority
<b>“HTA”</b>	health technology assessment
<b>“IAI”</b>	intra-abdominal infection
<b>“ICAAC”</b>	Interscience Conference on Antimicrobial Agents and Chemotherapy
<b>“ICU”</b>	intensive care unit
<b>“IDE”</b>	investigational device exemption
<b>“IFRS”</b>	International financial reporting standards as adopted by the European Union
<b>“IJT”</b>	invasive joint infections
<b>“INAAT”</b>	isothermal nucleic acid amplification
<b>“Interim Financial Statements”</b>	the unaudited interim condensed financial statements of the Company as of 30 June 2018 and for the six months ended 30 June 2018 and 2017.
<b>“IPAB”</b>	Independent Payment Advisory Board
<b>“IPO”</b>	initial public offering
<b>“IRS”</b>	US Internal Revenue Service
<b>“ISO”</b>	International Organisation for Standardisation
<b>“ISO 13485”</b>	specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services
<b>“Israeli Securities Law”</b>	Israeli Securities Law, 5728-1968
<b>“ITC”</b>	Belgian Income Tax Code 1992
<b>“ITI”</b>	implant and tissue infection
<b>“IUO”</b>	investigational use only
<b>“IVD”</b>	in vitro diagnostics
<b>“IVD Directive”</b>	European Directive 98/79/EC on in vitro diagnostic medical devices
<b>“IVD Regulation”</b>	Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices
<b>“KOLs”</b>	key opinion leaders
<b>“LDTs”</b>	laboratory developed tests
<b>“Liquidity Provider”</b>	Bank Degroof Petercam SA/NV
<b>“Listing Agent”</b>	ABN AMRO Bank N.V.
<b>“LOS”</b>	length of stay
<b>“LRT”</b>	lower respiratory tract
<b>“LRT Application Cartridge”</b>	the Unyvero LRT application specific cartridge
<b>“Management Board”</b>	the Company’s management board ( <i>bestuur</i> )



<b>“Management Board Rules”</b>	rules regarding the Management Board’s functioning and internal organisation
<b>“Managing Director(s)”</b>	member of the Management Board
<b>“Managers”</b>	Baader Bank and goetzpartners
<b>“Marx Realitäten”</b>	Marx Realitäten GmbH
<b>“Master Mix”</b>	the enzyme required to start the PCR and thus one of the critical components of any PCR-based MDx test
<b>“MDx”</b>	molecular diagnostics
<b>“Medicare”</b>	US health insurance program for US citizens aged 65 and older
<b>“Member State”</b>	each member state of the European Union
<b>“MGI”</b>	MGI Tech Co., Ltd.
<b>“Mid-Point Proceeds”</b>	approximately €16.3 million of gross proceeds from the Offering, which term is based on an Offer Price at the mid-point of the Offer Price Range and excludes the PSOP Proceeds
<b>“MiFID II”</b>	Directive 2014/65/EU of the European Union on markets in financial instruments
<b>“MiFID II Product Governance Requirements”</b>	the product governance requirements contained within: (a) MiFID II; (b) Articles 9 and 10 of Commission Delegated Directive (EU) 2017/593 supplementing MiFID II; and (c) local implementing measures
<b>“MoU”</b>	memorandum of understanding between Curetis and MGI, a fully-owned subsidiary of BGI Group, one of the world’s leading genome sequencing companies headquartered in Shenzhen, Guangdong, P. R. China, entered into on 12 September 2017
<b>“NGS”</b>	Next Generation Sequencing
<b>“Notified Body”</b>	an organisation designated by an EU country to assess the conformity of certain products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required.
<b>“NSE”</b>	not substantially equivalent
<b>“OEM”</b>	Original Equipment Manufacturer
<b>“ÖGHMP”</b>	Österreichische Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin
<b>“Offer Period”</b>	the period during which the Offering will take place, commencing on at 09:00 CET on 2 November 2018 and ending at 15:00 CET on 7 November 2018, subject to acceleration or extension of the timetable for the Offering
<b>“Offer Price “</b>	the offer price per Offer Share
<b>“Offer Price Range”</b>	the expected price range of €2.00 to €2.60 (inclusive) per Offer Share
<b>“Offer Shares”</b>	the Shares to be issued by the Company in the Offering

<b>“Offering”</b>	the offering of Offer Shares that solely consists of private placements to certain institutional investors in various jurisdictions
<b>“OFPs”</b>	organisations for financing pensions
<b>“OPS Code”</b>	<i>Operationen- und Prozedurenschlüssel</i>
<b>“PCR”</b>	polymerase chain reaction
<b>“PCT”</b>	Patent Cooperation Treaty
<b>“PFIC”</b>	passive foreign investment company
<b>“PIPE”</b>	private investment in public equity
<b>“PJI”</b>	prosthetic joint infections
<b>“PMA”</b>	pre-market approval
<b>“PRH XVI”</b>	PRH XVI, LP
<b>“Pricing Agreement”</b>	the pricing agreement to be entered into on or about 7 November 2018 between the Company and the Managers
<b>“Pricing Statement”</b>	the statement setting out the Offer Price and the exact number of Offer Shares, which will be deposited with the AFM and published through a press release
<b>“Prospectus Directive”</b>	Directive 2003/71/EC and amendments thereto, including Directive 2010/73/EU
<b>“Prospectus”</b>	this prospectus dated 2 November 2018
<b>“PSOP”</b>	Curetis AG Phantom Stock Option Incentive Plan 2010
<b>“PSOP Beneficiaries”</b>	certain of Curetis’ directors and employees as well as former employees and consultants on behalf of which the Company intends to issue and sell the PSOP Offer Shares
<b>“PSOP Offer Shares”</b>	342,803 Shares the Company intends to issue and sell on behalf of the PSOP Beneficiaries
<b>“PSOP Proceeds”</b>	funds generated by the issue and sale of the PSOP Offer Shares
<b>“PSOP Roll-Over Agreements”</b>	the roll-over agreements in relation to the pre-IPO PSOP
<b>“PSP”</b>	Pancreatic Stone Protein
<b>“PTO”</b>	US Patent and Trademark Office
<b>“PwC”</b>	PricewaterhouseCoopers Accountants N.V.
<b>“QC”</b>	Quality Control
<b>“QEF”</b>	qualified electing fund
<b>“Qiagen”</b>	Qiagen N.V.
<b>“QIBs”</b>	qualified institutional buyers within the meaning of, and pursuant to Rule 144A under the US Securities Act
<b>“qPCR”</b>	Quantitative PCR
<b>“QSR”</b>	Quality System Regulation for FDA regulated products
<b>“Regulation S”</b>	Regulation S under the US Securities Act

<b>“Relevant EEA Member State”</b>	each member state of the EEA that has implemented the Prospectus Directive
<b>“RoW”</b>	Rest of the World
<b>“Rule 144A”</b>	Rule 144A under the US Securities Act
<b>“RUO”</b>	research use only
<b>“SABs”</b>	Curetis’ E.U. Scientific Advisory Board and U.S. Scientific Advisory Board
<b>“sCAP”</b>	severe community-acquired pneumonia
<b>“Schedule”</b>	the first schedule to the Israeli Securities Law
<b>“Scholz”</b>	Horst Scholz GmbH & Co. KG   High Tech in Kunststoff
<b>“Securities Giro Act”</b>	the Dutch securities giro act ( <i>Wet giraal effecten verkeer</i> )
<b>“Settlement”</b>	delivery of the Offer Shares
<b>“Settlement Date”</b>	the date on which Settlement occurs which is expected to be on or about 9 November 2018, subject to acceleration or extension of the timetable of the Offering
<b>“SGM”</b>	Schweizer Gesellschaft für Mikrobiologie
<b>“Shareholder”</b>	a holder of Shares
<b>“Shares”</b>	the ordinary shares in the issued share capital of the Company, with a nominal value of €0.01 each
<b>“SHR”</b>	sepsis host response
<b>“SIRS”</b>	Systemic Inflammatory Response Syndrome
<b>“Sole Global Coordinator”</b>	Baader Bank
<b>“SSI”</b>	surgical site infections
<b>“STA”</b>	Siemens Technology Accelerator GmbH
<b>“Stock Exchange Tax Representative”</b>	a stock exchange tax representative in Belgium, subject to certain conditions and formalities
<b>“STRATEC”</b>	STRATEC Biomedical AG
<b>“Supervisory Board”</b>	the Company’s supervisory board ( <i>raad van commissarissen</i> )
<b>“Supervisory Board Rules”</b>	the rules regarding the Supervisory Board’s functioning and internal organisation
<b>“Supervisory Director”</b>	each member of the Supervisory Board
<b>“Systec”</b>	Systec Elektronik und Software GmbH
<b>“Target Market Assessment”</b>	the product approval process, which has determined that the Offer Shares are: (i) compatible with an end target market of investors who meet the criteria of professional clients and eligible counterparties, each as defined in MiFID II; and (ii) eligible for distribution through all distribution channels as are permitted by MiFID II
<b>“Tax on Securities Accounts”</b>	a tax of 0.15% levied on the share of Belgian resident and non-resident individuals in the average value of the qualifying financial instruments (including but not limited to shares, notes and units of undertakings for

	collective investment) held on one or more securities accounts during a reference period of twelve consecutive months starting on 1 October and ending on 30 September of the subsequent year
<b>“Terms of Reference”</b>	terms of reference on each Supervisory Board committee’s role, responsibilities and functioning, drawn up by the Supervisory Board
<b>“Top-End Proceeds”</b>	approximately €18.4 million of gross proceeds from the Offering, which term is based on an Offer Price at the upper end of the Offer Price Range and excludes the PSOP Proceeds
<b>“Treaty”</b>	the income tax treaty between the United States and the Netherlands
<b>“UAE”</b>	United Arab Emirates
<b>“UK”</b>	United Kingdom
<b>“Underwriting Agreement”</b>	the underwriting agreement entered into on 2 November 2018 between the Company and the Managers
<b>“United Kingdom” or “UK”</b>	the United Kingdom of Great Britain and Northern Ireland
<b>“United States” or “US”</b>	the United States of America, its territories and possessions, any state of the United States of America and the District of Columbia
<b>“Unyvero A30 RQ Analyzer”</b>	the Unyvero A30 RQ Analyzer was acquired as a prototype pursuant to the Gyronimo Acquisition. It is currently in the development stage, but is an integral part of Curetis’ product pipeline and intended to be fully and seamlessly integrated into the Unyvero System suite of products, to be used alongside the current Unyvero A50 Analyzer.
<b>“Unyvero A50 Analyzer”</b>	the Unyvero A50 Analyzer consists of mechanical, electronic, pneumatic and optical elements and enables a fully automatic random-access processing of the Application Cartridges.
<b>“Unyvero C8 Cockpit”</b>	the Unyvero C8 Cockpit
<b>“Unyvero L4 Lysator”</b>	Unyvero L4 Lysator
<b>“Unyvero Platform”</b>	the Application Cartridges together with the Unyvero System
<b>“Unyvero System”</b>	the system comprising of the L4 Lysator, the C8 Cockpit and the Unyvero A50 Analyzer
<b>“URTI”</b>	upper respiratory tract infections
<b>“US\$” or “US dollars”</b>	lawful currency of the United States
<b>“US Exchange Act”</b>	the US Securities Exchange Act of 1934, as amended
<b>“US Holder”</b>	owner of Shares and (i) a citizen or individual resident of the United States; (ii) a corporation created or organised in or under the laws of the United States, any state therein or the District of Columbia; (iii) an estate, the income of which is subject to US federal income taxation regardless of its source; or (iv) a trust if (a) a court within the United States is able to exercise primary supervision over its administration and one or more US persons have the authority to control all of the substantial decisions of such trust, or (b) such trust has a valid election in effect to be treated as a US person for US federal income tax purposes

<b>“US Securities Act”</b>	the US Securities Act of 1933, as amended
<b>“UTI”</b>	urinary tract infection
<b>“VAP”</b>	Ventilator-Associated Pneumonia”
<b>“Warrants”</b>	Share subscription warrants issued under the Yorkville Agreement
<b>“WHO”</b>	World Health Organisation
<b>“XRP”</b>	extended respiratory pane”
<b>“Yorkville” or “Investor”</b>	YA II PN, Ltd, an investment fund managed by Yorkville Advisors Global LP, a U.S.-based management firm
<b>“Yorkville Agreement”</b>	the up to €20,000 thousand financing facility between the Company and Yorkville dated October 2, 2018.
<b>“Zollner”</b>	Zollner Elektronik AG

The following explanations are not intended to be exhaustive definitions, but to assist understanding of certain terms used in this Prospectus.

<b>Assay</b>	In the field of diagnostics, an assay is a process or method aimed at determining the presence or amount (quantitative assay) of a certain substance in a sample.
<b>Biomarker (or Marker)</b>	A Biomarker is any molecular characteristic, feature or parameter that can be objectively measured through an assay and evaluated as an indicator of: (i) normal biologic processes; (ii) abnormal biologic processes; (iii) pathogenic processes; or (iv) pharmacologic responses to a therapeutic intervention or other action/intervention.
<b>Companion Diagnostics (CDx)</b>	CDx is a bio-analytical method designed to assess: (i) whether or not a patient will respond favourably to a specific medical treatment; (ii) what the optimal dose is for a patient; and (iii) whether the patient can expect certain side effects from a medical treatment. Any prescription of a drug with a CDx is based on the outcome of the CDx. CDx tests are also used in the drug development process
<b>CE-IVD-mark</b>	The CE-IVD-mark is a mandatory conformance mark on many products placed on the market in the European Union. With the CE-IVD-marking on a product, the manufacturer ensures that the product is in conformity with the essential requirements of the applicable European Union directives. The letters “CE” stand for “Conformité Européenne” (“ <b>European Conformity</b> ”).
<b>Deoxyribonucleic acid (DNA)</b>	DNA is a nucleic acid molecule that contains the genetic instructions used in the development and functioning of living organisms.
<b>Highplex</b>	Highplex applications typically cover broad panels of pathogens relevant in the respective indication as well as 15-20 AMR markers in typically four to five hours.
<b>Investigational Device Exemption (IDE)</b>	IDE is an FDA exemption that allows an investigational device to be used in a clinical study in order to collect the safety and effectiveness

	data required to support a PMA application or premarket notification to the FDA.
<b>In vitro diagnostics or In vitro diagnosis (IVD)</b>	IVD is a diagnostic test outside of a living body in contrast to “ <b>in vivo</b> ”, in which tests are conducted in a living body (for example an X-ray or CT-scan).
<b>Laboratory information systems (LIS)</b>	LIS are a class of software that process, store and manage data from all stages of medical laboratory processes and tests. LIS systems often interface with other information systems such as HIS.
<b>Lowplex</b>	Lowplex applications allow the parallel detection of about 1-5 pathogens in typically 45-90 minutes in larger patient populations.
<b>Midplex</b>	Midplex applications allow the parallel detection of about 10-40 pathogens and/or resistance markers in typically 1-2 hours in smaller, symptomatic patient populations. The systems either use native sample types or pre-cultured samples (e.g. in bloodstream infections).
<b>Molecular diagnostics (MDx)</b>	MDx is a form of diagnostic testing used to detect specific sequences in DNA or RNA that may or may not be associated with disease. Clinical applications of MDx include infectious disease testing, oncology, pharmacogenomics and genetic disease screening.
<b>Multiplex (Integrated Cartridge-Based Multiplex PCR Systems)</b>	These systems are characterized by the full integration of all steps from native sample preparation to the detection of the DNA/RNA in a single-use cartridge for the testing of an individual native patient sample, the parallel detection of multiple pathogens and resistance markers in one test (multiplexing) and fast time to result (1-5 hours). Based on their multiplexing capabilities, these lowplex to highplex systems are typically deployed for screening of smaller numbers of markers or syndromic testing of highly symptomatic patients.
<b>Multiplexing</b>	The simultaneous detection of more than one analyte or biomarker from a single sample.
<b>Pre-market approval (PMA)</b>	PMA is the most stringent type of device regulatory clearance required by the FDA before a medical device can be marketed in the United States. PMA is the FDA process of scientific and regulatory review to evaluate and review the safety and effectiveness of Class III medical devices. Class III medical devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.
<b>Protein</b>	Polypeptide chain built from the 20 natural amino acids. Proteins are synthesised from a messenger RNA copy of a gene and can have many functions in the cytoskeleton of the cell, enzymatic, messenger functions in cells and blood such as immune cytokines, DNA binding proteins that regulate expression, etc.
<b>Sample preparation</b>	Sample preparation refers to the ways in which a sample is treated prior to its analysis. Sample preparation is a very important step in most analytical techniques, because the techniques are often not responsive to the analytes in its original matrix, or the results are distorted by the

## **Sensitivity and specificity**

presence of interfering substances. Sample preparation may involve dissolution of matrix components, reaction with certain chemicals, pulverising the sample, treatment with a chelating agent (e.g. EDTA), masking or neutralisation of interfering substances, filtering, dilution or concentration of the analytes, sub-sampling or many other techniques.

Sensitivity and specificity are statistical measures of the performance of a binary classification test, also known in statistics as classification function. Sensitivity (also called recall rate in some fields) measures the proportion of actual positives that are correctly identified as such (e.g. the percentage of sick people who are correctly identified as having the condition). Specificity measures the proportion of negatives that are correctly identified (e.g. the percentage of healthy people who are correctly identified as not having the condition). These two measures are closely related to the concepts of type I and type II errors. A theoretical, optimal prediction aims to achieve 100% sensitivity (i.e., predict all people from the sick group as sick) and 100% specificity (i.e., not predict anyone from the healthy group as sick), however theoretically any predictor will possess a minimum error bound known as the Bayes error rate.

FDA Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests – When a new test is evaluated by comparison to a nonreference standard, you cannot directly calculate unbiased estimates of sensitivity and specificity. Therefore, the terms sensitivity and specificity are not appropriate to describe the comparative results. Instead, the same numerical calculations are made, but the estimates are called positive percent agreement and negative percent agreement, rather than sensitivity and specificity. This reflects that the estimates are not of accuracy but of agreement of the new test with the non-reference standard.

## **Sepsis**

### **US Food and Drug Administration (FDA)**

Severe overall inflammatory response of the body to an infection.

The FDA is a federal agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through the regulation and supervision of, among other things, medical devices.

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