

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

OPGEN, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

06-1614015
(I.R.S. Employer
Identification Number)

**708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878
(240) 813-1260**

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

**Timothy C. Dec
Chief Financial Officer
708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878
(240) 813-1260**

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

With a copy to:
**Peter Jaslow, Esquire
Ballard Spahr LLP
1735 Market Street, 51st Floor
Philadelphia, PA 19103
(215) 665-8500**

Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a registration statement filed pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act (Check one):

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Smaller Reporting Company

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Security	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common stock, par value \$0.01 per share	—	— (1)	50,000,000 (2)	\$6,490

(1) OpGen, Inc. is registering an indeterminate number of shares of its common stock to be issued and sold from time to time at indeterminate prices. In no event will the aggregate maximum offering price of all securities issued pursuant to this registration statement exceed \$50,000,000. In addition, pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), the securities registered hereunder include such indeterminate number of additional shares of common stock as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the amount of the registration fee required pursuant to Rule 457(o) under the Securities Act, which permits the registration fee to be calculated on the basis of the maximum aggregate offering price of all securities listed.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated January 28, 2020

PROSPECTUS



\$50,000,000 Common Stock

We may offer and sell from time to time, in one or more offerings, up to \$50,000,000 of our common stock.

Each time we sell common stock pursuant to this prospectus, we will provide the specific terms of the common stock offered in a supplement to this prospectus. The prospectus supplements will also describe the specific manner in which we will offer common stock and may also supplement, update or amend information contained in this prospectus. You should read this prospectus and any related prospectus supplement carefully before you invest in our securities.

The shares of common stock being registered for the account of the Company may be sold on a delayed or continuous basis directly by us, through dealers, agents or underwriters designated from time to time, or through any combination of these methods. If any dealers, agents or underwriters are involved in the sale of the common stock in respect of which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in any prospectus supplement.

Our common stock is traded on the NASDAQ Capital Market under the symbol "OPGN." On January 23, 2020, the closing price of our common stock was \$1.54 per share.

We are an "emerging growth company" as the term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. See "Prospectus Summary - Implications of Being an Emerging Growth Company."

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 29 of this prospectus and any similar heading in any prospectus supplement or other documents that are incorporated by reference into this prospectus.

This prospectus may not be used to offer or sell securities unless accompanied by a prospectus supplement for the securities being sold.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus is .

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You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell securities in any state where the offer or solicitation is not permitted. The information contained in this prospectus is complete and accurate as of the date on the front cover of this prospectus, but information may have changed since that date. We are responsible for updating this prospectus to ensure that all material information is included and will update this prospectus to the extent required by law.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data and we do not make any representation as to the accuracy of the information.

We own various U.S. federal trademark registrations and applications and unregistered trademarks and servicemarks, including OpGen®, Acuitas®, Acuitas Lighthouse®, AdvanDx®, QuickFISH® and PNA FISH®. The Curetis trademarks include Curetis®, Unyvero®, ARES® and ARES GENETICS®. All other trademarks, servicemarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are sometimes referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies, products or services.

Except as otherwise indicated herein in "Curetis Business Summary Financial Data" and "Unaudited Pro Forma Consolidated Combined Financial Information," all Curetis financial results and measures in this prospectus have been converted from Euros to U.S. dollars using an exchange rate of \$1.13667 to €1.00 as of June 30, 2019, based on Oanda.com. OpGen makes no representation that the Euro amounts could have been, or could be, converted, realized or settled in U.S. dollars at that rate on June 30, 2019, or at any other rate.

PROSPECTUS SUMMARY

This summary highlights information contained in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. You should read the entire prospectus carefully before making an investment in our securities. You should carefully consider, among other things, our financial statements and the related notes and the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in, or incorporated by reference into, this prospectus. When we refer to OpGen, Inc., and its subsidiaries, we use the terms “OpGen,” “the Company,” “us,” “we” and “our.”

Implementation Agreement with Curetis N.V.

As announced on September 4, 2019, OpGen has entered into an Implementation Agreement with Curetis N.V., a Dutch publicly-listed company on Euronext under ticker CURE, or the Implementation Agreement. Under the Implementation Agreement, OpGen has agreed to purchase, through Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and a wholly-owned subsidiary of OpGen, all of the outstanding shares and acquire all of the related business assets of Curetis GmbH, or Curetis, a private limited liability company organized under the laws of the Federal Republic of Germany and a wholly-owned subsidiary of Curetis N.V., to create a combined business within OpGen, which we refer to as “Newco” in this prospectus.

Pursuant to the Implementation Agreement, we have agreed to acquire (i) all of the issued and outstanding capital stock of Curetis, or the Transferred Shares, and (ii) all of the assets of Curetis N.V. that are solely and exclusively related to the business of Curetis, or the Transferred Assets. The Company has also agreed to assume (1) the Curetis N.V. 2016 Stock Option Plan, as amended, or the 2016 Stock Option Plan, and the outstanding awards thereunder, (2) the obligation to issue equity to the holders of awards under the Curetis AG Phantom Stock Option Incentive Plan of 2010, as amended, or the PSOP, and (3) the outstanding indebtedness of Curetis N.V. under certain convertible notes, or the Curetis Convertible Notes, including providing for conversion of such notes into shares of the Company’s common stock. We will also assume all of the liabilities of Curetis N.V. that are solely and exclusively related to the business being acquired.

Under the Implementation Agreement, the Company has agreed to issue, as the sole consideration, 2,662,564 shares of common stock, less the number of shares of common stock the issuance of which shall be reserved by the Company in connection with (a) its assumption of the 2016 Stock Option Plan, (b) any future issuance of shares of common stock under the PSOP, and (c) shares of common stock reserved for future issuance upon the conversion, if any, of the Curetis Convertible Notes, or together, the Consideration. The number of shares of common stock to be reserved for the deductions described above are based on a conversion ratio of 0.0959, which is the ratio of the Consideration as contrasted with the number of ordinary shares of Curetis N.V. on a fully diluted basis. Under the Implementation Agreement, the Company has agreed to issue, as the sole consideration, 2,662,564 shares of common stock, less the number of shares of common stock the issuance of which shall be reserved by the Company for future issuance in connection with (a) up to 135,421 shares of OpGen common stock reserved for its assumption of the 2016 Stock Option Plan, and (b) up to 500,000 shares of OpGen common stock reserved for future issuance upon the conversion of certain of the Curetis Convertible Notes, or together, the Consideration. The number of shares of common stock to be reserved for the deductions described above are based on a conversion ratio of 0.0959, which is the ratio of the Consideration as contrasted with the number of ordinary shares of Curetis N.V. on a fully diluted basis. If issued as of the date of this prospectus, the number of shares representing the Consideration would equal 32.3% of the outstanding shares of OpGen common stock. The number of shares of OpGen common stock to be issued to Curetis N.V. is fixed, therefore, the percentage ownership of the Company as of the date of closing will be different.

The Company has filed a Registration Statement on Form S-4 to register the Consideration. The transactions under the Implementation Agreement are subject to approval by the stockholders of the Company and the shareholders and debt holders of Curetis N.V. and Curetis GmbH. The Company has delivered a proxy statement to its stockholders and has called for a special meeting of its stockholders to be held on March 10, 2020 to approve the transactions contemplated by the Implementation Agreement.

The Implementation Agreement contains customary representations and warranties of the parties and the parties have agreed to use their commercially reasonable efforts to take all actions necessary to consummate the closing of the transactions contemplated by the Implementation Agreement. Pursuant to the Implementation Agreement, the Company committed to raise at least \$10 million of interim equity financing to support the continuing operations of both the Company and the Curetis Group. On October 28, 2019, the Company completed an offering of units and pre-funded units to raise gross proceeds of \$9.4 million, which the parties have agreed meets this closing condition under the Implementation Agreement, or the October 2019 Offering. The Company will use the proceeds from the October 2019 Offering for the following purposes: prior to the closing of the transaction with Curetis to (1) complete the transaction with Curetis; (2) provide short-term funding to Curetis under a subordinated loan facility, the Interim Facility, to fund the Curetis Group’s current operations; and (3) support research and development and regulatory activities for the Company’s anticipated FDA 510(k) submissions for the Acuitas AMR Gene Panel test and the Acuitas Lighthouse Software; and, if any proceeds remain following the closing of the Transaction, to: (4) commercialize Newco’s products, with a focus on the Unyvero platform and diagnostic tests, and the Acuitas AMR Gene Panel tests; (5) support further development and commercialization of the Ares Genetics database and Acuitas Lighthouse Software; (6) fund directed efforts to the customers and collaborators of each company to introduce the products and services of Newco; (7) invest in manufacturing and operations infrastructure to support sales of products; and (8) the balance, if any, for general corporate purposes. If the transaction with Curetis does not close, to the extent any proceeds remain, OpGen would use any remaining proceeds to support OpGen’s operations as far as possible into 2020.

This prospectus summary provides information about OpGen and about Curetis GmbH and its subsidiaries (together referred to as the Curetis Group), and forward-looking, pro forma information about the combined company following the closing of the transaction. We believe Newco will be a market leader positioned to capitalize on global opportunities in the infectious disease and antimicrobial resistance testing markets. We believe that Newco will have a unique portfolio of *in vitro* diagnostic, or IVD premier portfolio of Artificial Intelligence, or AI, powered bioinformatics solutions for multi-drug resistance diagnostics, and a global commercial channel with extensive capabilities and distribution partners.

We anticipate that Newco will achieve significant financial, operational, technical, and commercial synergies through the combination of the OpGen and Curetis businesses. We intend to derive commercial synergy by using a single sales and marketing infrastructure and working to distribute the OpGen products through the Curetis international distribution channels. Financial and operational synergies include the consolidation of the companies' separate infrastructures into one streamlined organization. We envision the technical organizations building off the capabilities of each individual organization and leveraging best practices and common systems.

Overview of OpGen

We are a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. We are developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. Our proprietary DNA tests and informatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize care decisions for patients with acute infections.

OpGen's molecular diagnostics and informatics products, product candidates and services combine its Acuitas molecular diagnostics and Acuitas Lighthouse informatics platform for use with its proprietary, curated MDRO knowledgebase. OpGen is working to deliver products and services, some in development, to a global network of customers and partners.

- Our molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include the Acuitas antimicrobial resistance, or AMR, Gene Panel (Urine) test in development for patients at risk for complicated urinary tract infections, or cUTI, the Acuitas AMR Gene Panel (Isolates) test in development for testing bacterial isolates, and the QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of our Acuitas AMR Gene Panel tests is currently available for sale in the United States for research use only, or RUO, and none have been granted FDA clearance to date. This means that, currently, we cannot market these tests for clinical diagnostic uses.
- Our Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that are designed to combine clinical lab test results with patient and hospital information to provide analytics and actionable insights to help manage MDROs in the hospital and patient care environment. Components of the informatics systems include the Acuitas Lighthouse Knowledgebase and the Acuitas Lighthouse Software. The Acuitas Lighthouse Knowledgebase is a relational database management system and a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens. The Acuitas Lighthouse Software system includes the Acuitas Lighthouse Portal, a suite of web applications and dashboards, the Acuitas Lighthouse Prediction Engine, which is a data analysis software, and other supporting software components. The Acuitas Lighthouse Software can be customized and made specific to a healthcare facility or collaborator, such as a pharmaceutical company. The Acuitas Lighthouse Software has not yet been cleared for marketing in the United States. It is currently available for RUO and may not be distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

In May 2019, OpGen filed a 510(k) submission with the FDA seeking clearance of its Acuitas AMR Gene Panel (Isolates) diagnostic test. In July 2019, it received an Additional Information, or AI, Request from the FDA detailing a number of questions related to the submission. At the time, questions from the FDA focused on the intended use of the test including the correlation between marker detection and antibiotic resistance, the level of evidence to support resistance marker/organism claims, whole genome sequencing, or WGS, test validation and use as a comparator method, clinical performance of the test compared to WGS and further analysis of individual study results, *in silico* analysis to support test evaluations, further analysis of analytical study results, additional information regarding instrumentation for use with the test, and test reporting and labeling. On January 6, 2020, OpGen filed a formal response to the FDA's July 2019 AI Request. Subsequently, the FDA issued a second AI Request on January 17, 2020 to formalize additional questions and remaining requests for information from the earlier July 2019 AI Request. OpGen will continue to work interactively with the FDA to provide responses necessary to address questions related to the submission as well as additional questions that may arise through this second interactive response review process.

Overview of the Curetis Group

Curetis is a wholly-owned subsidiary of Curetis N.V. Curetis owns 100% of three international subsidiaries. The Curetis Group develops, manufactures and commercializes innovative solutions for molecular microbiology.

The Curetis business is based on two complementary business pillars:

- The Unyvero A50 high-plex polymerase chain reaction, or PCR, platform for comprehensive and rapid diagnosis of severe infectious diseases in hospitalized patients. The platform is based on proven, intelligently integrated technologies, allowing for the testing of broad panels of pathogens and antibiotic resistance markers and the processing of a large variety of native patient samples with an intuitive workflow. The Unyvero A50 high-plex PCR platform's advantage is the timely access to comprehensive, actionable and reliable data. Curetis' molecular tests for different indications are commercially available in Europe, the United States, Asia and the Middle East. The Curetis Group is also developing the Unyvero A30 RQ Analyzer, which is designed to serve as a platform with low-to medium-plex capabilities that it ultimately intends to commercially leverage predominantly in collaborations with one or more diagnostics industry partners.
- The ARES AMR database, or *ARESdb*, is a comprehensive database of the genetics of antimicrobial resistance, or AMR, which permits Curetis to increasingly utilize the proprietary biomarker content in its own assay and cartridge development, as well as to build an independent business in next-generation sequencing, or NGS, based offerings for AMR research and diagnostics in collaboration with partners in the life science, pharmaceutical and diagnostics industries. *ARESdb* is not commercially available in the United States for diagnostic use, as it has not been cleared by the FDA for marketing. In September 2019, Ares Genetics, a wholly owned subsidiary of Curetis, or Ares Genetics, signed a technology evaluation agreement with an undisclosed global IVD corporation. In the first phase of the collaboration, expected to take about 10 months, Ares Genetics expects to further enrich *ARESdb* with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication.

Curetis GmbH's headquarters are based in Holzgerlingen, near Stuttgart in southern Germany, in addition to subsidiaries located in San Diego, California, USA and Vienna, Austria.

Overview of Newco

We anticipate that the focus of Newco will be on its combined broad portfolio of products, which include high impact rapid diagnostics and bioinformatics to interpret AMR genetic data. The two lead products we expect Newco to focus on are for lower respiratory infection and urinary tract infection:

- The Unyvero Lower Respiratory Tract, or LRT, test is the first FDA cleared test that can be used for more than 90% of infection cases of hospitalized pneumonia patients. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. The Unyvero LRT automated test detects 19 pathogens within less than five hours and with approximately two minutes of hands-on time and provides clinicians with a comprehensive overview of 10 genetic antibiotic resistance markers. We believe the Unyvero LRT test has the ability to help address a significant, previously unmet medical need that causes over \$10 billion in annual costs for the U.S. healthcare system, according to the Centers for Disease Control, or CDC.
- Commercializing the Unyvero LRT test for testing bronchoalveolar lavage, or BAL, specimens of U.S. patients with lower respiratory tract infections following FDA clearance received by Curetis in December 2019.
- The Acuitas AMR Gene Panel (Urine) test is being developed for patients at risk for cUTI, and is designed to test for up to five pathogens and up to 47 antimicrobial resistance genes. When paired with the Acuitas Lighthouse software, we believe the test will be able to help improve management of the more than one million patients in the United States with cUTI. The AMR Gene Panel (Urine) is in testing in preparation for FDA 510(k) submission. We are pursuing 510(k) clearance for the test in connection with an initial clinical indication to test bacterial isolates.

We anticipate that Newco will have an extensive offering of additional *in vitro* diagnostic tests including CE-marked Unyvero tests for implant and tissue infections, intra-abdominal infections, cUTI, and blood stream infections, and the QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures, which we believe have an established market position in the United States.

We believe Newco's combined AMR informatics offerings, once all such products are cleared for marketing, if ever, will offer important new tools to clinicians treating patients with AMR infections. OpGen has collaborated with Merck, Inc. to establish the Acuitas Lighthouse Knowledgebase, which is currently commercially available in the United States for RUO. The Acuitas Lighthouse Knowledgebase includes approximately 15,000 bacterial isolates from the Merck SMART surveillance network of 192 hospitals in 52 countries and other sources. The Curetis ARESdb is a comprehensive database of genetic and phenotypic information. ARESdb was originally designed based on the SIEMENS microbiology strain collection covering resistant pathogens over the last 30 years and its development has significantly expanded to now include approximately 35,000 sequenced isolate strains and phenotypic correlation data against over 50 antibiotics. In September 2019, Ares Genetics signed a technology evaluation agreement with an undisclosed global IVD corporation. In the first phase of the collaboration, expected to take about 10 months, Ares Genetics expects to further enrich ARESdb with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication. We anticipate that Newco will utilize the proprietary biomarker content in these databases, as well as to build an independent business in NGS and AI based offerings for AMR research and diagnostics in collaboration with partners in the life science, pharmaceutical and diagnostics industries.

The Unyvero A50 tests for up to 130 diagnostic targets (pathogens and resistance genes) in under five hours with approximately two minutes of hands-on time. The system was first CE Marked in 2012 and was FDA cleared in 2018 along with the LRT test through *de novo* clearance. As of December 31, 2019, there is an installed base of 173 Unyvero A50 Analyzers globally. The Unyvero A30 RQ is a new device designed to address the low to mid-plex testing market for 5-30 DNA targets and to provide results in 45 to 90 minutes with 2-5 minutes of hands on time. The Unyvero A30 has a small laboratory footprint and has an attractive cost of goods profile. Curetis has been executing a partnering strategy for the Unyvero A30, and the first partnering agreement is anticipated to be negotiated in 2020.

We expect that Newco will have extensive partner and distribution relationships to help accelerate the establishment of a global infectious disease diagnostic testing and informatics business. We expect its partners will include A. Menarini Diagnostics for pan-European distribution to currently 11 countries; MGI/BGI for NGS-based molecular microbiology applications in China; and Beijing Clear Biotech Co. Ltd. for Unyvero A50 product distribution in China. In total, Curetis has a network currently consisting of 18 distributors covering 43 countries.

We anticipate that Newco will continue to develop and seek FDA and other regulatory clearances or approvals, as applicable, for the Acuitas AMR Gene Panel (Urine) diagnostic test and the Acuitas Lighthouse Software products. We expect that Newco will continue to offer the Acuitas AMR Gene Panel (Isolates) and Acuitas Lighthouse Software as RUO products to hospitals, public health departments, clinical laboratories, pharmaceutical companies and contract research organizations, or CROs.

Pursuant to the Implementation Agreement, we have agreed to assume the Curetis Convertible Notes from Curetis N.V. and outstanding indebtedness of Curetis GmbH under a loan provided by the European Investment Bank, or EIB. As of November 1, 2019, the outstanding indebtedness under the Curetis Convertible Notes was \$1.4 million. Certain holders of the Curetis Convertible Notes have converted outstanding notes into capital stock of Curetis N.V. since June 30, 2019, and pursuant to the Implementation Agreement, after the closing, the Curetis Convertible Notes that remain outstanding will be convertible into shares of OpGen common stock. The assumption of the Curetis Convertible Notes and the determination of the conversion rate adjustment are subject to the approval of the holders of the Curetis Convertible Notes. As of June 30, 2019, the outstanding indebtedness under the EIB loan is \$20.4 million of principal and \$1.6 million in accrued interest.

In September 2018, OpGen announced a collaboration with The New York State Department of Health, or DOH, and ILÚM Health Solutions, LLC, or ILÚM, an entity created by Merck's Healthcare Services division to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions in New York State. The collaboration is called The New York State Infectious Disease Digital Health Initiative. The first stage of the collaboration, which commenced in February 2019, is the completion of a demonstration project, expected to last until March 2020. We believe a successful demonstration project will lead to a statewide program. Under the demonstration project, OpGen is working with DOH's Wadsworth Center and ILÚM to develop an infectious disease digital health and precision medicine platform that connects healthcare institutions to DOH and uses genomic microbiology for statewide surveillance and control of antimicrobial resistance. The DOH, ILÚM and OpGen are working collaboratively to build a sustainable, flexible infectious diseases reporting, tracking and surveillance tool for antimicrobial resistance that can be applied across New York State. The goal of this research project is to improve patient outcomes and save healthcare dollars by integrating real-time epidemiologic surveillance with rapid delivery of resistance results to care-givers via web-based and mobile platforms. ILÚM is leading the project with the implementation of its technology platform. OpGen is providing its Acuitas AMR Gene Panel (RUO) for rapid detection of multidrug-resistant bacterial pathogens along with its Acuitas Lighthouse Software (RUO) for high resolution pathogen tracking. Under the agreement, OpGen will receive approximately \$1.6 million for the 12-month demonstration portion of the project. If the demonstration project is successful, the parties have agreed to negotiate an agreement with a four-year term to fully implement the project. We expect this initiative to continue as part of Newco's business.

OpGen's Business

We are a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. We are developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by MDROs. Our proprietary DNA tests and informatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize care decisions for patients with acute infections.

OpGen is developing high resolution Acuitas AMR Gene Panel tests designed to determine pathogen levels in clinical specimens and the key drug resistance gene profiles of Gram-negative organisms. Currently, the Acuitas AMR Gene Panel tests are available for sale for RUO. Following completion of research and development efforts, and if OpGen is able to obtain the appropriate regulatory clearances, OpGen anticipates its Acuitas AMR Gene Panel tests will be used in the clinical setting to provide pathogen and antibiotic resistance gene information to aid in decision-making for patients at risk for cUTI, lower respiratory tract infections, blood stream infections, and for testing of bacterial isolates. OpGen currently offers its Acuitas AMR Gene Panel (RUO) tests to CROs, pharmaceutical companies, hospitals and other healthcare providers for RUO. OpGen offers its Acuitas Lighthouse Software to health care facilities and public health facilities for research purposes, primarily in relation to infection control and surveillance.

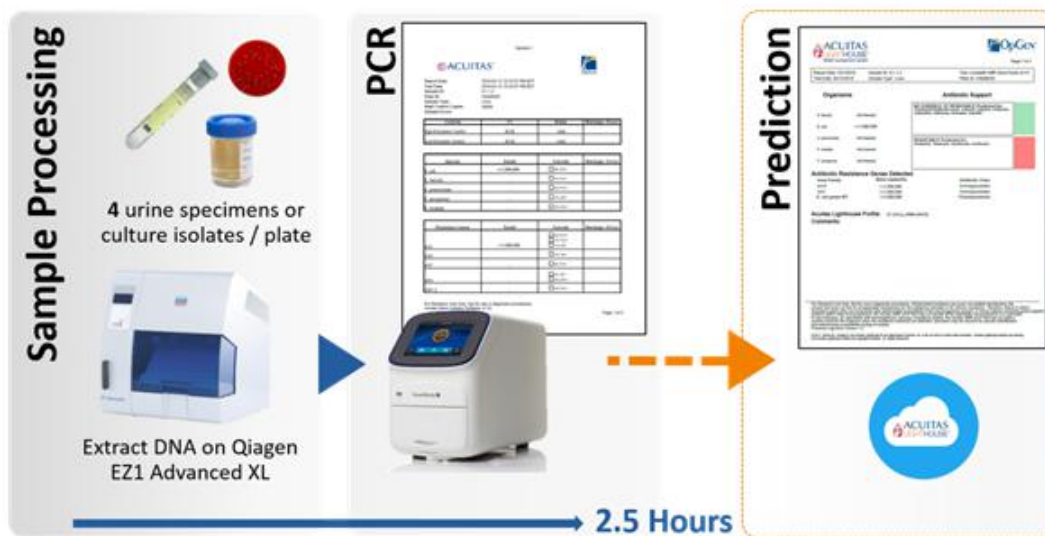
Acuitas AMR Gene Panel and Acuitas Lighthouse Software

The Acuitas AMR Gene Panel is a development-stage, qualitative and semi-quantitative nucleic acid-based *in vitro* diagnostic test that is designed for simultaneous detection and identification of multiple bacterial nucleic acids and select genetic determinants of antimicrobial resistance in urine specimens or bacterial colonies isolated from urine and other body sites. The Acuitas AMR Gene Panel (Urine) is intended as an aid in the diagnosis of specific agents of cUTIs for patients at risk of cUTI. The Acuitas AMR Gene Panel (Urine) employs automated deoxyribonucleic acid, or DNA, extraction on the Qiagen® EZ1 Advanced XL and multiplex real-time PCR on the Applied Biosystems™ QuantStudio 5 PCR System. The Acuitas AMR Gene Panel (Urine) test detects up to 47 gene targets which span 600 subtypes and convey resistance to nine classes of antibiotics directly from urine and isolated colonies, and is currently sold as a RUO test. Gene families detected include: KPC, NDM, VIM, IMP, OXA, CTXM-1, CTXM-9, CMY, MCR, and resistance genes to fluoroquinolone antibiotics. From urine specimens, the Acuitas AMR Gene Panel (Urine) will semi-quantitatively detect the most common bacterial causes of cUTI (*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *E. faecalis*). The Acuitas AMR Gene Panel (Urine) is designed to provide test results in under three hours, compared with traditional microbiology methods, which can take two to three days.

OpGen is also developing the Acuitas AMR Gene Panel (Isolates) test for testing bacterial isolates. This test is currently available in the United States for RUO and is being used in such capacity in connection with The New York State Infectious Disease Digital Health Initiative for testing of bacterial isolates. The test is contributing to the initiative's research mission by genotyping carbapenem resistant isolates from three health systems in the New York City Metro Area. Results are subsequently analyzed by the Acuitas Lighthouse Software (RUO) to support a series of infection control tracking capabilities that are of interest to The New York State Department of Health and healthcare providers. On May 13, 2019, OpGen filed a 510(k) submission with the FDA for clearance for its Acuitas AMR Gene Panel (Isolates) diagnostic test for the detection of antimicrobial resistance genes in bacterial isolates. In July 2019, we received an Additional Information, or AI, Request from the FDA detailing a number of questions related to the submission. At the time, questions from the FDA focused on the intended use of the test including the correlation between marker detection and antibiotic resistance, the level of evidence to support resistance marker/organism claims, whole genome sequencing, or WGS, test validation and use as a comparator method, clinical performance of the test compared to WGS and further analysis of individual study results, in silico analysis to support test evaluations, further analysis of analytical study results, additional information regarding instrumentation for use with the test, and test reporting and labeling. On January 6, 2020, OpGen filed a formal response to the FDA's July 2019 AI Request. Subsequently, the FDA issued a second AI Request on January 17, 2020 to formalize additional questions and remaining requests for information from the earlier July 2019 AI Request. OpGen will continue to work interactively with the FDA to provide responses necessary to address questions related to the submission as well as additional questions that may arise through this second interactive response review process.

The Acuitas Lighthouse Software (RUO) manages and evaluates data that identify the most common microbial causes of cUTI and key genetic determinants of antibiotic drug resistance, based on the amplification data of gene targets extracted from urine specimens. Through analysis of this data, the Acuitas Lighthouse Software can identify five bacterial species and predict resistance to up to fourteen different antibiotics from across nine antibiotic classes including: Aminoglycosides, Carbapenems, Cephalosporins, Fluoroquinolones, Polymyxins, Penicillins, Sulfonamides, Trimethoprim and Vancomycin. The Acuitas Lighthouse Software consists of the Acuitas Lighthouse Portal, a web application; the Acuitas Lighthouse Prediction Engine, data analysis software; and draws from the Lighthouse Knowledgebase, a relational database management system; and minor supporting software components. The Acuitas Lighthouse Software (RUO) was selected by The New York State Department of Health Wadsworth Center for the genomic microbiology component of The New York State Infectious Disease Digital Health Initiative. All components of the Acuitas Lighthouse Software are hosted in a cloud-based web application that is protected by security measures. The input to Acuitas Lighthouse Software is a data file generated by processing the results from the Acuitas AMR Gene Panel (Urine) test through the Acuitas AMR Gene Panel (Urine) Gene Analysis Software. This input file indicates which gene targets were detected by the assay and is loaded into the Acuitas Lighthouse Software via an interface of the Acuitas Lighthouse Portal, accessed by the user through a web browser. The Acuitas AMR Gene Panel (Urine) Gene Analysis Software results are retained by the Acuitas Lighthouse Knowledgebase and are sent to the Acuitas Lighthouse Prediction Engine for analysis. The Acuitas Lighthouse Prediction Engine contains software implementations of data models that were derived using a training panel of thousands of bacterial isolates with detailed genotypic and phenotypic characterizations, all stored within the Acuitas Lighthouse Knowledgebase. These models, each specific to one microbial species and antibiotic drug pairing, are used to make predictions of antibiotic resistance by analyzing the loaded input data. The results from the Acuitas Lighthouse Prediction Engine indicate whether there is evidence of resistance detected through the presence of specific genes, and if there is known intrinsic resistance to certain drugs. These final results are reported to the user via a Prediction Report and the Resistance Dashboard interface in the Acuitas Lighthouse Portal; both displays present the Acuitas Lighthouse Prediction Engine output in combination with selected input data and metadata, as well as the semi-quantitative counts of gene copies / mL for urine specimens. Our development of the Acuitas Lighthouse Software and the Acuitas AMR Gene Panel (Urine) test, thus far, has resulted from a comprehensive, multi-year effort, which remains ongoing, to help address urgent clinical needs for improved rapid antibiotic decision-making capabilities.

The figure below describes the workflow for the Acuitas AMR Gene Panel (Urine) test and the Acuitas Lighthouse Software.



In October 2018, OpGen entered into a supply agreement with QIAGEN GmbH, or QIAGEN, to advance OpGen’s rapid diagnostics for antimicrobial resistance. Under the agreement, OpGen will work to commercialize QIAGEN’s EZ1 Advanced XL automated nucleic acid purification instrumentation (EZ1) and reagent kits in the United States to be used with the Acuitas AMR Gene Panel products for research purposes. Under the terms of the agreement, OpGen will purchase EZ1 instruments and reagent kits from QIAGEN and sell or place them with customers in the United States for use with the Acuitas AMR Gene Panel products for RUO and, if the necessary 510(k) clearances are obtained, as diagnostic products. The EZ1 is a Class II Medical Device listed with the FDA that provides full automation with sample preparation throughput of up to 14 samples per one-hour run. QIAGEN is the global leader for nucleic acid sample preparation with a full line of instruments and reagents. There are thousands of EZ1 instruments currently used in laboratories worldwide.

In September 2018, OpGen announced a collaboration with The New York State DOH and ILÚM to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions in New York State. The collaboration is called The New York State Infectious Disease Digital Health Initiative. The first stage of the collaboration is the completion of a demonstration project, which commenced in February 2019 and is expected to last until March 2020. We believe a successful demonstration project will lead to a statewide program. Under the demonstration project, OpGen will work with DOH’s Wadsworth Center and ILÚM to develop an infectious disease digital health and precision medicine platform that connects healthcare institutions to DOH and uses genomic microbiology for statewide surveillance and control of antimicrobial resistance. The DOH, ILÚM and OpGen will work collaboratively to build a sustainable, flexible infectious diseases reporting, tracking and surveillance tool for antimicrobial resistance that can be applied across New York State. The goal of this research project is to improve patient outcomes and save healthcare dollars by integrating real-time epidemiologic surveillance with rapid delivery of resistance results to care-givers via web-based and mobile platforms. ILÚM is leading the project with the implementation of its technology platform. OpGen is providing its Acuitas AMR Gene Panel (RUO) for rapid detection of multidrug-resistant bacterial pathogens along with its Acuitas Lighthouse Software (RUO) for high resolution pathogen tracking. Under the agreement, OpGen will receive approximately \$1.6 million for the 12-month demonstration portion of the project, with the potential for full implementation during the next four years, should certain milestones be achieved.

In June 2017, OpGen entered into a supply agreement to use Thermo Fisher Scientific’s technology in the United States and Europe to support the commercialization of its rapid molecular products for RUO. Under the terms of the agreement, OpGen provides customer access to Thermo Fisher Scientific’s products to support the commercialization of our Acuitas QuickFISH Rapid Test and Acuitas Lighthouse Software to combat MDROs. In January 2018, the Company entered into a second supply agreement to incorporate Thermo Fisher Scientific’s real-time PCR technology in the Company’s Acuitas AMR Gene Panel tests. Specific products covered under these agreements include the QuantStudio 5 Real-Time PCR System, TaqMan® Fast Advanced Master Mix and TaqMan® MGB Probes for quick, multiplexed gene detection.

OpGen’s relationship with Merck & Co., Inc. includes investment from Merck Global Health Innovation Fund, or MGHIF, and a research agreement with Merck Sharp & Dohme, or MSD, to provide access to MSD’s 250,000 clinical isolate SMART bacterial surveillance archive. In December 2017, we entered into a subcontractor agreement with ILÚM, whereby ILÚM provided services to the Company in the performance of the Company’s CDC contract to deploy ILÚM’s commercially-available cloud- and mobile-based software platform for infectious disease management in three medical sites in Colombia with the aim of improving antibiotic use in resource-limited settings.

OpGen’s FDA cleared and CE marked QuickFISH and PNA FISH products are powered by PNA technology and provide rapid pathogen identification, typically in less than 30 minutes from a positive blood culture result.

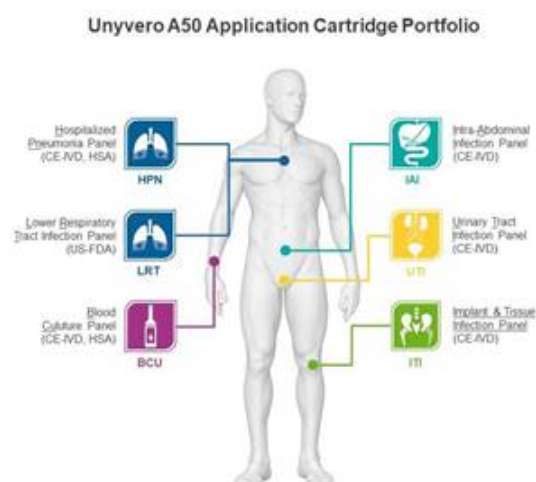
Intellectual Property

As of December 31, 2018, we had total ownership rights to 22 U.S. patents and applications, including six pending U.S. non-provisional patent applications, and 16 issued U.S. patents. More specifically, as of December 31, 2018, related to our FISH products, we had ownership rights to 11 U.S. patents and patent applications, including three pending U.S. non-provisional patent applications, and eight issued U.S. patents. These issued patents begin to expire in November 2024 and will be fully expired by March 2032. As of December 31, 2018, related to our Acuitas products, we had ownership rights to three pending U.S. non-provisional patent applications and no issued U.S. patents. As of December 31, 2018, related to our other products, we had ownership rights to eight issued U.S. patents. These issued patents begin to expire in June 2026 and will be fully expired by January 2032. A majority of our issued and exclusively licensed FISH patents from Dako Denmark A/S expired over the last six years. The remaining 17 exclusively licensed U.S. FISH patents expire between 2019 and 2024.

Curetis’ Business

Current Diagnostic Tests and Informatics

Curetis’ automated sample-to-answer product offerings are based on the Unyvero A50 platform that has been CE-IVD-marked since 2012 and was FDA cleared through the *de novo* process for the FDA cleared Unyvero LRT test. The Unyvero LRT test is designed to facilitate diagnoses in connection with the 500,000 to 750,000 complicated pneumonia cases each year in the United States, as estimated by pneumonia facts published by the American Thoracic Society in 2018. The test detects 19 microorganism targets and 10 antibiotic resistance markers from endotracheal aspirates of adult hospitalized patients with suspected lower respiratory tract infections. The Unyvero LRT test will also be available for testing bronchoalveolar lavage, or BAL, specimens of U.S. patients with lower respiratory tract infections if our 510(k) submission, the receipt of which was acknowledged by the FDA on July 23, 2019, is cleared for marketing in the United States. In Europe and other international markets Curetis offers five CE-marked application cartridges for hospitalized pneumonia, intra-abdominal infections, UTI, implant and tissue infections and blood stream infections. Curetis’ portfolio of these tests is highlighted in the figure below.



The Unyvero Platform is a highly automated cartridge-based 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. The Unyvero Platform's intuitive workflow with only minimal hands-on time enables hospital staff to perform molecular tests at the point of need, such as in the ICU setting. Unyvero and System Components are highlighted in the figure below. As of June 30, 2019, there were 170 Unyvero Analyzer placements globally.



Curetis' ARESdb informatics are currently commercialized through partnerships and an NGS service lab in Vienna, Austria. Curetis is accessing the AMR research market through its exclusive bioinformatics collaboration with QIAGEN. Curetis has development agreements with Sandoz to reposition antibiotics and recently introduced a specialized service laboratory offering of next-generation molecular AMR testing services with an initial focus on infection control, AMR epidemiology and surveillance, clinical research and pharmaceutical anti-infectives R&D. All services are based on NGS performed in Vienna, Austria and the ARESdb software.

Unyvero A30 RQ Instrument

The Curetis Unyvero A30 RQ is a new device candidate designed to address the low to mid-plex testing market for 5-30 DNA targets. The device provides results in 45 to 90 minutes with 2 to 5 minutes of hands on time. The Unyvero A30 RQ has a small laboratory footprint and has an attractive cost of goods profile. Fully functional instrument system prototypes have been available since the fourth quarter of 2018 and the first multiplex real-time PCR assays have been successfully transferred onto the Unyvero A30 RQ cartridges and successfully benchmarked against their performance on standard PCR instruments. Curetis is aiming to have the Unyvero A30 RQ platform ready for partnering in 2020. The compact Unyvero A30 instrument and test cartridges are illustrated below. We believe that the Unyvero A30 platform would also lend itself for the future development and regulatory approvals of certain panels from the Acuitas and/or Unyvero side of Newco onto this novel platform.



2019 Commercial Agreements

Curetis finalized the reorganization of its commercial organization in the first quarter of 2019 (a process initiated in December 2018) including a restructuring of its U.S. subsidiary Curetis USA Inc. As a result of these measures, Curetis GmbH retained a strong and highly experienced commercial partner support and customer service team to support its distribution partners and reduced the size of the U.S. commercial organization as of November 8, 2019 to 10, most of whom are field-based.

In February 2019, following the successful completion of analytical testing in 2018 and an expanded strategic collaboration between Curetis and Beijing Clear Biotech, or BCB, Curetis' exclusive commercial partner in greater China since mid-2018, for the Unyvero A50 System and Application Cartridges in greater China, BCB submitted the Unyvero System and HPN Application Cartridge to the Chinese National Medical Product Administration, or NMPA (formerly Chinese FDA). In July 2019, the NMPA held a panel meeting to discuss the application with local clinical experts and gave Curetis an opportunity to comment on various aspects of the application. As a result, Curetis now expects a near-term clarification on potential further requests for ancillary data and any required edits to the original application and potentially some limited set of additional clinical data to be generated in China.

Ares Genetics signed an exclusive global BioIT licensing and collaboration agreement with QIAGEN in February 2019 allowing QIAGEN to include aggregated data from ARESdb in its bioinformatics offering for the microbiology and AMR research community.

In March 2019 Curetis and A. Menarini Diagnostics (Menarini) announced an exclusive strategic pan-European commercial distribution agreement. Initially this collaboration covers 11 countries including key markets such as Germany, France, UK, Italy, as well as Spain and Portugal, Switzerland, Benelux and Sweden.

In July 2019, Curetis announced that it has entered into two distribution agreements with the Bosnian and Serbian branches of AKO MED, a manufacturer and distributor of medical products, AKO MED d.o.o., Banja Luka, Bosnia Hercegovina, and AKO MED d.o.o., Beograd, Serbia, respectively. Under the terms of the agreements, AKO MED has the exclusive right to commercialize Curetis' Unyvero A50 instrument system and application cartridges for the diagnosis of severe infections in hospitalized patients in Serbia, North Macedonia, Bosnia Hercegovina and Montenegro.

In July 2019, Curetis filed for the 510(k) clearance of an LRT Application Cartridge optimized for use with bronchoalveolar lavage, or BAL, as additional sample type. BAL is another common sample type for the diagnosis of lower respiratory tract infections. It is estimated that half of the samples obtained for the diagnosis of lower respiratory tract infections are BALs, and Curetis believes that a clearance of an Unyvero LRT Application Cartridge for this additional sample type would increase the total addressable market for Unyvero in the United States accordingly. Clearance was received in December 2019. Commercial launch is expected in the United States in the first quarter of 2020.

In August 2019, Ares Genetics opened a specialized service laboratory offering next generation molecular antimicrobial resistance, or AMR, testing services with an initial focus on infection control, AMR epidemiology and surveillance, clinical research and pharmaceutical anti-infectives R&D. All services are based on NGS and Curetis' proprietary, AI-powered antimicrobial resistance database, ARESdb. The newly opened laboratory is located at the Vienna Biocenter Campus in Vienna, Austria, and will serve researchers, hospitals, public health institutions, and pharmaceutical companies worldwide.

In September 2019, Ares Genetics entered into a multi-phase collaboration with an undisclosed leading global in vitro diagnostics corporation to jointly develop diagnostic solutions for infectious disease testing based on NGS technology. The companies signed an R&D and option agreement for the first phase of the collaboration fully funded by the collaborator. Furthermore, in return for an up-front option fee of €500,000, the collaborator obtained a right of first negotiation for an exclusive human clinical diagnostic use license to ARESdb and the ARES Technology Platform for the term of the agreement plus three months.

Newco's Strategy

We believe that by combining the Curetis and OpGen product offerings and products in development, we can build and commercialize a comprehensive precision medicine solution for combatting infectious disease with a focus on developing diagnostic tests for rapid pathogen identification and genetic profiling, antibiotic resistance analysis and advanced informatics to store and analyze MDRO and other infectious disease data for hospitals, out-patient settings and other healthcare providers. We believe that Newco will establish a market leadership position and will be able to capitalize on global opportunities in infectious disease and AMR detection. Key elements of Newco's anticipated strategy are to:

- continue to gain regulatory approvals and establish a market position for proprietary molecular diagnostic tests and platforms;
- capitalize on unique AMR bioinformatics solutions based on the Acuitas Lighthouse Software and ARESdb to help differentiate Newco's molecular diagnostic offerings and establish stand-alone product offerings directly or through strategic partners;
- leverage global commercial channel capabilities and partners to help accelerate growth and establish a global footprint for Newco's tests and informatics;
- pursue partner relationships to help fund product development and to support commercialization of products and services; and
- capitalize on the financial leverage, operational and research synergies to help improve return on capital and achieve future profitability.

The two core components of Newco's strategy are the development and commercialization of rapid diagnostic tests and leveraging AMR information services into new markets and channels.

We believe that antimicrobial resistance is an urgent global healthcare issue. MDROs have been prioritized as an urgent national and global threat by the CDC, the executive branch of the federal government and the World Health Organization. In March 2015, The White House issued a National Strategy for Combating Antibiotic-Resistant Bacteria. This strategy calls for the strengthening of surveillance efforts to combat resistance, the development and use of innovative diagnostic tests for identification and characterization of resistant bacteria and antibiotic stewardship and development.

The CDC estimates that in the United States more than two million people are sickened every year with antibiotic-resistant infections, with at least 23,000 dying as a result. Antibiotic-resistant infections add considerable but often avoidable costs to the U.S. healthcare system. In most cases, these infections require prolonged and/or costlier treatments, extended hospital stays, additional doctor visits and healthcare facilities use, and result in greater disability and death compared with infections that are treatable with antibiotics. Estimates for the total economic cost to the U.S. economy are difficult to calculate but the CDC has estimated such costs to be as high as \$20 billion in excess direct healthcare costs annually. As described in a December 2014 report issued by the Review on Antimicrobial Resistance commissioned by the U.K. Prime Minister, titled “Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations,” there are estimated to be 700,000 deaths each year from antimicrobial resistance, including 50,000 deaths annually in the United States and Europe.

- **Rapid diagnostics** – The two lead products for Newco’s rapid diagnostics business are for lower respiratory infection and urinary tract infection. The LRT test is based on the Unyvero A50 and was FDA cleared in 2018 for use with tracheal aspirates as a sample type. In July 2019, Curetis filed for the 510(k) clearance of an LRT application cartridge optimized for use with BAL as an additional sample type. BAL is another common sample type for the diagnosis of lower respiratory tract infections. In response to its July 2019 510(k) submission, Curetis received an AI request from the FDA in September 2019. After resolving the deficiencies identified in the AI request, FDA clearance was received in December 2019. Curetis believes that receipt of FDA clearance of an Unyvero LRT Application Cartridge for this additional sample type will significantly increase the total addressable market for Unyvero in the United States. Newco plans to continue to expand the commercial opportunity for the Unyvero products by developing new tests, running additional clinical trials, pursuing expanded regulatory approvals and through sales and marketing activities intended to help increase commercial adoption and test usage. OpGen is developing OpGen-branded Acuitas AMR Gene Panel tests for use on the Thermo Fisher Scientific Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System. The first of these new tests will be for antibiotic resistance testing of bacterial isolates. The second indication for the Acuitas AMR Gene Panel is for management of patients with UTI.
- **ARESdb and Acuitas Lighthouse informatics and services** – Newco plans to pursue commercial opportunities to provide the bio-informatics and companion genomic testing to pharmaceutical companies, CROs, health systems, third party *in vitro* diagnostic companies, and government agencies. Through OpGen’s participation in The New York State Infectious Disease Digital Health Initiative we anticipate deploying the Acuitas Lighthouse Software throughout the State of New York to help identify and track patients with Superbug infections. The focus in the health system segment is on helping guide antibiotic decision-making and supporting patient safety initiatives. Newco intends to actively pursue government funding for development and deployment of the Acuitas Lighthouse informatics in the United States and internationally.

In support of its strategy, we anticipate that Newco will focus on:

- commercializing the Unyvero A50 LRT test for BAL specimens and expand the base of commercial customers following FDA clearance in December 2019;
- entering into strategic partnering and licensing agreements to provide funding and support further development of the Unyvero A30 platform;
- obtaining FDA clearance to market the Acuitas AMR Gene Panel test for the detection of antimicrobial resistance genes in bacterial isolates and expand the base of commercial operations;
- completing development and clinical evaluations, obtaining necessary regulatory approvals, and successfully commercializing the Acuitas AMR Gene Panel (Urine) for cUTIs, with a goal of achieving three-hour antibiotic resistance analysis from the time of specimen collection;
- commercializing the Acuitas AMR Gene Panel tests for RUO, which started in January 2018 and for which on May 13, 2019, we filed a 510(k) submission with the FDA for clearance for the detection of antimicrobial resistance genes in bacterial isolates;
- making additional FDA 510(k) submissions for the Acuitas AMR Gene Panel (Urine) test and the Acuitas Lighthouse Software (AMR Gene Panel Prediction) anticipated in 2020;

- successfully completing the demonstration project of The New York State Digital Health Initiative to support Statewide deployment in subsequent years;
- obtaining third-party funding to expand the ARESdb offerings in conjunction with established *in vitro* diagnostic companies;
- expanding our business collaborations with Merck, Sandoz and other pharmaceutical companies;
- capitalizing on opportunities to deploy the Acuitas Lighthouse informatics and genomic testing for pharmaceutical/CRO services;
- growing the ARESdb and Acuitas Lighthouse data warehouse offerings for resistance and susceptibility data in hospital, hospital system, or broader community applications;
- seeking government funding to advance programs focused on identification and treatment of MDROs; and
- continuing development of the Acuitas Lighthouse Software and work to install Acuitas Lighthouse Software to customer sites in the United States and globally.

Company and Other Information

OpGen, Inc. was incorporated in Delaware in 2001. On July 14, 2015, the Company acquired AdvanDx, Inc., a Delaware corporation, as a wholly-owned subsidiary in a merger transaction, or the AdvanDx Merger. On September 3, 2019, we formed Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany for the sole purpose of acquiring the Transferred Shares and transferred assets and liabilities of the Curetis business. Our principal executive office is located at 708 Quince Orchard Road, Gaithersburg, Maryland, 20878, and our telephone number is (240) 813-1260. The Company also has operations in Copenhagen, Denmark and Bogota, Colombia. Our website address is www.opgen.com. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

Implications of Being an Emerging Growth Company

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. An “emerging growth company” may take advantage of exemptions from some of the reporting requirements that are otherwise applicable to public companies. These exceptions include:

- being permitted to present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering in May 2015. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenue exceeds \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

OPGEN SUMMARY FINANCIAL DATA

The following summary financial data should be read together with our financial statements and related notes, and “OpGen’s Management’s Discussion and Analysis of Financial Condition and Results of Operations” incorporated by reference into this prospectus. The summary statements of operations data for the years ended December 31, 2018 and 2017 and the nine months ended September 30, 2019 and 2018, and the balance sheet data as of September 30, 2019 have been derived from our audited financial statements and unaudited interim condensed financial statements incorporated by reference into this prospectus. Historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended December 31,		Nine Months Ended September 30,	
	2018	2017	2019	2018
(In thousands, except per share data)				
(Unaudited)				
Statements of Operation Data:				
Revenue	\$ 2,946	\$ 3,211	\$ 2,678	\$ 2,187
Operating expenses:				
Cost of products sold	1,223	1,613	682	940
Cost of services ⁽¹⁾	626	520	593	446
Research and development ⁽¹⁾	5,677	6,883	4,069	3,821
General and administrative ⁽¹⁾	7,069	6,693	4,901	5,365
Sales and marketing ⁽¹⁾	1,532	2,768	1,143	1,117
Transaction costs	—	—	538	—
Impairment of right-of-use asset	—	—	521	—
Total operating expenses ⁽¹⁾	16,127	18,477	(12,447)	(11,689)
Operating loss	(13,181)	(15,266)	(9,769)	(9,502)
Interest and other (expense) income	5	(87)	(8)	5
Interest expense	(191)	(233)	(143)	(140)
Foreign currency transaction gains (losses)	(10)	23	(9)	7
Change in fair value of derivative financial instruments	8	144	—	8
Provision for income taxes	—	—	—	—
Net loss	\$ (13,369)	\$ (15,419)	\$ (9,929)	\$ (9,636)
Net loss per common share, basic and diluted	\$ (44.49)	\$ (195.96)	\$ (13.32)	\$ (36.09)
Weighted average shares outstanding—basic and diluted	300	79	745	267

(1) Includes stock-based compensation as follows:

	Year Ended December 31,		Nine Months Ended September 30,	
	2018	2017	2019	2018
(Unaudited)				
Cost of services	\$ 1	\$ 14	\$ 1	\$ 1
Research and development	241	237	56	188
General and administrative	574	604	203	434
Sales and marketing	46	57	16	36
Total stock-based compensation	\$ 862	\$ 912	\$ 276	\$ 659

CURETIS BUSINESS SUMMARY FINANCIAL DATA

For purposes of the Curetis Business combined financial statements included in this prospectus, we refer to the business of Curetis N.V., principally operated by Curetis GmbH and its subsidiaries, or the Curetis Group, as the Curetis Business. In the Curetis Business combined financial statements included in the prospectus, the business of Curetis N.V. is presented, which comprises the Curetis Group as well as the Curetis Convertible Notes that are assumed by OpGen pursuant to the Implementation Agreement and certain costs related to the Curetis Business, primarily related to the compensation of certain members of senior management and its supervisory board that were historically incurred by Curetis N.V. but not charged to the Curetis Group.

The following summary financial data should be read together with the combined financial statements and related notes of the Curetis Business included in this prospectus. The combined statements of operations and other comprehensive income for the years ended December 31, 2018 and 2017, have been derived from the audited, combined financial statements of the Curetis Business for the years ended December 31, 2018 and 2017 included in this prospectus. All Curetis financial results and measures in this prospectus, other than the Curetis Business combined financial statements, have been translated from Euros to U.S. dollars using the translation rates listed below or, otherwise, of \$1.13667 to €1.00 as of June 30, 2019, based on Oanda.com. These translation rates are provided for convenience only, and OpGen makes no representation that the Euro amounts could have been, or could be, converted, realized or settled in U.S. dollars at that rate on June 30, 2019, or at any other rate.

The unaudited combined interim financial statements of the Curetis Business for the six months ended June 30, 2019 and 2018, and the combined statement of financial position data as of June 30, 2019, have been derived from the unaudited interim condensed combined financial statements of the Curetis Business as of and for the six months ended June 30, 2019. The combined financial statements as of and for the years ended December 31, 2018 and 2017 were prepared in accordance with IFRS as issued by the IASB. The unaudited interim condensed combined financial statements of the Curetis Business were prepared in accordance with IFRS as issued by the IASB applicable for interim reporting (IAS 34). Historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2017	2019	2018
Statements of Operations:				
(In thousands of USD (1))				
Revenue	\$ 1,623	\$ 1,422	\$ 1,237	\$ 940
Cost of sales	(1,558)	(1,582)	(1,525)	(1,275)
Gross loss	65	(160)	(288)	(335)
Distribution costs	(9,318)	(8,632)	(3,717)	(4,903)
Administrative expenses	(4,092)	(3,815)	(1,832)	(2,175)
Research & development expenses	(12,085)	(8,786)	(4,752)	(5,451)
Other income	715	206	130	220
Operating loss	(24,715)	(21,187)	(10,459)	(12,644)
Finance income	39	13	8	58
Finance costs	(1,374)	(835)	(846)	(575)
Finance result – net	(1,335)	(822)	(838)	(517)
Loss before income taxes	(26,050)	(22,009)	(11,297)	(13,161)
Income tax expense	(41)	65	(64)	30
Loss for the period	\$ (26,091)	\$ (21,944)	\$ (11,361)	\$ (13,131)

(1) Convenience translation performed from Euros to U.S. Dollars using the following exchange rate in effect as of each period end:

1.14379	1.19786	1.13667	1.16478
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	As of June 30, 2019 (In thousands of USD (1))
Combined Statement of Financial Position Data	
Cash and cash equivalents	5,432
Working capital	5,719
Total assets	26,478
Accumulated deficit	(193,632)
Total equity	(3,347)

(1) Convenience translation performed from Euros to U.S. Dollars using the following exchange rate in effect as of June 30, 2019:

1.13667

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

The following unaudited pro forma condensed combined financial information was prepared using the acquisition method of accounting under U.S. GAAP.

For purposes of this unaudited pro forma condensed combined financial information, we refer to the business of Curetis N.V., principally operated by Curetis GmbH and its subsidiaries as the Curetis Business. In the Curetis Business combined financial statements included in this prospectus, the business of Curetis N.V. is presented, which comprises the Curetis Group as well as the Curetis Convertible Notes that will be assumed by OpGen pursuant to the Implementation Agreement and certain costs related to the Curetis Business, primarily related to the compensation of certain members of senior management and its supervisory board that were historically incurred by Curetis N.V. but not charged to the Curetis Business.

We believe the business combination contemplated by the Implementation Agreement will be accounted for as a business combination in accordance with U.S. GAAP. Under this method of accounting, OpGen would be deemed to be the accounting acquirer for financial reporting purposes. In presenting this unaudited pro forma condensed combined financial information with OpGen as the accounting acquirer, we have considered, among other factors, the following: (i) the number of shares to be issued to Curetis N.V. under the Implementation Agreement; (ii) the number of units and pre-funded units sold in the October 2019 Offering; (iii) the fact that the percentage of voting rights held by OpGen's stockholders will continue to constitute a majority of the voting rights of Newco after the October 2019 Offering and after closing under the Implementation Agreement, currently estimated at 67.7%; (iv) the contractual right held by Curetis N.V. to designate a majority of the members of the initial board of directors of OpGen after the closing; (v) the change in the chief executive officer of OpGen after the closing to be the chief executive officer of Curetis N.V.; (vi) the retention of the chief financial officer of OpGen as the chief financial officer of Newco; and (vii) the agreement between OpGen and Curetis N.V. to add a seventh director to the OpGen Board of Directors following the closing of the Transaction, with such person recommended by OpGen. One of the conditions to closing the business combination under the Implementation Agreement is that OpGen raise at least \$10 million in interim financing. The parties have agreed that the \$9.4 million raised in the October 2019 Offering satisfies this closing condition. This closing condition was met with the closing of the October 2019 Offering. The consummation of the October 2019 Offering had a substantial impact on the final determination as to the accounting treatment of the business combination. We are presenting this unaudited pro forma condensed combined financial information as a business combination in accordance with U.S. GAAP for accounting purposes. This unaudited pro forma condensed combined financial information, as presented, includes the number of shares to be issued to Curetis N.V. under the Implementation Agreement and the number of units and pre-funded units sold in the October 2019 Offering, at an offering price of \$2.00 per unit and \$1.99 per pre-funded unit. As of the closing date of the business combination, the net assets of the Curetis Business would be recorded at their acquisition-date fair values in the financial statements of OpGen and the reported operating results prior to the business combination would be those of OpGen. In addition, transaction costs incurred by OpGen in connection with the business combination would be expensed as incurred.

The unaudited pro forma condensed combined balance sheet data assume that the business combination took place on September 30, 2019 and combines the historical balance sheets of OpGen and the Curetis Business as of such date. The unaudited pro forma condensed combined balance sheet data also assume the capital raise, as required by the Implementation Agreement, was completed on September 30, 2019. The unaudited pro forma condensed combined statement of operations data for the year ended December 31, 2018 and the nine months ended September 30, 2019, assume that the business combination took place as of January 1, 2018, and combine the historical results of OpGen and the Curetis Business for the year ended December 31, 2018 and the nine months ended September 30, 2019, respectively. The unaudited pro forma condensed combined financial information was prepared in accordance with the rules and regulations of Article 11 of SEC Regulation S-X. The historical financial statements of OpGen and the Curetis Business have been adjusted to give pro forma effect to events that are (i) directly attributable to the transaction, (ii) factually supportable, and (iii) with respect to the unaudited pro forma condensed combined statements of operations, expected to have a continuing impact on Newco's results.

The interim, combined financial statements of the Curetis Business were prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board, or IFRS. The consolidated financial statements of OpGen were prepared in accordance with U.S. GAAP. OpGen has performed a preliminary analysis and has not identified significant differences identified between IFRS and U.S. GAAP for the purposes of presenting the unaudited pro forma condensed combined financial statements. In addition, the unaudited condensed combined financial statements reflect reclassifications to conform the Curetis Business historical accounting presentation to OpGen's accounting presentation.

The consolidated financial statements of OpGen are presented in U.S. dollars, or USD, whereas, the financial statements of the Curetis Business are presented in Euros. Therefore, the unaudited pro forma condensed combined financial information includes adjustments to convert the Curetis Business' financial information from Euros to USD.

The Curetis Business' assets and liabilities will be measured and recognized at their fair values as of the transaction date and combined with the assets, liabilities and results of operations of OpGen after the consummation of the business combination. The allocation of the purchase price to acquired assets and assumed liabilities based on their underlying fair values requires the extensive use of significant estimates and management's judgment. The allocation of the purchase price is preliminary at this time, and will remain as such until management completes valuations and other studies in order to finalize the valuation of the net assets acquired. These provisional estimates will be adjusted upon the availability of further information regarding events or circumstances which exist at the acquisition date and such adjustments may be significant. The Curetis Business' intangible assets have not yet been determined and, therefore, the allocation of the purchase price in excess of the Curetis Business' net assets is shown entirely as goodwill.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed, including but not limited to the final assessment of the accounting acquirer, of the determination of differences between IFRS and U.S. GAAP, and of the application of purchase price adjustments, and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between these preliminary estimates and the final accounting, expected to be completed after the closing of the business combination, will occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and Newco's future results of operations and financial position.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the business of OpGen and the Curetis Business. The unaudited pro forma condensed combined financial information is preliminary and has been prepared for illustrative purposes only and is not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had OpGen and the Curetis Business been a combined company during the specified periods. The actual results reported in periods following the business combination may differ significantly from those reflected in the unaudited pro forma condensed combined financial information presented herein for a number of reasons, including, but not limited to, differences in actual performance compared to the assumptions used to prepare this pro forma financial information.

The unaudited pro forma condensed combined financial information, including the notes thereto, should be read in conjunction with the separate historical financial statements of OpGen and the Curetis Business, included elsewhere in this prospectus.

Accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications which are completed during the measurement period as defined in current accounting standards. The accounting policies of the Curetis Business may materially vary from those of OpGen. During preparation of the unaudited pro forma condensed combined financial information, management has performed a preliminary analysis and is not aware of any material differences, and accordingly, this unaudited pro forma condensed combined financial information assumes no material differences, in accounting policies. Following the acquisition, management will conduct a final review of the Curetis Business accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of the Curetis Business' results of operations or reclassification of assets or liabilities to conform to OpGen's accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on these unaudited pro forma condensed combined financial statements.

Following receipt of approval from stockholders at a special meeting of stockholders held on August 22, 2019, on August 28, 2019, OpGen filed an amendment to its Amended and Restated Certificate of Incorporation to effect a reverse stock split of the issued and outstanding shares of our common stock, at a ratio of one share for twenty shares. All financial information in this pro forma financial information has been adjusted to reflect the 2019 Reverse Stock Split.

OpGen, Inc.
Unaudited Pro Forma Condensed Combined Balance Sheet
September 30, 2019
(in thousands)

	OpGen	Curetis Business	Pro Forma Adjustments	Notes	Pro Forma Combined
Assets					
Current assets					
Cash and cash equivalents	\$ 626	\$ 1,451	\$ 8,280	G	\$ 10,357
Accounts receivable, net	377	889	—		1,266
Due from parent	—	538	—		538
Inventory, net	468	5,225	—		5,693
Contractual assets	—	180	—		180
Prepaid expenses and other current assets	533	547	—		1,080
Total current assets	2,004	8,830	8,280		19,114
Property and equipment, net	202	4,215	—		4,417
Finance lease right-of-use assets, net	1,097	—	—		1,097
Operating lease right-of-use assets	1,215	1,305	—		2,520
Goodwill	601	—	9,976	E	10,577
Intangible assets, net	885	7,992	—	E	8,877
Deferred tax assets	—	11	—		11
Other noncurrent assets	427	175	—		602
Total assets	\$ 6,431	\$ 22,528	\$ 18,256		\$ 47,215
Liabilities and Stockholders' Equity					
Current liabilities					
Accounts payable	\$ 1,873	\$ 2,219	\$ —		\$ 4,092
Due to parent	—	203	—		203
Accrued compensation and benefits	1,387	—	—		1,387
Accrued and other current liabilities	1,041	808	1,572	A,B,H	3,421
Deferred revenue	10	—	—		10
Short-term notes payable	508	2,166	—		2,674
Short-term finance lease liabilities	628	—	—		628
Short-term operating lease liabilities	988	478	—		1,466
Total current liabilities	6,435	5,874	1,572		13,881
Notes payable	329	21,642	—		21,971
Long-term finance lease liabilities	411	—	—		411
Long-term operating lease liabilities	813	839	—		1,652
Other noncurrent liabilities	—	48	—		48
Total liabilities	7,988	28,403	1,572		37,963
Stockholders' equity					
Common stock	9	6,074	(6,000)	C,D,G	83
Additional paid-in capital	170,449	179,819	(167,512)	C,D,G	182,756
Accumulated deficit	(172,007)	(191,709)	190,137	A,B,C,H	(173,579)
Accumulated other comprehensive loss	(8)	(59)	59	C	(8)
Total stockholders' equity (deficit)	(1,557)	(5,875)	16,684		9,252
Total liabilities and stockholders' equity	\$ 6,431	\$ 22,528	\$ 18,256		\$ 47,215

OpGen, Inc.
Unaudited Pro Forma Condensed Combined Statement of Operations
For the nine months ended September 30, 2019
(in thousands, except share and per share data)

	OpGen	Curetis Business	Pro Forma Adjustments (E)	Notes	Pro Forma Combined
Revenue	\$ 2,678	\$ 1,513	\$ —		\$ 4,191
Operating expenses:					
Cost of products sold	682	1,602	—		2,284
Cost of services	593	—	—		593
Research and development	4,069	6,727	—		10,796
General and administrative	4,901	2,356	—		7,257
Sales and marketing	1,143	5,021	—		6,164
Transaction costs	538	1,255	(1,793)	F	—
Impairment of right-of-use asset	521	—	—		521
Total operating expenses	12,447	16,961	(1,793)		27,615
Operating loss	(9,769)	(15,448)	1,793		(23,424)
Other (expense) income	(8)	529	—		521
Interest expense	(143)	(1,346)	—		(1,489)
Foreign currency transaction losses	(9)	—	—		(9)
Change in fair value of derivative financial instruments	—	—	—		—
Provision for income taxes	—	(68)	—		(68)
Net loss	\$ (9,929)	\$ (16,333)	\$ 1,793		\$ (24,469)
Net loss applicable to common stockholders	\$ (9,929)	\$ (16,333)	\$ 1,793		\$ (24,469)
Net loss per common share - basic and diluted	\$ (13.32)				\$ (3.02)
Weighted average shares outstanding - basic and diluted	745,471		7,362,564	D, G	8,108,035

OpGen, Inc.
Unaudited Pro Forma Condensed Combined Statement of Operations
For the year ended December 31, 2018
(in thousands,
except share and per share data)

	OpGen	Curetis Business	Pro Forma Adjustments (E)	Notes	Pro Forma Combined
Revenue	\$ 2,946	\$ 1,623	\$ —		\$4,569
Operating expenses:					
Cost of products sold	1,223	1,558	—		2,781
Cost of services	626	—	—		626
Research and development	5,677	12,085	—		17,762
General and administrative	7,069	4,092	—		11,161
Sales and marketing	1,532	9,318	—		10,850
Total operating expenses	16,127	27,053	—		43,180
Operating loss	(13,181)	(25,430)	—		(38,611)
Other income	5	754	—		759
Interest expense	(191)	(1,374)	—		(1,565)
Foreign currency transaction losses	(10)	—	—		(10)
Change in fair value of derivative financial instruments	8	—	—		8
Provision for income taxes	—	(41)	—		(41)
Net loss	\$ (13,369)	\$ (26,091)	\$ —		\$(39,460)
Net loss applicable to common stockholders	\$ (13,369)	\$ (26,091)	\$ —		\$(39,460)
Net loss per common share - basic and diluted	\$ (44.50)				\$(5.15)
Weighted average shares outstanding - basic and diluted	300,453		7,362,564	D,G	7,663,017

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of Transaction

As announced on September 4, 2019, OpGen and Curetis N.V. entered into the Implementation Agreement. Under the Implementation Agreement, OpGen has agreed to purchase all of the outstanding shares and acquire all of the related business assets of the Curetis Business to create a combined business within OpGen, which we refer to as “Newco” in this prospectus.

Pursuant to the Implementation Agreement, OpGen will acquire (i) all of the issued and outstanding capital stock, or the Transferred Shares of Curetis GmbH, and (ii) all of the assets of Curetis N.V. that are solely and exclusively related to the Curetis Business, or the Transferred Assets. OpGen has also agreed to assume (1) the 2016 Stock Option Plan and the outstanding awards thereunder, and (2) the outstanding indebtedness of Curetis N.V. under certain Curetis Convertible Notes, including providing for conversion of such Curetis Convertible Notes into shares of OpGen’s common stock. OpGen will also assume all of the liabilities of Curetis N.V. solely and exclusively related to the Curetis Business.

Under the Implementation Agreement, OpGen will issue, as the sole consideration, 2,662,564 shares of common stock, less the number of shares of common stock the issuance of which shall be reserved by OpGen in connection with (a) up to 135,421 shares of common stock reserved for its assumption of the 2016 Stock Option Plan and (b) up to 500,000 shares of common stock reserved for future issuance upon the conversion of certain of the Curetis Convertible Notes, or together, the Consideration. The number of shares of common stock to be reserved for the deductions described above are based on a conversion ratio of 0.0959, which is the ratio of the Consideration as contrasted with the number of the Curetis N.V. ordinary shares on a fully diluted basis. Since the date of the Implementation Agreement, Curetis has issued additional shares to the holders of the PSOPs, and all have been retired. The shares previously reserved to cover the PSOPs will be issued to Curetis N.V. as part of the Consideration.

In the Implementation Agreement, OpGen committed to raise at least \$10,000,000 of interim equity financing to support the continuing operations of both OpGen and the Curetis Business. The October 2019 Offering is such interim equity financing. We will use proceeds from the October 2019 Offering to support the operations of each of OpGen and the Curetis Business during the period between signing and closing of the Transaction and to support the combined operations of Newco after the closing occurs.

2. Curetis Business

The accompanying unaudited pro forma condensed combined financial statements reflect, what OpGen assumes would be the results and financial position on a U.S. GAAP basis, of the combined financial statements of the interim combined statement of financial position and interim combined statement of operations of the Curetis Business prepared in accordance with IFRS as issued by the IASB, which have been prepared solely for the unaudited pro forma condensed combined financial statements of the Curetis Business prepared in accordance with IFRS as issued by the IASB. OpGen has performed a preliminary analysis and has not identified significant differences identified between IFRS and U.S. GAAP for the purposes of presenting the unaudited pro forma condensed combined financial statements. In addition, the unaudited condensed combined financial statements reflect reclassifications to conform the Curetis Business historical accounting presentation to OpGen's accounting presentation and translation from Euros to USD based on OpGen's U.S. GAAP policies as follows.

OpGen, Inc.
Unaudited Curetis Business Condensed Combined Statement of Financial Position
September 30, 2019
(in thousands)

	<u>Curetis Business (Euros)</u>	<u>Curetis Business (USD) (1)</u>
Assets		
Current assets		
Cash and cash equivalents	€ 1,327	\$ 1,451
Trade receivables	813	889
Other receivables, related party	492	538
Contractual assets	165	180
Inventories	4,777	5,225
Prepaid expenses and other current assets	500	547
Total current assets	8,074	8,830
Intangible assets	7,307	7,992
Property, plant and equipment	3,854	4,215
Right of use assets	1,193	1,305
Other non-current financial assets	160	175
Deferred tax assets	10	11
Total assets	€ 20,598	\$ 22,528
Liabilities and Stockholders' Equity		
Current liabilities		
Trade and other payables	€ 2,029	\$ 2,219
Other liabilities, related party	186	203
Provisions current	151	165
Tax liabilities	—	—
Other current liabilities	588	643
Other current financial liabilities	1,980	2,165
Current lease liabilities	437	478
Total current liabilities	5,371	5,873
Provisions non-current	44	48
Other non-current financial liabilities	19,788	21,642
Non-current lease liabilities	767	839
Total liabilities	25,970	28,402
Equity		
Subscribed capital	5,554	6,074
Capital reserve	164,416	179,819
Currency translation differences	(54)	(59)
Retained earnings	(175,288)	(191,708)
Total stockholders' equity	(5,372)	(5,874)
Total liabilities and stockholders' equity	€ 20,598	\$ 22,528

(1) Convenience translation performed using the following exchange rate in effect as of September 30, 2019:

1.09368

OpGen, Inc.
Unaudited Curetis Business Condensed Combined Statement of Operations
For the nine months ended September 30, 2019
(in thousands, except share and per share data)

	Curetis Business (Euros)	Curetis Business (USD) (1)
Revenue	€ 1,383	\$ 1,513
Cost of sales	(1,465)	(1,602)
Gross loss	(82)	(89)
Distribution costs	(4,591)	(5,021)
Administrative expenses	(2,154)	(2,356)
Research & development expenses	(6,151)	(6,727)
Transaction costs	(1,147)	(1,255)
Other income	331	362
Operating loss	(13,794)	(15,086)
Finance income	153	167
Finance costs	(1,231)	(1,346)
Finance result -- net	(1,078)	(1,179)
Loss before income taxes	(14,872)	(16,265)
Income tax expense	(62)	(68)
Loss for the period	€ (14,934)	\$ (16,333)

(1) Convenience translation performed using the following exchange rate in effect as of September 30, 2019:

1.09368

OpGen, Inc.
Unaudited Curetis Business Condensed Combined Statement of Operations
For the year ended December 31, 2018
(in thousands, except share and per share data)

	Curetis Business (Euros)	Curetis Business (USD) (1)
Revenue	€ 1,419	\$ 1,623
Cost of sales	(1,362)	(1,558)
Gross loss	57	65
Distribution costs	(8,147)	(9,318)
Administrative expenses	(3,578)	(4,092)
Research & development expenses	(10,566)	(12,085)
Other income	625	715
Operating loss	(21,609)	(24,715)
Finance income	34	39
Finance costs	(1,201)	(1,374)
Finance result -- net	(1,167)	(1,335)
Loss before income taxes	(22,776)	(26,050)
Income tax expense	(36)	(41)
Loss for the period	€ (22,812)	\$ (26,091)

(1) Convenience translation performed using the following exchange rate in effect as of December 31, 2018:

1.14379

The accompanying unaudited pro forma condensed combined financial statements reflect Curetis Business unaudited combined financial statements prepared in accordance with IFRS mapped to OpGen's financial statements as follows:

Curetis Business Statement of Operations Descriptions	OpGen Consolidated Statements of Operations and Comprehensive Loss Descriptions
Revenue	Revenue
Cost of sales	Cost of products sold
Distribution costs	Sales and marketing
Administrative expenses	General and administrative
Research & development expenses	Research and development
Transaction costs	Transaction costs
Other income	Other income
Operating loss	Operating loss
Finance income	Other income
Finance costs	Interest expense
Income tax expense	Provision for income taxes
Loss for the period	Net loss
Curetis Business Statement of Financial Position Descriptions	OpGen Balance Sheet Descriptions
Cash and cash equivalents	Cash and cash equivalents
Trade receivables	Accounts receivable, net
Other receivables, related party	Due from parent
Contractual assets	Contractual assets *
Inventories	Inventory, net
Prepaid Expenses and other current assets	Prepaid expenses and other current assets
Total current assets	Total current assets
Intangible assets	Intangible assets, net
Property, plant and equipment	Property and equipment, net
Right of use assets	Operating lease right-of-use assets
Other non-current assets	Other noncurrent assets
Other non-current financial assets	Other noncurrent assets
Deferred tax assets	Deferred tax assets
Total assets	Total assets
Liabilities and Stockholders' Equity	Liabilities and Stockholders' Equity
Current liabilities	Current liabilities
Trade and other payables	Accounts payable
Other liabilities, related party	Due to parent
Provisions current	Provisions current
Tax liabilities	Accrued and other current liabilities
Other current liabilities	Accrued and other current liabilities
Other current financial liabilities	Accrued and other current liabilities
Current lease liabilities	Short-term operating lease liabilities
Total current liabilities	Total current liabilities
Provisions non-current	Other noncurrent liabilities*
Other non-current financial liabilities	Notes payable
Non-current lease liabilities	Long-term operating lease liabilities
Total liabilities	Total liabilities
Equity	Equity
Subscribed capital	Common stock
Capital reserve	Additional paid-in capital
Currency translation differences	Accumulated other comprehensive loss
Accumulated deficit	Accumulated deficit
Total stockholders' equity	Total stockholders' equity (deficit)
Total liabilities and stockholders' equity	Total liabilities and stockholders' equity

* Denotes Curetis description added to proforma balance sheet

3. Estimated Purchase Price

The accompanying unaudited pro forma condensed combined financial statements reflect an estimated acquisition price of approximately \$4.1 million based on the current OpGen stock price and the number of shares to be issued as Consideration. Given that the estimated purchase price is variable depending upon the price of OpGen's common stock, management performed a sensitivity analysis over the change in purchase consideration based on +/- 10% fluctuation in OpGen's stock price. An increase or decrease in the price of OpGen's common stock by 10% would increase or decrease the purchase consideration by approximately \$410 thousand.

The total estimated purchase price and allocated purchase price is summarized as follows (in thousands, except share and per share data):

Number of shares to be issued under the implementation agreement (i)		2,662,564
Multiplied by the fair market value per share of OpGen's common stock(ii)	\$	1.54
Total	\$	4,101

- (i) Under the Implementation Agreement, OpGen will issue, as the sole consideration, 2,662,564 shares of common stock, less the number of shares of common stock the issuance of which shall be reserved by OpGen in connection with (a) up to 135,421 shares of common stock reserved for its assumption of the 2016 Stock Option Plan, and (b) up to 500,000 shares of common stock reserved for future issuance upon the conversion of the Curetis Convertible Notes.
- (ii) The estimated purchase price was based on the closing price as reported on the Nasdaq Capital Market on January 13, 2020. The final purchase price arising from the actual fair market value of OpGen common stock outstanding immediately prior to the closing of the business combination could result in a total purchase price different from that assumed in this unaudited pro forma condensed combined financial information, and that difference may be material. Therefore, the estimated consideration expected to be transferred reflected in this unaudited pro forma condensed combined financial information does not purport to represent what the actual consideration transferred will be when the business combination is completed. The actual purchase price will fluctuate until the closing date of the business combination, and the final valuation of the purchase consideration could differ significantly from the current estimate.

For purposes of this pro forma analysis, the above estimated purchase price has been allocated based on a preliminary estimate of the fair value of assets and liabilities to be acquired.

Net assets as of September 30, 2019	\$	(5,875)
Goodwill		9,976
Total	\$	4,101

4. Pro Forma Adjustments

Adjustments included in the column under the heading "Pro forma Adjustments" are primarily based on information contained within the Implementation Agreement. Further analysis will be performed after the completion of the business combination to confirm the necessity of these estimates.

The pro forma adjustments relate to the following:

- A. To record OpGen's estimated transaction costs, such as legal, audit, advisory fees and transactional fees that were not incurred as of September 30, 2019.
- B. To record the Curetis Business's estimated transaction costs, such as legal, audit, advisory fees and transactional fees that were not incurred as of September 30, 2019.
- C. To eliminate the Curetis Business' common stock, historical paid-in-capital, accumulated other comprehensive loss, and accumulated deficit balances.
- D. To reflect potential shares to be issued at closing of the business combination. Under the Implementation Agreement, OpGen will issue, as the sole consideration, 2,662,564 shares of common stock, less the number of shares of common stock the issuance of which shall be reserved by OpGen in connection with (a) up to 135,421 shares of common stock reserved for its assumption of the 2016 Stock Option Plan and (b) up to 500,000 shares of common stock reserved for future issuance upon the conversion of certain of the Curetis Convertible Notes. Since the date of the Implementation Agreement, Curetis has issued additional shares to the holders of the PSOPs, and all have been retired. The shares previously reserved to cover the PSOPs will be issued to Curetis N.V. as part of the Consideration.

- E. To reflect the fair value of consideration transferred as part of the business combination in excess of the net assets acquired by OpGen. The Curetis Business's intangible assets have not yet been determined and, therefore, the allocation of the purchase price in excess of the Curetis Business's net assets is shown entirely as goodwill. Separately identifiable intangible assets may be determined to exist that may require amortization expense to be recognized in future periods.
- F. To reflect transaction costs incurred by OpGen and the Curetis Business during the nine months ended September 30, 2019.
- G. To record the receipt of \$9,400,000 in gross proceeds, and \$8,279,899 net proceeds, in cash for the issuance of 2,590,170 units and 2,109,830 pre-funded units in the October 2019 Offering, based on an offering price of \$2.00 per unit and \$1.99 per pre-funded unit.
- H. To record retention payments to be made to OpGen executives with change in control.

Adjustments to accrued expenses are as follows (in thousands):

	September 30, 2019
OpGen's estimated transaction costs (A)	\$ 650
Curetis Business estimated transaction costs (B)	492
Retention benefits to be paid to OpGen executives (H)	430
Total	<u>\$ 1,572</u>

Adjustments to additional paid-in capital are as follows (in thousands):

	September 30, 2019
Eliminate Curetis Business' historical additional paid-in-capital balance (C)	\$ (179,819)
To reflect shares to be issued under the implementation agreement (D)	4,074
To reflect shares to be issued to investors in a \$10 million public offering, net of offering costs (G)	8,233
Total	<u>\$ (167,512)</u>

Adjustments to common stock are as follows (in thousands):

	September 30, 2019
Eliminate Curetis Business' historical common stock balance (C)	\$ (6,074)
To reflect shares to be issued under the implementation agreement (D)	27
To reflect shares to be issued to investors in a \$10 million public offering, net of offering costs (G)	47
Total	<u>\$ (6,000)</u>

Adjustments to accumulated deficit are as follows (in thousands):

	September 30, 2019
OpGen's estimated transaction costs (A)	\$ (650)
Curetis Business estimated transaction costs (B)	(492)
Eliminate Curetis Business' historical accumulated deficit balance (C)	191,709
Retention benefits to be paid to OpGen executives (H)	(430)
Total	<u>\$ 190,137</u>

ABOUT THIS PROSPECTUS

This prospectus is part of a “shelf” registration statement that we filed with the U.S. Securities and Exchange Commission, or SEC. By using a shelf registration statement, we may, from time to time, issue shares of common stock in one or more offerings up to an aggregate maximum offering price of \$50,000,000. Each time we sell any of our common stock, we will provide a prospectus supplement that will contain more specific information about the offering and the terms of the common stock being sold. We may also add, update or change in the prospectus supplement any of the information contained in this prospectus or the documents incorporated by reference.

This prospectus provides you with a general description of the Company and our common stock. For further information about our business and our securities, you should refer to the registration statement and the reports incorporated by reference in this prospectus, as described in “Where You Can Find Additional Information.”

You should rely only on the information contained in this prospectus and in any prospectus supplement (including in any documents incorporated by reference herein or therein). We have not authorized anyone to provide you with any different information. We are offering to sell our common stock, and seeking offers to buy, only in jurisdictions where offers and sales are permitted.

You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date of this prospectus or any prospectus supplement and that any information we have incorporated herein by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any prospectus supplement or any sale of any security.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

This prospectus may not be used to consummate sales of our securities, unless it is accompanied by a prospectus supplement. To the extent there are inconsistencies between any prospectus supplement, this prospectus and any documents incorporated by reference, the document with the most recent date will control.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect” or the negative version of these words and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those referenced below under the heading “Risk Factors.” In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances included herein may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to successfully complete and close the Transaction;
- our need to apply a significant amount of the proceeds of our recent offering to support Curetis operations through the Interim Facility, and our ability to be repaid if the Transaction does not close;
- the commercialization of Newco’s products;
- the completion of the development efforts for the Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software, and the timing of FDA 510(k) clearance filings;
- our ability to successfully integrate the OpGen and Curetis businesses;
- our liquidity and working capital requirements, including cash requirements over the next 12 months for us and Newco;
- our ability to regain compliance with the ongoing listing requirements for the Nasdaq Capital Market;
- anticipated trends and challenges in our business and the competition that we face;
- the execution of Newco’s business plan and growth strategy;
- Newco’s expectations regarding the size of and growth in potential markets;
- Newco’s opportunity to successfully enter into new collaborative agreements;
- regulations and changes in laws or regulations applicable to our business, including regulation by the FDA and the EU;
- compliance with the U.S. and international regulations applicable to our business; and
- our expectations regarding future revenue and expenses.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. These risks should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to the risk factors described in this prospectus. Other risks may be described from time to time in our filings made under the securities laws. New risks emerge from time to time. It is not possible for our management to predict all risks. All forward-looking statements in this prospectus speak only as of the date made and are based on our current beliefs and expectations. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by applicable securities laws.

RISK FACTORS

Investing in our securities involves substantial risks. In addition to other information contained in this prospectus and any accompanying prospectus supplement, before investing in our securities, you should carefully consider the risks described under the heading “Risk Factors” in our Annual Report on Form 10-K or in our most recent Quarterly Report on Form 10-Q, as they may be amended, and in any other documents incorporated by reference into this prospectus, as updated by our future filings. These risks are not the only ones faced by us. Additional risks not known or that are deemed immaterial could also materially and adversely affect our financial condition, results of operations, our products, business and prospects. Any of these risks might cause you to lose all or a part of your investment.

USE OF PROCEEDS

Unless otherwise indicated in the applicable prospectus supplement, we intend to use the net proceeds from the sale of common stock under this prospectus, together with our existing cash resources, to support our business and the business of Curetis Group prior to the closing of the transactions contemplated by the Implementation Agreement.

The primary programs and activities to which we intend to devote the net proceeds of offerings under this prospectus are:

Prior to the closing of the transactions under the Implementation Agreement:

- for completing the business combination with Curetis;
- for provision of short-term funding to Curetis under the Interim Facility to fund the Curetis Group’s operations, including the Unyvero LRT BAL regulatory clearance-related activities, Unyvero platform R&D activities, Ares Genetics-related R&D and business development activities with potential collaborators and distributors; and
- for research and development and regulatory activities in support of the Company’s anticipated FDA 510(k) submissions for the Acuitas AMR Gene Panel test and the Acuitas Lighthouse Software.

Following the closing of the transactions under the Implementation Agreement:

- commercialization of Newco’s products, with a focus on the Unyvero platform and diagnostic tests, and the Acuitas AMR Gene Panel tests;
- further development and commercialization of the Ares Genetics database and Acuitas Lighthouse Software;
- directed efforts to the customers and collaborators of each company to introduce the products and services of Newco;
- investments in manufacturing and operations infrastructure to support sales of products; and
- the balance for general corporate purposes, such as general and administrative expenses, capital expenditures and working capital needs.

If the transactions under the Implementation Agreement do not close, and to the extent any proceeds remain, we plan to use any remaining proceeds to support OpGen’s operations in 2020.

Each time we issue securities, we will provide a prospectus supplement that will contain information about how we intend to use the proceeds from each such offering.

We cannot guarantee that we will receive any proceeds in connection with any offering hereunder because we may choose not to issue any of the securities covered by this prospectus.

PLAN OF DISTRIBUTION

Primary Offerings by the Company

We may sell shares of our common stock registered hereunder:

- through underwriters;
- through dealers;
- through agents;
- directly to purchasers;
- through registered direct offerings;
- through “at the market” offerings, within the meaning of Rule 415(a)(4) of the Securities Act, to or through a market maker or into an existing trading market on an exchange or otherwise; or
- through a combination of any of these methods or any other method permitted by law.

In addition, we may issue the securities as a dividend or distribution or in a subscription rights offering to our existing security holders.

We may directly solicit offers to purchase common stock, or agents may be designated to solicit such offers. In the prospectus supplement relating to such offering, we will name any agent that could be viewed as an underwriter under the Securities Act and describe any commissions that we must pay to any such agent. Any such agent will be acting on a best efforts basis for the period of its appointment or, if indicated in the applicable prospectus supplement, on a firm commitment basis. This prospectus may be used in connection with any offering of our common stock through any of these methods or other methods described in the applicable prospectus supplement.

The distribution of the common stock may be effected from time to time in one or more transactions:

- at a fixed price, or prices, which may be changed from time to time;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Each prospectus supplement will describe the method of distribution of the common stock and any applicable restrictions.

The prospectus supplement with respect to common stock of a particular series will describe the terms of the offering of the securities, including the following:

- the name of the agent or any underwriters, if any;
- the public offering or purchase price;
- any discounts and commissions to be allowed or paid to the agent or underwriters;
- all other items constituting underwriting compensation;
- any discounts and commissions to be allowed or paid to dealers; and
- any exchanges on which the securities will be listed.

If any underwriters or agents are used in the sale of common stock in respect of which this prospectus is delivered, we will enter into an underwriting agreement, sales agreement or other agreement with them at the time of sale to them, and we will set forth in the prospectus supplement relating to such offering the names of the underwriters or agents and the terms of the related agreement with them.

In connection with the offering of common stock, we may grant to the underwriters an option to purchase additional securities with an additional underwriting commission, as may be set forth in the accompanying prospectus supplement. If we grant any such option, the terms of such option will be set forth in the prospectus supplement for such securities.

If a dealer is used in the sale of common stock in respect of which the prospectus is delivered, we will sell such common stock to the dealer, as principal. The dealer, who may be deemed to be an “underwriter” as that term is defined in the Securities Act, may then resell such securities to the public at varying prices to be determined by such dealer at the time of resale.

If we offer common stock in a subscription rights offering to our existing security holders, we may enter into a *standby* underwriting agreement with dealers, acting as *standby* underwriters. We may pay the *standby* underwriters a commitment fee for the securities they commit to purchase on a *standby* basis. If we do not enter into a *standby* underwriting arrangement, we may retain a dealer-manager to manage a subscription rights offering for us.

Agents, underwriters, dealers and other persons may be entitled under agreements which they may enter into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, and may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

Certain agents, underwriters and dealers, and their associates and affiliates, may be customers of, have borrowing relationships with, engage in other transactions with, or perform services, including investment banking services, for us or one or more of our respective affiliates in the ordinary course of business.

In order to facilitate the offering of the common stock, any underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock or any other securities the prices of which may be used to determine payments on such common stock. Specifically, any underwriters may overallocate in connection with the offering, creating a short position for their own accounts. In addition, to cover overallocations or to stabilize the price of the common stock or of any such other securities, the underwriters may bid for, and purchase, the common stock or any such other securities in the open market. Finally, in any offering of the common stock through a syndicate of underwriters, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the common stock in the offering if the syndicate repurchases previously distributed common stock in transactions to cover syndicate short positions, in stabilization transactions or otherwise. Any of these activities may stabilize or maintain the market price of the common stock above independent market levels. Any such underwriters are not required to engage in these activities and may end any of these activities at any time.

We may engage in “at the market offerings” within the meaning of Rule 415(a)(4) under the Securities Act, to or through a market maker or into an existing trading market on an exchange or otherwise. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell common stock covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use common stock pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use common stock received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge common stock to a financial institution or other third party that in turn may sell the common stock short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our common stock or in connection with a concurrent offering of other securities.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

The anticipated date of delivery of offered common stock will be set forth in the applicable prospectus supplement relating to each offer.

We will bear all costs, expenses and fees in connection with the registration of the common stock, as well as the expense of all commissions and discounts, if any, attributable to sales of the securities by us.

DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 50,000,000 shares of common stock, par value \$0.01 per share, and 10,000,000 shares of preferred stock, par value \$0.01 per share, of which 7,690,572 shares are available for issuance. The following is a summary of the rights of our common and preferred stock and our outstanding warrants, and some of the provisions of our amended and restated certificate of incorporation, as amended, or our Certificate of Incorporation and amended and restated bylaws, or our Bylaws, and the Delaware General Corporation Law, or the DGCL. Because it is only a summary, it does not contain all of the information that may be important to you. Such summary is subject to and qualified in its entirety by our Certificate of Incorporation and our Bylaws, a copy of each of which has been incorporated as an exhibit to the registration statement of which this prospectus forms a part.

Common Stock

As of January 23, 2020, there were 5,582,280 shares outstanding, 5,135,609 shares of common stock reserved for the exercise of outstanding stock options, warrants and restricted stock units, and approximately 27 record holders. The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. The Board of Directors are elected to a one year term; the Company does not have a staggered board. Holders of our common stock are entitled to receive ratably any dividends declared by the Board of Directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Preferred Stock

Series A Convertible Preferred Stock

Of the authorized preferred stock, the Company had previously issued 2,309,428 shares of Series A Convertible Preferred Stock. The holder of the Series A Convertible Preferred Stock converted all 2,309,428 shares of Series A Convertible Preferred Stock into shares of common stock. All such converted shares of Series A Convertible Preferred Stock were canceled and will not be reissued. As of January 1, 2020, no shares of the Series A Convertible Preferred Stock were outstanding.

Additional Series of Preferred Stock

Our Board of Directors has the authority, without further action by our stockholders, to issue from time to time 7,690,572 shares of preferred stock in one or more series. Our Board of Directors will have the authority to establish the number of shares to be included in each series and fix the powers, preferences and rights of the shares of each wholly unissued series and any of its qualifications, limitations or restrictions. Our Board of Directors will also be able to increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by the stockholders.

The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of common stock or adversely affect the rights and powers, including voting rights, of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our Company, which could depress the market price of our common stock. We have no current plans to issue any additional shares of preferred stock.

Outstanding Warrants

IPO Warrants

The warrants to purchase common stock that we issued in our initial public offering, or the IPO Warrants, entitle the registered holder to purchase one share of common stock at a price equal to \$3,300.00 per share, subject to adjustment as discussed below, immediately following the issuance of such IPO Warrants and terminate at 5:00 p.m., New York City time, on May 8, 2020 or earlier upon the dissolution or winding up of the Company. We have listed the IPO Warrants on the Nasdaq Capital Market, as a standalone security under the symbol “OPGNW.”

The IPO Warrants were issued pursuant to a Warrant Agreement between us and our transfer agent as the Warrant Agent. The exercise price and number of shares of common stock issuable upon exercise of the IPO Warrants may be adjusted in certain circumstances, including in the event of a stock dividend or recapitalization, reorganization, merger or consolidation.

The IPO Warrants may be exercised upon surrender of the applicable Warrant Certificate on or prior to the applicable expiration date at the offices of the Warrant Agent, with the exercise form on the reverse side of the Warrant Certificate completed and executed as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, unless such holders are willing to exercise their IPO Warrants on a cashless basis, as further described in this Warrant Agreement, for the number of IPO Warrants being exercised. Under the terms of the Warrant Agreement, we have agreed to use our reasonable best efforts to maintain the effectiveness of a registration statement and prospectus relating to common stock issuable upon exercise of the IPO Warrants until the expiration of the IPO Warrants. The IPO Warrant holders do not have the rights or privileges of holders of common stock or any voting rights until they exercise their IPO Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the IPO Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

A holder may not exercise any portion of an IPO Warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would own more than 4.99% of the outstanding common stock after exercise, as such percentage ownership is determined in accordance with the terms of the IPO Warrant. The foregoing limitation on exercise shall not apply to any registered holder of an IPO Warrant who, together with his, her or its affiliates, and any persons acting as a group together with such registered holder and such registered holder’s affiliates, owned in excess of 4.99% immediately prior to the closing of the IPO. In addition, upon at least 61 days’ prior notice from the holder to us, the holder may waive such limitation.

No fractional shares of common stock will be issued upon exercise of the IPO Warrants. If, upon exercise of the IPO Warrant, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round to the nearest whole number of shares of common stock to be issued to the IPO Warrant holder. If multiple IPO Warrants are exercised by the holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all the IPO Warrants.

2016 PIPE Warrants

Pursuant to the terms of the Amended & Restated Purchase Agreement, dated as of May 18, 2016, by and among the Company and the purchasers party thereto, the purchasers purchased 18,107 warrants, or the PIPE Warrants, exercisable for an aggregate of 13,580 shares of common stock, or the PIPE Warrant Shares, in the PIPE Financing. The PIPE Warrants are exercisable at an exercise price of \$656.25 per share of common stock, became exercisable 90 days after the date of issuance, and may be exercised for five years from the date of issuance. The exercise price and the number of PIPE Warrant Shares will be adjusted to account for the subdivision or combination by the Company of outstanding shares of common stock. The exercise price may, at any time, also be voluntarily reduced at the discretion of the Board of Directors of the Company. The PIPE Warrants may be exercised pursuant to a cashless exercise, but only if a registration statement covering the resale of the PIPE Warrant Shares that are the subject of an exercise notice is not available for the resale of such PIPE Warrant Shares.

The PIPE Warrants also contain certain provisions providing for liquidated damages to be paid by the Company in the event the Company does not timely deliver registered shares of common stock to the holder upon exercise of a PIPE Warrant. Specifically, in addition to the PIPE Warrant holder's other available remedies, if the Company fails to issue and deliver (or cause to be delivered) to a holder by the required delivery date a certificate representing the shares so delivered to the Company by such holder that is free from all restrictive and other legends, the Company shall pay to a holder in cash, as partial liquidated damages and not as a penalty, an amount equal to 1% of the product of (A) the aggregate number of shares of common stock not issued to the holder on a timely basis and to which the holder is entitled and (B) the closing sale price on the trading day immediately preceding the required delivery date of the certificate, per trading day for each trading day after such required delivery date until such securities are delivered to the holder. In addition, if the Company fails to (i) issue and deliver (or cause to be delivered) to a holder by the required delivery date a certificate representing the shares so delivered to the Company by such holder that is free from all restrictive and other legends or (ii) if after the required delivery date such holder purchases (in an open market transaction or otherwise) shares of common stock to deliver in satisfaction of a sale by such holder of all or any portion of the number of shares of common stock, or a sale of a number of shares of common stock equal to all or any portion of the number of shares of common stock that such holder anticipated receiving from the Company without any restrictive legend, then, the Company shall either (y) pay cash to the holder in an amount equal to the holder's total purchase price (including brokerage commissions and other out-of-pocket expenses, if any) for the shares of common stock so purchased, or the Buy-In Price, at which point the Company's obligation to deliver such shares shall terminate, or (z) promptly honor its obligation to deliver to the holder a certificate or certificates representing such shares and pay cash to the holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (1) such number of shares of common stock that the Company was required to deliver multiplied by (2) the lowest closing sale price of the common stock on any trading day during the period commencing on the date of the delivery by such holder to the Company of the applicable shares (as the case may be) and ending on the date of such delivery and payment under this clause (z).

Warrants issued in Bridge Financing

Pursuant to the Note Purchase Agreement and the underlying transactions, the Company has issued warrants to purchase shares of its common stock to jVen Capital in an amount equal to 20% of the principal of each of the two bridge financing notes issued, or the jVen Capital Warrants, and warrants to purchase shares of its common stock to MGHIF in an amount equal to 20% of the outstanding principal and accrued interest under the amended and restated MGHIF Note on June 28, 2017, the date of issuance. The warrants each have a five year term from issuance, are first exercisable on the date that is six months after the date of issuance and have an exercise price equal to 110% of the closing price of the Company's common stock on the date immediately prior to the date of issuance. The terms of the warrants issued in connection with the Bridge Financing (other than the exercise price and the number of shares) may be amended, in the discretion of the holder, to reflect the terms of the warrants issued in the July 2017 Public Offering.

The jVen Capital Warrants each include a blocker provision that prevents the exercise of the jVen Capital Warrants if such exercise, when aggregated with the other issuances contemplated under the Note Purchase Agreement, would violate Nasdaq Listing Rule 5635, unless stockholder approval is first obtained by the Company.

Warrants issued in the July 2017 Public Offering

The Company issued warrants in connection with the July 2017 Public Offering. The common warrants issued in the July 2017 Public Offering entitle the registered holder to purchase one five-hundredths of a share of common stock at an exercise price of \$212.50 per share. In addition, the Company issued warrants to the placement agent that have an exercise price of \$250.00 per share of common stock. All of the warrants issued in the July 2017 Public Offering are immediately exercisable and have a five-year term from the date of issuance.

Warrants issued in the February 2018 Public Offering

The Company issued warrants in connection with the February 2018 Public Offering. The common warrants issued in the February 2018 Public Offering entitle the registered holder to purchase one-fortieth of a share of common stock at an exercise price of \$65.00 per share. In addition, the Company issued warrants to the placement agent that have an exercise price of \$81.25 per share of common stock. All of the warrants issued in the February 2018 Public Offering are immediately exercisable and have a five-year term from the date of issuance.

Common Warrants in the October 2019 Offering

The following is a summary of certain terms and provisions of the common warrants included in the units and the pre-funded units that were sold in the October 2019 Offering.

Duration and Exercise Price

Each common warrant included in the units and the pre-funded units has an initial exercise price per share equal to \$2.00. The common warrants are immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The common warrants were issued separately from the common stock included in the units, or the pre-funded warrants included in the pre-funded units, as the case may be, and may be transferred separately.

Cashless Exercise

If, at the time a holder exercises its common warrants, a registration statement registering the issuance of the shares of common stock underlying the common warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the common warrants.

Exercisability

The common warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the common warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's common warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the common warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Transferability

Subject to applicable laws, a common warrant may be transferred at the option of the holder upon surrender of the common warrant to us together with the appropriate instruments of transfer.

Trading Market

There is no trading market available for the common warrants on any securities exchange or nationally recognized trading system.

Right as a Stockholder

Except as otherwise provided in the common warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the common warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their common warrants.

Fundamental Transaction

In the event of a fundamental transaction which is within our control, other than the business combination pursuant to the Implementation Agreement, the holders of the common warrants have the right to require us or a successor entity to redeem the common warrant for cash in the amount of the Black-Scholes value of the unexercised portion of the common warrant on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which not in our control, including a fundamental transaction that is not approved by our Board, the holders of the common warrants have the right to require us or a successor entity to redeem the common warrant for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the common warrant on the date of the consummation of the fundamental transaction.

Registration Rights

Investors' Rights Agreement

Under the Third Amended and Restated Investors' Rights Agreement, dated as of December 18, 2013, among the Company and certain investors, or the investors' rights agreement, we granted registration rights to the holders of shares acquired prior to our initial public offering, or their permitted transferees. These rights are provided under the terms of the investors' rights agreement, and include demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered. As of the date of this prospectus, the holders of 11,619 shares of our common stock have registration rights under the investors' rights agreement. The investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable shares in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them. The registration rights granted under the investors' rights agreement will terminate at the earlier of the closing of a deemed liquidation event and when all of the holders of registrable securities are eligible to be sold without restrictions under Rule 144 promulgated under the Securities Act within any 90-day period.

Bridge Financing Registration Rights

In connection with the bridge financing the Company entered into a registration rights agreement with jVen Capital and with MGHIF, pursuant to which the investors were granted certain demand registration rights and piggyback registration rights in connection with subsequent registered offerings of the Company's common stock. The registrable securities include the shares of common stock underlying the warrants issued to jVen Capital and to MGHIF under the terms of the bridge financing promissory notes.

Anti-Takeover Effects of Our Certificate of Incorporation, Bylaws and Delaware Law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only the Chair of the Board, the Chief Executive Officer or a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our certificate of incorporation must be approved by not less than 66 2/3% of the outstanding shares entitled to vote on the amendment, and not less than 66 2/3% of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least 66 2/3% of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue from time to time 7,690,572 shares of preferred stock in one or more series. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Exclusive Jurisdiction for Certain Actions

Our certificate of incorporation provides that, once our common stock is a "covered security," unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar exclusive forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could rule that this provision in our certificate of incorporation is inapplicable or unenforceable.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol “OPGN” and our IPO Warrants are listed on the Nasdaq Capital Market under the symbol “OPGNW.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Philadelphia Stock Transfer, Inc. The transfer agent’s address is 2320 Haverford Rd., Suite 230, Ardmore, PA 19003.

LEGAL MATTERS

Certain legal matters with respect to the securities offered hereby have been passed upon by Ballard Spahr LLP.

EXPERTS

The consolidated financial statements of OpGen, Inc. and its subsidiaries as of December 31, 2018 and 2017, and for the years then ended, have been incorporated by reference herein in reliance upon the report, also incorporated by reference herein, of CohnReznick LLP, an independent registered public accounting firm, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2018 consolidated financial statements contains an explanatory paragraph that states that the Company has experienced losses and negative cash flows from operations since its inception, has an accumulated deficit, and has debt obligations which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

The audited historical combined financial statements of the Curetis Business as of December 31, 2018, December 31, 2017 and January 1, 2017 and for each of the two years in the period ended December 31, 2018 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 3.22 to the financial statements) of PricewaterhouseCoopers GmbH Wirtschaftsprüfungsgesellschaft, independent accountants, given on the authority of said firm as experts in auditing and accounting. PricewaterhouseCoopers GmbH Wirtschaftsprüfungsgesellschaft is a member of the Chamber of Public Accountants (*Wirtschaftsprüferkammer*), Berlin, Germany.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We filed with the SEC a registration statement under the Securities Act of 1933 for the shares of common stock under this prospectus. This prospectus does not contain all of the information in the registration statement and the exhibits and schedule that were filed with the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits and schedule that were filed with the registration statement. Statements contained in this prospectus about the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and we refer you to the full text of the contract or other document filed as an exhibit to the registration statement. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding registrants that file electronically with the SEC. The address of the website is www.sec.gov.

We file periodic reports under the Securities Exchange Act of 1934, including annual, quarterly and special reports, and other information with the Securities and Exchange Commission. These periodic reports and other information are available for inspection and copying at the SEC regional offices, public reference facilities and on the website of the SEC referred to above.

We make available free of charge on or through our internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The information found on our website, www.opgen.com, other than as specifically incorporated by reference in this prospectus, is not part of this prospectus.

INCORPORATION BY REFERENCE

The SEC allows us to “incorporate by reference” in this prospectus the information in other documents that we file with it, which means that we can disclose important information to you by referring you to those documents containing such information. This prospectus is part of a registration statement we filed with the SEC. You should rely on the information incorporated by reference in this prospectus and the registration statement. The information incorporated by reference is considered to be part of this prospectus and information we file later with the SEC will automatically update and supersede this information and information contained in documents filed earlier with the SEC. We incorporate by reference the documents listed below and any future filings made with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of the offering; provided, that we are not incorporating by reference any documents or information deemed to have been furnished and not filed in accordance with SEC rules. The documents we are incorporating by reference are:

- our [Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on February 27, 2019](#);
- our Quarterly Reports on [Form 10-Q for the quarters ended March 31, 2019, June 30, 2019, and September 30, 2019](#), filed with the SEC on May 15, 2019, August 14, 2019, and November 14, 2019, respectively;
- our Current Reports on Form 8-K filed with the SEC on [February 25, 2019 \(Items 5.02 and 9.01\)](#), [March 26, 2019 \(Items 1.01, 8.01 and 9.01\)](#), [April 15, 2019 \(Item 5.02\)](#), [May 10, 2019 \(Item 3.01\)](#), [May 14, 2019 \(Items 8.01 and 9.01\)](#), [July 1, 2019 \(Item 5.02\)](#), [August 22, 2019 \(Item 5.07\)](#), [August 23, 2019 \(Item 3.01\)](#), [August 28, 2019 \(Items 5.03 and 9.01\)](#), [September 4, 2019 \(Items 1.01 and 9.01\)](#) (except for Exhibit 99.2)), [September 18, 2019 \(Item 8.01\)](#), [October 28, 2019 \(Items 1.01, 3.01 and 9.01\)](#), [October 31, 2019 \(Items 3.01 and 9.01\)](#) and [January 23, 2020 \(Item 8.01\)](#);
- our proxy statement for the [Annual Meeting of Stockholders held on August 22, 2019, filed with the SEC on July 12, 2019](#); and
- the description of our common stock contained in the [Registration Statement on Form 8-A filed on April 30, 2015](#) and any amendments to such Registration Statement filed subsequently thereto, including all amendments or reports filed for the purpose of updating such description.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC after the effective date of the registration statement of which this prospectus forms a part pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, until the termination of the offering of the securities made by this prospectus and will become a part of this prospectus from the date that such documents are filed with the SEC. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

We will furnish to you, on written or oral request, a copy of any or all of the documents that have been incorporated by reference, including exhibits to these documents. You may request a copy of these filings at no cost by writing or telephoning our Secretary at the following address and telephone number:

OpGen, Inc.
Attention: Timothy C. Dec, Corporate Secretary
708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878
Telephone No.: (240) 813-1260

**CURETIS BUSINESS
COMBINED FINANCIAL STATEMENTS**

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CURETIS BUSINESS**COMBINED STATEMENT OF OPERATIONS AND OTHER COMPREHENSIVE LOSS**

For the years ended 31 December

in kEuro	Note	2018	2017
Revenue	4	1,419	1,187
Cost of sales	5	(1,362)	(1,321)
Gross profit (loss)		57	(134)
Distribution costs	5,6	(8,147)	(7,206)
Administrative expenses	5,7	(3,578)	(3,185)
Research & development expenses	5,8	(10,566)	(7,335)
Other income		625	172
Operating loss		(21,609)	(17,688)
Finance income		34	11
Finance costs		(1,201)	(697)
Finance result - net	10	(1,167)	(686)
Net loss before income tax		(22,776)	(18,374)
Income tax expenses	11	(36)	54
Net loss for the period		(22,812)	(18,320)
Foreign currency translation gain (loss)*		88	(133)
Total comprehensive loss for the period		(22,724)	(18,453)

* Exchange differences on translation of foreign operations, which may be recycled through profit and/or loss in the future.

The accompanying notes are an integral part of these combined financial statements.

CURETIS BUSINESS
COMBINED STATEMENT OF FINANCIAL POSITION

in kEuro	Note	31 December 2018	31 December 2017	1 January 2017
Current assets		11,888	10,204	12,210
Cash and cash equivalents	21	4,800	3,468	6,434
Trade receivables	12,21	323	200	101
Other receivables, related party	25	453	824	1,370
Inventories	13	6,052	5,453	4,078
Prepaid expenses and other current assets	14	260	259	227
Non-current assets		10,850	11,324	12,311
Intangible assets	15	7,425	7,524	7,520
Property, plant and equipment	16	3,196	3,566	4,466
Other non-current financial assets	21	158	156	325
Deferred tax assets	11	71	78	—
Total assets		22,738	21,528	24,521
Current liabilities		5,773	2,890	2,501
Trade and other payables	21	921	850	672
Other liabilities, related party	25	187	580	617
Provisions current		65	124	51
Tax liabilities	11	22	24	10
Other current liabilities	18	881	838	683
Other current financial liabilities	19,21	3,697	474	468
Non-current liabilities		13,993	10,385	40
Provisions non-current		44	43	40
Other non-current financial liabilities	20,21	13,949	10,342	—
Total liabilities		19,766	13,275	2,541
Equity		2,972	8,253	21,980
Subscribed capital		5,554	5,554	5,554
Capital reserve		157,847	140,402	135,675
Currency translation differences		(75)	(160)	(28)
Accumulated deficit		(160,354)	(137,543)	(119,221)
Total Equity and liabilities		22,738	21,528	24,521

The accompanying notes are an integral part of these combined financial statements.

CURETIS BUSINESS
COMBINED STATEMENT OF CASH FLOWS

For the years ended 31 December

in kEuro	Note	2018	2017
Net loss for the period		(22,812)	(18,320)
Adjustment for:			
- Net finance income (costs)	10	1,167	686
- Depreciation, amortization and impairments	15,16	1,257	1,327
- Share based payment expense	22	366	528
- Changes in deferred tax assets and liabilities	11	7	(78)
Changes in working capital relating to:			
- Inventories	13	(599)	(1,375)
- Trade receivables and other receivables	12,14	245	586
- Trade payables and other payables	21,18	(422)	153
Income taxes received (+) / paid (-)		36	(54)
Interest paid (-)		(406)	6
Net cash flow used in operating activities		(21,161)	(16,541)
Payments for intangible assets		(119)	(110)
Payments for property, plant and equipment		(670)	(323)
Net cash flow used in investing activities		(789)	(433)
Proceeds from other non-current financial liabilities		3,000	10,000
Proceeds from current financial liabilities (convertible notes), net of issuance cost		3,109	—
Capital increase from shareholder		15,984	3,000
Shareholder contributions		1,095	1,199
Net cash flow provided by financing activities		23,188	14,199
Net decrease / increase in cash and cash equivalents		1,238	(2,775)
Net cash and cash equivalents at the beginning of the year		3,468	6,434
Effects of exchange rate changes on cash and cash equivalents		94	(191)
Net Cash and cash equivalents at the end of the period		4,800	3,468

The accompanying notes are an integral part of these combined financial statements.

CURETIS BUSINESS
COMBINED STATEMENT OF CHANGES IN EQUITY

For the years ended 31 December

in kEuro	Subscribed capital	Capital Reserve	Currency translation difference	Accumulated deficit	TOTAL equity
Balance at 1 January 2017	5,554	135,675	(28)	(119,222)	21,979
Loss of the period				(18,320)	(18,320)
Other comprehensive income			(132)		(132)
Total comprehensive income	0	0	(132)	(18,320)	(18,452)
Transactions with owners in their capacity as owners					
Capital increase		3,000			3,000
Shareholder contributions		1,199			1,199
Share-based payments		528			528
Balance as of 31 December 2017	5,554	140,402	(160)	(137,542)	8,254

in kEuro	Subscribed capital	Capital Reserve	Currency translation difference	Accumulated deficit	TOTAL equity
Balance at 1 January 2018	5,554	140,402	(160)	(137,542)	8,254
Loss of the period				(22,812)	(22,812)
Other comprehensive income			85		85
Total comprehensive income	0	0	85	(22,812)	(22,727)
Transactions with owners in their capacity as owners					
Capital increase		15,984			15,984
Shareholder contributions		1,095			1,095
Share-based payments		366			366
Balance as of 31 December 2018	5,554	157,847	(75)	(160,354)	2,972

The accompanying notes are an integral part of these combined financial statements.

1. GENERAL INFORMATION ABOUT THE COMPANY

These combined financial statements comprise the business of Curetis N.V. (collectively referred to as “the Group”, “Curetis” or the “Company”). Refer to note 2.1 for further information. The Group’s headquarters is located at Max-Eyth-Str. 42, 71088 Holzgerlingen, Germany. The Group is an early commercial-stage molecular diagnostics (MDx) company focused on rapid infectious disease testing for hospitalized patients with the aim to improve the treatment of hospitalized, critically ill patients with suspected microbial infections. The Curetis business is primarily operated by Curetis GmbH and its wholly owned subsidiaries.

The first Group entity, Curetis AG, was created in Germany in 2007 and was primarily funded through equity investments from venture capital and private equity investors. In 2015, in connection with an initial public offering (“IPO”), Curetis N.V. was created as a parent entity to Curetis AG and in that same year the stock of Curetis N.V. was sold in an IPO on the Euronext market. In 2016 Curetis AG was changed to Curetis GmbH. Since 2015, Curetis has been financed through contributions from Curetis N.V. from proceeds of the initial offerings, secondary offerings, various other financing agreements Curetis N.V. has entered into, including Convertible Notes (see notes 19 and 21), the EIB financing (see note 20) and government grants.

At 15 September 2019 the Management Board authorized the combined financial statements for issue and passed it through to the Supervisory Board for review and authorization.

1.1. General Information about the business and the commercial development of the Company

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

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

In addition to the existing Unyvero A50 multiplex platform, Curetis has expanded its product portfolio with the development of a low- and midplex analyzer, the new Unyvero A30 RQ for Unyvero integration or as a standalone operation.

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

2. BASIS OF PREPARATION – COMBINED FINANCIAL STATEMENTS

2.1. Basis of presentation

The accompanying combined financial statements of Curetis have been prepared for filing with the United States Securities and Exchange Commission (SEC) in connection with the proposed acquisition of all of the outstanding shares of Curetis GmbH by OpGen Inc. (“OpGen”), pursuant to an agreement to combine the two companies’ businesses. Following the agreement, OpGen will acquire 100% of Curetis GmbH’s assets and liabilities through the acquisition of all outstanding shares of Curetis GmbH, including the Curetis name, as well as the outstanding indebtedness of Curetis N.V. under certain convertible notes, including providing that the conversion rights of the notes may be changed from a right to convert into shares of Curetis N.V. to a right to convert into shares of OpGen. In addition, OpGen has also agreed to acquire all of the assets of Curetis N.V. that are solely and exclusively related to the business of Curetis GmbH and assume (1) the Curetis N.V. 2016 Stock Option Plan, as amended, and the outstanding awards thereunder, or the 2016 Stock Option Plan, and (2) the obligation to issue equity to the holders of awards under the Curetis AG Phantom Stock Option Plan, or the PSOP. OpGen will also assume all of the liabilities of Curetis N.V. solely and exclusively related to the business being acquired.

The business combination is subject to a number of conditions including (i) the satisfaction of customary conditions to closing for a transaction of this type, including the absence of a material adverse event for either party, (ii) for each OpGen and Curetis, appropriate approvals by their respective shareholders, (iii) for Curetis, consents from certain debt financing providers, (iv) OpGen’s Form S-4 having been declared effective by the U.S. Securities and Exchange Commission, (v) the new shares of OpGen’s common stock to be issued (or reserved for issuance) in connection with the transaction having been approved for listing on Nasdaq and (vi) OpGen having secured additional funding prior to Closing.

The business of Curetis N.V. is primarily operated by Curetis GmbH and its wholly owned subsidiaries. However, certain costs related to the Curetis business, primarily related to the compensation of certain members of senior management and its supervisory board, have historically been incurred by Curetis N.V. but have not been recharged by Curetis N.V. to Curetis GmbH or its subsidiaries. SEC Staff Accounting Bulletin (SAB) Topic 1.B. (“SAB 1.B”) Allocation of Expenses and Related Disclosure in Financial Statements of Subsidiaries, Divisions or Lessor Business Components of Another Entities states that the historical income statements of a registrant should reflect all of its costs of doing business and therefore in specific situations requires a subsidiary to reflect certain expenses incurred by the parent on its behalf. In addition, the combined financial statements include the convertible notes issued by Curetis N.V. as well as related expenses. The proceeds of the issuance of the convertible notes were historically contributed to the Curetis GmbH via cash contributions to capital reserves. Accordingly, the combined financial statements of Curetis have been prepared to combine the consolidated financial statements of Curetis GmbH together with certain costs incurred by Curetis N.V. on behalf of Curetis GmbH. As a result, the combined financial statements of Curetis does not currently constitute a separate group of legal entities.

The combined financial statements and notes have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (IASB). During 2017 and 2018, the costs incurred by Curetis N.V. that have been allocated to the Company for the purposes of preparing the combined financial statements are based on a specific identification basis where possible. Management believes that the assumptions used in determining these allocations are reasonable. However, the financial statements may not necessarily reflect the Company’s financial position, results of operations, or cash flows in the future, or what its financial position, results of operations, or cash flows would have been if it had been a stand-alone entity during the periods presented.

The Group has not published standalone financial statements in the past. As a result, these combined financial statements have been derived from the Curetis N.V. accounting records, which were prepared in accordance with IFRS. As it is the first time that the Group is applying IFRS for the preparation of these standalone combined financial statements, IFRS 1 (“First-time Adoption of International Financial Reporting Standards”) was required to be applied. Additional IFRS 1 disclosures related to the 1 January 2017 combined statement of financial position are presented in the notes to the financial statements; however, the footnotes exclude the various reconciliation disclosures otherwise required by IFRS 1 as they are not applicable.

IFRS does not provide principles for the preparation of combined financial statements for carve-out financial statements, and accordingly in preparing the combined financial statements certain accounting and allocation conventions commonly used in practice for the preparation of carve-out financial statements were applied. The assets and liabilities included in the combined balance sheets were measured at the carrying amounts recorded in the Curetis N.V. consolidated financial statements.

The combined financial statements have been prepared on the historical cost basis, except for certain assets and liabilities as separately stated in Note 3 “Summary of significant accounting policies”. The combined statement of operations and other comprehensive loss has been prepared in accordance with the function of expense method. The financial statements have been prepared on a going concern basis (see also Note 3.22 below). These combined financial statements are presented in Euro – where appropriate – have been rounded to the nearest thousand (abbreviated kEUR). All intercompany accounts and transactions have been eliminated in the combination. The financial year corresponds to the calendar year.

2.2. Scope of combination

Curetis GmbH is domiciled in Germany.

Details of the Group's subsidiaries at the end of the reporting period are as follows:

Name	Registration No.	Country	Participation	Main activity
Curetis USA Inc.	EIN 81-3113346	USA	100.00%	Sale of molecular diagnostic products
Curetis UK Ltd.	10164457	UK	100.00%	Sale of molecular diagnostic products
Curetis France S.A.R.L.	TI 822952511	France	100.00%	Sale of molecular diagnostic products
Curetis BeNeLux B.V.	KvK66281814	Netherlands	100.00%	Sale of molecular diagnostic products
Curetis Schweiz GmbH	CHE-228.103.501	Switzerland	100.00%	Sale of molecular diagnostic products
Ares Genetics GmbH	468899h	Austria	100.00%	Maximize R&D and related scientific opportunities with Aresdb Bio-IT platform (previously GEAR)

2.3. Critical accounting judgements and key sources of estimation uncertainty

The preparation of financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue, income and expenses during the reporting periods. Significant estimates and assumptions reflected in these combined financial statements include, but are not limited to, the useful life of intangible assets, provisions, and inventory valuation. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.

Preparing these carve-out combined financial statements required management to make judgement within the identification of certain costs incurred by Curetis N.V. on behalf of Curetis GmbH and reflected back to the combined financial statements of Curetis GmbH. Management evaluated on historical experience the best approach by identifying such costs.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

3.1. New standards and interpretations applied for the first time

The International Accounting Standards Board (IASB) continues to issue new standards, interpretations and amendments to existing standards. Curetis applies these new standards as required. Curetis has not opted for early adoption for any of these standards. New standards, amendments to standards and new or amended interpretations are effective for annual periods beginning on or after 1 January 2018, and have been applied in preparing these financial statements.

Standard/Interpretation	Content	Application mandatory from
Amendment to IFRS 9	Prepayment Features with Negative Compensation	1 January 2019
IFRS 16	Accounting of Leasing-transactions	1 January 2019
IFRIC 23	Uncertainty over Income Tax Treatments	1 January 2019
Amendments to IFRS 3, IAS 11, IAS 12, IAS 23	Amended by Annual Improvements to IFRS Standards 2015–2017 Cycle.	1 January 2019
Amendments to IAS 19	Plan Amendment, Curtailment or Settlement	1 January 2020
Amendments to IFRS 3	Clarifying the definition of “businesses”	1 January 2020
Amendments to IAS 1 and IAS 8	Clarifying the definition of “material”	1 January 2020
IFRS 17 (replaces IFRS 4)	Insurance Contract	1 January 2021

First time adoption of IFRS 9 – financial Instruments

Transition of IFRS 9

The Group has applied the new IFRS 9 *Financial Instruments* standard for financial instruments since 1 January 2018, whereby the exception granted by IFRS 9 Section 7.2.15 is applied for the transitional provisions for classification and measurement, according to which, the adjustment of prior year figures is not required.

On 1 January 2018 (the date of initial application of IFRS 9), the Group’s management has assessed which business models apply to the financial assets held by the Group and has classified its financial instruments into the appropriate IFRS 9 categories. Trade Receivables and Cash and cash equivalents that would have previously been classified as “loan and receivables” (LaR) are now classified at “amortized cost” (AC). The Group intends to hold the assets to maturity to collect contractual cash flows and these cash flows consist solely of payments of principal and interest on the principal amount outstanding. There was no difference between the previous carrying amount and the revised carrying amount of both classes at 1 January 2018 to be recognized in opening Accumulated deficit.

Financial Liabilities are classified as “Financial Liabilities at amortized Costs” (FLAC) which will be continued under IFRS 9. See note 21.

in kEuro	LaR	AC	Accumulated deficit
Closing Balance 31.12.2017	3,824	—	—
Reclassify trade receivables from LaR to AC	(200)	200	—
Reclassify cash and cash equivalents from LaR to AC	(3,468)	3,468	—
Reclassify rent deposits and pledged security deposits from LaR to AC	(156)	156	—
Opening Balance 01.01.2018	—	3,824	—

The Group has two types of financial assets that are subject to IFRS 9’s new expected credit loss model:

- trade receivables
- debt instruments at amortized cost (i.e. cash and cash equivalents and rent deposits)

The Group was required to revise its impairment methodology under IFRS 9 for each of these classes of assets. The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables. Historical losses have been very limited; therefore the expected losses on trade receivables is immaterial. Lifetime expected credit losses do not significantly exceed the impairment under IAS 39.

Other instruments are considered to have a low credit risk when the issuer has a strong capacity to meet its contractual cash flow obligations in the near term. In that meaning, Cash and cash equivalents are only placed at banks with credit ratings at investment grade. Rent deposits are trust assets that means that in case of a default of the counterparty the assets are separated from the insolvency estate and are paid back primarily.

Due to the immaterial expected losses on financial assets, the Group did not change the loss allowance as of 1 January 2018. The recognized loss allowance contained only specific loss provisions which are assigned to stage 3 of the new credit deterioration model and expected losses are immaterial.

Curetis did not apply hedge accounting under IAS 39, therefore IFRS 9 has no impact on the recognition of hedging relationships.

First time adoption of IFRS 15 – Revenues from Contracts with Customers

Transition of IFRS 15

The Group has adopted IFRS 15 *Revenues from Contracts with Customers* from 1 January 2018. IFRS 15 establishes a comprehensive framework for determining whether, how much and when revenue is recognized. It replaces IAS 18 *Revenue* and IAS 11 *Construction Contracts* and related interpretations. In accordance with the transition provision in IFRS 15, the Group has adopted the new rules by applying the modified retrospective approach. Consequently, the information presented for 2017 has not been restated. The impact of transition from IAS 18 to IFRS 15 did not result in a significant change to the Group’s revenue recognition policy and therefore the impact on Accumulated deficit and on other financial statement line items was immaterial and therefore not adjusted in the opening balance sheet.

IFRS 15 Accounting policies

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

The Group's revenue consist mainly of the sale of Unyvero Application cartridges and Unyvero Systems. The sale of Unyvero Application cartridges and the sale of Unyvero Systems represent separate performance obligations. Curetis recognizes revenues at a point in time when the control is transferred to the customer. The control of the product transfers upon shipment to the customer or when the product is made available to the customer, provided that the Group did not retain any significant risks of ownerships or future obligations with respect to the product shipped.

The Group has identified its performance obligation and noted that there are no other significant performance obligations outside the shipment of the products as outlined above. In certain contracts Curetis has a relationship both as a supplier and as a customer. Subject to the underlying transaction, any costs associated with services received by Curetis as a customer are recorded in operating expenses.

Furthermore, the Group offers Bio-IT related services via its subsidiary Ares Genetics GmbH. the Group recognizes revenues for such project related services over the period of time in which the services are being provided, in accordance with IFRS 15.

Service revenues also includes license fees. A license may be provide the customer (licensee) the right to use the Company's (licensor) intellectual property as it exists at the point in time the license is granted. For such license, revenue is recognized at a point in time when controls transfers to the licensee (i.e., the licensee is able to use and benefit from the license) and the license period begins. As opposed to the right to use IP, as described above, a license may provide access to the Company's IP as it exists throughout the license period (right to access IP), such license being a performance obligation satisfied over time which results in revenue recognized over time accordingly, provided that all criteria in IFRS 15.

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

Payment is generally due at the time of delivery or in line with customary payment terms. Deferred payment terms may be agreed in rare circumstances, however; the deferral never exceeds twelve months. The transaction price is therefore not adjusted for the effects of a significant financing component.

The other new standards and amendments to standards noted in the table above had no effect on the combined financial statements of the Group as of 31 December 2017 and 2018.

3.2. Standards, interpretations, and amendments issued, but not yet applied

The following new standards and interpretations and amendments to existing standards will become effective after 1 January 2019.

Standard/Interpretation	Content	Application mandatory from
Amendment to IFRS 9	Prepayment Features with Negative Compensation	1 January 2019
IFRS 16	Accounting of Leasing-transactions	1 January 2019
IFRIC 23	Uncertainty over Income Tax Treatments	1 January 2019
Amendments to IFRS 3, 11, IAS 12, IAS 23	Amended by Annual Improvements to IFRS Standards 2015–2017 Cycle.	1 January 2019
Amendments to IAS 19	Plan Amendment, Curtailment or Settlement Clarifying the definition of businesses	1 January 2020
Amendments to IFRS 3	Clarifying the definition of "material"	1 January 2020
Amendments to IAS 1 and IAS 8 IFRS 17 (replaces IFRS 4)	Insurance Contract	1 January 2021

The Group has assessed the accounting standards effective after 1 January 2019 and determined that none are likely to have a material impact on the combined financial statements with the exception of IFRS 16.

IFRS 16 *Leases* replaces IAS 17 as well as the associated interpretations. The new standard requires leases to be recorded on the balance sheets by recording a right-of-use asset and lease liability for all leases with a term of greater than 12 months. Leases with a term of 12 months or less may be accounted for similar to existing guidance on operating leases prior to adoption.

As at the reporting date, the Group has operating lease commitments of kEUR 1,301. Of these commitments, an immaterial amount relate to short-term leases and low value leases which will both be recognized on a straight-line basis as expense in profit or loss.

For the remaining lease commitments, the Group expects the adoption to result in recognition of right-of-use assets and lease liabilities of kEUR 1,494 on its combined balance sheets. No material impacts are expected on the combined statement of operations or net cash flows. The impact of changes under IFRS 16 to the statement of operations would be a positive impact to operating income (loss) due to operating lease expense being replaced by depreciation and interest expense, the latter of which is not recognized within results from operations. Further, changes to the combined statement of cash flows would be to decrease the cash used in operating activities and decrease net cash provided by financing activities by the same amount as repayment of the principal portion of the lease liabilities will be classified as cash flows from financing activities.

The Group's activities as a lessor are not material and hence the Group does not expect any significant impact on the financial statements.

The Group will apply the standard from its mandatory adoption date of 1 January 2019. The Group intends to apply the simplified transition approach and will not restate comparative amounts for the year prior to adoption.

3.3. Segment Reporting

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

3.4. Current and non-current distinction

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

3.5. Foreign currency translation

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

Transactions in foreign currencies are translated into Euros at the exchange rates at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the reporting date are translated into Euros at the exchange rate at the reporting date. Curetis converted amounts from each corresponding currency to the functional currency with the exchange rates indicated in the table below.

1 EUR =	31 December 2018	31 December 2017	1 January 2017
USD	1.1450	1.1993	1.0541
CHF	1.1269	1.1702	1.0739
GBP	0.8945	0.8872	0.8561

Foreign currency transactions are translated into the functional currency using the spot exchange rate at the transaction date. Foreign currency monetary items are translated into the functional currency using the exchange rate as of the end of the reporting period. Non-monetary items measured at historical cost in foreign currencies are translated into the functional currency using the exchange rates at the transaction date. Non-monetary items measured at fair value that are denominated in foreign currencies are translated into the functional currency using the exchange rates at the date when the fair value is measured. Exchange differences arising from the translation or settlement are recognized in profit or loss, except for those recognized in other comprehensive loss.

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

3.6. Cash flow statement

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

3.7. Revenue recognition

The Group recognizes revenue most significantly from the sale of Unyvero-cartridges, disposables and systems, as well as other disposables.

Revenue is measured based in the consideration to which the Group expects to be entitled in a contract with a customer and excludes amounts collected on behalf of third parties (if applicable). The Group recognizes revenue when it transfers control of a product or service to a customer. The impact of transition from IAS 18 to IFRS 15 did not result in a significant change in the Group's revenue recognition policy. Refer to note 3.1 for further information on adoption of the new standard and additional accounting policy information. As of 31 December 2017 and 2018 the Group did not have material contract assets or liabilities.

3.8. Cost of Sales

Cost of sales includes the costs for products sold in terms of manufacturing, obsolescence write-downs of inventories as well as delivery costs for the products sold. 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 changes in semi-finished and finished inventories.

3.9. Research and development expenses

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

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

3.10. Leases

Leasing transactions are classified according to the lease agreements and to the underlying risks and rewards. Curetis has entered into agreements in which it is the lessor and other agreements in which it is the lessee. Additionally, certain arrangements are analyzed with regard to embedded leases (IFRIC 4). If specific criteria are met, certain arrangements should be accounted for as leases even if they do not take the legal form of a lease. The Group did not elect to adopt IFRS 16 *Leases* early.

Curetis leases certain property, plant and equipment. Leasing transactions in which Curetis is the lessee are classified either as finance leases or operating leases. Leases of property, plant and equipment where Curetis bears substantially all of the risks and rewards of ownership are classified as finance leases. Finance leases are recognized at the lease's commencement at the lower of the fair value of the leased property and the present value of the minimum lease payments. Accordingly, Curetis recognizes the asset and the associated liability in equal amounts. The leased property is depreciated over its useful economic life or, if it is shorter, the term of the lease. The lease liability is discounted by using the interest rate implicit to the lease.

Each lease payment is allocated between the liability and finance charges. The corresponding rental obligations, net of finance charges, are included in other current financial liabilities and other non-current financial liabilities. The interest element of the finance cost is charged to the statement operations and other comprehensive loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The property, plant and equipment acquired under finance leases are depreciated over the shorter of the useful life of the asset and lease term.

All other transactions not classified as a finance lease in which Curetis is the lessee, if any, would be classified as operating leases. Payments made under operating leases (net of any incentives received from the lessor) are charged to the statement operations and other comprehensive loss on a straight-line basis over the period of the lease.

In 2017 and 2018 Curetis did not have any material agreements in which they operated as a lessor.

3.11. Finance income and finance costs

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

3.12. Fair value measurements

Historic cost is generally based on the fair value of the consideration given in exchange for assets.

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

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

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

3.13. Inventories

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

If the net realizable value of a finished good is lower than its cost, inventories are written down to their net realizable value and the related expenses are recognized in Cost of sales.

3.14. Intangible assets

Licenses and patents

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

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

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

3.15. Property, plant and equipment

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

Asset retirement obligations are recognized at the cost of tangible fixed assets and expensed over the asset's estimated useful life. The estimated useful lives of the principal property, plant and equipment categories are as follows:

Asset class	Depreciation term
Land and buildings	Max. 10 years
Machines and technical equipment	3-13 years
Office equipment	2-14 years
Unyvero-Platforms	3-5 years

Office equipment and Unyvero-Platforms, used for internal demands, are combined into Other tangible assets (refer to note 16).

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

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

3.16. Financial instruments

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

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

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

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

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

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

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

Purchases or sales of financial assets that require delivery of assets within a time frame established by regulation or convention in the market place (regular way trades) are recognized on the trade date, i.e. the date that the Group commits to purchase or sell the asset.

Financial Assets

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

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

Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortized cost. Interest income from these financial assets is included in finance income using the effective interest rate method. Any gain or loss arising on the de-recognition is recorded directly in profit or loss and presented in finance income (cost). Impairment losses are presented as separate line item in the statement of operations and other comprehensive loss.

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

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

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

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

Financial Assets are derecognized when the contractual rights to the cash flows from the financial asset expire or it transfers all contractual rights of the financial asset.

Financial Liabilities

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

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

Financial liabilities are analyzed to determine whether they contain any embedded derivatives. Embedded derivatives not closely related to the host contract will be separated and accounted for separately at FVTPL.

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

Impairment

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

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

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

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

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

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

Offsetting financial assets and financial liabilities

Curetis currently has not recognized any financial instruments that are offset. The Group did not enter into any enforceable netting arrangements or other derivative instruments or offsetting arrangements that meet the offsetting criteria in IAS 32.

Cash and Cash equivalents

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

Trade receivables

Trade receivables are amounts due from customers for merchandise sold or services performed in the ordinary course of business. A specific valuation adjustment is established, when there is objective evidence that Curetis will not be able to collect all amounts due, according to the original terms of the receivables. If collection is expected in one year or less, they are classified as current assets. If not, they are presented as non-current assets.

Trade and other payables

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

3.17. Provisions for other liabilities and charges

Provisions are recognized when Curetis has a present legal or factual obligation as a result of past events; and it is probable that an outflow of resources will be required to settle the obligation and the amount can be reliably estimated. Where the effect of the time value of money is material, provisions are discounted using a current pre-tax rate. If discounting is used, the increase in the provision over time is recognized as interest expense. Gains from the reversal of other current liabilities that arose originally in previous years are recognized as other operating income.

3.18. Current and deferred tax income

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

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

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

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

Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income taxes assets and liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities where there is an intention to settle the balances on a net basis.

In accordance with IAS 1 'Presentation of financial statements', the current part of deferred taxes is recognized as non-current assets/ liabilities in the statement of financial position.

3.19. Equity

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recognized at the proceeds received, net of direct issue costs. Capital reserves within Equity includes capital increases from Curetis N.V. to fund the operations of the business; shareholder contributions related to costs incurred by Curetis N.V. primarily related to the compensation of certain members of senior management and its supervisory board for the benefit of the business, which have historically been incurred by Curetis N.V. but have not been recharged by Curetis N.V. to Curetis GmbH or its subsidiaries; and share-based payment transactions with Curetis GmbH employees that are based on Curetis N.V. shares. In both the case of shareholder contributions and share-based payments, the cost for these items have been recognized as expenses in the statement of operations and comprehensive loss.

3.20. Share-based payments

The Employee Stock Option Plan 2016 (“ESOP”)

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

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

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

Valuation model, input parameters, recognized expenses and further details are stated in Note 22.

3.21. Use of assumptions and estimates

The preparation of financial statements in conformity with IFRS requires management 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 income and expenses during the period. Actual results could differ from those estimates.

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

The determination of the useful economic life for intangible assets and property, plant and equipment of Curetis is subject to the estimates made by the management.

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

When accounting for provisions, management must make assumptions regarding the estimated amounts, timing, and probability of economic outflows which form the basis for the measurement of provisions.

To evaluate the recoverability of intangible assets with indefinite useful lives, the Company compares the carrying values of the asset to the asset's fair value, determined using a discounted cash flow approach or other methods, if appropriate. In determining the discounted cash flows, management must estimate future revenues and weighted average cost of capital (“WACC”), both of which are considered significant assumptions.

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 forecasting 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.

In accordance with IFRS 2 – *Share based Payment*, the fair value of the options at grant date is recognized as an expense in the statement of operations and other comprehensive loss over the vesting period of delivery of work. Subsequently, the fair value of equity-settled stock options is not re-measured. The fair value of each option granted during the year is calculated using the binominal valuation model. This valuation model requires the input of subjective assumptions, which are detailed in note 22.

3.22. Going concern

Since inception, the Company's activities have consisted primarily of performing research and development to advance its technologies and more recently, establishing sales and distribution networks to commercialize its technology. Through 31 December 2018, the Company has not yet established a stable ongoing source of revenues sufficient to cover its operating costs and has funded its operations through proceeds from equity investments, collaboration and licensing agreements, grants and borrowings under various agreements with funding agencies, and contributions from Curetis N.V., the ultimate holding company of Curetis GmbH as of 31 December 2017 and 2018, from the sale of Curetis N.V. stock in an Initial Public Offering, secondary offerings and various other financing agreements. Since inception, the Company has incurred recurring losses (with the exception of 2015 due to an extraordinary gain), including net losses of EUR 18.3 million and EUR 22.8 million for the years ended 31 December 2017 and 2018, respectively. As of 31 December 2018, the Company had an accumulated deficit of EUR 160.4 million, EUR 4.8 million in cash and cash equivalents, trade receivables of EUR 0.3 million, and EUR 0.5 million VAT refund receivable shown within Group Receivables.

The Company also realized the following inflows of funds from financing during 2019.

- EIB Debt Financing Facility has funded the EUR 5 million milestone tranche in June 2019, however, Curetis believes this was the last of the debt financing tranches that Curetis could or would access under the current EIB facility.
- Yorkville Convertible Note facility withdrawal of EUR 3.5 million.

Despite the cost reduction measures already implemented in Europe and the USA, the Company expects to continue to generate operating losses in the foreseeable future, and the existing current assets, including cash, as well as the aforementioned secured external funding sources are not sufficient to finance Curetis' operating activities for said 12 months after the signing date of these financial statements. Substantial doubt regarding the Group's ability to continue as a going concern exists as of 15 September 2019, the issuance date of these combined financial statements.

The Group's Management believes that if it can realize cash-inflow and funding measures, execute on strategy options, realize liquidity planning and implement these planned measures as needed, funding of our business operations for a period of at least 12 months after the issue date of these financial statements is achievable. Curetis is in the process of evaluating and progressing strategic and liquidity planning options to be able to raise additional capital and reduce costs, including:

- The negotiation and implementation of a strategic option and scenario that, if successful, would allow Curetis to access the capital markets and raise additional capital again.
- Curetis aims at accessing cash relating to entering into one or more licensing and partnering deal(s) around its Unyvero A30 RQ platform and Aresdb. A draft term sheet has been received for Unyvero A30 RQ and is currently under negotiation; however, none are currently committed or secured.
- Potentially putting on hold, delaying, or reducing further expenditures for certain R&D, commercialization and operational programs.

The Company has also engaged financial and other advisors to assist it in those efforts. The Company will seek additional funding and to execute on these strategic business and commercial plans in order to reach its development and commercialization objectives. There are no assurances the Company will be able to obtain financing on acceptable or favorable terms, or at all, and the Company may not be able to execute on strategic business and commercial plans or to enter into collaborations or other arrangements. The Company is primarily dependent on its parent, Curetis N.V., for financing. Further, Curetis N.V. is not an operational entity which generates cash inflows, rather, is reliant on its shareholders and other external financing to remain funded. In the event the Company is unable to successfully raise additional capital during or before the fourth quarter of 2019, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to immediately and significantly reduce general and administrative expenses, delay research and development projects, and product portfolio expansion or commercialization efforts until it is able to obtain sufficient financing, which could adversely affect its business prospects. If such sufficient financing is not received on a timely basis, the Company would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

The accompanying combined financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The combined financial statements do not reflect any adjustments relating to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

3.23. Government grants

Government grants are not recognized until there is reasonable assurance that the Company will comply with the conditions attached to them and that the grants will be received. The Group receives grants related to research projects from governmental agencies, these are recognized at their fair value when the Group receives grants from the agency and will comply with the conditions attached to the grants, but in no event prior to the formal grant approval. The grants are accounted for as other operating income in the statement of operations and other comprehensive loss. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed.

4. REVENUE

in kEUR	2018	2017
Sale of Unyvero-Systems	546	448
Sale of cartridges	811	722
Sale of services	62	17
Total	1,419	1,187

In accordance with IFRS 8, Curetis is a single-segment entity. Revenues from external customers by territory, based on the destination of the customers are as follows:

in kEUR	2018	2017
EMEA direct markets	676	274
USA	32	7
Asia	286	269
Rest of the world	425	637
Total	1,419	1,187

All revenues are derived from external customers, including hospitals as well as distribution partners.

5. EXPENSES BY NATURE

in kEUR	2018	2017
Personnel expenses	10,780	8,614
Depreciation, amortization and impairment charges	1,256	1,327
Raw material, goods and consumables used	848	610
Facility expenses	777	519
Disposables for clinical trials and R&D-activities	832	751
Third party services for clinical trials incl. US-FDA-trial	331	377
Marketing and travel expenses	1,659	1,392
Other consulting, advisory & third party support	3,276	1,780
Other expenses	3,894	3,677
Total Cost of sales, Distribution costs, Administrative expenses and Research & development expenses	23,653	19,047

The Personnel expenses in 2018 include kEUR 366 (2017: kEUR 528) expenses recognized for the valuation of equity-settled share-based payment transactions. Refer to Note 22 for additional information.

6. DISTRIBUTION COSTS

in kEUR	2018	2017
Personnel expenses	5,016	4,155
<i>thereof from share-based payments equity-settled</i>	113	370
Depreciation and Amortization	74	170
Other operating expenses	3,057	2,881
<i>thereof marketing expenses</i>	1,410	1,138
<i>thereof travel expenses</i>	746	520
<i>thereof consulting, advisory & third party service</i>	255	412
Total	8,147	7,206

Distribution costs include all direct individual sales and marketing costs as well as overhead costs. These include all expenses for sales, marketing, public relations, and business development such as personnel, materials, depreciation, and other related expenditures.

7. ADMINISTRATIVE EXPENSES

in kEUR	2018	2017
Personnel expenses	1,264	1,117
<i>thereof from share-based payments equity-settled</i>	111	116
Depreciation and Amortization	90	104
Other expenses	2,224	1,964
<i>thereof for remuneration of supervisory board</i>	409	359
<i>thereof consulting, advisory & third party service</i>	500	291
Total	3,578	3,185

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

8. RESEARCH AND DEVELOPMENT EXPENSES

in kEUR	2018	2017
Personnel expenses	4,182	3,124
<i>thereof from share-based payments equity-settled</i>	141	32
Depreciation and Amortization	861	810
Material expenses	513	407
Other expenses	5,010	2,994
<i>thereof IP-fees and expenses for patent lawyers</i>	576	—
<i>thereof external services for clinical trial</i>	351	367
<i>thereof costs for laboratory demand</i>	473	303
<i>thereof consulting, advisory & third party service</i>	1,999	—
<i>thereof other manufacturing expenses for cartridges used in R&D</i>	736	284
Total	10,566	7,335

9. PERSONNEL EXPENSES

in kEUR	2018	2017
Wages and salaries	8,715	6,870
Social security costs	1,699	1,216
EPOs / PSOs granted to management and employees	366	528
Total	10,780	8,614

The employer's contribution paid to the statutory retirement insurance (*Deutsche Rentenversicherung*) in Germany amounted to kEUR 409 in 2018 (2017: kEUR 374).

10. FINANCE RESULT / COSTS NET

Finance result, net loss of kEUR 1,167 (2017: loss of kEUR 686) is primarily from interest on the 13 million Euro tranche drawn from the EIB debt facility and foreign currency exchange difference resulting from the exchange rate difference of USD vs. EUR.

in kEUR	2018	2017
Foreign exchange differences	6	(69)
Interests for borrowings	(1,079)	(621)
Interest and finance expenses for convertible notes	(93)	—
Other finance income / finance costs	(1)	4
Finance result/costs net	(1,167)	(686)

Interests for borrowings represent interest and financing charges paid/payable for financial liabilities not at fair value through profit or loss using the effective interest method.

11. INCOME TAX

Income tax expense:

in kEUR	2018	2017
Current Income taxes		
Germany	—	—
other countries	29	24
Total current income taxes	29	24
Deferred taxes	7	(78)
Total	36	(54)

In Germany, Income tax consists of trade tax ('Gewerbesteuer') and corporate income tax ('Körperschaftsteuer'). Corporate income tax is imposed at a uniform rate of 15% and is additionally subject to a solidarity surcharge of 5.5%, resulting in an effective tax rate of 15.825% (2017: 15.825%).

Municipalities impose a trade tax. Each municipality set its individual local multiplier rate, so that no uniform trade tax rate exists in Germany. In 2018, Curetis has a trade tax rate of 12.05% (2017: 12.05%).

The Company is fully taxable in Germany with the business seat in Holzgerlingen, Germany.

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

in kEUR	2018	2017
Loss before income tax	(22,776)	(18,374)
Expected income tax at a tax rate 2018: 27.88% (2017: 27.88%)	6,350	5,123
Non-taxable income and non-deductible expenses	(34)	(37)
Expenses resulting from Equity settled stock options	(138)	(232)
Changes in the recognition of deferred tax assets on tax loss carry-forwards	(4,087)	(3,803)
Effect from revaluation of DTA (in context with DTL)	74	(79)
Tax effect from local taxes	(33)	(20)
Tax effect of the application of foreign tax rates and use of foreign tax losses carried forward	(2,128)	(927)
Other effects	(40)	29
Income tax as stated in P&L	(36)	54
Effective tax rate	0%	0%

Changes in the recognition of deferred tax assets on tax loss carry-forwards of kEUR 4,087 in Germany are due to unrecognized deferred tax assets on tax loss carryforwards for 2018.

Tax effects of the application of foreign tax rates and use of foreign tax losses carried forward comprise mainly to unrecognized deferred tax assets for the loss of Curetis USA Inc. as there is no reliable certainty that these losses will be usable.

Deferred tax assets and liabilities:

in kEUR	31 December 2018		31 December 2017		1 January 2017	
	Total	thereof current	Total	thereof current	Total	thereof current
DTA	426	30	430	104	430	61
DTL	426	93	430	73	430	61

Deferred taxes relate to the following statement of financial position items:

in kEUR	Deferred tax assets			Deferred tax liabilities		
	31 December 2018	31 December 2017	1 January 2017	31 December 2018	31 December 2017	1 January 2017
Assets						
Trade and other receivables	—	—	—	—	—	—
Inventories	—	—	—	93	73	61
Property, plant and equipment	—	—	—	280	357	369
Receivables unrealized currency differences	30	104	—	—	—	—
Liabilities						
Financial liabilities	—	—	—	—	—	—
Provisions current	—	—	—	—	—	—
Other current liabilities	15	16	8	—	—	—
Other current financial liabilities	—	—	33	53	—	—
Provisions non-current	2	4	5	—	—	—
Other non-current financial liabilities	—	—	—	—	—	—
Equity						
Accumulated deficit	379	306	384	—	—	—
Deferred taxes (gross)	426	430	430	426	430	430
Offsetting	426	430	430	426	430	430
Deferred taxes (net)	—	—	—	—	—	—

Deferred tax assets for losses carried forward have been recognized in the amount of existing deferred tax liabilities. Due to the uncertainty surrounding the Group's ability to realize taxable profits in the near future, the Company did not recognize any further deferred tax assets. Deferred tax assets shown under the non-current assets result from the elimination of intercompany profits.

Due to differences in the valuation of the shares in Curetis GmbH (former AG) between IFRS and national (German) tax law. While the valuation under IFRS is based on the net asset value of Curetis GmbH (former AG), the valuation under German tax law is based on the taxable net book value. The resulting difference is however a permanent one which does not result in a deferred tax entry.

As of 31 December 2018, Curetis had tax loss carryforwards that were not utilizable and for which no deferred taxes were recognized. These tax loss carryforwards amount to kEUR 96,587 for corporate tax purposes and kEUR 96,098 for trade tax purposes (31 December 2017: kEUR 82,173 for corporate tax purposes and kEUR 81,957 for trade tax purposes). The aforementioned tax loss carryforwards exist only in Germany hence they are only in Germany available unlimited for offsetting against future taxable profits of Curetis. Deferred tax assets have not been recognized in respect of these losses as no sufficient certainty is given, whether mid-term such tax loss carryforwards will enable Curetis to offset its future taxable profits.

Overview of the Group's tax loss carryforwards:

Curetis GmbH			
in kEUR	31 December 2018	31 December 2017	1 January 2017
Tax loss carryforwards corporate tax	96,587	82,173	68,377
Tax loss carryforwards trade tax	96,098	81,957	68,328
Non-taxable income and non-deductible expenses	(34)	(37)	(32)
Expenses resulting from Equity settled stock options	(138)	(232)	

12. TRADE RECEIVABLES

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

in kEUR	31 December 2018	31 December 2017	1 January 2017
Trade receivables, gross	325	202	127
less loss allowance	(2)	(2)	(26)
Trade receivables, net	323	200	101

The aging of the gross trade receivables at the reporting date was as follows:

in kEUR	31 December 2018	31 December 2017	1 January 2017
Gross			
Amounts not due	242	195	103
Past due 0-30 days	60	4	8
Past due 31-60 days	23	3	2
More than 60 days	—	—	14
Total	325	202	127

The Company did not have any material amounts of past due receivables as of December 31, 2017 and 2018. As of 31 December 2018, trade receivables of kEUR 83 (31 December 2017 kEUR 7 and 1 January 2017 kEUR 24) were past due, however no significant impairments were identified. The aging analysis of these trade receivables is as follows:

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

in kEUR	2018	2017
Balance as of 1 January	(2)	(26)
Net additions (-) / reversals (+)	—	(1)
Write-offs	—	25
Balance as of 31 December	(2)	(2)

13. INVENTORIES

in kEUR	31 December 2018	31 December 2017	1 January 2017
Raw materials	838	875	898
Semi-finished goods	61	46	61
Trade goods	4,987	4,419	3,040
Finished goods	65	47	63
Spare parts	101	66	16
Total inventories, net	6,052	5,453	4,078

Semi-finished goods comprise not yet completely assembled or manufactured parts of our disposables, such as reagent containers, base plates, PCR chambers, etc. Trade goods comprise Unyvero Systems-components.

As outlined in note 3.21 the assessment of the obsolescence write-downs on inventories is considered a significant estimate with inherent uncertainty. Given Curetis does not yet have a reliable sales-track-record; the write-downs are based on the best estimate considering technical aging and estimated sales volumes and prices for systems. If assumptions regarding future sales prices, volumes, useful life or end product market potentials are not appropriate, this may lead to a further need for write-off. A change in the estimated sales price of +/- 10% would result in a decrease or increase of obsolescence write-downs of kEUR 280, respectively. A change in the estimated useful life of five years of the Unyvero systems by +/- 1 year would result in an decrease or increase of obsolescence write-downs kEUR 692, respectively.

The change of write-off to net asset value of inventories recognized as an expense and included in 'Cost of Sales' in 2018 amounted to kEUR 244 (2017: kEUR 192).

14. PREPAID EXPENSES AND OTHER CURRENT ASSETS

in kEUR	31 December 2018	31 December 2017	1 January 2017
Prepaid Expenses	177	148	80
Other current assets	83	111	147
Total	260	259	227

Prepaid expenses and other current assets mainly include lease payments, travel expenses, insurance fees, tax refunds and receivables, and conference and exhibition fees.

15. INTANGIBLE ASSETS

in kEUR	Software	Licenses & Patents	Unyvero A30 technology	Advance payments	Total
Cost:					
Balance as of 1 January 2017	574	2,484	5,000	—	8,058
Additions	83	—	—	27	110
Balance as of 31 December 2017	657	2,484	5,000	27	8,168
Accumulated amortizations:					
Balance as of 1 January 2017	(509)	(29)	—	—	(538)
Amortization	(53)	(53)	—	—	(106)
Balance as of 31 December 2017	(562)	(82)	—	—	(644)
Carrying value as of 31 December 2017	95	2,402	5,000	27	7,524
Cost:					
Balance as of 1 January 2018	657	2,484	5,000	27	8,168
Additions	34	1	—	84	119
Balance as of 31 December 2018	691	2,485	5,000	111	8,287
Accumulated amortizations:					
Balance as of 1 January 2018	(562)	(82)	—	—	(644)
Amortization	(76)	(142)	—	—	(218)
Balance as of 31 December 2018	(638)	(224)	—	—	(862)
Carrying value as of 31 December 2018	53	2,261	5,000	111	7,425

In 2018 amortization of kEUR 0 (2017: kEUR 0) is included in 'Cost of sales', in Distribution costs kEUR 2 (2017: kEUR 17), in R&D costs kEUR 152 (2017: kEUR 60) and kEUR 10 (2017: kEUR 29) in Administrative expenses.

The GEAR platform, held within the Licenses & Patents, was transferred from Curetis GmbH in Q4-2017 to the wholly owned subsidiary Ares Genetics GmbH and continues under the name Aresdb. The platform had not been amortized from its acquisition in Q4-2016 until the transfer to Ares Genetics GmbH as it had not been available to be used. Subsequent to the transfer, the platform has been in commercial use and is being amortized according to the runtime of the main patent (17.8 years) and the remaining amortization period of the GEAR platform as of 31 December 2018 is 16.6 years. Curetis continues to invest further in these assets.

Intangible assets not yet available for use (Unyvero A30 RQ) must be tested for impairment at least annually. The acquired Gyronimo-asset has meanwhile been renamed to Unyvero A30, and will be developed by Curetis into a partnering-ready asset. The platform is still in a development phase and the development takes place by the same team that had developed and continues to maintain the Unyvero A50-multiplex-platform. As the Unyvero A30 RQ is not yet fully developed and ready for sale, it has no defined residual amortization period.

Intangible assets are tested annually for impairment or more frequently if events or changes in circumstances indicate that they might be impaired. The recoverable amount for the Licenses and patents, most significantly Ares platform, and for Unyvero A30 is defined by assessing the separately identifiable cash inflows, which are largely independent of the cash inflows from other assets. For 2017 and 2018 there were no indicators of potential impairment as the recoverable amounts of all intangible assets exceeded their carrying amount, hence no impairment losses have been recognized.

16. PROPERTY, PLANT AND EQUIPMENT

in kEUR	Land and buildings	Machines and technical equipment	Other tangible assets	Assets under construction	Total
Cost:					
Balance as of 1 January 2017	72	7,853	2,413	199	10,537
Additions	—	1	232	90	323
Disposals	—	(2)	(9)	—	(11)
Balance as of 31 December 2017	72	7,852	2,636	289	10,849
Accumulated depreciation:					
Balance as of 1 January 2017	(42)	(4,409)	(1,619)	—	(6,070)
Disposals	—	1	7	—	8
Depreciation	(7)	(835)	(379)	—	(1,221)
Balance as of 31 December 2017	(49)	(5,243)	(1,991)	—	(7,283)
Carrying amount as of 31 December 2017	23	2,609	645	289	3,566
Cost:					
Balance as of 1 January 2018	72	7,852	2,636	289	10,849
Additions	—	31	215	424	670
Disposals	—	—	(81)	—	(81)
Reclassifications	—	417	—	(417)	—
Balance as of 31 December 2018	72	8,300	2,770	296	11,438
Accumulated depreciation:					
Balance as of 1 January 2018	(49)	(5,243)	(1,991)	—	(7,283)
Disposals	—	—	80	—	80
Depreciation	(8)	(701)	(330)	—	(1,039)
Reclassifications	—	—	—	—	—
Balance as of 31 December 2018	(57)	(5,944)	(2,341)	—	(8,242)
Carrying amount as of 31 December 2018	15	2,356	529	296	3,196

Other tangible assets comprise office equipment and Unyvero-Platforms used for internal demands.

Curetis did not own any of these assets under any lease programs in 2017 or 2018. All property, plant and equipment are free from any rights held by third parties. For further details, please refer to note 24.

17. PHANTOM STOCK OPTION INCENTIVE PLAN

Prior to the IPO of Curetis N.V. shares, a share-based compensation plan, Curetis AG Phantom Stock Option Incentive Plan 2010 (“PSOP”), was implemented under which the Company received services from employees and freelancers who received Phantom Stock Options (“PSO”) as consideration.

Subsequent to the IPO in 2015, all remaining outstanding PSOPs were contractually tied to a payment claim to be settled in a fixed number of shares (PSOP-Roll-Over Agreements), the value of which had previously been measured at fair value and was fully expensed and recognized in equity prior to 2017. Furthermore, all rights remain valid indefinitely; therefore, there have been no changes in valuation and no effect to be accounted for in the statement operations and other comprehensive loss in 2017 or 2018. No PSOPs were exercised or forfeited during 2017 or 2018.

Under the PSOP-Roll-Over Agreements the beneficiaries are entitled to receive 659,237 new shares in the parent company, Curetis N.V. as of 31 December 2018.

18. OTHER CURRENT LIABILITIES

in kEUR	31 December 2018	31 December 2017	1 January 2017
Accruals for vacation	244	232	172
Accruals for Employee Bonuses	10	220	196
Accrual for Severance / Restructuring	136	—	—
Accruals for audit and preparation of financial statements	46	46	57
Other tax liabilities	148	124	84
Other liabilities	297	216	174
Total	881	838	683

19. OTHER CURRENT FINANCIAL LIABILITIES

Other current financial liabilities include liabilities for outstanding invoices and finance lease.

in kEUR	31 December 2018	31 December 2017	1 January 2017
Liabilities for outstanding invoices	245	195	350
Provision for deferred interest (refer to note 20)	343	279	118
Convertible notes	3,109	—	—
Total	3,697	474	468

Convertible notes

Key facts of the convertible note facility

On 02 October 2018, Curetis N.V. established a convertible note facility with Yorkville Advisors (Yorkville), a US institutional investor, consisting of several tranches. Under the first tranche, 500 notes are available for issuance, whereby each note has a nominal value of kEUR 10 and a maturity of one year. As of 31 December 2018, the Company had issued 350 notes from the first tranche with an issuance date of 02 October 2018. The notes were issued at an 8% discount, due to a 4% commitment fee and a 4% subscription fee. The Company incurred kEUR 120 in issuance costs related to due diligence and legal fees.

The holders of the outstanding notes have the right to convert the notes in exchange for shares of Curetis N.V. at any time. The number of shares to be issued upon conversion of a note is determined by the nominal amount of the note divided by 93% of the last 10-day lowest VWAP (volume weighted average price) of a common share of Curetis N.V. on the conversion date. As of 31 December 2018, 20 notes had been converted to shares of Curetis N.V.

All of the notes issued as of 31 December 2018 have a maturity date of 02 October 2019. Under the terms of the notes, the Company has the right to extend the maturity date (up to four times) by 12 months. When extending the maturity date, the Company must pay a 5% fee on the outstanding balance as of the extension date. Alternatively, Curetis also has the option to redeem the notes in cash at the maturity date.

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

The Company assumed an initial fair value of the notes, based on the Company's share price as of the issuance date divided by 93%. The Company accounts for the notes payable using the effective interest method, using an effective interest rate of 8% and the initial loan term of 12 months. The Company accounts for the outstanding convertible notes as a current liability, as the likelihood for executing the extension option is remote.

As the legal issuer and obligor of these notes, Curetis N.V. contributed the original proceeds to Curetis GmbH. As a result, for purposes of the combined financial statements, the liability is attributed to the Company as a reduction of capital contributions in equity. Subsequent interest expenses allocated to the Company are reflected as an increase to the liability and interest expense.

20. OTHER NON-CURRENT FINANCIAL LIABILITIES

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

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

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

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

in kEUR	31 December 2018		31 December 2017		1 January 2017	
	current	non-current	current	non-current	current	non-current
Loan from EIB	—	13,000	—	10,000	—	—
Deferred interest	343	949	279	342	—	—
Total	343	13,949	279	10,342	—	—

21. FINANCIAL INSTRUMENTS

For each class of financial instrument the fair value of financial assets and liabilities, together with their carrying amounts contained in the combined financial statements are shown in the following schedules.

in kEUR	31 December 2018				31 December 2017			
	Category in accordance with IFRS9	Carrying amount	Fair Value	Fair Value Level	Category in accordance with IAS 39	Carrying amount	Fair Value	Fair Value Level
Current Assets								
Cash and Cash Equivalents	AC	4,800	n/a *	n/a	LaR	3,468	n/a *	n/a
Trade Receivables	AC	323	n/a *	n/a	LaR	200	n/a *	n/a
Non-current Assets								
Other non-current financial assets	AC	158	158	2	LaR	156	156	2

(n/a *): For short-term financial instruments a fair value disclosure is not required as the carrying amount approximates the fair value.

in kEUR	31 December 2018				31 December 2017			
	Category in accordance with IFRS9	Carrying amount	Fair Value	Fair Value Level	Category in accordance with IAS 39	Carrying amount	Fair Value	Fair Value Level
Current Liabilities								
Trade and other Payables	FLAC	921	n/a *	n/a	FLAC	850	n/a *	n/a
Other current financial liabilities	FLAC	3,154 ⁽¹⁾	n/a *	n/a	FLAC	474	n/a *	n/a
Other current financial liabilities	FVTPL	543 ⁽²⁾	543	3	—	—	—	—
Non-current Liabilities								
Other non-current financial liabilities	FLAC	13,949	13,546	2	FLAC	10,342	10,368	2

(n/a *): For short-term financial instruments a fair value disclosure is not required as the carrying amount approximates the fair value.

(1) Consists of liabilities for outstanding invoices, Convertible notes and provision for deferred interest

(2) Consists of conversion rights related to Convertible notes

in kEUR

1 January 2017

	Category in accordance with IAS 39	Carrying amount	Fair Value	Fair Value Level
Current Assets				
Cash and Cash Equivalents	LaR	6,434	n/a *	n/a
Trade Receivables	LaR	101	n/a *	n/a
Non-current Assets				
Other non-current financial assets	LaR	326	326	2

(n/a *): For short-term financial instruments a fair value disclosure is not required as the carrying amount approximates the fair value.

in kEUR

1 January 2017

	Category in accordance with IAS 39	Carrying amount	Fair Value	Fair Value Level
Current Liabilities				
Trade and other Payables	FLAC	672	n/a *	n/a
Other current financial liabilities	FLAC	468	n/a *	n/a
Non-current Liabilities				
Other non-current financial liabilities	FLAC	—	—	n/a

(n/a *): For short-term financial instruments a fair value disclosure is not required as the carrying amount approximates the fair value.

The fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The fair value hierarchy is defined as follows:

Level 1	Quoted (unadjusted) market prices in active markets for identical assets and liabilities.
Level 2	Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable.
Level 3	Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

The fair values of the Group's non-current other financial assets and the non-current financial liabilities were calculated based on cash flows discounted using market interest rates and a credit spread. The spread included in the calculation for the financial assets is derived by observable ratings of the counterparties (i.e. banks). The credit spread of the own credit risk is derived from the margin included in the interest rates of the own borrowings. The fair value of non-current financial assets and liabilities is included in level 2 of the fair value hierarchy, as the input factors for the fair value calculation are observable in the market. The fair value of the compound embedded derivative separated from the convertible note is determined using observable inputs (Curetis N.V. share price, own credit spread) and assumptions about the rational economic behavior of the related parties which are not observable input parameters. These assumptions lead to the inclusion of the fair value within level 3 of the fair value hierarchy.

Secured liabilities and assets pledged as security

Curetis has pledged cash on bank accounts as rent deposit for lease agreements with a total value of kEUR 64 and for credit card deposits and bank guarantees with a total value of kEUR 94.

22. SHARE-BASED PAYMENTS

The Executives and Supervisory Board as well as certain employees of the Group are included in the Employee Stock Option Plan 2016 "ESOP" of Curetis N.V.. The expenses associated with these individuals are recognized by the Group, which employ and benefit from the employment of the individuals holding notional stocks in Curetis N.V..

Capital reserve increased correspondingly to the expenses accounted for the share-based payment of the ESOP 2016 (see note 3.20).

The following table illustrates the number and exercise prices of the movements in employee stock options during the year, as well as the grant date and the remaining term of the option (Note, valuation inputs; stock price, dividend yields, volatility etc. are related to the stock of Curetis N.V.):

Grant date	Tranche 1	Tranche 2	Tranche 3	Tranche 4	Tranche 5
	1 July 2016	1 October 2016	1 January 2017	1 April 2017	1 July 2017
Granted stock options	170,000	45,000	42,500	5,000	20,000
Remaining contractual term of the option	7.50 years	7.75 years	8.00 years	8.25 years	8.50 years
Exercise price	6.45 Euro	6.41 Euro	6.42 Euro	5.81 Euro	4.93 Euro
Outstanding at 1 January 2018	155,000	25,000	42,500	5,000	20,000
Granted during the year	—	—	—	—	—
Forfeited during the year	22,222	2,500	1,042	—	12,222
Exercised during the year	—	—	—	—	—
Outstanding at 31 December 2018	132,778	22,500	41,458	5,000	7,778
Exercisable at 31 December 2018	—	—	—	—	—

	<u>Tranche 6</u>	<u>Tranche 7</u>	<u>Tranche 8</u>	<u>Tranche 9</u>	<u>Tranche 10</u>
Grant date	1 October 2017	1 January 2018	1 March 2018	1 July 2018	1 October 2018
Granted stock options	123,500	25,000	102,000	40,500	110,000
Remaining contractual term of the option	8.75 years	9.00 years	9.17 years	9.50 years	9.75 years
Exercise price	4.98 Euro	3.86 EUR	6.51 EUR	4.62 EUR	3.29 EUR
Outstanding at 1 January 2018	123,000	—	—	—	—
Granted during the year	—	25,000	102,000	40,500	110,000
Forfeited during the year	16,667	—	5,000	3,000	—
Exercised during the year	—	—	—	—	—
Outstanding at 31 December 2018	106,833	25,000	97,000	37,500	110,000
Exercisable at 31 December 2018	—	—	—	—	—

Vesting conditions

Each option grant will vest over a period of three years whereby the first third of any such option grant will vest at the first anniversary of the date of grant and the remaining two thirds of such granted options will vest in monthly increments over the following twenty-four months.

Upon the occurrence of a termination of employment event after the first anniversary of the date of grant, the optionee's options shall either be forfeited, lapse or continue to be exercisable as set forth below:

- In case of termination for cause, both the options of such optionee that have vested (to the extent not exercised) and the options of such optionee that have not yet vested shall be forfeited at the date of termination for cause, unless agreed otherwise by the management board (with regard to optionees being managing directors or supervisory directors);
- In case of a termination without cause, the options of such optionee that have vested (to the extent not exercised) shall not be forfeited and the remaining part of the options of such optionee that have not yet vested shall be forfeited at the date of termination without cause.

Exercise of options

Vested options may not be exercised prior to the third anniversary of the date of grant and may be exercised until ten years from the date of grant or such shorter period of time remaining under the stock options plan. Options which have not been exercised prior to the end of the exercised period shall lapse automatically without any compensation whatsoever being due to the optionee. Exercises of options are settled in Curetis N.V. shares.

Valuation model and input parameters

The fair value of the stock options is measured using a binominal option pricing model taking into account the terms and conditions upon which the options were granted. The following table lists the inputs to the model used for the options granted in 2016, 2017 and 2018 at the measurement date:

	Tranche 1	Tranche 2	Tranche 3	Tranche 4	Tranche 5
Measurement date	5 July 2016 ¹	1 October 2016	1 January 2017	1 April 2017	1 July 2017
Expected life of the option on the grant date (years)	5.0	5.0	5.0	5.0	5.0
Share price on the measurement date (€)	6.44	6.18	6.34	5.69	4.74
Weighted avg. exercise price	6.45	6.41	6.42	5.81	4.93
Expected dividend yield (%)	—	—	—	—	—
Risk-free interest rate (%)	(0.61)	(0.61)	(0.49)	(0.40)	(0.19)
Expected volatility of the share price (%)	78.15	81.36	60.90	57.99	55.75
Option value (€)	3.94	3.86	3.14	2.69	2.15

Measurement date	Tranche 6	Tranche 7	Tranche 8	Tranche 9	Tranche 10
	1 October 2017	1 January 2018	1 March 2018	1 July 2018	1 October 2018
Expected life of the option on the grant date (years)	5.0	5.0	5.0	5.0	5.0
Share price on the measurement date (€)	4.86	3.83	6.20	4.17	3.24
Weighted avg. exercise price	4.98	3.86	6.51	4.62	3.29
Expected dividend yield (%)	—	—	—	—	—
Risk-free interest rate (%)	(0.28)	(0.15)	(0.01)	(0.28)	(0.10)
Expected volatility of the share price (%)	55.55	65.33	65.63	62.42	62.01
Option value (€)	2.22	2.04	3.26	2.03	1.64

¹ The measurement date represents the acceptance date of the options.

For stock option valuation the possibility of early exercise was considered in the binomial model. Management determined an estimated early exercise is expected five years after the date of grant of the options based on considered the following factors:

The length of the vesting period has been considered since the stock options cannot be exercised until the end of the 3-year vesting period – i. e. the expected option life of 5 years is 2 years after the first possible exercise date.

The Company does not have historical data points or experience from past option programs and to date no options have been exercised, however, due to normal fluctuation as well as fluctuations triggered by the recent re-organization there have been multiple cases of forfeited options. As a result, the Company does not have any actual data available regarding the average length of time that similar options have remained outstanding in the past or if the employee's level within the Company will impact the timing of exercise.

The risk-free interest rate is the implied yield currently available on German government issued bonds with a remaining term equal to the term of the options.

The future volatility for the lives of the options was estimated based on historical volatility of peer group companies.

The expense recognized during 2017 and 2018 is shown in the following table:

in kEUR	2018	2017
Expense arising from equity-settled share-based payment transactions		
Cost of sales	—	11
Distribution costs	113	370
Administrative expenses	111	116
Research & development expenses	141	32
Total	365	529

The Group does not consider paying dividends as long as the result from operating activities in the combined statement of operations and other comprehensive loss and the cash flows from operating activities are negative.

23. FINANCIAL RISK MANAGEMENT

23.1. Financial risk factors

This note explains the Group's exposure to financial risks and how these risks could affect the Group's future financial performance. Current year profit and loss information has been included where relevant to add further context.

Curetis' activities expose the Company to a variety of financial risks such as currency risks, fair value interest risks, cash flow risks, interest rate risks and price risks. Curetis' finance department has created controlling instruments and key metrics to identify and evaluate such risks in close co-operation with the operating units.

a) Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Curetis has a strong international business focus and therefore the Company is influenced by foreign currency exchange rates and interest rates. However, Curetis currently does not hold any financial instruments measured at fair value and Curetis keeps all its liquidity in immediately available money market funds.

aa) Foreign exchange risk

Curetis is exposed to foreign currency risks primarily through its operating activities. Curetis identifies the main currency risk in US Dollar, because certain purchase transactions are undertaken in US Dollar ("USD"). The net exposure to exchange differences of the monetary assets (being cash and cash equivalents) held in USD of the Group were kEUR 676 at 1 January 2017, and kEUR 690 and kEUR 683 at 31 December 2017 and 2018, respectively.

If the USD/EUR exchange rate were to increase/decrease by 10%, compared to year-end 2018 exchange rates, this would have a negative impact of kEUR 62 (2017: kEUR 62) / positive impact of kEUR 76 (2017: kEUR 77). The Group considers a shift in the exchange rates of 10% as a realistic scenario.

ab) Interest rate risk

Curetis is exposed to interest rate risk because entities in the Group borrow funds based a rate indexed to the EURIBOR, plus a fixed rate of interest. The following sensitivity analysis is prepared assuming the amount of liability outstanding at reporting date was outstanding for the whole year.

The Group's exposure to variable interest rates based on the EURIBOR at the end amounted to EUR 13 million as of 31 December 2018 (EUR 10 million as of 31 December 2017 and EUR 0 as of 1 January 2017).

If the interest rates had been one per cent higher/lower and all other variables were held constant, the Group's profit for the year ended 31 December 2018 would decrease/increase by kEUR 130 (2017: decrease/increase by kEUR 100). This is mainly due to the Group's exposure to interest rates on its variable borrowings.

b) 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.

c) Credit risk

The finance department works in close cooperation with the other operating departments to identify credit risks related to account receivables balances. Curetis analyzes the credit risk of each new client before standard payment and delivery terms and conditions are offered. Curetis has also implemented a well-organized dunning system. Curetis had immaterial write-downs on trade receivables as of 1 January 2017 as well as during 2017 and 2018. The credit risk on the accounts receivables is limited because Curetis primarily sells to big laboratories, pharma-companies and major public hospitals in Curetis' direct markets in Central and Western Europe and in the USA, all of these partners have very good credit ratings. Outside of Europe and the USA Curetis works together with large and experienced distributors. If Curetis were to expand the business to other more credit-risky countries Curetis would consider implementing a commercial credit insurance to cover the risks. Considering the aforementioned reasons Curetis summarizes all trade receivables under one risk category 'common credit risk' and impairs all trade receivables using an average default risk of approximately 1% deducted from observable credit risk parameters of the healthcare industry. Curetis is in exchange with different commercial credit insurers and is evaluation other credit risk mitigations periodically with the expansion of its customer base.

In 2017 the following customer accounts each represented > 10% of total annual revenues: ATC Kuwait, Axonlab Austria, Synttergy Consult Ltd. and in 2018 the following customers each represented > 10% of revenues: Diamed Care Germany, Axonlab Austria. Similarly on the supplier side there is a significant concentration risk with single source suppliers of major strategic relevance such as Zollner Elektronik for Unyvero systems, Scholz HTIK for injection molding plastics parts, as well as certain single source suppliers of critical reagents.

Cash and cash equivalents as well as short-term deposits which are disclosed under other financial assets are invested in EUR (with the exemption of the amounts mentioned under aa) foreign exchange risk' in this note. Curetis follows a decisive 'no-risk-policy' which means that Curetis has sight deposits at banks only, and sometimes time deposits with short runtimes.

d) Liquidity risk

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

The Group monitors its risk of a shortage of funds using short and mid-term liquidity planning. This takes account of the expected cash flows from all activities. The supervisory board undertakes regular reviews of the budget and forecast.

In 2018 Curetis drew down a EUR 3 million tranche from the up to EUR 25 million debt financing facility from the EIB (European Investment Bank), in addition to the EUR 10 million already drawn down in 2017. Subsequent to obtaining an EIB waiver which waived the requirement for the Group to meet various milestones in order to draw down additional tranches, another EUR 5 million became available for disbursement immediately upon finalization of legal documentation for the amendment to the Finance Contract with EIB that sets out the terms and conditions for the equity linked participation for EIB upon maturity of the EUR 5 million tranche in 2024 and beyond. Curetis management currently believes that this EUR 5 million tranche would be the last of the debt financing tranches that Curetis could or would access under the current EIB facility. As of year-end 2018 Curetis has cash & cash equivalents balance of EUR 4.8 million at year-end 2018, and the EUR 0.4 million VAT refund.

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

- the cost and timing of getting market traction in the U.S., as the USA are the most important market for diagnostic products;
- market acceptance of Curetis' products;
- the cost and timing of establishing further 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 unfavorable terms and conditions.

The following table depicts an analysis of the Company's financial liabilities into relevant maturity groupings based on the remaining term on the balance sheet date.

Balance as at 31 December 2018	Up to 1 year	1-3 years	3-5 years	More than 5 years
Trade and other payables	921	—	—	—
Other financial liabilities	245	—	—	—
Loans	—	—	13,000	—
Convertible note	3,300	—	—	—
Interests accrued	520	1,040	4,540	—
TOTAL	4,986	1,040	17,540	—

Balance as at 31 December 2017	Up to 1 year	1-3 years	3-5 years	More than 5 years
Trade and other payables	850	—	—	—
Other financial liabilities	195	—	—	—
Loans	—	—	10,000	—
Interests accrued	400	800	3,800	—
TOTAL	1,445	800	13,800	—

Balance as at 1 January 2017	Up to 1 year	1-3 years	3-5 years	More than 5 years
Trade and other payables	672	—	—	—
Other financial liabilities	350	—	—	—
Loans	—	—	—	—
Interests accrued	118	—	—	—
TOTAL	1,140	—	—	—

23.2. Capital Management

Capital comprises equity attributable to shareholders, cash and cash equivalents. Curetis' policy is to maintain a strong base in terms of equity capital and sufficient cash balance in order to maintain investor and creditors confidence and to sustain the future development of the business. Our primary goals when managing capital are to ensure sufficient liquidity to meet our working capital requirements, fund capital investments and purchases and to safeguard our ability to continue operating as a going concern. See note 3.22 for further discussion of going concern.

Curetis monitors all capital positions regularly (at least monthly) within its financial reporting, discusses the capital status frequently within the management meetings and also within its supervisory board meetings.

24. COMMITMENTS AND CONTINGENCIES

Operating lease and purchase commitments

Curetis leases its offices, laboratories, and production facility under non-cancellable operating lease agreements. The lease term is 5 years and the agreements are renewable at the end of the lease term at market rate. The manufacturing facility in Bodelshausen Curetis has a prolongation option.

Curetis also leases machinery and vehicles under non-cancellable operating lease agreements. The lease term is 3 years and the agreements are not renewable at the end of the lease term. The future aggregate minimum lease payments under non-cancellable operating leases and existing purchase commitments are as per the table below.

in kEUR	31 December 2018	31 December 2017	1 January 2017
From lease contracts:			
No later than 1 year	482	380	354
Later than 1 year and no later than 5 years	819	629	321
Later than 5 years	0	0	0
Total from lease contracts	1,301	1,009	675
From purchase and service agreements:			
No later than 1 year	4,487	4,575	5,227
Later than 1 year and no later than 5 years	4,331	2	813
Later than 5 years	0	0	0
Total from purchase and service agreements	8,818	4,577	6,040
Total	10,119	5,586	6,715

Curetis places frame-work orders for Unyvero-Systems and for raw materials for its cartridge manufacturing to ensure availability during commercial ramp-up-phase and also to gain volume-scale-effects with regards to purchase prices. Some of the electronic parts used for the production of Unyvero-Systems have lead times of many months, hence it is necessary to order such systems with long-term framework-orders to ensure the demands from market are covered.

25. RELATED PARTIES

The Company has reflected transactions with the parent company, Curetis N.V., as related party balances within the statement of operations and other comprehensive loss and the combined statement of financial position. Other related party transactions have been included below.

Curetis N.V. charges certain management fees for services rendered by the senior management of Curetis N.V. to Curetis GmbH and its subsidiaries resulting in other expenses from related parties. The transactions are charged at cost. Curetis N.V. is the controlling company for VAT purposes and receives VAT amounts due to Curetis GmbH as a controlled company, resulting in Other receivables, related party.

Curetis has entered into arrangements with a number of its subsidiaries, the financial impacts of which are eliminated in combination. Curetis considers transactions with key management personnel to be related party transactions. Any transactions with such individuals are also recorded in related party accounts.

During 2017 and 2018, the Curetis Business received shareholder contributions from Curetis N.V. of kEUR 3,000 and kEUR 19,000 of which kEUR 3,109 are presented as proceeds from current liabilities, net of issuance costs as that amount relates to the convertible notes that were issued by Curetis N.V. and legally contributed to the capital reserve of Curetis GmbH. For presentation purposes (See Note 2), that amount was presented as if the Curetis Business has issued such convertible notes.

Total compensation of key management: Certain amounts of these totals have previously been recharged in the normal course of business. For those amounts not recharged, they have been included in Shareholder contribution in Equity. See Note 3.19.

2018

in kEUR

Name	Base salary/ consultancy fee	Annual bonus ¹	Company Car	Share based payments and other incentives	Total remuneration
Johannes Bacher	220 ²	12	—	60 ³	292
Dr. Achim Plum	200	15	5	60 ³	280
Oliver Schacht	240	18	—	60 ³	318
Total	660	45	5	180	890

1 Relates to the bonus that was paid in 2018 post FDA clearance

2 Includes holiday compensation payouts

3 Expenses recognized for granted ESOP

2017

in kEUR

Name	Base salary/ consultancy fee	Annual bonus ¹	Company Car	Share based payments and other incentives	Total remuneration
Johannes Bacher	221	32	—	196	449
Dr. Achim Plum	215	30	5	196	446
Andreas Boos	128	17	—	23	168
Oliver Schacht	244	45	—	196	485
Total	808	124	5	611	1,548

¹ Relates to the bonus for performance year 2017 that was paid in 2018

in kEUR

	2018	2017
Salaries and other short-term employee benefits	705	965
Post-employment benefits ¹	8	—
Share based payments	180	622
Other	5	5
Total	898	1,592

¹ Post-employment benefits relate to the remuneration of a former managing director

Total compensation of Supervisory Board: Certain amounts of these totals have previously been recharged in the normal course of business. For those amounts not recharged, they have been included in Shareholder contribution in Equity. See note 3.19.

The compensation of Supervisory Board is shown below:

in kEUR	2018	2017
William E. Rhodes	105	95
Dr. Werner Schäfer	83	75
Mario Crovetto	64	55
Prabhavathi Fernandes	53	45
Nils Clausnitzer	51	31
Dr. Holger Reithinger	(11)	11
Total	345	312
thereof from equity stock options	99	66

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

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

Curetis does not grant any loans, advance payments and guarantees to members of the Management and Supervisory Board. There have been no other notable related party transactions.

EVENTS AFTER THE BALANCE SHEET DATE

Subsequent to 31 December 2018:

- Curetis GmbH entered into an agreement to combine its business with OpGen. See Note 2.1 for further information
- Curetis GmbH has drawn EUR 5 million on the existing EIB tranche.
- Curetis has drawn down the remaining EUR 1.5 million from the first tranche of the existing Yorkville Convertible Notes Facility.
- Curetis liquidated two of their wholly owned subsidiaries, Curetis France S.A.R.L. and Curetis BeNeLux B.V.

Holzgerlingen, 15 September 2019
Curetis GmbH

/s/ Oliver Schacht, PhD

Oliver Schacht, PhD
Chief Executive Officer (CEO)
Managing Director

/s/ Johannes Bacher

Johannes Bacher
Chief Operating Officer (COO)
Managing Director

/s/ Achim Plum

Dr. Achim Plum
Chief Business Officer (CBO)
Managing Director

/s/ Heiko Schorr

Heiko Schorr
Director Finance
Managing Director

Report of Independent Auditors

To the management of Curetis GmbH

We have audited the accompanying combined financial statements of the Curetis business of Curetis N.V., which comprise the combined statements of financial position as of December 31, 2018, December 31, 2017, and January 1, 2017 and the related combined statements of operations and other comprehensive loss, cash flows and changes in equity for the years ended December 31, 2018 and December 31, 2017.

Management's Responsibility for the Combined Financial Statements

Management is responsible for the preparation and fair presentation of the combined financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of combined financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on the combined financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the combined financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the combined financial statements. The procedures selected depend on our judgment, including the assessment of the risks of material misstatement of the combined financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the Company's preparation and fair presentation of the combined financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the combined financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the combined financial statements referred to above present fairly, in all material respects, the financial position of the Curetis business of Curetis N.V. as of December 31, 2018, December 31, 2017 and January 1, 2017 and the results of its operations and its cash flows for the years ended December 31, 2018 and December 31, 2017 in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Emphasis of Matter

The accompanying combined financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3.22 to the combined financial statements, the Company has suffered recurring losses from operations, has an accumulated deficit, and negative cash outflows from operating activities, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 3.22. The combined financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Munich, Germany
September 15, 2019

PricewaterhouseCoopers GmbH
Wirtschaftsprüfungsgesellschaft

/s/ Dietmar Eglauer

Dietmar Eglauer
Wirtschaftsprüfer
(German Public Auditor)

/s/ ppa. Andreas Schuster

ppa. Andreas Schuster
Wirtschaftsprüfer
(German Public Auditor)

CURETIS BUSINESS**UNAUDITED INTERIM CONDENSED COMBINED STATEMENT OF OPERATIONS AND OTHER COMPREHENSIVE LOSS**

For the six months ended 30 June

in kEuro	Note	six months ended 30 June 2019	six months ended 30 June 2018
Revenue	4	1,088	807
Cost of sales		(1,342)	(1,095)
Gross profit (loss)		(254)	(288)
Distribution costs	5	(3,270)	(4,209)
Administrative expenses	6	(1,612)	(1,867)
Research & development expenses	7	(4,181)	(4,680)
Other income		114	189
Operating loss		(9,203)	(10,855)
Finance income		7	50
Finance costs		(744)	(494)
Finance result - net	8	(737)	(444)
Loss before income tax		(9,940)	(11,299)
Income tax expenses		(56)	26
Loss for the period		(9,996)	(11,273)
Foreign currency translation gain (loss)*		13	53
Total comprehensive loss for the period		(9,983)	(11,220)

*Exchange differences on translation of foreign operations, which may be recycled through profit and/or loss in the future.

The accompanying notes are an integral part of these combined financial statements.

CURETIS BUSINESS
UNAUDITED INTERIM CONDENSED COMBINED STATEMENT OF FINANCIAL POSITION

As of 30 June 2019 and 31 December 2018

in kEuro

	Note	30 June 2019	31 December 2018
Current assets		10,732	11,888
Cash and cash equivalents	13	4,779	4,800
Trade receivables	13	196	323
Other receivables, related party	16	264	453
Contractual assets		215	—
Inventories	9	4,715	6,052
Prepaid Expenses and Other current assets		563	260
Non-current assets		12,563	10,850
Intangible assets		7,354	7,425
Property, plant and equipment	10	3,738	3,196
Right of use assets	11	1,298	—
Other non-current financial assets	13	158	158
Deferred tax assets		15	71
Total assets		23,295	22,738
Current liabilities		5,701	5,773
Trade and other payables	13	731	921
Other liabilities, related party	16	186	187
Provisions current		130	65
Tax liabilities		2	22
Other current liabilities		952	881
Other current financial liabilities	12,13	3,267	3,697
Current lease liabilities	15	433	—
Non-current liabilities		20,539	13,993
Provisions non-current		44	44
Other non-current financial liabilities	12,13	19,623	13,949
Non-current lease liabilities	15	872	—
Total liabilities		26,240	19,766
Equity		(2,945)	2,972
Subscribed capital		5,554	5,554
Capital reserve		161,913	157,847
Currency translation differences		(62)	(75)
Accumulated deficit		(170,350)	(160,354)
Total Equity and liabilities		23,295	22,738

The accompanying notes are an integral part of these combined financial statements.

CURETIS BUSINESS
UNAUDITED INTERIM CONDENSED COMBINED STATEMENT OF CASH FLOWS
For the six months ended 30 June

in kEuro

	Note	six months ended 30 June 2019	six months ended 30 June 2018
Net loss for the period		(9,996)	(11,273)
Adjustment for:			
- Net finance income (costs)	8	737	444
- Depreciation, amortization and impairments	10,11	825	618
- Share-based payment expense	14	247	251
- Changes in deferred tax assets and liabilities		56	(45)
Changes in working capital relating to:			
- Inventories	9	1,337	(215)
- Trade receivables and other receivables		(197)	608
- Trade payables and other payables		235	(409)
Income taxes received (+) / paid (-)		56	(26)
Interest paid (-)		(530)	(406)
Net cash flow used in operating activities		(7,230)	(10,453)
Payments for intangible assets		(31)	(67)
Payments for property, plant and equipment	10	(1,049)	(163)
Net cash flow used in investing activities		(1,080)	(230)
Proceeds from other non-current financial liabilities	12	5,000	3,000
Proceeds from current financial liabilities (convertible notes), net of issuance cost		1,373	—
Capital increase in cash from shareholder		1,627	10,000
Shareholder contributions		478	725
Principle elements of leases paid		(203)	—
Net cash flow provided by financing activities		8,275	13,725
Net decrease / increase in cash and cash equivalents		(35)	3,042
Net cash and cash equivalents at the beginning of the year		4,800	3,468
Effects of exchange rate changes on cash and cash equivalents		14	76
Net Cash and cash equivalents at the end of the period		4,779	6,586

The accompanying notes are an integral part of these combined financial statements.

CURETIS BUSINESS

UNAUDITED INTERIM CONDENSED COMBINED STATEMENT OF CHANGES IN EQUITY

For the six months ended 30 June

in kEuro	Subscribed capital	Capital reserve	Currency translation difference	Accumulated deficit	TOTAL equity
Balance at 1 January 2018	5,554	140,402	(160)	(137,543)	8,253
Loss of the period				(11,273)	(11,273)
Other comprehensive income			50		50
Total comprehensive income	—	—	50	(11,273)	(11,223)
Transactions with owners in their capacity as owners					
Capital increase		10,000			10,000
Shareholder contributions		725			725
Share-based payments		251			251
Balance as of 30 June 2018	5,554	151,378	(110)	(148,816)	8,006

in kEuro	Subscribed capital	Capital reserve	Currency translation difference	Accumulated deficit	TOTAL equity
Balance at 1 January 2019	5,554	157,847	(75)	(160,354)	2,972
Loss of the period				(9,996)	(9,996)
Other comprehensive income			13		13
Total comprehensive income	—	—	13	(9,996)	(9,983)
Transactions with owners in their capacity as owners					
Capital increase		3,341			3,341
Shareholder contribution		478			478
Share-based payments		247			247
Balance as of 30 June 2019	5,554	161,913	(62)	(170,350)	(2,945)

The accompanying notes are an integral part of these combined financial statements.

1. GENERAL INFORMATION ABOUT THE COMPANY

These combined financial statements comprise the Curetis business (collectively referred to as “the Group,” “Curetis” or the “Company”). The Group’s headquarter is located at Max-Eyth-Str. 42, 71088 Holzgerlingen, Germany. The Group is an early commercial-stage molecular diagnostics (MDx) company focused on rapid infectious disease testing for hospitalized patients with the aim to improve the treatment of critically ill patients with suspected microbial infections. The Curetis business is primarily operated by Curetis GmbH and its wholly owned subsidiaries.

The first Group entity, Curetis AG, was created in Germany in 2007 and was primarily funded through equity investments from venture capital and private equity investors. In 2015, in connection with an initial public offering (“IPO”), Curetis N.V. was created as a parent entity to Curetis AG and in that same year the stock of Curetis N.V. was sold in an IPO on the Euronext market. In 2016 Curetis AG was changed to Curetis GmbH. Since 2015, the operations of Curetis have been financed through contributions from Curetis N.V. from proceeds of the IPO, secondary offerings, and various other financing agreements Curetis N.V. has entered into, including Convertible Notes, the EIB financing and government grants.

At 15 September 2019 the Management Board authorized the unaudited interim condensed combined financial statements for issue and passed it through to the Supervisory Board for review and authorization.

1.1. General information about the business and the commercial development of the company.

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

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

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

- Curetis UK Ltd., London, UK (in liquidation)
- Curetis Schweiz GmbH, Zug, Switzerland (in liquidation)
- Curetis BeNeLux B.V. , Amsterdam, the Netherlands (dissolved 25.06.2019)
- Curetis France S.A.R.L., Strasbourg, France (dissolved 24.03.2019)

2. BASIS OF PREPARATION – UNAUDITED INTERIM CONDENSED COMBINED FINANCIAL STATEMENTS

2.1. Basis of presentation

The accompanying unaudited interim condensed combined financial statements of Curetis have been prepared for filing with the United States Securities and Exchange Commission (SEC) in connection with the proposed acquisition of all of the outstanding shares of Curetis GmbH by OpGen Inc. (“OpGen”), pursuant to an agreement to combine the two companies’ businesses. Following the agreement, OpGen will acquire 100% of Curetis GmbH’s assets and liabilities, including the Curetis name as well as the outstanding indebtedness of Curetis N.V. under certain convertible notes, including providing that the conversion rights of the notes may be changed from a right to convert into shares of Curetis N.V. to a right to convert into shares of OpGen. In addition, OpGen has also agreed to acquire all of the assets of Curetis N.V. that are solely and exclusively related to the business of Curetis GmbH and assume (1) the Curetis N.V. 2016 Stock Option Plan, as amended, and the outstanding awards thereunder, or the 2016 Stock Option Plan, and (2) the obligation to issue equity to the holders of awards under the Curetis AG Phantom Stock Option Plan, or the PSOP. OpGen will also assume all of the liabilities of Curetis N.V. solely and exclusively related to the business being acquired.

The business combination is subject to a number of conditions including (i) the satisfaction of customary conditions to closing for a transaction of this type, including the absence of a material adverse event for either party, (ii) for each OpGen and Curetis, appropriate approvals by their respective shareholders, (iii) for Curetis, consents from certain debt financing providers, (iv) the Form S-4 having been declared effective by the U.S. Securities and Exchange Commission, (v) the new shares of OpGen’s common stock to be issued (or reserved for issuance) in connection with the transaction having been approved for listing on Nasdaq and (vi) OpGen having secured additional funding prior to Closing.

The Curetis business is primarily operated by Curetis GmbH and its wholly owned subsidiaries. However, certain costs related to the Curetis business, primarily related to the compensation of certain members of senior management and its supervisory board, have historically been incurred by Curetis N.V. but have not been recharged by Curetis N.V. to Curetis GmbH or its subsidiaries. SEC Staff Accounting Bulletin (SAB) Topic 1.B. (“SAB 1.B”) *Allocation of Expenses and Related Disclosure in Financial Statements of Subsidiaries, Divisions or Lessor Business Components of Another Entities* states that the historical income statements of a registrant should reflect all of its costs of doing business and therefore in specific situations requires a subsidiary to reflect certain expenses incurred by the parent on its behalf. In addition, the unaudited interim combined financial statements include the convertible notes issued by Curetis N.V. as well as related expense. The proceeds of the issuance of the convertible notes were historically contributed to the Curetis GmbH via cash contributions to capital reserves. Accordingly, the unaudited interim condensed combined financial information of Curetis have been prepared to combine the consolidated interim financial statements of Curetis GmbH together with certain costs incurred by Curetis N.V. on behalf of Curetis GmbH. As a result, the unaudited interim condensed combined financial statements of Curetis do not currently constitute a separate group of legal entities.

During the six months ended 30 June 2018 and 2019, the costs incurred by Curetis N.V. that have been allocated to the Company for the purposes of preparing the unaudited interim condensed combined financial statements are based on a specific identification basis where possible. Management believes that the assumptions used in determining these allocations are reasonable. However, the financial statements may not necessarily reflect the Company’s financial position, results of operations, or cash flows in the future, or what its financial position, results of operations, or cash flows would have been if it had been a stand-alone entity during the periods presented.

IFRS does not provide principles for the preparation of combined financial statements for carve-out financial statements, and accordingly in preparing the unaudited interim condensed combined financial statements certain accounting and allocation conventions commonly used in practice for the preparation of carve-out financial statements were applied. The assets and liabilities included in the unaudited interim condensed combined statement of financial position were measured at the carrying amounts recorded in the Curetis N.V. condensed interim consolidated financial statements.

The unaudited interim condensed combined financial statements and notes for the six months ended 30 June 2019 have been prepared in accordance with International Accounting Standards (“IAS”) 34 *Interim Financial Reporting* and have been prepared on the same basis of accounting as the audited annual combined financial statements, with the exception of the accounting of lease agreements, which are accounted for according to IFRS 16 *Leases* starting 1 January 2019 (refer to note 3.1). Certain information and footnote disclosures typically included in annual financial statements prepared in accordance with IFRS have been condensed or omitted. Accordingly, these unaudited interim condensed combined financial statements should be read in conjunction with the Company’s combined financial statements as of and for the year ended 31 December 2018.

The condensed combined financial statements have been prepared on a going concern basis (see also Note 3.4 below). These condensed combined financial statements are presented in Euro and, where appropriate, have been rounded to the nearest thousand (abbreviated kEUR). All intercompany accounts and transactions have been eliminated in consolidation.

2.2. Scope of combination

Curetis GmbH is domiciled in Germany. Details of the Group's subsidiaries at the end of the reporting period are as follows:

Name	Registration No.	Country	Participation	Main activity
Curetis USA Inc.	EIN 81-3113346	USA	100.00%	Sale of molecular diagnostic products
Curetis UK Ltd.	10164457	UK	100.00%	Sale of molecular diagnostic products
Curetis Schweiz GmbH	CHE-228.103.501	Switzerland	100.00%	Sale of molecular diagnostic products
Ares Genetics GmbH	468899h	Austria	100.00%	Maximize R&D and related scientific opportunities with Aresdb Bio-IT platform (previously GEAR)

2.3. Critical accounting judgements and key sources of estimation uncertainty

The preparation of financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue, income and expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed combined financial statements include, but are not limited to, the useful life of intangible assets, provisions, inventory valuation, and lease term. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.

Preparing these carve-out combined financial statements required management to make judgement within the identification of certain costs incurred by Curetis N.V. on behalf of Curetis GmbH and reflected back to the combined financial statements of Curetis GmbH. Management evaluated on historical experience the best approach by identifying such costs.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

3.1. New standards and interpretations applied for the first time

The accounting policies adopted in the preparation of the interim financial statements are consistent with those followed in the preparation of the Group's annual combined financial statements for the year ended 31 December 2018, except for the adoption of new standards effective as of 1 January 2019. New standards, amendments to standards and new or amended interpretations are effective for annual periods beginning on or after 1 January 2019, and have been applied as required in preparing these financial statements. Curetis has not opted for early adoption for any of these standards.

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

The Group has assessed the accounting standards effective after 1 January 2019 and determined that none have a material impact on the unaudited condensed combined financial statements with the exception of IFRS 16, which has been applied in these interim financial statements and as required by IAS 34, the nature and effect of these changes are disclosed below.

First time adoption of IFRS 16 – Leases

Adopted as of current period

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

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

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

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

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

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

Transition and impact assessment on IFRS 16

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

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

In kEUR

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

The adoption of IFRS 16 had no impact on the Company's sales. Lease expense has been replaced by depreciation and interest expense, which had an immaterial impact to the statement of operations for the six months ended 30 June 2019.

In addition, the cash flow from operating activities for the six months ended 30 June 2019 was positively impacted by approximately kEUR 224 as, under the new standard, cash payments for the principal portion of the lease liabilities are classified in the cash flow from financing activities rather than in the cash flow from operating activities.

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

Leases previously accounted for as operating leases

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

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

in kEUR

Operating lease commitments as of 31 December 2018	1,301
Impact of present value discount	-107
Short term leases excluded	-94
Impact of lease extensions entered into in 2019	394
IFRS 16 opening balance impact on lease liabilities as of 1 January 2019	1,494

Summary of new accounting policies

Right-of-use assets

The Company recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any re-measurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date, less any lease incentives received. Unless the Company is reasonably certain ownership of the leased asset will be obtained at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of-use assets are subject to impairment assessment.

Lease liabilities

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

In calculating the present value of lease payments, the Company uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is reduced for the lease payments made. In addition, the carrying amount of lease liabilities is re-measured if there is a contract modification, change in the lease term, change in the in-substance fixed lease payments, or a change in the assessment to purchase the underlying asset.

Significant judgement in determining the lease term of contracts with renewal options

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

3.2. Standards, interpretations, and amendments issued, but not yet applied

The following new standards and interpretations and amendments to existing standards will become effective after 1 January 2020.

Standard/Interpretation	Content	Application mandatory from
Amendments to IFRS 3	Clarifying the definition of “businesses”	1 January 2020
Amendments to IAS 1 and IAS 8	Clarifying the definition of “material”	1 January 2020
IFRS 17 (replaces IFRS 4)	Insurance Contract	1 January 2021

The Group has assessed the accounting standards effective after 1 January 2020 and determined that none are likely to have a material impact on the combined financial statements.

3.3. Use of assumptions and estimates

The preparation of interim financial statements in conformity with IFRS requires management 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. Except for the judgement and estimates mentioned in relation to the adoption of IFRS 16, the significant estimates and judgements in preparing the condensed combined interim financial statements, made by management in applying the accounting policies and the sources of estimation uncertainty, were the same as those applied to the Company’s combined financial statements for the year ended 31 December 2018.

3.4. Going concern

Since inception, the Company's activities have consisted primarily of performing research and development to advance its technologies and more recently, establishing sales and distribution networks to commercialize its technology. Through 30 June 2019, the Company has not yet established a stable ongoing source of revenues sufficient to cover its operating costs and has funded its operations through proceeds from equity investments, collaboration and licensing agreements, grants and borrowings under various agreements with funding agencies, and contributions from Curetis N.V., the ultimate holding company of Curetis GmbH as of 30 June 2018 and 2019, from the sale of Curetis N.V. stock in an Initial Public Offering, secondary offerings and various other financing agreements. Since inception, the Company has incurred recurring losses (with the exception of 2015 due to an extraordinary gain), including net losses of EUR 10.0 million and EUR 22.7 million for the six months ended 30 June 2019 and year ended 31 December 2018, respectively. As of 30 June 2019, the Company had an accumulated deficit of EUR 170.4 million, EUR 4.8 million in cash and cash equivalents, trade receivables of EUR 0.2 million.

The Company also realized the following inflows of funds from financing during 2019.

- EIB Debt Financing Facility has funded the EUR 5 million milestone tranche in June 2019, however, Curetis believes this was the last of the debt financing tranches that Curetis could or would access under the current EIB facility.
- Yorkville Convertible Notes facility withdrawal of EUR 1.5 million.
- Capital contribution from Curetis N.V. of EUR 1.6 million.

Despite the cost reduction measures already implemented in Europe and the USA, the Company expects to continue to generate operating losses in the foreseeable future, the existing current assets, including cash, as well as the aforementioned secured external funding sources are not sufficient to finance Curetis' operating activities for said 12 months after the signing date of these financial statements.

Substantial doubt regarding the Group's ability to continue as a going concern exists as of 15 September 2019, the issuance date of these unaudited condensed combined interim financial statements. The Company's Management believes that if it can realize cash-inflow and funding measures, execute on strategy options, realize liquidity planning and implement these planned measures as needed, funding of our business operations for a period of at least 12 months after the issue date of these financial statements is achievable. Curetis is in the process of evaluating and progressing strategic and liquidity planning options to be able to raise additional capital and reduce costs, including:

- The negotiation and implementation of a strategic option and scenario that, if successful, would allow Curetis to access the capital markets and raise additional capital again.
- Curetis aims at accessing cash relating to entering into one or more licensing and partnering deal(s) around its Unyvero A30 RQ platform and Aresdb. A draft term sheet has been received for Unyvero A30 RQ and is currently under negotiation; however, none are currently committed or secured.
- Potentially putting on hold, delaying, or reducing further expenditures for certain R&D, commercialization and operational programs.

The Company has also engaged financial and other advisors to assist it in those efforts.

The Company will seek additional funding and to execute on these strategic business and commercial plans in order to reach its development and commercialization objectives. There are no assurances the Company will be able to obtain financing on acceptable or favorable terms, or at all, and the Company may not be able to execute on strategic business and commercial plans or to enter into collaborations or other arrangements. The Company is primarily dependent on its parent, Curetis N.V., for financing. Further, Curetis N.V. is not an operational entity that generates cash inflows, rather, is reliant on its shareholders and other external financing to remain funded. In the event the Company is unable to successfully raise additional capital during or before the fourth quarter of 2019, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to immediately and significantly reduce general and administrative expenses, delay research and development projects, and product portfolio expansion or commercialization efforts until it is able to obtain sufficient financing, which could adversely affect its business prospects. If such sufficient financing is not received on a timely basis, the Company would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

The accompanying condensed combined interim financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The condensed combined financial statements do not reflect any adjustments relating to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

4. REVENUE

in kEUR	six months ended 30 June 2019	six months ended 30 June 2018
Sale of Unyvero-Systems	146	369
Sale of cartridges	425	435
Sale of services	517	3
Total	1,088	807

The Sale of services includes 215 kEUR of revenues recognized for services provided but not yet billed, which are recorded as a contractual asset as of 30 June 2019.

In accordance with IFRS 8, Curetis is a single-segment entity. Revenues from external customers by territory, based on the destination of the customers are as follows:

in kEUR	six months ended 30 June 2019	six months ended 30 June 2018
EMEA	940	657
USA	82	32
Asia	66	118
Total	1,088	807

All revenues are derived from external customers, including hospitals as well as distribution partners.

5. DISTRIBUTION COSTS

in kEUR	six months ended 30 June 2019	six months ended 30 June 2018
Personnel expenses	1,843	2,671
Depreciation and Amortization	46	51
Other operating expenses	1,381	1,487
<i>thereof marketing expenses</i>	534	712
<i>thereof travel expenses</i>	192	365
<i>thereof consulting, advisory & 3rd party service</i>	108	107
TOTAL	3,270	4,209

6. ADMINISTRATIVE EXPENSES

in kEUR	six months ended 30 June 2019	six months ended 30 June 2018
Personnel expenses	565	646
Depreciation and Amortization	218	44
Other expenses	829	1,177
<i>thereof for remuneration of supervisory board</i>	206	210
<i>thereof consulting, advisory & 3rd party service</i>	178	302
TOTAL	1,612	1,867

7. RESEARCH AND DEVELOPMENT EXPENSES

in kEUR	six months ended 30 June 2019	six months ended 30 June 2018
Personnel expenses	1,805	1,992
Depreciation and Amortization	373	354
Material expenses	274	139
Other expenses	1,729	2,195
<i>thereof IP-fees and expenses for patent lawyers</i>	121	370
<i>thereof external services for clinical trial</i>	99	83
<i>thereof costs for laboratory demand</i>	115	278
<i>thereof consulting, advisory & 3rd party service</i>	785	890
<i>thereof other manufacturing expenses for cartridges used in R&D</i>	252	120
TOTAL	4,181	4,683

8. FINANCE RESULT / COSTS NET

In the six months ended 30 June 2019 the net finance loss of kEUR 640 (six months ended 30 June 2018 to a loss of kEUR 444), is primarily from interest from the EUR 18 million cumulative tranche drawn downs from the EIB debt facility and foreign currency exchange difference resulting from the exchange rate difference of USD vs. EUR.

in kEUR	six months ended 30 June 2019	six months ended 30 June 2018
Foreign exchange differences	1	27
Interests for borrowings	(628)	(471)
Interest and finance expenses for convertible notes	(97)	—
Other finance income / finance costs	(13)	—
Finance result/costs net	-737	-444

Interests for borrowings represent interest and financing charges paid/payable for financial liabilities not at fair value through profit or loss using the effective interest method.

9. INVENTORIES

in kEUR	30 June 2019	31 December 2018
Raw materials	759	838
Semi-finished goods	36	61
Trade goods	3,657	4,987
Finished goods	125	65
Spare parts	138	101
Total inventories, net	4,715	6,052

The obsolescence write-downs on inventories is considered a significant estimate with inherent uncertainty. Given Curetis does not yet have a reliable sales-track-record, the write-downs are based on the best estimate considering technical aging and estimated sales volumes and prices for systems. If assumptions regarding future sales prices, volumes, useful life or product market potentials are not appropriate, this may lead to a further need for write-off. A reduction in the estimated sales price of 10% would result in an increase of obsolescence write-downs of kEUR 310, whereas an increase in the estimated sales price of 10% would result in a decrease of the obsolescence write-downs of kEUR 217. A reduction in the estimated useful life of five years of the Unyvero system by one year would result in an increase of obsolescence write-downs of kEUR 630, whereas an increase in the estimated useful life of the Unyvero systems by one year would result in a decrease of obsolescence write-downs of kEUR 592.

The change of write-off to net asset value of inventories recognized as an expense and included in 'Cost of Sales' in the six months ended 30 June 2019 amounted to kEUR 556 (2018: kEUR 126).

10. PROPERTY, PLANT AND EQUIPMENT

in kEUR	Land and buildings	Machines and technical installation	Other tangible assets	Assets under construction	Total
Cost:					
Balance as of 1 January 2018	72	7,852	2,636	289	10,849
Additions	—	31	215	424	670
Disposals	—	—	(81)	—	(81)
Reclassifications	—	417	—	(417)	—
Balance as of 31 December 2018	72	8,300	2,770	296	11,438
Accumulated depreciation:					
Balance as of 1 January 2018	(49)	(5,243)	(1,991)	—	(7,283)
Disposals	—	—	80	—	80
Depreciation	(8)	(701)	(330)	—	(1,039)
Reclassifications	—	—	—	—	—
Balance as of 31 December 2018	(57)	(5,944)	(2,241)	—	(8,242)
Carrying amount as of 31 December 2018	15	2,356	529	296	3,196
Cost:					
Balance as of 1 January 2019	72	8,300	2,770	296	11,438
Additions	—	50	576	425	1,051
Disposals	—	(4)	(11)	—	(15)
Reclassifications	—	193	—	(193)	—
Balance as of 30 June 2019	72	8,539	3,335	528	12,474
Accumulated depreciation:					
Balance as of 1 January 2019	(57)	(5,944)	(2,241)	—	(8,242)
Disposals	—	3	7	—	10
Depreciation	(4)	(343)	(157)	—	(504)
Reclassifications	—	—	—	—	—
Balance as of 30 June 2019	(61)	(6,284)	(2,391)	—	(8,736)
Carrying amount as of 30 June 2019	11	2,255	944	528	3,738

Curetis did not own any of these assets under any lease programs in 2018 or 2019. All property, plant and equipment are free from any rights held by third parties.

11. RIGHT-OF-USE ASSETS

in kEUR	Real estate	IT-Equipment	car fleet	Total
Cost:				
Balance as of 1 January 2018	-	-	-	-
Cost:				
Initial recognition 01.01.2019	1,450	5	39	1,494
Additions	—	—	22	22
Balance as of 30 June 2019	1,450	5	61	1,516
Accumulated amortization:				
Balance as of 1 January 2019	—	—	—	—
Amortization:	(207)	(2)	(9)	(218)
Balance as of 30 June 2019	(207)	(2)	(9)	(218)
Carrying amount as of 30 June 2019	1,243	3	52	1,298

Refer to Note 3.1 for additional information on right-of-use assets.

12. FINANCIAL LIABILITIES

Current financial liabilities consist of the Convertible notes that were issued to Yorkville Advisors (Yorkville) on 02 October 2018 by Curetis N.V. Under the first tranche, 500 notes are available for issuance, of which 350 notes were issued as of 02 October 2018 (subscription date) and 150 notes were issued in June 2019. Each note has a nominal value of kEUR 10 and a maturity of one year. The notes were issued at an 8% discount, due to a 4% commitment fee and a 4% subscription fee. The Company incurred kEUR 120 in issuance costs related to due diligence and legal fees.

The holders of the outstanding notes have the right to convert the notes in exchange for shares of Curetis N.V. at any time. The number of shares to be issued upon conversion of a note is determined by the nominal amount of the note divided by 93% of the last 10-day lowest VWAP (volume weighted average price) of a common share of Curetis N.V. on the conversion date. As of 30 June 2019, 198 notes had been converted to shares of Curetis N.V. and subsequent to that date an additional 152 notes have been converted.

In connection with the proposed acquisition of Curetis by OpGen, it is expected that the remaining notes are expected to be converted into shares of OpGen, rather than of shares of Curetis N.V., subject to the consent of Yorkville. Curetis assumes that all notes will be converted within the original maturity of one year from the date of issuance and that the likelihood of executing the extension option is remote.

In June 2019 Curetis has drawn down a third tranche of EUR 5 million from the EIB (European Investment Bank). In line with all prior tranches, the majority of interest is also deferred into the bullet repayment structure upon maturity. In return for EIB waiving the condition precedent of a minimum cumulative equity capital raised of EUR 15 million to disburse this EUR 5 million tranche, the parties have agreed on a 2.1% participation percentage interest (PPI). Upon maturity of the tranche, i.e. not before around mid-2024 (and no later than mid-2025), EIB will be entitled to an additional payment that is equity-linked and equivalent to 2.1% of the then total valuation of Curetis. This right constitutes an embedded derivative, which is separated and measured at fair value with changes being accounted for through profit or loss.

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

in kEUR	30 June 2019		31 December 2018	
	current	non-current	current	non-current
Loan from EIB	—	18,000	—	13,000
Embedded derivative	—	301	—	—
Accrued interest	88	1,322	343	949
Total	88	19,623	343	13,949

13. FINANCIAL INSTRUMENTS

For each class of financial instrument the fair value of financial assets and liabilities, together with their carrying amounts contained in the condensed combined financial statements are shown in the following schedules.

in kEUR	30 June 2019				31 December 2018			
	Category in accordance with IFRS9	Carrying amount	Fair Value	Fair Value Level	Category in accordance with IAS 39	Carrying amount	Fair Value	Fair Value Level
Current Assets								
Cash and Cash Equivalents	AC	4,779	n/a *	n/a	AC	4,800	n/a *	n/a
Trade Receivables	AC	196	n/a *	n/a	AC	323	n/a *	n/a
Non-current Assets								
Other non-current financial assets	AC	158	158	2	AC	158	158	2

n/a*: For short-term financial instruments a fair value disclosure is not required as the carrying amount approximates the fair value.

in kEUR	30 June 2019				31 December 2018			
	Category in accordance with IFRS9	Carrying amount	Fair Value	Fair Value Level	Category in accordance with IAS 39	Carrying amount	Fair Value	Fair Value Level
Current Liabilities								
Trade and other Payables	FLAC	731	n/a *	n/a	FLAC	921	n/a *	n/a
Other current financial liabilities	FLAC	2,776 ⁽¹⁾	n/a *	n/a	FLAC	3,154	n/a *	n/a
Other current financial liabilities	FVTPL	491 ⁽²⁾	491	3	FVTPL	543	543	3
Non-current Liabilities								
Other non-current financial liabilities	FLAC	19,623	19,084	2	FLAC	13,949	13,546	2

n/a* = For short-term financial Instruments a fair value disclosure is not required as the carrying amount approximates the fair value.

(1) Consists of liabilities for outstanding invoices, Convertible notes and provision for deferred interest.

(2) Consists of conversion rights related to Convertible notes

During the six months ended 30 June 2019, there were no reclassifications of financial assets or financial liabilities between the classes.

The fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The fair value of the embedded derivative separated from the third tranche of the EIB loan was determined using observable inputs (Curetis N.V. share price, own credit spread) and assumptions for not observable inputs (exercise of conversion rights regarding the convertible notes; date of requesting for PPI payment within a 12 months period from about the due date of the third tranche of the EIB loan). These assumptions lead to the inclusion of the fair value within level 3 of the fair value hierarchy. The fair value of the compound embedded derivative separated from the convertible note is determined using observable inputs (Curetis N.V. share price, own credit spread) and assumptions about the rational economic behavior of the related parties which are not observable input parameters. These assumptions lead to the inclusion of the fair value within level 3 of the fair value hierarchy.

Secured liabilities and assets pledged as security

Curetis has pledged cash on bank accounts as rent deposit for lease agreements with a total value of kEUR 64 and for credit card deposits and bank guarantees with a total value of kEUR 94.

14. SHARE-BASED PAYMENTS

The Executives and Supervisory Board of Curetis GmbH as well as certain employees of the Group are included in the Employee Stock Option Plan 2016 “ESOP” of Curetis N.V.. The expenses associated with these individuals are recognized by the Group, which employ and benefit from the employment of the individuals holding notional stocks in Curetis N.V..

Capital reserve increase corresponding to the expenses accounted for the share-based payment of the ESOP 2016.

The following table illustrates the number and exercise prices of the movements in employee stock options during the year, as well as the grant date and the remaining term of the option (Note, valuation inputs; stock price, dividend yields, volatility etc. are related to the stock of Curetis N.V.):

	<u>Tranche 1</u>	<u>Tranche 2</u>	<u>Tranche 3</u>	<u>Tranche 4</u>	<u>Tranche 5</u>	<u>Tranche 6</u>
	1 July 2016	1 October 2016	1 January 2017	1 April 2017	1 July 2017	1 October 2017
Grant date	1 July 2016	1 October 2016	1 January 2017	1 April 2017	1 July 2017	1 October 2017
Granted stock options	170,000	45,000	42,500	5,000	20,000	123,500
	7.00	7.25	7.50	7.75	8.00	8.25
Remaining contractual term of the option	years	years	years	years	years	years
	6.45	6.41	6.42	5.81	4.93	4.98
Exercise price	Euro	Euro	Euro	Euro	Euro	Euro
Outstanding at 1 January 2019	132,778	22,500	41,458	5,000	7,778	106,833
Granted during the year	—	—	—	—	—	—
Forfeited during the year	833	—	6,667	—	—	14,583
Exercised during the year	—	—	—	—	—	—
Outstanding at 30 June 2019	131,945	22,500	34,791	5,000	7,778	92,250
Exercisable at 30 June 2019	131,945	—	—	—	—	—

	Tranche 7	Tranche 8	Tranche 9	Tranche 10	Tranche 11
Grant date	1 January 2018	1 March 2018	1 July 2018	1 October 2018	1 January 2019
Granted stock options	25,000	102,00	40,500	110,000	322,000
Remaining contractual term of the option	8.50 years	8.67 years	9.00 years	9.25 years	9.50 years
Exercise price	3.86 Euro	6.51 Euro	4.62 Euro	3.29 Euro	1.40 Euro
Outstanding at 1 January 2019	25,000	97,000	37,500	110,000	—
Granted during the year	—	—	—	—	322,000
Forfeited during the year	16,389	21,445	22,000	—	35,000
Exercised during the year	—	—	—	—	—
Outstanding at 30 June 2019	8,611	75,555	15,500	110,000	287,000
Exercisable at 30 June 2019	—	—	—	—	—

The Annual General Shareholder meeting (“AGM”) on 27 June 2019 approved the granting of additional stock options under the ESOP 2016 Plan to the members of the Management Board as well as Supervisory Board, respectively. These were granted effective 1 July 2019 and had the same terms as other grants under the ESOP 2016.

Valuation model and input parameters

The fair value of the stock options is measured using a binominal option pricing model taking into account the terms and conditions upon which the options were granted. The following table lists the inputs to the model used for the options granted in the first six months of 2019 at the measurement date (all other input parameters for grants prior to 2019 remain unchanged from the combined financial statements as of 31 December 2018:

	Tranche 11
Measurement date ¹	1 January 2019
Expected life of the option on the grant date (years)	5
Share price on the measurement date (€)	1.5
Weighted avg. exercise price	1.4
Expected dividend yield (%)	0
Risk-free interest rate (%)	-0.3
Expected volatility of the share price (%)	64.25
Option value (€)	0.81

¹ The measurement date represents the acceptance date of the option

For stock option valuation the possibility of early exercise was considered in the binomial model. Management determined an estimated early exercise is expected five years after the date of grant of the options based on considered the following factors:

The length of the vesting period has been considered since the share options cannot be exercised until the end of the 3-year vesting period – i. e. the expected option life of 5 years is 2 years after the first possible exercise date.

The Company does not have historical data points or experience from past option programs and to date no options have been exercised, however, due to normal fluctuation as well as fluctuations triggered by the recent re-organization there have been multiple cases of forfeited options. As a result, the Company does not have any actual data available regarding the average length of time that similar options have remained outstanding in the past or if the employee's level within the Company will impact the timing of exercise.

The risk-free interest rate is the implied yield currently available on German government issued bonds with a remaining term equal to the term of the options.

The future volatility for the lives of the options was estimated based on historical volatility of peer group companies.

The expense recognized during the six months ended 30 June 2019 and the six months ended 30 June 2018 is shown in the following table:

in kEUR	30 June 2019	30 June 2018
<i>Expense arising from equity-settled share-based payment transactions</i>		
Cost of sales	6	—
Distribution costs	132	122
Administrative expenses	51	62
Research & development expenses	59	67
Total	248	251

The Group does not consider paying dividends as long as the result from operating activities in the condensed combined statement of operations and other comprehensive loss and the cash flows from operating activities are negative.

15. LEASE LIABILITIES

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

Extension and termination options are included in a number of property and equipment leases across the group. These terms are used to maximize operational flexibility in terms of managing contracts. The majority of extension and termination options held are exercisable only by the group and not by the respective lessor. No lease payments made in 2019 were optional.

The following table shows the maturity analysis of lease liabilities as of 30 June 2019.

Contractual Maturities of Financial Liabilities	Up to One Year	Between One and Five Years	More than Five Years	Total Contractual Cash Flows	Carrying Amount Liabilities
Lease Liabilities	454	816	73	1,343	1,305

Refer to Note 3.1 for additional information on lease liabilities.

16. RELATED PARTIES

The Company has reflected transactions with the parent company, Curetis N.V., as related party balances within the statement of operations and other comprehensive loss and the combined statement of financial position. Other related party transactions have been included below.

Curetis N.V. charges certain management fees for services rendered by the senior management of Curetis N.V. to Curetis GmbH and its subsidiaries resulting in other expenses from related parties. The transactions are charged at cost. Curetis N.V. is the controlling company for VAT purposes and receives VAT amounts due to Curetis GmbH as a controlled company, resulting in Other receivables, related party.

Curetis has entered into arrangements with a number of its subsidiaries, the financial impacts of which are eliminated in combination. Curetis considers transactions with key management personnel to be related party transactions. Any transactions with such individuals are also recorded in related party accounts.

During the six months ended 2019 and 2018, the Curetis Business received shareholder contributions from Curetis N.V. of kEUR 3,000 and kEUR 10,000 of which kEUR 1,627 are presented as proceeds from current liabilities, net of issuance costs as that amount relates to the convertible notes that were issued by Curetis N.V. and legally contributed to the capital reserve of Curetis GmbH. For presentation purposes (See Note 2), that amount was presented as if the Curetis Business has issued such convertible notes.

17. EVENTS AFTER THE REPORTING DATE

Subsequent to 30 June 2019:

- Curetis elected share settlement for excess entitlement under first tranche of Yorkville convertible notes
- Curetis GmbH entered into a definitive agreement to combine its business with OpGen. See Note 2.1 for further information.

Holzgerlingen, 15 September 2019
Curetis GmbH

/s/ Oliver Schacht, PhD

Oliver Schacht, PhD

Chief Executive Officer (CEO)

Managing Director

/s/ Johannes Bacher

Johannes Bacher

Chief Operating Officer (COO)

Managing Director

/s/Achim Plum

Dr. Achim Plum

Chief Business Officer (CBO)

Managing Director

/s/ Heiko Schorr

Heiko Schorr

Director of Finance

Managing Director



\$50,000,000 of Shares of Common Stock

PROSPECTUS

, 2020

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The costs and expenses payable by the Company in connection with the offerings described in this registration statement are as follows:

SEC registration fee	\$6,490.00
Legal fees and expenses	*
Accounting fees and expenses	*
Printer costs and expenses	*
Total	*

* These fees depend on the number of issuances and amount of securities sold and accordingly cannot be estimated at this time.

Item 15. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors, such executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us and/or in furtherance of our rights. Additionally, each of our directors may have certain rights to indemnification, advancement of expenses and/or insurance provided by their affiliates, which indemnification relates to and might apply to the same proceedings arising out of such director's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors are primary and any obligation of the affiliates of those directors to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

A stockholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees regarding which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 16. Exhibits.

The following exhibits are filed as part of, or incorporated by reference into this registration statement:

<u>Exhibit Number</u>	<u>Identification of Exhibit</u>
1.1 +	Form of Underwriting Agreement
3.1	<u>Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of Current Report on Form 8-K, filed on May 13, 2015)</u>
3.2	<u>Certificate of Correction to Amended and Restated Certificate of Incorporation of OpGen, Inc., filed June 6, 2016 (incorporated by reference to Exhibit 3.1 of Current Report on Form 8-K, filed on June 6, 2016)</u>
3.3	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant dated and filed with the Delaware Secretary of State on January 17, 2018 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on January 17, 2018)</u>
3.4	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation, as amended, of the Registrant dated and filed with the Delaware Secretary of State on August 28, 2019 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on August 28, 2019)</u>
3.5	<u>Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 of Form S-1, filed on March 3, 2015)</u>

- 4.1 [Form of Common Stock Certificate of the Registrant \(incorporated by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018, filed on February 27, 2019\)](#)
- 4.2 [Form of Offered Warrant to Purchase Common Stock \(IPO Warrant\) \(incorporated by reference to Exhibit 4.8 of the Registrant's Form S-1/A, File No. 333-202478, filed on March 20, 2015\)](#)
- 4.3 [Form of Warrant to Purchase Common Stock \(issued to jVen Capital, LLC and Merck Global Health Innovation Fund\) \(incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K Amendment No. 2, filed on July 10, 2017\)](#)
- 4.4 [Form of Common Stock Purchase Warrant for February 2018 Public Offering \(incorporated by reference to Exhibit 4.3 to the Registrant's Form S-1/A, File No. 333-222140, filed on January 31, 2018\)](#)
- 4.5 [Form of Pre-Funded Common Stock Purchase Warrant for February 2018 Public Offering \(incorporated by reference to Exhibit 4.4 to the Registrant's Form S-1/A, File No. 333-222140, filed on January 31, 2018\)](#)
- 4.6 [Form of Placement Agent Warrant for February 2018 Public Offering \(incorporated by reference to Exhibit 4.5 to the Registrant's Form S-1/A, File No. 333-222140, filed on January 31, 2018\)](#)
- 4.7 [Form of Common Stock Purchase Warrant for July 2017 Public Offering \(incorporated by reference to Exhibit 4.4 to the Registrant's Form S-1, Amendment No. 2, File No. 333-218392, filed on July 11, 2017\)](#)
- 4.8 [Form of Placement Agent Warrant for July 2017 Public Offering \(incorporated by reference to Exhibit 4.5 to the Registrant's Form S-1, File No. 333-218392, filed on July 11, 2017\)](#)
- 4.9 [Form of Pre-funded Warrant \(incorporated by reference to Exhibit 4.9 to the Registrant's Registration Statement on Form S-1, Amendment No. 1, File No. 333-233775, filed on October 15, 2019\)](#)
- 4.10 [Form of Underwriter's Warrant \(incorporated by reference to Exhibit 4.10 to the Registrant's Registration Statement on Form S-1, Amendment No. 1, File No. 333-233775, filed on October 15, 2019\)](#)
- 4.11 [Form of Common Stock Purchase Warrant \(incorporated by reference to Exhibit 4.11 to the Registrant's Registration Statement on Form S-1, Amendment No. 1, File No. 333-233775, filed on October 15, 2019\)](#)
- 5.1 * [Opinion of Ballard Spahr LLP](#)
- 23.1 * [Consent of CohnReznick LLP](#)
- 23.2 * [Consent of PricewaterhouseCoopers GmbH Wirtschaftsprüfungsgesellschaft](#)
- 23.2 * [Consent of Ballard Spahr LLP \(included in Exhibit 5.1\)](#)
- 24.1 * [Power of Attorney \(on signature page\)](#)

+ To be filed, if applicable, as an exhibit to a report filed pursuant to Sections 13(a), 13(c) or 15(d) of the Exchange Act or by post-effective amendment to the Registration Statement if securities are sold through one or more underwriters.

* Filed herewith.

Item 17. Undertakings.

- (a) The undersigned registrant hereby undertakes:
 - (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, however, that:

Paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) (i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof, provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness, provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby further undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in said act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Gaithersburg, State of Maryland on the 28th day of January, 2020.

OpGen, Inc.

By: /s/ Evan Jones
Evan Jones
Chief Executive Officer
(principal executive officer)

By: /s/ Timothy C. Dec
Timothy C. Dec
Chief Financial Officer and Secretary
(principal financial officer and
principal accounting officer)

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENT, that each individual whose signature appears below hereby constitutes and appoints each of Evan Jones and Timothy C. Dec as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement (or any Registration Statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement and Power of Attorney has been signed by the following persons in the capacities and on the date indicated.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Evan Jones</u> Evan Jones	Chief Executive Officer and Director (principal executive officer)	January 28, 2020
<u>/s/ Timothy C. Dec</u> Timothy C. Dec	Chief Financial Officer (principal financial officer and principal accounting officer)	January 28, 2020
<u>/s/ R. Donald Elsey</u> R. Donald Elsey	Director	January 28, 2020
<u>/s/ Tina S. Nova</u> Tina S. Nova	Director	January 28, 2020
<u>/s/ Misti Ushio</u> Misti Ushio	Director	January 28, 2020



1735 Market Street, 51st Floor
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TEL 215.665.8500
FAX 215.864.8999
www.ballardspahr.com

January 28, 2020

OpGen, Inc.
708 Quince Orchard Road
Suite 205
Gaithersburg, Maryland 20878

RE: OpGen, Inc. Form S-3 Registration Statement

Ladies and Gentlemen:

We have acted as counsel to OpGen, Inc., a Delaware corporation (the "Company"), in connection with the preparation of a Registration Statement on Form S-3 (the "Registration Statement") filed by the Company with the U.S. Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), on January 28, 2020, with respect to the registration of \$50,000,000 of shares of the Company's common stock (the "Shares").

The Company has informed us that the Shares will be sold or delivered on a delayed or continuous basis from time to time as set forth in the Registration Statement (and any amendments thereto), the prospectus contained therein and any prospectus supplement. We understand that prior to the sale of any Shares under the Registration Statement, the Company will afford us an opportunity to review the operative documents pursuant to which such Shares are to be sold and will file any applicable amendment to the Registration Statement or Current Report on Form 8-K (which may include as an exhibit an update to this opinion) or prospectus supplement as are necessary or appropriate by reason of the terms of the sale of such Shares.

We have examined originals or copies (certified or otherwise identified to our satisfaction) of (i) the Amended and Restated Certificate of Incorporation of the Company together with all amendments thereto; (ii) the Certificate of Correction to the Amended and Restated Certificate of Incorporation; (iii) the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock; (iv) the Amended and Restated Bylaws of the Company; (v) the Registration Statement and the exhibits thereto; (vi) the Prospectus; (vii) such other corporate records, agreements, documents and instruments; and (viii) such certificates or comparable documents of public officials and other sources, believed by us to be reliable, and of officers and representatives of the Company, and have made such inquiries of such officers and representatives, as we have deemed relevant and necessary as a basis for the opinions hereinafter set forth.

In such examination, we have assumed the genuineness of all signatures, the legal capacity of all natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified, conformed or photostatic copies and the authenticity of the originals of such latter documents. As to all questions of fact material to this opinion that have not been independently established, we have relied upon certificates or comparable documents of officers and representatives of the Company.

We have also assumed that (i) the Registration Statement and any amendments or supplements thereto (including any post-effective amendments) will have become effective and comply with all applicable laws and no stop order suspending the Registration Statement's effectiveness will have been issued and remain in effect, in each case, at the time the Shares are offered or issued as contemplated by the Registration Statement, (ii) a prospectus supplement will have been prepared and filed with the Commission describing the Shares offered thereby and will at all relevant times comply with all applicable laws, (iii) the Company will have timely filed all necessary reports pursuant to the Securities Exchange Act of 1934, as amended, which are incorporated into the Registration Statement by reference, (iv) all Shares will be issued and sold in compliance with applicable federal and state securities laws and in the manner stated in the Registration Statement and the appropriate prospectus supplement and (v) a definitive purchase, underwriting or similar agreement and any other necessary agreement with respect to any Shares will have been duly authorized and validly executed and delivered by the Company and the other party or parties thereto.

Assuming that the issuance and terms of any Common Stock and the terms of the offering thereof have been duly authorized, when (i) the Company has received the consideration therefor specified in any applicable underwriting agreement or purchase agreement approved by the Company's board of directors or any authorized committee thereof and (ii) the consideration for such Common Stock is at least equal to the aggregate par value of such Common Stock, such Common Stock will be validly issued, fully paid and non-assessable.

We express no opinion as to the laws of any jurisdiction other than the federal laws of the United States of America and the laws of the State of Delaware.

We hereby consent to the filing of this opinion with the Commission as an exhibit to the Registration Statement in accordance with the requirements of Item 601(b)(5) of Regulation S-K promulgated under the Securities Act, and to the use of this firm's name therein and in the Prospectus under the caption "Legal Matters." In giving this consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Securities Act and the rules and regulations promulgated thereunder.

Sincerely yours,

/s/ Ballard Spahr LLP

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement on Form S-3 (the "Registration Statement") of OpGen, Inc. of our report, dated February 27, 2019, which includes an explanatory paragraph related to OpGen, Inc.'s ability to continue as a going concern, on our audits of the consolidated financial statements of OpGen, Inc. as of December 31, 2018 and 2017 and for the years then ended included in the Annual Report on Form 10-K of OpGen, Inc. for the year ended December 31, 2018, and also incorporated by reference in the Registration Statement. We also consent to reference to our firm under the caption "Experts" in the Registration Statement.

/s/ CohnReznick LLP

Tysons, Virginia
January 27, 2020

CONSENT OF INDEPENDENT AUDITORS

We hereby consent to the use in this Registration Statement on Form S-3 of OpGen, Inc. of our report dated September 15, 2019 relating to the financial statements of the Curetis Business, which appears in this Registration Statement. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

Munich, Germany
January 27, 2020

PricewaterhouseCoopers GmbH
Wirtschaftsprüfungsgesellschaft

/s/ Dietmar Eglauer

Dietmar Eglauer
Wirtschaftsprüfer
(German Public Auditor)

/s/ ppa. Andreas Schuster

ppa. Andreas Schuster
Wirtschaftsprüfer
(German Public Auditor)