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Registration No. 333-233775

Prospectus

2,590,170 Units (each Unit contains One Share of Common Stock and One Common Warrant to purchase One Share of Common Stock)

2,109,830 Pre-funded Units (each Pre-funded Unit contains One Pre-funded Warrant to Purchase One Share of Common Stock and One Common Warrant to purchase One Share of Common Stock)

2,109,830 Shares of Common Stock Underlying the Pre-funded Warrants and

4,700,000 Shares of Common Stock Underlying the Common Warrants

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We are offering 2,590,170 units (each unit consisting of one share of our common stock and one common warrant to purchase one share of our common stock) pursuant to this prospectus. Each common warrant contained in a unit has an exercise price of $2.00 per share. The common warrants contained in the units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the units and pre-funded units.

We are also offering 2,109,830 pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock) to each purchaser whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, in lieu of units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each pre-funded warrant contained in a pre-funded unit is exercisable for one share of our common stock. The purchase price of each pre-funded unit is equal to the price per unit being sold to the public in this offering, minus $0.01, and the exercise price of each pre-funded warrant included in the pre-funded unit is $0.01 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants contained in the pre-funded units sold in this offering. Each common warrant contained in a pre-funded unit has an exercise price of $ 2.00 per share. The common warrants contained in the pre-funded units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the pre-funded units.

The units and pre-funded units will not be issued or certificated. The shares of common stock or pre-funded warrants, as the case may be, and the common warrants included in the units or pre-funded units, can only be purchased together in this offering, but the securities contained in the units or the pre-funded units will be issued separately and will be immediately separable upon issuance.

Our common stock is listed on the Nasdaq Capital Market under the symbol “OPGN.” On October 23, 2019, the last reported sale price of our common stock on the Nasdaq Capital Market was $3.66 per share. The public offering price per unit or pre-funded unit, as the case may be, will be determined between us and the underwriter based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. Therefore, the recent market price used throughout this prospectus may not be indicative of the final offering price.

There is no established public trading market for the pre-funded warrants or the common warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the pre-funded warrants or the common warrants on any securities exchange or other nationally recognized trading market. Without an active trading market, the liquidity of the pre-funded warrants and the common warrants will be limited.

Following receipt of approval from stockholders at an annual meeting of stockholders held on August 22, 2019, on August 28, 2019, we filed an amendment to our 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 unit, share, per unit price and per share price in this prospectus have been adjusted to reflect the reverse stock split.

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 34.

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

	Per Unit	Per Pre-Funded Unit	Total
Public offering price	$ 2.000	$ 1.990	$ 9,378,900
Underwriting discounts and commissions (7%) (1)	$ 0.140	$ 0.140	$ 658,000
Proceeds, before expenses, to OpGen, Inc.	$ 1.860	$ 1.850	$ 8,720,900

(1) We have also agreed to pay the underwriter a non-accountable expense allowance of $50,000 and reimbursement for legal fees and expenses in the amount of up to $100,000. As additional compensation, we plan to issue the underwriter or its designees warrants to purchase a number of shares of common stock equal to 5% of the number of shares of common stock (i) included within the units and (ii) issuable upon the exercise of the pre-funded warrants included within the pre-funded units that are, in each case, sold in this offering. The exercise price for these warrants will be $2.60 per share, which represents 130% of the public offering price per unit. For a description of the additional compensation to be received by the underwriter, see “Underwriting” for more information.

The offering is being underwritten on a firm commitment basis. The underwriter has an option exercisable within 30 days from the date of this prospectus to purchase up to 705,000 additional shares of common stock and/or common warrants to purchase up to an additional 705,000 shares of common stock from us at the public offering price, less the underwriting discounts and commissions. If the underwriter exercises this option in full, the total underwriting discounts and commissions payable by us will be $756,700 and the total proceeds to us, before expenses, will be $10,032,202, excluding potential proceeds from the exercise of the common warrants included in such option.

We expect to deliver the securities to purchasers on or about October 28, 2019.

H.C. Wainwright & Co.

Prospectus dated October 23, 2019

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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. The Consideration is equal to 72.5% of the common stock of the Company on a fully diluted basis as of the date of the Implementation Agreement. The number of shares of OpGen common stock to be issued to Curetis N.V. is fixed, therefore, the percentage ownership of the Company on a fully diluted basis as of the date of closing will be different. Such difference is likely to be material as a result of the shares to be offered and sold in this offering.

The Company has agreed to file 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 plans to call a special meeting of its stockholders as soon as practicable and deliver a proxy statement to its stockholders in advance of such special meeting.

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 has committed to raise at least $10,000,000 of interim equity financing to support the continuing operations of both the Company and the Curetis Group. Accordingly, we intend to use certain proceeds from this offering to support the operations of each of OpGen and the Curetis Group during the period between signing and closing of the transactions under the Implementation Agreement and, if any proceeds remain, to support the combined operations of Newco after the closing occurs. See "Use of Proceeds." If the closing does not occur, we plan to use the remaining proceeds from this offering to support OpGen's business operations.

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) application with the FDA seeking clearance of its Acuitas AMR Gene Panel (Isolates) diagnostic test. In July 2019, we received an Additional Information, or AI, Request from the FDA detailing a number of questions related to such submission. We are currently evaluating the FDA correspondence and preparing our response, which we must submit within 180 days from the date of the AI Request.

Overview of the Curetis Group

Curetis is a wholly-owned subsidiary of Curetis N.V. Curetis owns 100% of four international subsidiaries (two of which either have been or are expected to be dissolved prior to the closing of the transactions contemplated by the Implementation Agreement and do not have any ongoing operations). 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, 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 (with other subsidiaries based in London, U.K., and Zug, Switzerland, both of which either have been or are expected to be dissolved prior to the closing of the transactions contemplated by the Implementation Agreement).

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 approximately two minutes of hands-on time and provides clinicians with a comprehensive overview of 10genetic 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.

- 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. There is currently an installed base of 170 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 October 10, 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.

Financing Needs

Since its initial public offering in May 2015, OpGen has raised approximately $57.5 million, and Curetis N.V. has raised $159 million since its inception in 2007 to invest in their respective businesses.

OpGen has incurred substantial losses since its inception. For the years ended December 31, 2018 and 2017, we had net losses of $13.4 million and $15.4 million, respectively. Net loss for the six months ended June 30, 2019 was $6.5 million. From our inception through June 30, 2019, we had an accumulated deficit of $168.5 million. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2018 and 2017 contains explanatory language that substantial doubt exists about our ability to continue as a going concern.

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 Curetis Business has incurred substantial losses since its inception. For the years ended December 31, 2018 and 2017, Curetis Business had net losses of $26.1 million and $21.9 million, respectively. Net loss for the six months ended June 30, 2019 was $11.4 million. From its inception through June 30, 2019, Curetis Business had an accumulated deficit of $193.6 million. As of June 30, 2019, the Curetis Business had cash and cash equivalents of $5.4 million. In the event Curetis N.V. is unable to successfully raise additional capital during or before the fourth quarter of 2019, Curetis N.V. will not have sufficient cash flows and liquidity to finance the Curetis Business operations as currently contemplated. Curetis GmbH believes that this raises substantial doubt about its ability to continue as a going concern. See Note 3.22 to the Curetis Business combined financial statements included elsewhere in this prospectus for additional information on Curetis' assessment. Similarly, the report of Curetis' independent auditors on the Curetis Business' combined financial statements as of and for the year ended December 31, 2018, includes an emphasis of matter paragraph that made reference to Curetis GmbH's statement that there is substantial doubt about Curetis´ ability to continue as a going concern.

This offering represents an interim financing to raise capital to support the operations of OpGen and the Curetis Group during the period between the signing of the Implementation Agreement and the closing of the transaction, and then to fund the operations of Newco. If we are successful in raising the desired capital, we anticipate the proceeds from this offering will be sufficient to fund both OpGen and the Curetis Group through the transition period and Newco until the end of the first quarter of 2020. If the Newco transaction is terminated for failure to meet any of the conditions to closing during 2019, OpGen intends to use the proceeds of this offering to support its operations and anticipates that the remaining proceeds would support its operations into the second quarter of 2020.

We expect that Newco will continue to incur losses for the next few years and will incur significant operating expenses relating to, among other things:

- developing additional Unyvero tests and the Acuitas AMR Gene Panel products and services for antibiotic resistance testing;
- commercializing the Unyvero LRT tests as an FDA-cleared test, and the Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software, additional Unyvero tests and ARESdb informatics services, as RUO products and, if cleared, as diagnostic products and services;
- conducting additional clinical trials as Newco seeks regulatory approval for certain product offerings;
- developing, presenting and publishing additional clinical and economic utility data intended to increase clinician adoption of Newco's current and future products and services;
- developing additional collaborative arrangements;
- maintaining, expanding and protecting its intellectual property portfolio and trade secrets;
- expanding the size and geographic reach of Newco's sales force and marketing capabilities to commercialize potential future products and services; and
- recruiting and retaining quality assurance and compliance personnel and maintaining compliance with regulatory requirements.

If we are not successful in raising sufficient capital in this offering, Newco will need to raise capital through equity offerings, indebtedness, collaborations or other sources sooner than anticipated. If this offering is not completed by October 15, 2019, each of OpGen and Curetis N.V. have the right to terminate the Implementation Agreement. If that occurs, or if the parties proceed without raising sufficient capital to meet the requirements set forth in the Implementation Agreement, we would then need to pursue a plan to license or sell assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

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.

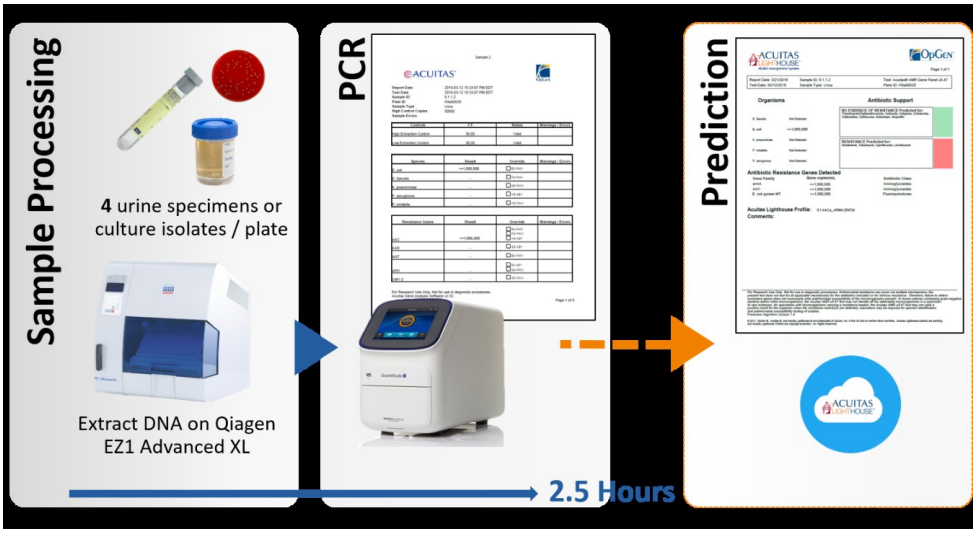
Acuitas AMR Gene Panel and Acuitas Lighthouse Software

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 test for the detection of antimicrobial resistance genes in bacterial isolates. The FDA responded to our submission with an AI Request in July 2018, to which we have 180 days to submit a complete response. In the meantime, our 510(k) submission is on hold. If we are able to obtain FDA clearance of the Acuitas AMR Gene Panel (Isolates) test, we expect use of the test to expand from current research uses to include the clinical diagnostic use of test information to support antibiotic decision making in acute care patient management of patients with MDRO infections.

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.

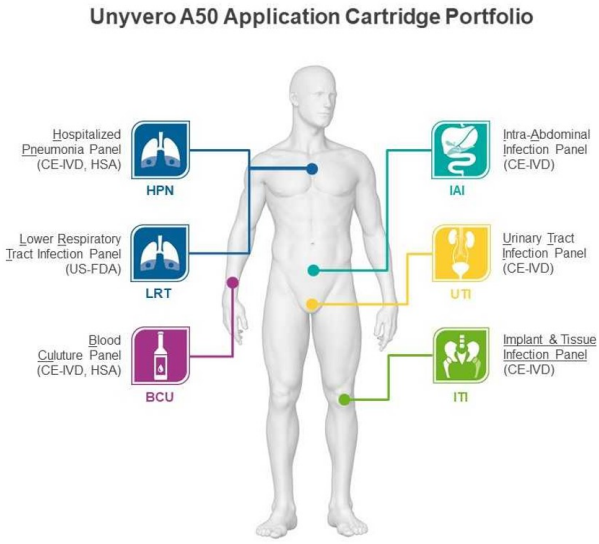
Intellectual Property

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.

Current Commercial Agreements

Curetis has entered into a number of distribution and collaboration agreements in the past few years, including:

- 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. Additional clinical isolates of such pathogens will be sequenced by Ares Genetics at its recently established NGS laboratory in Vienna, Austria. Based on this enlarged and enriched dataset, Ares Genetics expects to further optimize the algorithms for predictive antibiotic resistance testing for drug/pathogen combinations particularly relevant in the targeted indication to enable NGS-based infectious disease diagnostics. Under the agreement, the collaborator will fully fund Ares Genetics' research and development activities for the genotypic and phenotypic characterization of additional bacterial strains to augment ARESdb and the development of optimized algorithms for predicting antibiotic resistance. Furthermore, in return for an up-front option fee, the collaborator obtained a right of first negotiation for an exclusive, worldwide, human clinical diagnostic use license to ARESdb and the ARES Technology Platform for the term of the technology evaluation agreement plus three months. The collaborator has the right to terminate the technology evaluation agreement by providing limited notice to Ares Genetics.

- In March 2019, Curetis signed a distribution agreement with A. Menarini Diagnostics covering the Unyvero A50 product line. Menarini is an established global healthcare company with total revenues in 2018 of €3.6 billion, with over 1,000 employees in clinical diagnostics and an installed base of 10,000 instruments in Europe. The collaboration initially includes 11 European countries with the option to expand into the Middle East and Africa. Including the Menarini relationship, we anticipate that Newco will have 18 partners covering 43 countries in Europe, the Middle East, South America and Asia.

- In February 2019 Ares Genetics and QIAGEN GmbH entered into a global strategic licensing agreement for ARESdb and ARESтools in the area of AMR research that aims to create a community platform for antimicrobial resistance research. Under the terms of the agreement, QIAGEN obtained a restricted license to exclusively develop and commercialize general bioinformatics offerings and services for AMR research based on Ares Genetics' database on the genetics of antimicrobial resistance. On the signing of the agreement, Ares Genetics received a technology access fee and will be entitled to a milestone payment at product launch, as well as industry-standard royalty rates on net sales of products and services based on ARESdb and ARESтools. Ares Genetics retains the full rights to use ARESdb and ARESтools for AMR research, customized bioinformatics services, and the development of specific AMR assays and applications for the Curetis Group including Ares Genetics, as well as third parties, including other diagnostics companies or partners in the pharmaceutical industry. The license to QIAGEN excludes any human diagnostic uses of ARESdb and/or ARESтools. Under a separate agreement QIAGEN has also provided the bulk of laboratory automation and equipment at favorable reagent rental conditions to Ares Genetics.

- In September 2015, Curetis entered into an eight-year China distribution agreement with Beijing Clear Biotech, which includes a minimum purchase commitment of Unyvero A50 systems. The agreement also requires a minimum number of cartridge purchases. Following completion of clinical trials, Beijing Clear Biotech Co. Ltd. has recently filed for regulatory approval of the Unyvero A50 LRT test with the Chinese National Medical Products Administration (NMPA; formerly Chinese Food and Drug Administration). Following a recent expert panel hearing with the NMPA, approval is expected in 2020 with commercial launch also anticipated in 2020.

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, effectively placing the 510(k) submission on hold until the FDA determines that the deficiencies identified in the AI request have been resolved. Curetis has started the response process in an interactive review format. Curetis anticipates it will be able to respond to all information requests by the end of 2019. Curetis believes that receipt of FDA clearance of an Unyvero LRT Application Cartridge for this additional sample type would 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 cUTI.

- **ARESdb and Acuitas Lighthouse informatics and services** – Newco plans to pursue commercial opportunities to provide the Acuitas Lighthouse 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:

- obtaining FDA clearance to market the Unyvero A50 LRT test for BAL specimens and expand the base of commercial customers;

- entering into strategic partnering and licensing agreements to provide funding and support further development of the Unyvero A30 platform;

- 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 anticipated in the first quarter of 2020, and the Acuitas Lighthouse Software (AMR Gene Panel Prediction) anticipated in the first half of 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.

Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled "Risk Factors" immediately following this prospectus summary. These risks include, but are not limited to, the following:

- we have a history of losses and expect to incur losses for the next several years;
- we have not yet consummated the Newco transaction with Curetis, and need to raise additional funds to support our business and the operations of Curetis prior to the closing under the Implementation Agreement, and to support Newco's business after the closing;
- the transactions contemplated by the Implementation Agreement may not close because of failure to meet one of the conditions to closing;
- many of the material terms of the short-term, subordinated credit facility with Curetis required by the Implementation Agreement, or the Interim Facility, including the interest rate, term and committed amount, have not yet been negotiated, and we may be unable to negotiate favorable terms;
- we may need to pursue an additional financing to fund Newco's operations after the closing;
- the process of obtaining FDA clearance and/or approval is time-consuming and expensive, and we may not be successful in obtaining such clearances or approvals in a timely manner or at all;
- our products may never achieve significant commercial market acceptance;
- our contracts with government agencies could be subject to uncertain future funding;
- our sales cycle is lengthy and variable; and
- we may not be able to compete successfully with the products and services sold by other companies in our industry, who are better capitalized than we are.

Nasdaq Listing Requirements and Reverse Stock Split

On May 6, 2019, the Listing Qualifications Staff of the Nasdaq Capital Market notified us that the closing bid price of our common stock had, for 30 consecutive business days preceding the date of such notice, been below the $1.00 per share minimum required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Marketplace Rule 5550(a)(2), or the Minimum Bid Price Rule. In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), we were provided 180 calendar days, or until November 4, 2019, to regain compliance. If at any time before November 4, 2019, the closing bid price of our common stock is at least $1.00 for a minimum of ten consecutive trading days, we will regain compliance.

On August 22, 2019, at the annual meeting of stockholders, our stockholders approved an amendment to our Amended and Restated Certificate of Incorporation, authorizing a reverse stock split of the issued and outstanding shares of our common stock, at a ratio within a range of not less than five-to-one and not more than twenty-five-to-one, such ratio and the implementation and timing of such reverse stock split to be determined in the discretion of our Board of Directors. On August 22, 2019, our Board of Directors approved a reverse stock split of one share for every twenty outstanding shares, or the 2019 Reverse Stock Split. On August 28, 2019, we filed an amendment to our Amended and Restated Certificate of Incorporation to effect the 2019 Reverse Stock Split. All of the Company's historic share and share prices in this prospectus have been adjusted to reflect the 2019 Reverse Stock Split.

In implementing the 2019 Reverse Stock Split, the number of shares of our common stock held by each stockholder was reduced by dividing the number of shares held immediately before the 2019 Reverse Stock Split by twenty and then rounding down to the nearest whole share. We are paying cash to each stockholder in lieu of issuing any fractional shares. The 2019 Reverse Stock Split did not affect any stockholder's percentage ownership interest in our Company or proportionate voting power, except to the extent that interests in fractional shares were paid in cash.

In addition, we have adjusted all outstanding shares of any restricted stock units, stock options and warrants entitling the holders to purchase shares of our common stock as a result of the 2019 Reverse Stock Split, as required by the terms of these securities. In particular, we have reduced the conversion ratio for each security, and increased the exercise price in accordance with the terms of each security based on 2019 Reverse Stock Split ratio (i.e., the number of shares issuable under such securities has been divided by twenty, and the exercise price per share has been multiplied by twenty). Also, we proportionately reduced the number of shares reserved for issuance under our existing 2015 Equity Incentive Plan, or the 2015 Plan, based on the 2019 Reverse Stock Split ratio. The 2019 Reverse Stock Split did not otherwise affect any of the rights currently accruing to holders of our common stock, or options or warrants exercisable for our common stock.

We have regained compliance with the Minimum Bid Price Rule as of September 13, 2019, as a result of the 2019 Reverse Stock Split. Although we expect that the 2019 Reverse Stock Split will result in a sustained increase in the market price of our common stock, the 2019 Reverse Stock Split may not result in a permanent increase in the market price of our common stock, which is dependent on many factors, including general economic, market and industry conditions and other factors detailed from time to time in the reports we file with the SEC.

On August 19, 2019, OpGen, received a written notification from The Nasdaq Stock Market LLC, or Nasdaq, notifying the Company that it has failed to comply with Nasdaq Marketplace Rule 5550(b)(1) because the Company's stockholders' equity as of June 30, 2019 fell below the required minimum of $2,500,000, and as of June 30, 2019, the Company did not meet the alternative compliance standards of market value of listed securities or net income from continuing operations for continued listing. In accordance with Nasdaq's listing requirements, the Company had 45 calendar days to submit a plan to regain compliance. If the plan is accepted, Nasdaq can grant the Company an extension of up to 180 calendar days from the date it received the notification to evidence compliance. The Company submitted a plan to Nasdaq to regain compliance with the Nasdaq minimum stockholders' equity standard on October 3, 2019, which plan includes information regarding this offering. The Company believes that if this offering is successful, we will regain compliance with the minimum stockholders' equity standard for continued listing. However, there can be no assurance that the Company's plan will be accepted or that if it is, that the Company will be able to regain compliance.

THE OFFERING

Units offered by us in this offering:	2,590,170 units, each consisting of one share of our common stock and one common warrant to purchase one share of our common stock.
Pre-funded units offered by us in this offering:	We are also offering 2,109,830 pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock) to each purchaser whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, in lieu of units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. The purchase price of each pre-funded unit is equal to the price at which the units are being sold to the public in this offering, minus $0.01, and the exercise price of each pre-funded warrant included in each pre-funded unit is $0.01 per share. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants underlying the pre-funded units sold in this offering.
Common warrants offered by us in the offering	Common warrants to purchase an aggregate of 4,700,000 shares of our common stock. Each unit and each pre-funded unit includes a common warrant to purchase one share of our common stock. Each common warrant has an exercise price of $2.00 per share, will be immediately separable from the common stock or pre-funded warrant, as the case may be, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.
Option to purchase additional securities:	The underwriter has a 30-day option to purchase up to 705,000 additional shares of our common stock and/or warrants to purchase up to an additional 705,000 shares of our common stock from us at the public offering price, less underwriting discounts and commissions.
Common stock outstanding prior to this offering:	882,268 shares of common stock.
Common stock outstanding after this offering:	5,582,268 shares (or 6,287,268 shares if the underwriter exercises its option to purchase additional shares in full), in each case assuming all of the pre-funded warrants issued in this offering are exercised and assuming none of the common warrants issued in this offering are exercised.

Use of Proceeds:	We currently intend to use the net proceeds of this offering for the following purposes: prior to the closing of the transactions contemplated by the Implementation Agreement to (1) complete the business combination with Curetis; (2) provide short-term funding to Curetis under 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 transactions under the Implementation Agreement, 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 transactions under the Implementation Agreement do not close, to the extent any proceeds remain, we plan to use any remaining proceeds to support OpGen's operations as far as possible into 2020. Many of the material terms of the Interim Facility, including the interest rate, term and committed amount, have not yet been negotiated, and we may be unable to negotiate favorable terms. See "Use of Proceeds" on page 64 of this prospectus and "Risk Factors" beginning on page 34 of this prospectus.
Risk Factors:	Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 34 of this prospectus and the other information included or incorporated by reference in this prospectus.
Nasdaq Capital Market symbol:	"OPGN." There is no established trading market for the common warrants or the pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the common warrants or the pre-funded warrants on Nasdaq, any national securities exchange or any other nationally-recognized trading system. Without an active trading market, the liquidity of the common warrants and pre-funded warrants will be limited.

The number of shares of common stock to be outstanding immediately after this offering is based on 882,268 shares of our common stock outstanding as of June 30, 2019, and excludes:

- 10,542 shares of common stock issuable upon the exercise of outstanding options granted as of June 30, 2019, under our equity incentive plans at a weighted average exercise price of $410.31 per share;
- 175,982 shares of common stock issuable upon the exercise of outstanding warrants issued as of June 30, 2019, at a weighted average exercise price of $288.25 per share;
- 15,663 shares of common stock issuable upon vesting of outstanding restricted stock units granted as of June 30, 2019; and
- 4,221 shares of common stock available for future issuance under our equity incentive plans as of June 30, 2019;
- 235,000 shares of common stock, or 270,250 shares of common stock if the underwriter exercises its option to purchase additional securities in full, issuable upon exercise of warrants to be issued to the underwriter at an exercise price of 130% of the public offering price as described in "Underwriting";
- 4,700,000 shares of common stock issuable upon the exercise of the common warrants to be issued to purchasers in this offering at an exercise price of $2.00 per share; and
- up to 2,662,564 shares of common stock issuable pursuant to the terms of the Implementation Agreement.

The number of outstanding options, restricted stock units and shares of common stock available for future issuances under our equity incentive plans does not reflect grants of 1,500 shares of common stock issuable upon vesting of restricted stock units, the expiration of stock options to purchase 499 shares of our common stock, forfeitures of stock options to purchase 107 shares of our common stock or forfeitures of 500 shares of our common stock issuable upon vesting of restricted stock units since June 30, 2019.

Unless otherwise indicated, all information contained in this prospectus assumes (i) that the underwriter has not exercised its option to purchase additional securities, (ii) no exercise of options issued under our equity incentive plans and (iii) no exercise of warrants, including the common warrants offered in this offering and the underwriter's warrants to be issued to the underwriter in connection with this offering.

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 "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our latest Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and incorporated by reference into this prospectus. The summary statements of operations data for the years ended December 31, 2018 and 2017 and the six months ended June 30, 2019 and 2018, and the balance sheet data as of June 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,		Six Months Ended June 30,	
	2018	2017	2019	2018
	(In thousands, except per share data)		(Unaudited)	
Statements of Operation Data:				
Revenue	$ 2,946	$ 3,211	$ 2,030	$ 1,635
Operating expenses:				
Cost of products sold	1,223	1,613	419	646
Cost of services[(1)]	626	520	396	348
Research and development[(1)]	5,677	6,883	2,930	2,535
General and administrative[(1)]	7,069	6,693	3,340	3,622
Sales and marketing[(1)]	1,532	2,768	766	756
Impairment of right-of-use asset	—	—	521	—
Total operating expenses[(1)]	16,127	18,477	8,372	7,907
Operating loss	(13,181)	(15,266)	(6,342)	(6,272)
Interest and other (expense) income	5	(87)	(9)	5
Interest expense	(191)	(233)	(94)	(112)
Foreign currency transaction gains (losses)	(10)	23	—	(10)
Change in fair value of derivative financial instruments	8	144	—	8
Provision for income taxes	—	—	—	—
Net loss	$ (13,369)	$ (15,419)	(6,445)	(6,381)
Net loss per common share, basic and diluted	$ (44.49)	$ (195.95)	$ (9.54)	$ (25.78)
Weighted average shares outstanding—basic and diluted	300	79	676	248

(1) Includes stock-based compensation as follows:

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2017	2019	2018
			(Unaudited)	
Cost of services	$ 1	$ 14	$ 1	$ 4
Research and development	241	237	35	131
General and administrative	574	604	137	292
Sales and marketing	46	57	11	25
Total stock-based compensation	$ 862	$ 912	$ 184	$ 452

	As of June 30, 2019	
	Actual	As Adjusted
	(In thousands) (Unaudited)	
Balance Sheet Data:		
Cash and cash equivalents	$ 3,056	$ 11,371
Working capital (deficiency)	(584)	7,730
Total assets	8,933	17,248
Accumulated deficit	(168,525)	(168,525)
Total stockholders' equity	1,827	10,142

The preceding table presents a summary of our balance sheet data as of June 30, 2019:

- on an actual basis;
- on an as adjusted basis to give effect to the receipt of the estimated net proceeds from the sale of an aggregate of 2,590,170 units and 2,109,830 pre-funded units in this offering at the public offering price of $2.00 per unit and $1.99 pre-funded unit, respectively, and the issuance of 2,590,170 shares of common stock included in the units.

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 the 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 Profits or Loss:	(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

	As of June 30, 2019
	(In thousands of USD (1))
Consolidated 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 CONSOLIDATED 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 these 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 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.

If the business combination contemplated by the Implementation Agreement was consummated after this offering, it would 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. One of the conditions to closing the business combination under the Implementation Agreement is that OpGen raise at least $10 million in interim financing. In presenting this unaudited pro forma consolidated combined financial information, 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 this offering; (iii) whether the percentage of voting rights held by OpGen's stockholders would continue to constitute a majority of the voting rights of the combined company after this offering and after closing under the Implementation Agreement; (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; and (v) the change in the chief executive officer of OpGen after the closing to be the chief executive officer of Curetis N.V. The consummation of this offering will have a substantial impact on the final determination as to the accounting treatment of the business combination. We are presenting this unaudited pro forma consolidated combined financial information as a business combination in accordance with U.S. GAAP for accounting purposes. This unaudited pro forma consolidated 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 to be offered and sold in this 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.

We have assumed, for purposes of these unaudited pro forma condensed combined financial statements, that OpGen will continue to hold a majority of the outstanding shares of the combined company's common stock at the closing of the business combination.

The unaudited pro forma condensed combined balance sheet data assume that the business combination took place on June 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 minimum capital raise, as required by the Implementation Agreement, was completed on June 30, 2019. The unaudited pro forma condensed combined statement of operations data for the year ended December 31, 2018 and the six months ended June 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 six months ended June 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 combined financial statements of the Curetis Business were prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. 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 US 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's 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 US 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 the combined company's future results of operations and financial position. In addition, depending on the number of shares issued in the interim equity offering contemplated by this prospectus, the method for accounting of the business combination could change.

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, incorporated by reference in this prospectus or included elsewhere in this prospectus. OpGen's audited statement of operations for the year ended December 31, 2018 is derived from OpGen’s Annual Report on Form 10-K for the year ended December 31, 2018. OpGen's unaudited financial statements for the six months ended June 30, 2019 are derived from OpGen's Quarterly Report on Form 10-Q for the six months ended June 30, 2019.

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
June 30, 2019
(in thousands)

	OpGen	Curetis Business	Pro Forma Adjustments	Notes	Pro Forma Combined
Assets					
Current assets					
Cash and cash equivalents	$ 3,056	$ 5,432	$ 8,315	G	$ 16,803
Accounts receivable, net	773	223	—		996
Due from parent	—	300	—		300
Inventory, net	567	5,359	—		5,926
Contractual assets	—	244	—		244
Prepaid expenses and other current assets	178	640	—		818
Total current assets	**4,574**	**12,198**	**8,315**		**25,087**
Property and equipment, net	198	4,249	—		4,447
Finance lease right-of-use assets, net	985	—	—		985
Operating lease right-of-use assets	1,382	1,475	—		2,857
Goodwill	601	—	13,092	E	13,693
Intangible assets, net	952	8,359	—	E	9,311
Deferred tax assets	—	17	—		17
Other noncurrent assets	241	180	—		421
Total assets	**$ 8,933**	**$ 26,478**	**$ 21,407**		**$ 56,818**
Liabilities and Stockholders' Equity					
Current liabilities					
Accounts payable	$ 1,259	$ 831	$ —		$ 2,090
Due to parent	—	211	—		211
Accrued compensation and benefits	1,191	—	—		1,191
Accrued and other current liabilities	821	1,232	5,469	A,B,H	7,522
Deferred revenue	10	—	—		10
Short-term notes payable	343	3,713	—		4,056
Short-term finance lease liabilities	576	—	—		576
Short-term operating lease liabilities	959	492	—		1,451
Total current liabilities	**5,159**	**6,479**	**5,469**		**17,107**
Notes payable	495	22,305	—		22,800
Long-term finance lease liabilities	380	—	—		380
Long-term operating lease liabilities	1,072	991	—		2,063
Other noncurrent liabilities	—	50	—		50
Total liabilities	**7,106**	**29,825**	**5,469**		**42,400**
Stockholders' equity					
Common stock	9	6,313	(6,260)	C,D,G	62
Additional paid-in capital	170,358	184,042	(166,035)	C,D,G	188,365
Accumulated deficit	(168,525)	(193,632)	188,163	A,B,C,H	(173,994)
Accumulated other comprehensive loss	(15)	(70)	70	C	(15)
Total stockholders' equity (deficit)	**1,827**	**(3,347)**	**15,938**		**14,418**
Total liabilities and stockholders' equity	**$ 8,933**	**$ 26,478**	**$ 21,407**		**$ 56,818**

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

	OpGen	Curetis Business	Pro Forma Adjustments (E)	Notes	Pro Forma Combined
Revenue	$ 2,030	$ 1,237	$ —		$ 3,267
Operating expenses:					
Cost of products sold	419	1,525	—		1,944
Cost of services	396	—	—		396
Research and development	2,930	4,752	—		7,682
General and administrative	3,340	1,832	(130)	F	5,042
Sales and marketing	766	3,717	—		4,483
Impairment of right-of-use asset	521	—	—		521
Total operating expenses	8,372	11,826	(130)		20,068
Operating loss	(6,342)	(10,589)	130		(16,801)
Other (expense) income	(9)	138	—		129
Interest expense	(94)	(846)	—		(940)
Foreign currency transaction losses	—	—	—		—
Change in fair value of derivative financial instruments	—	—	—		—
Provision for income taxes	—	(64)	—		(64)
Net loss	$ (6,445)	$ (11,361)	$ 130		$ (17,676)
Net loss applicable to common stockholders	$ (6,445)	$ (11,361)	$ 130		$ (17,676)
Net loss per common share - basic and diluted	$ (9.54)				$ (2.98)
Weighted average shares outstanding - basic and diluted	675,932		5,252,734	D,G	5,928,666

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 (H)	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	$ (44.69)				$ (7.11)
Weighted average shares outstanding - basic and diluted for the year ended December 31, 2018	300,453		5,252,734	D,G	5,553,187

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 business of Curetis, or the Transferred Assets. OpGen has also agreed to assume (1) the 2016 Stock Option Plan and the outstanding awards thereunder, (2) the obligation to issue equity to the holders of awards under the PSOP, and (3) 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) 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 the Curetis N.V. ordinary shares on a fully diluted basis. The Consideration is equal to 72.5% of the common stock of OpGen on a fully diluted basis as of the date of the Implementation Agreement.

In the Implementation Agreement, OpGen has 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 offering contemplated by this prospectus is the interim equity financing. We intend to use certain proceeds from this offering to support the operations of each of OpGen and the Curetis Business during the period between signing and closing of the transactions under the Implementation Agreement, and to support the combined operations of Newco after the closing occurs. See "Use of Proceeds."

2. Curetis Business

The accompanying unaudited pro forma condensed combined financial statements reflect, what the Company assumes would be the results and financial position on a US GAAP basis, of the 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.

Unaudited Curetis Business Condensed Combined Statement of Financial Position
June 30, 2019
(in thousands)

	Curetis Business (Euros)	Curetis Business (USD) (1)
Assets		
Current assets		
Cash and cash equivalents	€ 4,779	$ 5,432
Trade receivables	196	223
Other receivables, related party	264	300
Contractual assets	215	244
Inventories	4,715	5,359
Prepaid expenses and other current assets	563	640
Total current assets	**10,732**	**12,198**
Intangible assets	7,354	8,359
Property, plant and equipment	3,738	4,249
Right of use assets	1,298	1,475
Other non-current financial assets	158	180
Deferred tax assets	15	17
Total assets	**€ 23,295**	**$ 26,478**
Liabilities and Stockholders' Equity		
Current liabilities		
Trade and other payables	€ 731	$ 831
Other liabilities, related party	186	211
Provisions current	130	148
Tax liabilities	2	2
Other current liabilities	952	1,082
Other current financial liabilities	3,267	3,713
Current lease liabilities	433	492
Total current liabilities	**5,701**	**6,479**
Provisions non-current	44	50
Other non-current financial liabilities	19,623	22,305
Non-current lease liabilities	872	991
Total liabilities	**26,240**	**29,825**
Equity		
Subscribed capital	5,554	6,313
Capital reserve	161,913	184,042
Currency translation differences	(62)	(70)
Retained earnings	(170,350)	(193,632)
Total stockholders' equity	**(2,945)**	**(3,347)**
Total liabilities and stockholders' equity	**€ 23,295**	**$ 26,478**

(1) Convenience translation performed using the following exchange rate in effect as of June 30, 2019: 1.13667

Unaudited Curetis Business Condensed Combined Statement of Operations
For the six months ended June 30, 2019
(in thousands, except share and per share data)

	Curetis Business (Euros)	Curetis Business (USD) (1)
Revenue	€ 1,088	$ 1,237
Cost of sales	(1,342)	(1,525)
Gross loss	**(254)**	**(288)**
Distribution costs	(3,270)	(3,717)
Administrative expenses	(1,612)	(1,832)
Research & development expenses	(4,181)	(4,752)
Other income	114	130
Operating loss	**(9,203)**	**(10,459)**
Finance income	7	8
Finance costs	(744)	(846)
Finance result - net	**(737)**	**(838)**
Loss before income taxes	**(9,940)**	**(11,297)**
Income tax expense	(56)	(64)
Loss for the period	**€ (9,996)**	**$ (11,361)**

(1) Convenience translation performed using the following exchange rate in effect as of June 30, 2019 1.13667

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
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 pro forma balance sheet

3. Estimated Purchase Price

The accompanying unaudited pro forma condensed combined financial statements reflect an estimated acquisition price of approximately $9.7 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 $1.0 million.

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)	$	3.66
Total	$	9,745

(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) 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.

(ii) The estimated purchase price was based on the closing price as reported on the Nasdaq Capital Market on October 23, 2019. 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.

The Curetis Business' net assets as of June 30, 2019	$	(3,347)
Goodwill		13,092
Total	$	9,745

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 June 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 June 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) 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.
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 Busienss'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 six months ended June 30, 2019.
G. To record the receipt of $9,378,902 in gross proceeds, $8,315,000 estimated net proceeds, in cash for the issuance of 2,590,170 units and 2,109,830 pre-funded units in a public 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):

	June 30, 2019
OpGen's estimated transaction costs (A)	$ 1,606
Curetis Business estimated transaction costs (B)	2,841
Retention benefits to be paid to OpGen executives (H)	1,022
Total	$ 5,469

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

	June 30, 2019
Eliminate the Curetis Business' historical additional paid-in-capital balance (C)	$ (184,042)
To reflect shares to be issued under the implementation agreement (D)	9,718
To reflect shares to be issued to investors in a $9.4 million public offering, net of offering costs (G)	8,289
Total	$ (166,035)

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

	June 30, 2019
Eliminate Curetis Business' historical common stock balance (C)	$ (6,313)
To reflect shares to be issued under the implementation agreement (D)	27
To reflect shares to be issued to investors in a $9.4 million public offering, net of offering costs (G)	26
Total	$ (6,260)

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

	June 30, 2019
OpGen's estimated transaction costs (A)	$ (1,606)
Curetis Business estimated transaction costs (B)	(2,841)
Eliminate the Curetis Business' historical accumulated deficit balance (C)	193,632
Retention benefits to be paid to OpGen executives (H)	(1,022)
Total	$ 188,163

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described below, and incorporated by reference herein, together with all of the other information in, or incorporated by reference in, this prospectus, including our financial statements and related notes incorporated by reference herein, before making an investment decision. If any of these risks occur, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline and you could lose part or all of your investment.

Risks Related to this Offering and Our Securities

We need to raise capital in this offering to support our operations. If the offering is not successful, our financial position will be materially adversely impacted.

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the six months ended June 30, 2019, we had a net loss of $6.5 million. From our inception through June 30, 2019, we had an accumulated deficit of $168.5 million. We believe that current cash on hand will be sufficient to fund operations into October 2019. In addition, the report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2018 and 2017 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. In the event we are unable to successfully raise sufficient capital in this offering, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing. We have no additional committed sources of capital and may find it difficult to raise money on terms favorable to us or at all. The failure to obtain sufficient capital to support our operations would have a material adverse effect on our business, financial condition and results of operations. If such sufficient financing is not received timely, we would then need to pursue a plan to license or sell assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

We received a deficiency notice from the Nasdaq Capital Market. If we are unable to cure this deficiency and meet the Nasdaq continued listing requirements, we could be delisted from the Nasdaq Capital Market, which would negatively impact the trading of our common stock.

On August 19, 2019, OpGen received a written notification from Nasdaq notifying the Company that it has failed to comply with Nasdaq Marketplace Rule 5550(b)(1) because the Company's stockholders' equity as of June 30, 2019 fell below the required minimum of $2,500,000, and as of June 30, 2019, the Company did not meet the alternative compliance standards of market value of listed securities or net income from continuing operations for continued listing. We submitted a plan to Nasdaq to regain compliance with the Nasdaq minimum stockholders' equity standard on October 3, 2019, which plan included information regarding this offering. We believe that if this offering is successful, we will regain compliance with the minimum stockholders' equity standard for continued listing. However, there can be no assurance that the Company's plan will be accepted or that if it is, the Company will be able to regain compliance.

If our common stock is delisted by Nasdaq, our common stock may be eligible for quotation on an over-the-counter quotation system or on the pink sheets. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of stockholders to sell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be eligible for trading or quotation on any alternative exchanges or markets.

If our common stock is delisted by Nasdaq, our common stock may be eligible for quotation on an over-the-counter quotation system or on the pink sheets. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of stockholders to sell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be eligible for trading or quotation on any alternative exchanges or markets.

Delisting from Nasdaq could adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Management will have broad discretion as to the use of the net proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion as to the application of the net proceeds and intends to use them to support the operations of both of OpGen and the Curetis Group during the period prior to the closing of the transaction under the Implementation Agreement, and then, if any proceeds remain, for the operations of Newco if the transactions pursuant to the Implementation Agreement close. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not increase our results of operations or the market value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development and approval of our products and cause the price of our common stock to decline.

If you purchase our securities sold in this offering, you will experience immediate dilution as a result of this offering.

Because the effective price per unit being offered may be higher than the net tangible book value per share of our common stock, you will experience dilution to the extent of the difference between the effective offering price per unit you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value as of June 30, 2019, was approximately $274 thousand, or $0.31 per share of common stock. Net tangible book value per share is equal to our total tangible assets minus total liabilities, all divided by the number of shares of common stock outstanding. See “Dilution” on page 67 of this prospectus for a more detailed discussion of the dilution you will incur in this offering.

If you purchase our securities in this offering you may experience future dilution as a result of future equity offerings or other equity issuances.

In order to raise additional capital, we believe that we will offer and issue additional shares of our common stock or other securities convertible into or exchangeable for our common stock in the future. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per unit paid by purchasers in this offering, and investors purchasing other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per unit in this offering.

In addition, we have a significant number of stock options, restricted stock units and warrants outstanding and anticipate that we will grant additional equity awards following the closing of the Implementation Agreement transaction. To the extent that outstanding stock options or warrants have been or may be exercised or other shares issued, you may experience further dilution. Further, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

The market price of our common stock has been, and may continue to be, highly volatile, and such volatility could cause the market price of our common stock to decrease and could cause you to lose some or all of your investment in our common stock.

During the period from our initial public offering in May 2015 through October 23, 2019, the market price of our common stock fluctuated from a high of $2,720.00 per share to a low of $3.26 per share, and our stock price continues to fluctuate. The market price of our common stock may continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- our ability to grow our revenue and customer base;
- the announcement of new products or product enhancements by us or our competitors;
- the trading volume of our common stock;
- developments concerning regulatory oversight and approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- successes or challenges in our collaborative arrangements or alternative funding sources;
- developments in the health care and life science industries;
- the results of product liability or intellectual property lawsuits;
- future issuances of common stock or other securities;
- the addition or departure of key personnel;
- announcements by us or our competitors of acquisitions, investments or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

Further, the stock market in general, and the market for health care and life science companies in particular, has recently experienced extreme price and volume fluctuations. The volatility of our common stock is further exacerbated due to its low trading volume. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock and the loss of some or all of your investment.

Trading of our common stock is limited, and trading restrictions imposed on us by applicable regulations may further reduce trading in our common stock, making it difficult for our stockholders to sell their shares; and future sales of common stock could reduce our stock price.

Trading of our common stock is currently conducted on the Nasdaq Capital Market. The liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also as it may be adversely affected by delays in the timing of transactions and reduction in security analysts' and the media's coverage of us, if any. These factors may result in different prices for our common stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and asked prices for our common stock. In addition, without a large public float, our common stock is less liquid than the stock of companies with broader public ownership, and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future, if at all.

The exercise of outstanding common stock purchase warrants and stock options will have a dilutive effect on the percentage ownership of our capital stock by existing stockholders.

As of June 30, 2019, we had outstanding warrants to acquire 175,982 shares of our common stock, and stock options to purchase 10,542 shares of our common stock. The expiration of the terms of such options and warrants range from November 2019 to June 2028. A significant number of such warrants are out of the money, but the holders have the right to effect a cashless exercise of such warrants. If a significant number of such warrants and stock options are exercised by the holders, the percentage of our common stock owned by our existing stockholders will be diluted.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, an amended and restated promissory note issued in June 2017 to Merck Global Health Innovation Fund, a principal investor, or the MGHIF Note, and the related security agreement restricts our ability to pay cash dividends on our common stock. We may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our Board of Directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for the foreseeable future.

There is no public market for the pre-funded warrants or the common warrants being offered by us in this offering.

There is no established public trading market for the pre-funded warrants or the common warrants and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants or the common warrants on any national securities exchange or other nationally recognized trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of the pre-funded warrants and the common warrants will be limited.

The common warrants are speculative in nature.

The common warrants do not confer any rights of common stock ownership on its holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the common warrants may exercise their right to acquire the common stock and pay an exercise price of $2.00 per share, subject to certain adjustments, prior to five years from the date of issuance, after which date any unexercised common warrants will expire and have no further value. Moreover, following this offering, the market value of the common warrants, if any, is uncertain and there can be no assurance that the market value of the common warrants will equal or exceed their imputed offering price. The common warrants will not be listed or quoted for trading on any market or exchange. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of our common warrants, and consequently, whether it will ever be profitable for holders of the common warrants to exercise the common warrants.

Risks Related to the Pending Business Combination Transaction with Curetis

We may not be successful in consummating the proposed business combination transaction with Curetis, which failure could have a material adverse effect on us.

The proposed combination with Curetis is subject to the approval of our stockholders and by the shareholders and debt holders of Curetis N.V. and Curetis GmbH, and we cannot provide any assurance that such approvals will be obtained. If the proposed transaction is not approved by our stockholders at the special meeting called to approve the Newco transaction, we may become liable to reimburse Curetis N.V. for its expenses up to a maximum amount of $250,000. We may also be liable to pay Curetis N.V. a termination fee of $500,000 if our board of directors changes its recommendation to approve the proposed transaction or, if following a refusal by our stockholders to approve the proposed transaction at the special meeting, we enter into a definitive agreement implementing an alternative transaction with a third party. Curetis N.V. has undertaken the same obligations with respect to us if the shareholders of Curetis N.V. do not approve the proposed transaction or if the boards of Curetis N.V. change their recommendation to approve the proposed transaction. In case of termination of the Implementation Agreement in accordance with its terms, Curetis N.V. would also be required to repay us under the Interim Facility, and we would need to re-focus our attention on OpGen as a stand-alone business. Any of these events could have a material adverse impact on our financial condition.

Completion of the Newco transaction is subject to the fulfillment or the waiver, as the case may be, of a number of conditions precedent, which may prevent, delay, hinder or otherwise adversely affect the proposed business combination transaction.

Completion of the Newco transaction is subject to the fulfillment or the waiver, as the case may be, of a number of conditions precedent as described in the Implementation Agreement. These include, in addition to customary closing conditions, the necessary shareholder approvals by the requisite majority of shareholders of Curetis N.V. and the stockholders of OpGen; the completion by OpGen of an interim equity financing of at least $10,000,000 to support the continuing operations of both the Company and the Curetis Group; the documentation implementing the potential for conversion of the Curetis Convertible Notes into shares of OpGen's common stock having been agreed and executed with the holders of such Curetis Convertible Notes; the Interim Facility having been put in place within five business days of completion of the interim equity financing; and the receipt of the applicable consents or waivers to be received or granted by certain debt financing providers of Curetis N.V. and Curetis GmbH. Failure to satisfy any of the conditions may result in the Newco transaction not being closed.

We have agreed to use a significant portion of the capital raised in this offering to support the operations of the Curetis Group in the period prior to the closing. This reduces the proceeds invested in OpGen's operations, which could have a negative impact on us if the proposed business combination is not consummated, or if the approval process takes longer than anticipated.

Pursuant to the Implementation Agreement, we have agreed to use a significant part of the proceeds of this offering to fund and support the operations, and satisfy the current obligations, of the Curetis Group in the period prior to closing. Such amount could range between 40% and 50% of the net proceeds of this offering. If such period extends for a longer period than anticipated or the amount loaned to Curetis is higher than expected, such commitment could negatively impact the availability of resources to devote to the OpGen business or to the business of Newco if the closing occurs, and we may be required to raise additional capital.

We will document this agreement by entering the Interim Facility. We have not entered into the Interim Facility as of the date of this prospectus. The Interim Facility will be unsecured, subordinated to the existing indebtedness of both Curetis and Curetis N.V., including the Curetis Convertible Notes, and will provide a mechanism for us to lend funds to the Curetis Group to support its then current business and pay its short-term obligations. Many of the material terms of the Interim Facility, including the interest rate, term and committed amount, have not yet been negotiated, and we may be unable to negotiate favorable terms. We may also need to lend more money to Curetis than anticipated. If that happens, we will have less money available to fund Newco, or to fund OpGen if the transactions contemplated by the Implementation Agreement do not close. If the transactions contemplated by the Implementation Agreement do not close, we anticipate that it will be difficult for Curetis to repay us under the Interim Facility, if at all. Any unanticipated loans under the Interim Facility, or failure to be repaid under the Interim Facility would have a material adverse effect on our financial condition.

If the combination with Curetis does not occur, our financial condition will be materially adversely affected.

If we or Curetis N.V. cannot meet all of the conditions to close under the Implementation Agreement, and the business combination does not occur, we will be in a difficult financial position. We will have lent funds to Curetis under the Interim Facility, and there is a real possibility that Curetis would not be able to repay us some or all of such debt. In addition, we would have to refocus our attention on OpGen as a stand-alone business and would likely need to raise additional funds to support that business going forward. We cannot assure you that we would be able to continue OpGen as a stand-alone business or be able to raise sufficient capital to do so. If we are unable to raise equity capital, we may need to incur debt financing, if possible, sell assets, curtail business programs, seek bankruptcy protection or dissolve.

We will incur significant indebtedness as a result of the combination with Curetis, which could have a material adverse effect on our financial condition.

If the combination with Curetis closes, we will assume the indebtedness of Curetis N.V. under the Curetis Convertible Notes. As of October 10, 2019, Curetis N.V. owed indebtedness of $1.4 million to lenders under the Curetis Convertible Notes and Curetis owed indebtedness of $20.4 million of principal (plus interest of $1.6 million) under a loan provided by the EIB. In addition, OpGen has secured indebtedness to MGHIF under the MGHIF Note. Pursuant to the Implementation Agreement, OpGen will be required to assume this indebtedness of Curetis N.V. (subject to approval of the holder of the Curetis Convertible Notes) and Curetis, and Newco will therefore be obligated under substantially more indebtedness than OpGen currently owes. Newco may not be able to generate sufficient cash to service all of its indebtedness and may be forced to take other actions to satisfy its obligations under indebtedness that may not be successful. The inability in the future to repay such indebtedness when due would have a material adverse effect on Newco.

The proposed business combination transaction with Curetis will significantly change the business and operations of OpGen. We may face challenges integrating the businesses.

Following the consummation of the proposed combination with Curetis, OpGen will continue as the operating entity and both the size and geographic scope of OpGen's business will significantly increase. Most of the Curetis business is currently conducted in Europe, Asia and other countries outside of the United States, and many of the Curetis employees are located outside of the United States. In addition, the majority of the initial board of directors will consist of individuals appointed by Curetis N.V., and we expect that the focus of Newco may shift to Curetis operations. We may face challenges integrating such geographically diverse businesses and implementing a smooth transition of business focus and governance in a timely or efficient manner. In particular, if the effort we devote to the integration of our businesses with that of Curetis diverts more management time or other resources from carrying out our operations than we originally planned, our ability to maintain and increase revenues as well as manage our costs could be impaired. Furthermore, our capacity to expand other parts of our existing businesses may be impaired. We also cannot assure you that the combination of the OpGen and Curetis businesses will function as we anticipate, or that significant synergies will result from the business combination. Any of the above could have a material adverse effect on our business.

Management and the board of directors of OpGen will change upon the consummation of the Curetis transaction. We cannot assure you that this will not have a material impact on the Newco.

The current chief executive officer of Curetis N.V., Oliver Schacht, Ph.D., will be the chief executive officer of Newco, and Timothy C. Dec will continue to serve as chief financial officer. The Implementation Agreement provides that four members of the initial board of directors of Newco following the closing will be appointed by Curetis N.V. and two by the board of directors of OpGen. The parties currently intend to pursue a board of up to seven members post-closing. The current members of the management board of Curetis N.V. do have experience serving on the boards of companies listed on Euronext and German prime standard companies, but not on U.S. publicly-listed companies and this could impact the transition of Newco.

The combination of the OpGen and Curetis businesses may not lead to the growth and success of the combined business that we believe will occur.

Although we believe the combination of the OpGen and Curetis businesses provides a significant commercial opportunity for growth, we may not realize all of the synergies that we anticipate and may not be successful in implementing our commercialization strategy. Our combined business will be subject to all of the risks and uncertainties inherent in the pursuit of growth in our industry and we may not be able to successfully sell our products, obtain the regulatory clearances and approvals we apply for or, or realize the anticipated benefits from our distribution, collaboration and other commercial partners. If we are not able to grow the business of Newco as a commercial enterprise, our financial condition will be negatively impacted.

Integrating the businesses of OpGen and Curetis may disrupt or have a negative impact on Newco.

We could have difficulty integrating the assets, personnel and business of OpGen and Curetis. The proposed transaction is complex and we will need to devote significant time and resources to integrating the businesses. Risks that could impact us negatively include:

- the difficulty of integrating the acquired companies, and their concepts and operations;
- the difficulty in combining our financial operations and reporting;
- the potential disruption of the ongoing businesses and distraction of our management;
- changes in our business focus and/or management;
- risks related to international operations;
- the potential impairment of relationships with employees and partners as a result of any integration of new management personnel; and
- the potential inability to manage an increased number of locations and employees.

If we are not successful in addressing these risks effectively, the business of Newco could be severely impaired.

We expect our ability to utilize our net operating loss carryforwards will be limited as a result of an "ownership change," as defined in Section 382 of the Internal Revenue Code triggered by consummation of the transaction with Curetis.

As of December 31, 2018, we had approximately $178.2 million of net operating loss, or NOL, carryforwards for U.S. federal tax purposes. Under U.S. federal income tax law, we generally can use our NOL carryforwards (and certain tax credits) to offset ordinary taxable income, thereby reducing our U.S. federal income tax liability, for up to 20 years from the year in which the losses were generated, after which time they will expire. State NOL carryforwards (and certain tax credits) generally may be used to offset future state taxable income for 20 years from the year in which the losses are generated, depending on the state, after which time they will expire. The rate at which we can utilize our NOL carryforwards is limited (which could result in NOL carryforwards expiring prior to their use) each time we experience an "ownership change," as determined under Section 382 of the Internal Revenue Code. A Section 382 ownership change generally occurs if a shareholder or a group of shareholders who are deemed to own at least 5% of our common stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. If an ownership change occurs, Section 382 generally would impose an annual limit on the amount of post-ownership change taxable income that may be offset with pre-ownership change NOL carryforwards equal to the product of the total value of our outstanding equity immediately prior to the ownership change (reduced by certain items specified in Section 382) and the U.S. federal long-term tax-exempt interest rate in effect at the time of the ownership change. A number of special and complex rules apply in calculating this Section 382 limitation. While the complexity of Section 382 makes it difficult to determine whether and when an ownership change has occurred, and if a portion of our NOLs is subject to an annual limitation under Section 382, we believe that an additional ownership change may occur upon the consummation of the transaction with Curetis. In addition, our ability to use our NOL carryforwards will be limited to the extent we fail to generate enough taxable income in the future before they expire. Existing and future Section 382 limitations and our inability to generate enough taxable income in the future could result in a substantial portion of our NOL carryforwards expiring before they are used. In addition, under the 2017 Tax Cut and Jobs Act, effective for losses arising in taxable years beginning after December 31, 2017, the deduction for NOLs is limited to 80% of taxable income, NOLs can no longer be carried back, and NOLs can be carried forward indefinitely.

Current OpGen stockholders will have a reduced ownership and voting interest after the business combination and will exercise less influence over management.

Current OpGen stockholders have the right to vote in the election of the OpGen board of directors and on other matters affecting OpGen. Immediately after the business combination is completed, it is estimated that then current OpGen stockholders, including purchasers in this offering, will own approximately 67.7%, and Curetis N.V. will own approximately 32.3% of the outstanding shares of OpGen, in each case based on the sale of 2,590,170 units and 2,109,830 pre-funded units in this offering and the exercise of all pre-funded warrants. As a result of the business combination, current OpGen stockholders will have less influence on the management and policies of OpGen post-closing than they currently have.

The unaudited pro forma financial statements included in this prospectus are presented for illustrative purposes only and the actual financial condition and results of operations of Newco following the business combination may differ materially.

The unaudited pro forma financial statements contained in this prospectus are presented for illustrative purposes only, are based on various adjustments, assumptions and preliminary estimates and may not be an indication of the Newco's financial condition or results of operations following the business combination for several reasons. The actual financial condition and results of operations of Newco following the business combination may not be consistent with, or evident from, these unaudited pro forma financial statements. In addition, the assumptions used in preparing the unaudited pro forma financial information may not prove to be accurate, and other factors may affect Newco's financial condition or results of operations following the business combination. Any potential decline in the combined company's financial condition or results of operations may cause significant variations in the stock price of the combined company.

The market price of Newco common stock after the business combination may be affected by factors different from those affecting the shares of OpGen currently.

Curetis' business differs in important respects from that of OpGen, and, accordingly, the results of operations of Newco and the market price of Newco common stock after the completion of the business combination may be affected by factors different from those currently affecting the results of operations of each of OpGen. For a discussion of the business of OpGen and of certain factors to consider in connection with OpGen's business, see "Prospectus Summary—OpGen's Business" included elsewhere in this prospectus and incorporated by reference herein, and the consolidated financial statements of OpGen incorporated by reference herein. For a discussion of the business of Curetis and of certain factors to consider in connection with Curetis' business, see "Prospectus Summary—Curetis' Business" and the financial statements of Curetis included elsewhere in this prospectus.

The business of Newco, like the businesses of OpGen and Curetis, will be heavily regulated.

Both OpGen and Curetis are pursuing business strategies that require FDA clearance, CE marking and other regulatory approvals in order to offer products and services for diagnostic purposes. Both OpGen and Curetis are currently responding to additional information requests from the FDA. Pursuit of the necessary regulatory clearances and approvals is time-consuming and expensive. We cannot assure you that Newco will obtain the necessary regulatory clearances and approvals. The failure to obtain such regulatory clearances and approvals could have a material adverse effect on Newco's business.

Newco will be responsible for retention and severance payments to certain OpGen executive officers, and satisfaction of PSOPs awards issued to Curetis executive officers and directors.

Under the OpGen, Inc. Retention Plan for Executives, effective September 21, 2018, retention payments equal to 4% of the value of the business combination transaction will be paid over time to four executive officers of OpGen following the closing of the proposed business combination. We currently estimate the cost of such retention payments will be approximately $1.0 million. In addition, severance payments, including an amount equal to one times his base salary, will be paid to Evan Jones, the current Chief Executive Officer of OpGen under his Change in Control Severance Agreement when he is terminated as Chief Executive Officer of OpGen in connection with the closing under the Implementation Agreement. OpGen has also agreed to replace the PSOP awards granted to Curetis executive officers and directors with equity awards of OpGen. Such payments and issuances will be obligations of Newco after the closing. Although the payments to the OpGen executives may be payable over a two-year period, if the other OpGen executives have an eligible termination of employment under the retention plan, such payments will be accelerated, which could have an adverse effect on Newco's financial position.

Risks Related to Our Business

We have a history of losses, and we expect to incur losses for the next several years. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2018 and 2017 contains explanatory language that substantial doubt exists about our ability to continue as a going concern.

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the years ended December 31, 2018 and 2017, we had net losses of $13.4 million and $15.4 million, respectively. Net loss for the six months ended June 30, 2019 was $6.5 million. From our inception through June 30, 2019, we had an accumulated deficit of $168.5 million. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2018 and 2017 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. We completed a number of financings in 2019, 2018 and 2017, including offerings in March 2019, October 2018, February 2018, July 2017, and an at-the-market, or ATM, public offering commenced in September 2016 and terminated in October 2018. The net proceeds from such financings were approximately $35.8 million.

We expect to continue to incur significant operating expenses relating to, among other things:

- developing our Acuitas AMR Gene Panel products and services for antibiotic resistance testing;
- commercializing our Acuitas AMR Gene Panel tests and Acuitas Lighthouse informatics services, as RUO products and, once cleared, as diagnostic products and services;
- conducting additional clinical trials as we seek regulatory approval for some of our product offerings;
- developing, presenting and publishing additional clinical and economic utility data intended to increase clinician adoption of our current and future products and services;
- expanding our operating capabilities;
- developing additional collaborative arrangements;
- maintaining, expanding and protecting our intellectual property portfolio and trade secrets;
- expanding the size and geographic reach of our sales force and our marketing capabilities to commercialize potential future products and services; and
- recruiting and retaining our quality assurance and compliance personnel and maintaining compliance with regulatory

requirements.

Even if we achieve significant revenues, we may not become profitable, and even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain consistently profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business or continue to pursue our growth strategy. We believe that current cash on hand will be sufficient to fund operations into October 2019. In the event we are unable to successfully raise additional capital during or before the middle of October 2019, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing. We have no committed sources of capital and may find it difficult to raise money on terms favorable to us or at all. In addition, if we are unable to complete this offering by October 15, 2019 we or Curetis N.V. will have the right to terminate the Implementation Agreement. The failure to obtain sufficient capital to support our operations would have an adverse effect on our business, financial condition and results of operations.

We expect to make significant additional investment in the future related to our diagnostic products and services, which investments will require additional financing transactions through the issuance of equity or debt. If we are unable to make such investments our business will suffer.

We anticipate that we will need to make significant investments in our Acuitas AMR Gene Panel tests in development and Acuitas Lighthouse Software in order to make our business profitable. We need to expend significant investments to develop such products and services. There can be no assurance that we can obtain sufficient resources or capital from operations or future financings to support these development activities.

To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements and business combination transactions. We believe that additional equity financings are the most likely source of capital. There can be no assurance that we will be able to complete any such financing transaction on acceptable terms or otherwise.

In July 2015, in connection with our acquisition of our subsidiary, AdvanDx, MGHIF made investments in the Company, including the $1 million MGHIF Note, secured by a security interest in substantially all of our assets, including our intellectual property assets. The debt is due to be paid in six semi-annual payments of $166,667 beginning on January 2, 2019 and ending on July 1, 2021. Such secured creditor rights could negatively impact our ability to raise money in the future. If we default on payments under the MGHIF Note, MGHIF has the rights of a secured creditor. If those rights are exercised, it could have a material adverse effect on our financial condition.

The process to obtain and maintain FDA clearances or approvals for our products is complex and time-consuming. If we fail to obtain such clearances or approvals, our business and results of operations will be materially adversely impacted.

The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. Anyone who wants to market in the United States a Class I, II, or III device intended for human use for which a Premarket Approval application, or a PMA, is not required, must submit a 510(k) application to the FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act, or the FD&C Act. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is "substantially equivalent" to an existing, or "predicate," FDA-cleared product. A device may not be marketed in the United States until the applicant receives a letter declaring the device substantially equivalent. If the FDA declares a device as *not* substantially equivalent, the device is automatically classified as a Class III (high-risk) device for which a PMA or *de novo* clearance is required. After an FDA determination that a device is not substantially equivalent, the 510(k) applicant may: (i) resubmit another 510(k) with new data; (ii) request a Class I or II designation through the *de novo* classification process; (iii) file a reclassification petition; or (iv) submit a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use.

We submitted a 510(k) application seeking FDA clearance for our Acuitas AMR Gene Panel (Isolates) product in May 2019. In connection with the FDA's Substantive Review, we received an AI Request in July 2019 effectively placing our submission on hold until we submit a complete response, which must be done within 180 days of the date listed on the AI Request. We plan to submit a complete response to the FDA's AI Request in the fourth quarter of 2019. We anticipate making an additional FDA submission in the first quarter of 2020 for our Acuitas AMR Gene Panel (Urine) product and in the first half of 2020 for the Acuitas Lighthouse software. If we are not able to achieve clearance of such products and services on a timely basis, or at all, we will not be able to pursue our business strategy on the anticipated timeline and our business, results of operations and financial condition will be materially adversely impacted.

Our products and services may never achieve significant commercial market acceptance.

Our products and services may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits for us. Our ability to achieve commercial market acceptance for our products will depend on several factors, including:

- our ability to convince the medical community of the clinical utility of our products and services and their potential advantages over existing tests, including our surveillance services offering, despite the lack of reimbursement for such services;
- our ability to successfully develop automated rapid pathogen identification and antibiotic resistance testing products and services, including bioinformatics, and convince hospitals and other healthcare providers of the patient safety, improved patient outcomes and potential cost savings that could result;
- our ability to grow our microbial isolate and antibiotic resistance genes knowledgebase;
- our ability to convince the medical community of the accuracy and speed of our products and services, as contrasted with the current methods available; and
- the willingness of hospitals and physicians to use our products and services.

Our future success is dependent upon our ability to expand our customer base.

The current customers we are targeting for our Acuitas AMR Gene Panel (RUO) and Acuitas Lighthouse Software (RUO) test products and services are hospital systems, acute care hospitals, particularly those with advanced care units, such as intensive care units, community-based hospitals and governmental units, such as public health facilities. If the Acuitas AMR Gene Panel and Acuitas Lighthouse Software products are approved for diagnostic use, we will need to provide a compelling case for the savings, patient safety and recovery, reduced lengths of stay and reduced costs, among other benefits, that come from adopting our MDRO diagnosis and antibiotic stewardship products and services. If we are not able to successfully increase our customer base and lawfully commercialize these products for diagnostic use, sales of our products and our margins may not meet expectations. Attracting new customers and introducing new products and services requires substantial time and expense. Any failure to expand our existing customer base, or launch new products and services, would adversely affect our ability to improve our operating results.

We have seen declining revenues from our current customers for our QuickFISH products as we work to transition to Acuitas automated rapid pathogen identification products. Continued decline without additional product offerings could materially, adversely affect our business.

We are developing new in vitro diagnostic tests for more rapid identification of MDROs and antibiotic resistance genomic information. If we are unable to successfully develop, receive regulatory clearance or approval for or commercialize such new products and services, our business will be materially, adversely affected.

We are developing the Acuitas AMR Gene Panel (Urine) as a new under-three-hour antibiotic resistance diagnostic product that we believe, if cleared for clinical diagnostic use, could help address many of the current issues with the need for more rapid identification of infectious diseases and testing for antibiotic resistance. Development of new diagnostic products is difficult and we cannot assure you that we will be successful in such product development efforts, or, if successful, that we will receive the necessary regulatory clearances to commercialize such products. We have identified up to 47 antibiotic resistance genes that, if cleared for clinical diagnostic use, could help guide clinician antibiotic therapy decisions when test results are evaluated using the Acuitas Lighthouse Software, if similarly cleared. Although we have demonstrated preliminary feasibility, and confirmed genotype/phenotype predictive algorithms, such product development efforts will require us to work collaboratively with other companies, academic and government laboratories, and healthcare providers to access sufficient numbers of microbial isolates, develop the diagnostic tests, successfully conduct the necessary clinical trials and apply for and receive regulatory clearances or approvals for the intended use of such diagnostic tests. In addition, we would need to successfully commercialize such products. Such product development, clearance or approval and commercialization activities are time-consuming and expensive and there can be no assurance that we will have sufficient funds to successfully complete such efforts. We currently plan to complete development and submit for FDA clearance to market such antibiotic resistance diagnostic tests in the United States in late 2019. Any significant delays or failures in this process could have a material adverse effect on our business and financial condition.

We offer these products in development to the RUO market and for other non-clinical research uses prior to receiving clearance or approval to commercialize these products in development for use in the clinical setting. As such, we are required to comply with the applicable laws and regulations regarding such other uses. Failure to comply with such laws and regulations may have a significant impact on the Company.

We may enter into agreements with U.S. or other government agencies, which could be subject to uncertain future funding.

The presence of MDROs and the need for antibiotic stewardship activities have prompted state, federal and international government agencies to develop programs to combat the effects of MDROs. In 2019, we have been party to a collaboration, called The New York State Infectious Disease Digital Health Initiative, with The New York State DOH and ILÚM to develop a research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions in New York State.

In the future, we may seek to enter into additional agreements with governmental funding sources or contract with government healthcare organizations to sell our products and services. Under such agreements, we would rely on the continued performance by these government agencies of their responsibilities under these agreements, including adequate continued funding of the agencies and their programs. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal.

Government agencies may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies. In addition, we may fail to perform our responsibilities under these agreements. Any government agreements would be subject to audits, which may occur several years after the period to which the audit relates. If an audit identified significant unallowable costs, we could incur a material charge to our earnings or reduction in our cash position. As a result, we may be unsuccessful entering, or ineligible to enter, into future government agreements.

If the utility of our current products and products in development is not supported by studies published in peer-reviewed medical publications, the rate of adoption of our current and future products and services by clinicians and healthcare facilities may be negatively affected.

The results of our clinical and economic validation studies involving our Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software have been presented at major infectious disease and infection control society meetings. We need to maintain and grow a continued presence in peer-reviewed publications to promote clinician adoption of our products. We believe that peer-reviewed journal articles that provide evidence of the utility of our current and future products and services, and adoption by key opinion leaders in the infectious disease market, are very important to our commercial success. Clinicians typically take a significant amount of time to adopt new products and testing practices, partly because of perceived liability risks and the uncertainty of a favorable cost/benefit analysis. It is critical to the success of our sales efforts that we educate a sufficient number of clinicians and administrators about our products and demonstrate their clinical benefits. Clinicians may not adopt our current and future products and services unless they determine, based on published peer-reviewed journal articles and the experience of other clinicians, that our products provide accurate, reliable, useful and cost-effective information that is useful in MDRO diagnosis, screening and outbreak prevention. If our current and future products and services or the technology underlying our products and services or our future product offerings do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption could be negatively affected. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing our products, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenue from any product that is the subject of a study.

Our sales cycle for our marketed products and services is lengthy and variable, which makes it difficult for us to forecast revenue and other operating results.

We believe the sales cycles for our Acuitas AMR Gene Panel and Acuitas Lighthouse Software as diagnostic products will be lengthy, which will make it difficult for us to accurately forecast revenues in a given period, and may cause revenue and operating results to vary significantly from period to period. Potential customers for our products typically need to commit significant time and resources to evaluate our products, and their decision to purchase our products may be further limited by budgetary constraints and numerous layers of internal review and approval, which are beyond our control. We spend substantial time and effort assisting potential customers in evaluating our products. Even after initial approval by appropriate decision makers, the negotiation and documentation processes for the actual adoption of our products on a facility-wide basis can be lengthy. As a result of these factors, based on our experience to date, our sales cycle, the time from initial contact with a prospective customer to routine commercial use of our products, has varied and could be 12 months or longer, which has made it difficult for us to accurately project revenues and operating results. In addition, the revenue generated from sales of our products may fluctuate from time to time due to changes in the testing volumes of our customers. As a result, our results may fluctuate on a quarterly basis, which may adversely affect the price of our common stock.

We are currently party to, and may enter into additional, collaborations with third parties to develop product and services candidates. If these collaborations are not successful, our business could be adversely affected.

We are currently party to a few collaborations, and anticipate that we will enter into additional collaborations, related to our MDRO and informatics products and services. Such collaborations are and may be with pharmaceutical companies, platform companies or other participants in our industry. We have limited control over the amount and timing of resources that any such collaborators could dedicate to the development or commercialization of the subject matter of any such collaboration. Our ability to generate revenues from these arrangements would depend on our and our collaborators' abilities to successfully perform the functions assigned to each of us in these arrangements. Our relationships with collaborators may pose several risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- we may not achieve any milestones, or receive any milestone payments, under our collaborations, including milestones and/or payments that we expect to achieve or receive;
- the clinical trials, if any, conducted as part of these collaborations may not be successful;
- a collaborator might elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors, such as an acquisition, that diverts resources or creates competing priorities;
- we may not have access to, or may be restricted from disclosing, certain information regarding product or services candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product or services candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product or services candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product or services, which may cause collaborators to cease to devote resources to the commercialization of our product or services candidates;

- a collaborator with marketing and distribution rights to one or more of our product or services candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product or services candidates, may cause delays or termination of the research, development or commercialization of such product or services candidates, may lead to additional responsibilities for us with respect to such product or services candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- disputes may arise with respect to the ownership of intellectual property developed pursuant to a collaboration;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product or services candidates.

If our collaborations do not result in the successful development and commercialization of products or services, we may not receive any future research funding or milestone or royalty payments under the collaborations. If we do not receive the funding we would expect under these agreements, our development of product and services candidates could be delayed and we may need additional resources to develop our product candidates.

We may not be successful in finding strategic collaborators for continuing development of certain of our product or services candidates or successfully commercializing or competing in the market for certain indications.

We may seek to develop strategic partnerships for developing certain of our product or services candidates, due to capital costs required to develop the product or services candidates or manufacturing constraints. We may not be successful in our efforts to establish such a strategic partnership or other alternative arrangements for our product or services candidates because our research and development pipeline may be insufficient, our product or services candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product or services candidates as having the requisite potential to demonstrate commercial success.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product or service candidate, reduce or delay our development program, delay our potential commercialization, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates and our business, financial condition, results of operations and prospects may be materially and adversely affected.

We are an early commercial stage company and may never be profitable.

We rely principally on the commercialization of our QuickFISH and Acuitas Gene Panel (RUO) test products and our Acuitas Lighthouse Software (RUO) to generate future revenue growth. To date, our Acuitas test products and Acuitas Lighthouse services have delivered only minimal revenue, as they have not-yet been cleared for clinical diagnostic use. We believe that our commercialization success is dependent upon our ability to significantly increase the number of hospitals, long-term care facilities and other inpatient healthcare settings that use our products. If demand for products does not increase as quickly as we have planned, we may be unable to increase our revenue levels as expected. We are currently not profitable. Even if we succeed in increasing adoption of our products by our target markets, maintaining and creating relationships with our existing and new customers and developing and commercializing additional molecular testing products, we may not be able to generate sufficient revenue to achieve or sustain profitability.

We have limited experience in marketing and selling our products, and if we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenue to achieve or sustain profitability.

We sell our products through our own direct sales force, which sells our Acuitas AMR Gene Panel (RUO) tests and Acuitas Lighthouse Software and our QuickFISH products. All of these products and services may be offered and sold to different potential customers or involve discussions with multiple personnel in in-patient facilities. Our future sales will depend in large part on our ability to increase our marketing efforts and adequately address our customers' needs. The inpatient healthcare industry is a large and diverse market. We will need to attract and develop sales and marketing personnel with industry expertise. Competition for such employees is intense. We may not be able to attract and retain sufficient personnel to maintain an effective sales and marketing force. If we are unable to successfully market our products and adequately address our customers' needs, it could negatively impact sales and market acceptance of our products, and we may never generate sufficient revenue to achieve or sustain profitability.

If our sole manufacturing facility becomes inoperable, our Acuitas, QuickFISH and PNA FISH products, and our business will be harmed.

We manufacture our Acuitas, QuickFISH and PNA FISH products in our facility in Gaithersburg, Maryland. We do not have redundant facilities. Our facility and the equipment we use manufacture our products would be costly to replace and could require substantial lead time to repair or replace if damaged or destroyed. The facility may be harmed or rendered inoperable by natural or man-made disasters, including flooding and power outages, which may render it difficult or impossible for us manufacture our products for some period of time. The inability to manufacture our products may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

In order to establish a redundant facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. Additionally, any new manufacturing facility opened by us would be subject to FDA inspection and certification. If we fail to maintain our FDA certification or if our FDA certification is suspended, limited or revoked, we would not be able manufacture our products.

If demand for these products increases beyond our current forecasts or, regulatory requirements arise, we may not be able to meet our obligations to manufacture these products, and a backlog or reduced demand for such products could occur. If any of these issues occur, it could have a material adverse effect on our financial condition and results of operations.

We rely on a limited number of suppliers or, in some cases, a sole supplier, for some of our materials and may not be able to find replacements or immediately transition to alternative suppliers.

We rely on several sole suppliers and manufacturers, including Thermo Fisher Scientific, QIAGEN, and Fluidigm Corporation, for supplying certain reagents, raw materials, supplies and substances that we use to manufacture our products. An interruption in our operations could occur if we encounter delays or difficulties in securing these items or manufacturing our products, or if we are unable to obtain an acceptable substitute in the event of such delays or difficulties. Any such interruption could significantly affect our business, financial condition, results of operations and reputation.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenue or achieve and sustain profitability.

Our competitors include rapid diagnostic testing and traditional microbiology companies, commercial laboratories, information technology companies, and hospital laboratories who may internally develop testing capabilities. Principal competitive factors in our target market include: organizational size, scale, and breadth of product offerings; rapidity of test results; quality and strength of clinical and analytical validation data and confidence in diagnostic results; cost effectiveness; ease of use; and regulatory approval status.

Our principal competition comes from traditional methods used by healthcare providers to diagnose and screen for MDROs and from other molecular diagnostic companies creating screening and diagnostic products such as Cepheid, Becton-Dickinson, bioMérieux, Accelerate Diagnostics, T2 Biosystems, GenMark, and Nanosphere.

We also face competition from commercial laboratories, such as Bio-Reference Laboratories, Inc., Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, Pathnostics, and EuroFins, which we believe have strong infrastructure to support the commercialization of diagnostic laboratory services.

Competitors may develop their own versions of competing products in countries where we do not have patents, where our patents do not cover competitor products, or where our intellectual property rights are not recognized.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical, research and development and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by hospitals, physicians and payers as functionally equivalent to our product and service offering, or offer products at prices designed to promote market penetration, which could force us to lower the list prices of our product and service offerings and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

Our products and services are not covered by reimbursement by Medicare, Medicaid and other governmental and third-party payors. If we cannot convince our customers that the savings from use of our products and services will increase their overall reimbursement, our business could suffer.

Our products and services do not currently receive reimbursement from Medicare, Medicaid, other governmental payors or commercial third-party payors. Policy and rule changes in reimbursement announced by the United States Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS), including potential financial incentives for reductions in hospital acquired infection, and penalties and decreased Medicare reimbursement for patients with hospital acquired infections provide us with an opportunity to establish a business case for the purchase and use of our screening and diagnostic products and services. If we cannot convince our customers that the savings from use of our products and services will increase or stabilize their overall profitability and improve clinical outcomes, our business will suffer.

Failure in our information technology, storage systems or our Acuitas Lighthouse Software could significantly disrupt our operations and our research and development efforts, which could adversely impact our revenues, as well as our research, development and commercialization efforts.

Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology systems, which support our operations and our research and development efforts, as well as our storage systems and our analyzers. Due to the sophisticated nature of the technology we use in our products and service offerings, including our Acuitas Lighthouse Software services, we are substantially dependent on our information technology systems. Information technology systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, and in particular to operate our Acuitas Lighthouse Software, could adversely affect our ability to operate our business. Any interruption in the operation of our Acuitas Lighthouse Software, due to information technology system failures, part failures or potential disruptions in the event we are required to relocate our instruments within our facility or to another facility, could have an adverse effect on our operations.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including legally protected health information and personally identifiable information about our customers and their patients. We also store sensitive intellectual property and other proprietary business information, including that of our customers. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data center systems. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information.

We face four primary risks relative to protecting this critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of our being unable to identify and audit our controls over the first three risks.

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store this critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions.

A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise our networks, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the federal HIPAA and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill facilities or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare Company financial information, provide information about our current and future solutions and other patient and clinician education and outreach efforts through our website, and manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the United States and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

If we are unable to develop products to keep pace with rapid technological, medical and scientific change, our operating results and competitive position could be harmed. New test development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize our diagnostic and screening products and services. The further development and commercialization of additional diagnostic and screening product and service offerings are key to our growth strategy.

A key element of our strategy is to discover, develop, validate and commercialize a portfolio of additional diagnostic and screening products and services to rapidly diagnose and effectively treat MDRO infections and reduce the associated costs to patients, inpatient facilities and the healthcare industry. We cannot assure you that we will be able to successfully complete development of, or commercialize any of our planned future products and services, or that they will be clinically usable. The product development process involves a high degree of risk and may take up to several years or more. Our new product development efforts may fail for many reasons, including:

- failure of the tests at the research or development stage;
- lack of clinical validation data to support the effectiveness of the tests;
- delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner;
- failure to obtain or maintain necessary certifications, licenses, clearances or approvals to market or perform the test; or
- lack of commercial acceptance by in-patient healthcare facilities.

Few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of new products, or we may be required to expend considerable resources repeating clinical studies or trials, which would adversely impact the timing for generating potential revenues from those new products. In addition, as we develop new products, we will have to make additional investments in our sales and marketing operations, which may be prematurely or unnecessarily incurred if the commercial launch of a product is abandoned or delayed.

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employee benefits liability, property, umbrella, business interruption, workers' compensation, product liability, errors and omissions and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

If we use hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the use of hazardous materials and the handling of patient samples. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We are, or may in the future be, subject to compliance with additional laws and regulations relating to the protection of the environment and human health and safety, including those relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and Occupational Safety and Health Administration requirements. The requirements of these laws and regulations are complex, change frequently and could become more stringent in the future. Failure to comply with current or future environmental laws and regulations could result in the imposition of substantial fines, suspension of production, alteration of our production processes, cessation of operations or other actions, which could severely harm our business.

If we are sued for product liability or errors and omissions liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our products could lead to product liability claims if someone were to allege that a product failed to perform as it was designed. We may also be subject to liability for errors in the results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. For example, if we diagnosed a patient as having an MDRO but such result was a false positive, the patient could be unnecessarily isolated in an in-patient setting or receive inappropriate treatment. We may also be subject to similar types of claims related to products we may develop in the future. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain product liability and errors and omissions insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or errors and omissions liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our products and services. The occurrence of any of these events could have an adverse effect on our business and results of operations.

We may be adversely affected by the current economic environment and future adverse economic environments.

Our ability to attract and retain customers, invest in and grow our business and meet our financial obligations depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States and inflationary pressures. We cannot anticipate all the ways in which the current economic climate and financial market conditions, and those in the future, could adversely impact our business.

We are exposed to risks associated with reduced profitability and the potential financial instability of our customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and diagnostic testing. If fewer patients are seeking medical care because they do not have insurance coverage, we may experience reductions in revenues, profitability and/or cash flow. In addition, if economic challenges in the United States result in widespread and prolonged unemployment, either regionally or on a national basis, a substantial number of people may become uninsured or underinsured. To the extent such economic challenges result in less demand for our proprietary tests, our business, results of operations, financial condition and cash flows could be adversely affected.

Risks Related to Our Public Company Status

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Act of 2010, as well as rules implemented by the SEC and the Nasdaq Stock Market, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, compliance with these rules and regulations has increased our legal, accounting and financial compliance costs and has made some activities more time-consuming and costly. It is also more expensive for us to obtain director and officer liability insurance.

If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated.

When we are no longer an emerging growth company and a smaller reporting company, our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

When we are no longer an emerging growth company and a smaller reporting company, if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in a restatement of our financial results in the future.

We are an emerging growth company and have elected to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an emerging growth company, as defined under the Securities Act. We will remain an emerging growth company until May 2020, although if our revenue exceeds $1.07 billion in any fiscal year before that time, we would cease to be an emerging growth company as of the end of that fiscal year. In addition, if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our second fiscal quarter of any fiscal year before May 2020, we would cease to be an emerging growth company as of December 31 of that year. As an emerging growth company, we take advantage of exemptions from various reporting requirements applicable to certain other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced financial statement and financial-related disclosures, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirement of holding a nonbinding advisory vote on executive compensation and obtaining stockholder approval of any golden parachute payments not previously approved by our stockholders. We cannot predict whether investors will find our common stock less attractive if we choose to rely on any of these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure we may make, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks Related to Regulation of Our Business

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our Acuitas AMR Gene Panel tests or Acuitas Lighthouse Software, or for any other future products we may develop, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

Before we begin to label and market our products for use as clinical diagnostics in the United States, unless an exemption applies, we are required to obtain prior 510(k) clearance or a PMA from the FDA. We are currently in the process of review or completing and submission of three 510(k) filings with the FDA for our Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software. Such process is complex, time consuming and expensive. The FDA may not clear or approve these products for the indications that are necessary or desirable for successful commercialization. Failure to receive, or a significant delay in receiving, a required clearance or approval for our products would have a material adverse effect on our ability to expand our business.

Any 510(k) clearance, *de novo* authorization or PMA approval we obtain for any future product would place substantial restrictions on how our device is marketed or sold. The FDA will continue to place considerable restrictions on our products, including, but not limited to, the obligation to comply with the Quality System Regulation, or QSR, registering manufacturing facilities, listing the products with the FDA, and complying with labeling, marketing, complaint handling, medical device reporting requirements, and reporting certain corrections and removals. Obtaining FDA clearance or approval for diagnostics can be expensive and uncertain, and generally takes from several months to several years from submission, and generally requires detailed and comprehensive scientific and clinical data, as well as compliance with FDA regulations. In addition, we have limited experience in obtaining PMA approval from the FDA and are therefore supplementing our operational capabilities to manage the more complex processes needed to obtain and maintain PMAs. Notwithstanding the expense, these efforts may never result in FDA approval, *de novo* authorizations, or 510(k) clearance. Even if we were to obtain regulatory approval, authorization or clearance, it may not be for the uses we believe are important or commercially attractive, in which case we would not market our product for those uses.

We may be subject to fines, penalties, injunctions or other enforcement actions if the FDA determines that we are promoting unapproved devices or marketing our products for unapproved or "off-label" uses.

We are currently offering for sale our FDA-cleared QuickFISH and PNA FISH products for clinical diagnostic use and our Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software for RUO to CROs, pharmaceutical companies, hospitals and other healthcare facilities. An RUO product may not be marketed for clinical diagnostic use and must be labeled accordingly. Products that are intended for research use only and are properly labeled as RUO are exempt from compliance with the FDA's pre- and post-market requirements to which traditional devices are subject, including the requirement that the product be cleared or approved before commercialization and QSR requirements. However, merely including the required RUO labeling will not necessarily exempt the device from the FDA's 510(k) clearance, premarket approval, or other requirements if the circumstances surrounding the distribution of the product indicate an objective intent to market the product for clinical diagnostic use.

According to the FDA's November 2013 Guidance, circumstances indicating manufacturer intent to market an in vitro device for diagnostic use may include written or verbal marketing claims regarding a product's clinical efficacy or performance in clinical applications, instructions for clinical interpretation, clinical information, product names, or descriptors that claim or suggest that the IVD product may be used for any clinical diagnostic use, including a clinical investigation that is not exempt from the FDA's investigational device exemption regulations. Other indications include a manufacturer's provision of technical support for clinical validation or clinical applications or solicitation of business from clinical laboratories that do not conduct research activities.

We believe that our promotional activities for our ROU products fall within the scope of the FDA's enforcement discretion, as described in its November 2013 Guidance, and applicable premarket exemptions. However, the FDA could disagree and require us to stop promoting our Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software as RUO devices and obtain FDA clearance or approval for such tests. We could be subject to regulatory or enforcement actions for any of the violations described above, including, but not limited to, the issuance of an untitled letter, a Form 483 letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

A number of the rapid diagnostic products are regulated by the FDA and non-U.S. regulatory authorities. If we or our suppliers fail to comply with ongoing FDA, or other foreign regulatory authority, requirements, or if we experience unanticipated problems with the products, these products could be subject to restrictions or withdrawal from the market.

We do not have significant experience in complying with the rules and regulations of the FDA and foreign regulatory authorities. In vitro diagnostic products are generally regulated as medical devices, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such products, are subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, for any of our products commercialized as medical devices, we and our suppliers are required to comply with the following regulatory requirements, among others:

- the registration and listing regulation, which requires manufacturers to register all manufacturing facilities and list all medical devices placed into commercial distribution;

- the QSR, which requires manufacturers, including third party manufacturers, to follow elaborate design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during the manufacturing process;
- labeling regulations and unique device identification requirements;
- advertising and promotion requirements;
- restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- the FDA's general prohibition against promoting products for unapproved or "off-label" uses;
- the Medical Device Reporting, or MDR, regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur;
- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post approval study and post market surveillance requirements.

The FDA enforces the QSR and similarly, other regulatory bodies with similar regulations enforce those regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions against us: (1) untitled letters, Form 483 observation letters, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products; (7) operating restrictions; (8) withdrawing 510(k) clearances or PMA approvals that have already been granted; (9) refusal to grant export approval for our products; or (10) criminal prosecution.

If any of these actions were to occur it could harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, if any of our key component suppliers are not in compliance with all applicable regulatory requirements we may be unable to produce our products on a timely basis and in the required quantities, if at all.

Some of the clearances obtained are subject to limitations on the intended uses for which the product may be marketed, which can reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

If we were to lose, or have restrictions imposed on, FDA clearances received to date, or clearances we may receive in the future, our business, operations, financial condition and results of operations would likely be significantly adversely affected.

Modifications to our marketed products may require new 510(k) clearances or PMA approvals, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

If we modify any of our FDA-cleared products, such modifications would require additional clearances or approvals. Modifications to a 510(k)-cleared device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review the manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA requires us to seek 510(k) clearance or file a PMA for any modification to a previously cleared product, we may be required to cease marketing and distributing, or to recall the modified product until we obtain such clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA.

Our products have in the past been, and may in the future be, subject to product recalls and other similar actions that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of regulated products in the event of certain health risks and/or material deficiencies or defects in design or manufacture. Medical device recalls are typically conducted voluntarily by the manufacturer. to correct a material product deficiency, improve device performance, or correct violations of applicable FDA regulations. When a recall is initiated to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device which may present a risk to health, the FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA.

We have voluntarily initiated a number of device recalls in the past. For example, on May 14, 2018, we issued a recall of certain QuickFISH products due to a quality-control failure that occurred prior to distribution, which would have invalidated test results, and, on March 18, 2019, we issued a recall of a batch of our PNA FISH products due to the potential for diminished performance that could result in an invalid control result. The 2018 recall was terminated on April 8, 2019, and the 2019 recall was terminated on August 5, 2019.

We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

We may generate a larger portion of our future revenue internationally and would then be subject to increased risks relating to international activities which could adversely affect our operating results.

We believe that a portion of our future revenue growth will come from international sources as we implement and expand overseas operations, including South America and Europe. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign health care and other regulatory requirements and laws, such as those relating to patient privacy;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act, or FCPA, and U.K. Bribery Act, data privacy requirements, labor laws and anti- competition regulations;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- foreign exchange controls;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties protecting or procuring intellectual property rights.

As we expand internationally, our results of operations and cash flows would become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States. If the value of the U.S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected as we convert future revenue from local currencies to U.S. dollars. If we dedicate resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer.

We face the risk of potential liability under the FCPA for past international distributions of products and to the extent we distribute products or otherwise operate internationally in the future.

In the past, we have distributed certain of our products internationally, and in the future we may distribute our products internationally and possibly engage in additional international operations. The FCPA prohibits companies such as us from engaging, directly or indirectly, in making payments to foreign government and political officials for the purpose of obtaining or retaining business or securing any other improper advantage, including, among other things, the distribution of products and other international business operations. Like other U.S. companies operating abroad, we may face liability under the FCPA if we, or third parties we have used to distribute our products or otherwise advance our international business, have violated the FCPA. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

Risks Related to Compliance with Healthcare Regulations

Changes in healthcare policy, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and operations.

In March 2010, both the Patient Protection and Affordable Care Act, or Affordable Care Act, and the reconciliation law known as Health Care and Education Reconciliation Act, with the Affordable Care Act, the 2010 Health Care Reform Legislation, were enacted. The constitutionality of the 2010 Health Care Reform Legislation was confirmed twice by the Supreme Court of the United States. The 2010 Health Care Reform Legislation has changed the existing state of the health care system by expanding coverage through voluntary state Medicaid expansion, attracting previously uninsured persons through the new health care insurance exchanges and by modifying the methodology for reimbursing medical services, drugs and devices. The U.S. Congress is seeking to replace the 2010 Health Care Reform Legislation. At this time the Company is not certain as to the impact of federal health care legislation on its business.

The 2010 Health Care Reform Legislation includes the Open Payments Act (formerly referred to as the Physician Payments Sunshine Act), which, in conjunction with its implementing regulations, requires manufacturers of certain drugs, biologics, and devices that are reimbursed by Medicare, Medicaid and the Children's Health Insurance Program to report annually certain payments or "transfers of value" provided to physicians and teaching hospitals and to report annually ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. Recent amendments to the Open Payments Act expand the categories of health care providers for which reporting is required. We are evaluating the impact of such expansion on our business. The failure to report appropriate data accurately, timely, and completely could subject us to significant financial penalties. Other countries and several states currently have similar laws and more may enact similar legislation.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the Healthcare Reform Law and judicial challenges continue, and may increase in light of the current administration and legislative environment. We cannot predict the impact on our business of future legislative and legal challenges to the Healthcare Reform Law or other changes to the current laws and regulations. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for therapeutics affected by the legislation. From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing coverage, reimbursement, and marketing of pharmaceutical products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

Since taking office, President Trump has continued to support the repeal of all or portions of the Healthcare Reform Law. President Trump has also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Healthcare Reform Law and in which he directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the Healthcare Reform Law to the maximum extent permitted by law. Congress has enacted legislation that repeals certain portions of the Healthcare Reform Law, including but not limited to the Tax Cuts and Jobs Act, passed in December 2017, which included a provision that eliminates the penalty under the Healthcare Reform Law's individual mandate, effective January 1, 2019, as well as the Bipartisan Budget Act of 2018, passed in February 2018, which, among other things, repealed the Independent Payment Advisory Board (which was established by the Healthcare Reform Law and was intended to reduce the rate of growth in Medicare spending). There have also been more recent examples of judicial challenges, such as federal judges attempting to invalidate the entire Healthcare Reform Law based on the individual mandate. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation and the expansion in government's effect on the United States healthcare industry may result in decreased profits to us, which may adversely affect our business, financial condition and results of operations.

We are subject to potential enforcement actions involving false claims, kickbacks, physician self-referral or other federal or state fraud and abuse laws, and we could incur significant civil and criminal sanctions, which would hurt our business.

The government has made enforcement of the false claims, anti-kickback, physician self-referral and various other fraud and abuse laws a major priority. In many instances, private whistleblowers also are authorized to enforce these laws even if government authorities choose not to do so. In most of these cases, private whistleblowers brought the allegations to the attention of federal enforcement agencies. The risk of our being found in violation of these laws and regulations is increased by the fact that some of the laws and regulations have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. We could be subject to enforcement actions under the following laws:

- the federal Anti-Kickback Statute, which constrains certain marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent;
- federal physician self-referral laws, such as the Stark Law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral;
- the federal transparency requirements under The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, enacted into law in the United States in March 2010 (known collectively as the "Affordable Care Act"), including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third party payor, including commercial insurers, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If we or our operations are found to be in violation of any of these laws and regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. We will monitor changes in government enforcement as we grow and expand our business. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and hurt our reputation. If we were excluded from participation in U.S. federal healthcare programs, we would not be able to receive, or to sell our tests to other parties who receive reimbursement from Medicare, Medicaid and other federal programs, and that could have a material adverse effect on our business.

Risks Related to Our Intellectual Property

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.

In the future, we may license third-party technology to develop or commercialize new products. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our solutions. Royalties are a component of cost of services and affect the margins on our products. We may also need to negotiate licenses to patents and patent applications after introducing a commercial product. Our business may suffer if we are unable to enter into the necessary licenses on acceptable terms, or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable.

If we are unable to protect our intellectual property effectively, our business would be harmed.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

In July 2015, we issued a senior secured promissory note, in the principal amount of $1 million to MGHIF. Such promissory note is secured by a lien on our assets, including our intellectual property assets. If we default on our payment obligations under this secured promissory note, MGHIF has the right to control the disposition of our assets, including our intellectual property assets. If such default occurs, and our intellectual property assets are sold or licensed, our business could be materially adversely affected.

We apply for patents covering our products and technologies and uses thereof, as we deem appropriate, however we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our current or future patented technologies. We may not be successful in defending any challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation can be uncertain and any attempt by us to enforce our patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA.

In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests, like ours, are particularly uncertain. Various courts, including the U.S. Supreme Court, have recently rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that patent claims that recite laws of nature (for example, the relationship between blood levels of certain metabolites and the likelihood that a dosage of a specific drug will be ineffective or cause harm) are not themselves patentable. What constitutes a law of nature is uncertain, and it is possible that certain aspects of genetic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned and licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We may also be subject to claims that our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and face increased competition to our business. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential products, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Further, competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of our products and technologies. If our intellectual property does not adequately protect us against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We have not yet registered certain of our trademarks in all of our potential markets. If we apply to register these trademarks, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate coverage of our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

We may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect our business, operating results or financial condition.

We may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties' proprietary rights from time to time. Some of these claims may lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or challenging the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us.

We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings, or other post-grant proceedings declared by the United States Patent and Trademark Office that could result in substantial cost to us. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, recent changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require on acceptable terms or at all. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and, in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that making, having made, using, selling, offering to sell or importing our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses on acceptable terms, if at all. We could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our financial results. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our business and our ability to gain market acceptance for our products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements. All statements other than statements of historical facts contained in this prospectus, 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 described in "Risk Factors." In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus 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 need to raise capital and the uses of such capital, including funding the Interim Facility;
- our ability to successfully complete and close the transaction with Curetis;
- our need to apply a significant amount of the proceeds of this offering to support Curetis operations, 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.

These factors 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.

USE OF PROCEEDS

The net proceeds from this offering will be approximately $8.3 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriter exercises its option to purchase additional securities in full, the net proceeds from this offering will be approximately $9.6 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If all of the common warrants sold in this offering were to be exercised in cash at the exercise price of $2.00 per share, we would receive additional net proceeds of approximately $9.4 million, and if all of the pre-funded warrants sold in this offering were to be exercised in cash at an exercise price of $0.01 per share, we would receive additional net proceeds of approximately $21,000. We cannot predict when or if the common warrants or the pre-funded warrants will be exercised and they may expire and may never be exercised.

The primary programs and activities to which we intend to devote the net proceeds of this offering 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.

If any proceeds remain, 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 as far as possible into 2020.

Many of the material terms of the Interim Facility, including the interest rate, term and committed amount, have not yet been negotiated, and we may be unable to negotiate favorable terms.

The expected use of net proceeds of this offering represents our current intentions based upon our present plan and business conditions. We may use a portion of the net proceeds for the acquisitions of businesses, products, technologies or licenses that are complementary to our business, although we have no present commitments or agreements to do so. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. Our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2019 as follows:

- on an actual basis; and
- on an as adjusted basis to give effect to the sale by us of 2,590,170 units in this offering at the public offering price of $2.00 per unit, and the sale by us of 2,109,830 pre-funded units at the public offering price of $1.99 per pre-funded unit, after deducting the estimated underwriting discounts and commissions and estimated offering expenses, assuming the exercise of all pre-funded warrants and including proceeds of $0.01 per pre-funded warrant and excluding the proceeds, if any, from the exercise of common warrants issued in this offering.

You should read this table in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in, or incorporated by reference into, this prospectus.

	As of June 30, 2019	
	Actual	As Adjusted
	(In thousands, except share and per share data)	
Cash and cash equivalents	$ 3,056	$ 11,371
Debt	$ 838	$ 838
Stockholders' equity:		
Common stock, par value $0.01 per share: 50,000,000 shares authorized, 882,268 shares issued and outstanding, actual; 50,000,000 shares authorized, 5,582,268 issued and outstanding, as adjusted	9	56
Preferred stock, par value $0.01 per share; 10,000,000 shares authorized, no shares outstanding, actual and as adjusted	—	—
Additional paid-in capital	170,358	178,647
Accumulated other comprehensive loss	(15)	(15)
Accumulated deficit	(168,525)	(168,525)
Total stockholders' equity	1,827	10,163
Total capitalization	$ 2,665	$ 11,001

The number of shares of common stock to be outstanding immediately after this offering is based on 882,268 shares of our common stock outstanding as of June 30, 2019, and excludes:

- 10,542 shares of common stock issuable upon the exercise of outstanding options granted as of June 30, 2019, under our equity incentive plans at a weighted average exercise price of $410.31 per share;
- 175,982 shares of common stock issuable upon the exercise of outstanding warrants issued as of June 30, 2019, at a weighted average exercise price of $288.25 per share;

- 15,663 shares of common stock issuable upon vesting of outstanding restricted stock units granted as of June 30, 2019; and
- 4,221 shares of common stock available for future issuance under our equity incentive plans as of June 30, 2019;
- 235,000 shares of common stock, or 270,250 shares of common stock if the underwriter exercises its option to purchase additional securities in full, issuable upon exercise of warrants to be issued to the underwriter at an exercise price of 130% of the public offering price as described in "Underwriting;"
- 4,700,000 shares of common stock issuable upon the exercise of the common warrants to be issued to purchasers in this offering at an exercise price of $2.00 per share; and
- up to 2,662,564 shares of common stock issuable pursuant to the terms of the Implementation Agreement.

The number of outstanding options, restricted stock units and shares of common stock available for future issuances under our equity incentive plans does not reflect grants of 1,500 shares of common stock issuable upon vesting of restricted stock units, the expiration of stock options to purchase 499 shares of our common stock, forfeitures of stock options to purchase 107 shares of our common stock or forfeitures of 500 shares of our common stock issuable upon vesting of restricted stock units since June 30, 2019.

DILUTION

Our net tangible book value as of June 30, 2019 was approximately $274 thousand, or $0.31 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of June 30, 2019. Dilution with respect to net tangible book value per share represents the difference between the amount per unit paid by purchasers in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of 2,590,170 units in this offering at a public offering price of $2.00 per unit and 2,109,830 pre-funded units in this offering at a price of $1.99 per pre-funded unit, and after deducting estimated underwriting fees and estimated offering expenses payable by us, assuming the exercise of all pre-funded warrants and including proceeds of $0.01 per pre-funded warrant our as adjusted net tangible book value as of June 30, 2019 would have been approximately $8.6 million, or $1.54 per share. This represents an immediate increase in net tangible book value of $1.23 per share to existing stockholders and immediate dilution of $0.46 per share to purchasers purchasing our securities in this offering at the public offering price. The following table illustrates this dilution on a per share basis:

Public offering price per unit			$	2.00
Net tangible book value per share of as June 30, 2019	$	0.31		
Increase in net tangible book value per share attributable to this offering	$	1.23		
As adjusted net tangible book value per share as of June 30, 2019, after giving effect to this offering			$	1.54
Dilution per share to investors in this offering			$	0.46

If the underwriter exercises its option to purchase additional shares of common stock and/or common warrants to purchase common stock in full, the as adjusted net tangible book value per share after giving effect to this offering would be $1.58 per share, and the dilution in net tangible book value per share to new purchasers in this offering would be $0.42 per share.

The number of shares of common stock to be outstanding immediately after this offering is based on 882,268 shares of our common stock outstanding as of June 30, 2019, and excludes:

- 10,542 shares of common stock issuable upon the exercise of outstanding options granted as of June 30, 2019, under our equity incentive plans at a weighted average exercise price of $410.31 per share;
- 175,982 shares of common stock issuable upon the exercise of outstanding warrants issued as of June 30, 2019, at a weighted average exercise price of $288.25 per share;
- 15,663 shares of common stock issuable upon vesting of outstanding restricted stock units granted as of June 30, 2019; and

- 4,221 shares of common stock available for future issuance under our equity incentive plans as of June 30, 2019;
- 235,000 shares of common stock, or 270,250 shares of common stock if the underwriter exercises its option to purchase additional securities in full, issuable upon exercise of warrants to be issued to the underwriter at an exercise price of 130% of the public offering price as described in “Underwriting;”
- 4,700,000 shares of common stock issuable upon the exercise of the common warrants to be issued to purchasers in this offering at an exercise price of $2.00 per share; and
- up to 2,662,564 shares of common stock issuable pursuant to the terms of the Implementation Agreement.

The number of outstanding options, restricted stock units and shares of common stock available for future issuances under our equity incentive plans does not reflect grants of 1,500 shares of common stock issuable upon vesting of restricted stock units, the expiration of stock options to purchase 499 shares of our common stock, forfeitures of stock options to purchase 107 shares of our common stock or forfeitures of 500 shares of our common stock issuable upon vesting of restricted stock units since June 30, 2019.

PRICE RANGE FOR OUR COMMON EQUITY AND RELATED SHAREHOLDER MATTERS

Market Information

Our common stock and warrants we issued in our initial public offering, or the IPO Warrants, have traded on the Nasdaq Capital Market under the symbols “OPGN” and “OPGNW,” respectively, since May 5, 2015. Prior to such time, there was no public market for our common stock or our warrants.

Stockholder Information

On October 23, 2019, the last reported sale price of our common stock on the Nasdaq Capital Market was $3.66 per share. As of October 23, 2019, there were approximately 27 stockholders of record of our common stock, which does not include stockholders that beneficially own shares held in a “nominee” or in “street” name.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future, and we intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

MARKET AND INDUSTRY DATA

This prospectus and the documents incorporated by reference in this prospectus contain market data and industry statistics that are based on independent industry publications and other publicly available information. Although we believe that these sources are reliable, we do not guarantee the accuracy or completeness of the information and we have not independently verified this information. Although we are not aware of any misstatements regarding the market and industry data presented or incorporated by reference in this prospectus, these estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled “Risk Factors” or incorporated by reference herein, and any related free writing prospectus. Accordingly, purchasers should not place undue reliance on this information.

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 some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws and the Delaware General Corporation Law. 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 amended and restated certificate of incorporation and our amended and restated bylaws, a copy of each of which has been incorporated as an exhibit to the registration statement of which this prospectus forms a part.

Following receipt of approval from stockholders at a special meeting held on January 17, 2018, we filed an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split, or the 2018 Reverse Stock Split, of the issued and outstanding shares of our common stock, at a ratio of one share for each twenty-five shares outstanding, and to reduce the authorized shares of common stock from 200,000,000 to 50,000,000 shares. In implementing the 2018 Reverse Stock Split, the number of shares of our common stock held by each stockholder was reduced by dividing the number of shares held immediately before the 2018 Reverse Stock Split by twenty-five and then rounding down to the nearest whole share. We paid cash to each stockholder in lieu of any fractional interest in a share to which each stockholder would otherwise be entitled as a result of the 2018 Reverse Stock Split. The 2018 Reverse Stock Split did not affect any stockholder's percentage ownership interest in our Company or proportionate voting power, except to the extent that interests in fractional shares were paid in cash. At the time of the 2018 Reverse Stock Split, we also adjusted all then outstanding shares underlying restricted stock units, stock options and warrants.

On August 22, 2019, at the annual meeting of stockholders, our stockholders approved an amendment to our Amended and Restated Certificate of Incorporation, authorizing a further reverse stock split, or the 2019 Reverse Stock Split, of the issued and outstanding shares of our common stock, at a ratio within a range of not less than five-to-one and not more than twenty-five-to-one, such ratio and the implementation and timing of such reverse stock split to be determined in the discretion of our Board of Directors. On August 22, 2019, our Board of Directors approved the 2019 Reverse Stock Split of one share for twenty outstanding shares. On August 28, 2019, we filed an Amendment to our Amended and Restated Certificate of Incorporation to effect the 2019 Reverse Stock Split. The 2019 Reverse Stock Split became effective on Nasdaq on August 29, 2019. In implementing the 2019 Reverse Stock Split, the number of shares of our common stock held by each stockholder was reduced by dividing the number of shares held immediately before the 2019 Reverse Stock Split by twenty. We paid cash to each stockholder in lieu of any fractional shares to which each stockholder would otherwise be entitled as a result of the 2019 Reverse Stock Split. The 2019 Reverse Stock Split did not affect any stockholder's percentage ownership interest in our Company or proportionate voting power, other than to the extent of fractional shares settled in cash.

In addition, we have adjusted all outstanding shares underlying all outstanding restricted stock units, stock options and warrants entitling the holders to purchase shares of our common stock, as required by the terms of these securities. In particular, we have reduced the number of underlying shares, and increased the exercise price in accordance with the terms of each security based on 2019 Reverse Stock Split ratio (i.e., the number of shares issuable under such securities have been divided by twenty, and the exercise price per share has been multiplied by twenty). Also, we reduced the number of shares reserved for issuance under our existing 2015 Equity Incentive Plan, or the 2015 Plan, based on the 2019 Reverse Stock Split ratio. The 2019 Reverse Stock Split does not otherwise affect any of the rights currently accruing to holders of our common stock, or restricted stock units, stock options or warrants exercisable for our common stock.

Common Stock

As of October 23, 2019, there were 882,268 shares outstanding, 202,581 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 October 9, 2019, 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, owns in excess of 4.99% immediately prior to the closing of this offering. 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.

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.

AdvanDx Merger and MGHIF Investment

In connection with the July 2015 merger transaction among the Company, a merger sub and AdvanDx, Inc., and the related transactions in which MGHIF purchased shares of our common stock and initially issued the MGHIF Note, the Company also entered into a registration rights agreement with the AdvanDx stockholders receiving merger consideration 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. MGHIF also received rights to participate on a pro-rata basis in future securities offerings by the Company. MGHIF is the only holder of registrable securities under this registration rights agreement.

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.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering (i) 2,590,170 units, each unit consisting of one share of our common stock and one common warrant to purchase one share of our common stock, and (ii) 2,109,830 pre-funded units, each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock. The shares of common stock and accompanying common warrant included in each unit will be issued separately and will be immediately separable upon issuance, and the pre-funded warrant to purchase one share of common stock and the accompanying common warrant included in each pre-funded unit will be issued separately and will be immediately separable upon issuance. The units and pre-funded units will not be issued or certificated. We are also registering the shares of common stock included in the units and the shares of common stock issuable from time to time upon exercise of the pre-funded warrants included in pre-funded units and common warrants included in the units and the pre-funded units offered hereby.

Common Stock

The material terms and provisions of our common stock and each other class of our securities which qualifies or limits our common stock are described under the caption “Description of Capital Stock” in this prospectus.

Pre-Funded Warrants

The following summary of certain terms and provisions of the pre-funded warrants included in the pre-funded units that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective purchasers should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price

Each pre-funded warrant offered hereby has an initial exercise price per share equal to $0.01. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. 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 pre-funded warrants will be issued separately from the accompanying common warrants included in the pre-funded units, and may be transferred separately immediately thereafter.

Exercisability

The pre-funded 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 pre-funded 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 pre-funded 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 pre-funded warrants. Purchasers of pre-funded units in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Cashless Exercise

If, at the time a holder exercises its pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the pre-funded 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 pre-funded warrants.

Transferability

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

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the pre-funded 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.

Trading Market

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

Right as a Stockholder

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

Common Warrants

The following summary of certain terms and provisions of common warrants included in the units and the pre-funded units that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the common warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective purchasers should carefully review the terms and provisions of the form of common warrant for a complete description of the terms and conditions of the common warrants.

Duration and Exercise Price

Each common warrant included in the units and the pre-funded units offered hereby has an initial exercise price per share equal to $2.00. The common warrants will be 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 will be 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 immediately thereafter. A common warrant to purchase one share of our common stock will be included in each unit or pre-funded unit purchased in this offering.

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.

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. The following descriptions are summaries of the material terms of our Amended and Restated Certificate of Incorporation, as amended, and Amended and Restated Bylaws. We refer in this section to our Amended and Restated Certificate of Incorporation as our certificate of incorporation, and we refer to our Amended and Restated Bylaws as our bylaws.

Meetings of Stockholders

Our certificate of incorporation provides 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.”

On August 19, 2019, the Company received a written notification from Nasdaq notifying the Company that it has failed to comply with Nasdaq Marketplace Rule 5550(b)(1) because the Company’s stockholders’ equity as of June 30, 2019 fell below the required minimum of $2,500,000 and as of June 30, 2019, the Company did not meet the alternative compliance standards of market value of listed securities or net income from continuing operations for continued listing. In accordance with Nasdaq’s listing requirements, the Company had 45 calendar days to submit a plan to regain compliance. If the plan is accepted, Nasdaq can grant the Company an extension of up to 180 calendar days from the date it received the notification to evidence compliance. The Company submitted a plan to Nasdaq to regain compliance with the Nasdaq minimum stockholders’ equity standard on October 3, 2019, which plan included information regarding this offering. However, there can be no assurance that the Company’s plan will be accepted or that if it is, the Company will be able to regain compliance.

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.

UNDERWRITING

We have entered into an underwriting agreement dated October 23, 2019 with H.C. Wainwright & Co., LLC, as underwriter, with respect to the securities being offered hereby. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriter and the underwriter has agreed to purchase from us, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, 2,590,170 units and 2,109,830 pre-funded units.

A copy of the form of underwriting agreement has been filed as an exhibit to the registration statement of which this prospectus is a part. The securities we are offering are being offered by the underwriter subject to certain conditions specified in the underwriting agreement.

We have been advised by the underwriter that it proposes to offer the units and pre-funded units, as the case may be, directly to the public at the public offering prices set forth on the cover page of this prospectus. Any units and pre-funded units sold by the underwriter to securities dealers will be sold at the public offering price less a selling concession not in excess of $0.09 per unit or pre-funded unit.

The underwriting agreement provides that the underwriter's obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement. The underwriter is obligated to purchase and pay for all of the securities offered by this prospectus if any of these securities are purchased, other than those shares of common stock and/or warrants covered by the option to purchase additional securities described below.

No action has been taken by us or the underwriter that would permit a public offering of the units or pre-funded units in any jurisdiction where action for that purpose is required. None of the securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of units and pre-funded units and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the units or pre-funded units in any jurisdiction where that would not be permitted or legal.

Underwriting Discounts, Commissions and Expenses

The following table shows the public offering price, underwriting discounts and commissions and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriter's option to purchase additional shares of common stock and/or common warrants to purchase shares of common stock.

	Per Unit	Per Pre-funded Unit	Total Without Option	Total With Option
Public offering price	$ 2.000	$ 1.990	$ 9,378,900	$ 10,788,900
Underwriting discounts and commissions	$ 0.140	$ 0.140	$ 658,000	$ 756,700
Proceeds before expenses	$ 1.860	$ 1.850	$ 8,720,900	$ 10,032,200

We estimate the total expenses payable by us for this offering, excluding the underwriting discounts and commissions, to be approximately $406,000, which includes (i) $50,000 non-accountable expense allowance payable to the underwriter, (ii) reimbursement of the accountable expenses of the underwriter equal to $100,000, including the legal fees of the underwriter and other out-of-pocket expenses being paid by us and (iii) other estimated expenses of approximately $256,000, which include legal, accounting, printing costs and various fees associated with the registration and listing of our securities sold in this offering.

In addition, we have agreed to issue to the underwriter warrants to purchase up to 235,000 shares of common stock, or 270,250 shares of common stock if the underwriter exercises its option to purchase additional securities in full, which represents 5% of the aggregate number of shares of common stock shares of common stock (i) included within the units and (ii) issuable upon the exercise of the pre-funded warrants included within the pre-funded units sold in this offering, at an exercise price of $2.60 per share (representing 130% of the public offering price per unit or a pre-funded unit to be sold in this offering). The underwriter warrants will be exercisable immediately and for five years from the effective date of the registration statement. Pursuant to FINRA Rule 5110(g), the underwriter warrants and any shares issued upon exercise of the underwriter warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the underwriter or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

Option to Purchase Additional Securities

We have granted to the underwriter an option, exercisable not later than 30 days after the date of this prospectus, to purchase up to an additional 705,000 shares of common stock at a public offering price of $1.99 per share and/or up to 705,000 additional common warrants to purchase an aggregate of 705,000 shares of common stock at a public offering price of $0.01 per common warrant less the underwriting discounts and commissions of $0.1393 per share and $0.0007 per common warrant. If any additional shares of common stock and/or common warrants are purchased pursuant to such option, the underwriter will offer these securities on the same terms as those on which the securities are being offered hereby.

Tail Financing Payments

We have also agreed to pay the underwriter a tail fee equal to the cash and warrant compensation in this offering, if any investor, who was contacted or introduced to us by the underwriter during the term of the underwriter's engagement, provides us with capital in any public or private offering or other financing or capital raising transaction, subject to certain exceptions, during the six-month period following expiration or termination of our engagement of the underwriter.

Lock-up Agreements

Our officers and directors have agreed with the underwriter to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our common stock, or any securities convertible into, or exercisable or exchangeable for, shares of common stock, for 90 days following the closing of this offering, subject to certain exemptions. The underwriter may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

Stabilization, Short Positions and Penalty Bids

The underwriter may engage in syndicate covering transactions, stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock:

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect purchasers who purchase in the offering.

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.

- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of our securities in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriter make any representation that the underwriter will engage in these transactions or that any transactions, once commenced, will not be discontinued without notice.

Indemnification

We have agreed to indemnify the underwriter against certain liabilities, including certain liabilities arising under the Securities Act of 1933, as amended, or to contribute to payments that the underwriter may be required to make for these liabilities.

Determination of Offering Price

The offering price of the securities we are offering was negotiated between us and the underwriter based on the trading of our common stock prior to the offering, among other things.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by the underwriter, if any, participating in this offering and the underwriter may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus form a part, has not been approved or endorsed by us or the underwriter, and should not be relied upon by purchasers.

Other Relationships

The underwriter and its respective affiliates have provided, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates for which they have received and may continue to receive customary fees and commissions. The underwriter of this offering also acted as our placement agent in connection with the registered public offerings we consummated in July 2017 and February 2018.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol "OPGN." We do not intend to apply for listing of the common warrants or pre-funded warrants on any securities exchange or other nationally recognized trading system.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following is a summary of the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock and pre-funded warrants and the acquisition, ownership, exercise, expiration or disposition of common warrants acquired in this offering, but does not purport to be a complete analysis of all the potential tax considerations relating thereto. Throughout this summary, all references to our common stock are meant to include the common stock issuable upon exercise of the pre-funded warrants in the pre-funded units. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed or subject to differing interpretations, possibly with retroactive effect, with the resulting U.S. federal income tax consequences being different from those set forth below. We have not sought and will not seek any ruling from the Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This summary also does not address the tax considerations arising under the laws of any U.S. state or local or any non-U.S. jurisdiction, estate or gift tax, the 3.8% Medicare tax on net investment income or any alternative minimum tax consequences. In addition, this discussion does not address tax considerations applicable to a holder's particular circumstances or to a holder that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions;
- tax-exempt or government organizations;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than 5.0% of our capital stock;
- certain U.S. expatriates, citizens or former long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction," synthetic security, other integrated investment, or other risk reduction transaction;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes);
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- pension plans;
- partnerships, or other entities or arrangements treated as partnerships for U.S. federal income tax purposes, or investors in any such entities;
- persons for whom our stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code;
- integral parts or controlled entities of foreign sovereigns;

- passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax; or
- persons that acquire our common stock as compensation for services.

In addition, if a partnership, including any entity or arrangement classified as a partnership for U.S. federal income tax purposes, holds our common stock, the tax treatment of a partner generally will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors regarding the U.S. federal income tax consequences to them of the purchase, ownership, and disposition of our common stock.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax rules or under the laws of any U.S. state or local or any non-U.S. or other taxing jurisdiction or under any applicable tax treaty.

Allocation of Purchase Price and Characterization of a Unit

Each unit and pre-funded unit should be treated for U.S. federal income tax purposes as an investment unit consisting of one share of common stock and one warrant. For U.S. federal income tax purposes, each holder must allocate the purchase price of the unit or pre-funded unit between that share of common stock or pre-funded warrant, as applicable, and the warrant based on the relative fair market value of each at the time of issuance. The price allocated to each share of common stock, pre-funded warrant and common warrant generally will be the holder's tax basis in such share or warrant, as the case may be.

Treatment of Pre-Funded Warrant

Although it is not entirely free from doubt, we believe a pre-funded warrant should be treated as common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of our common stock, as described below. Accordingly, no gain or loss should be recognized upon the exercise of a pre-funded warrant and, upon exercise, the holding period of a pre-funded warrant should carry over to the common stock received. Similarly, the tax basis of the pre-funded warrant should carry over to the common stock received upon exercise, increased by the exercise price of $0.01 per share**.** However, our characterization of a pre-funded warrant is not binding on the IRS, and the IRS may treat our pre-funded warrants as warrants to acquire our common stock. If so, the amount and character of your gain with respect to an investment in our pre-funded warrants could change. Accordingly, each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of pre-funded warranst pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that our characterization described above is respected for U.S. federal income tax purposes.

Definition of a U.S. Holder

For purposes of this summary, a "U.S. Holder" is any beneficial owner of our common stock, pre-funded warrants or common warrants that is a "U.S. person," and is not a partnership, or an entity treated as a partnership or disregarded from its owner, each for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

For purposes of this summary, a "Non-U.S. Holder" is any beneficial owner of our common stock, pre-funded warrants or common warrants that is not a U.S. Holder or a partnership, or other entity treated as a partnership or disregarded from its owner, each for U.S. federal income tax purposes.

Tax Consequences to U.S. Holders

Exercise and Expiration of Warrants

In general, a U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a warrant, except to the extent the U.S. Holder receives a cash payment for a such fractional share that would otherwise have been issuable upon exercise of the warrant, which will be treated as a sale subject to the rules described under "Sale or Other Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants" below. The U.S. Holder will take a tax basis in the shares acquired on the exercise of a warrant equal to the exercise price of the warrant. The U.S. Holder's holding period in the shares of our common stock acquired on exercise of the warrant will begin on the date of exercise of the warrant, and will not include any period for which the U.S. Holder held the warrant. The lapse or expiration of a warrant will be treated as if the U.S. Holder sold or exchanged the warrant and recognized a capital loss equal to the U.S. Holder's tax basis in the warrant. The deductibility of capital losses is subject to limitations.

Certain Adjustments to the Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the warrants, or an adjustment to the exercise price of the warrants, may be treated as a constructive distribution to a U.S. Holder of the warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. Holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our stockholders). Adjustments to the exercise price of warrants made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the warrants generally should not be considered to result in a constructive distribution. Such constructive distribution would be treated as a dividend, return of capital or capital gain as described under the heading "Distributions" below. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property.

On April 12, 2016, the IRS issued proposed regulations addressing the amount and timing of deemed distributions, obligations of withholding agents and filing and notice obligations of issuers. If adopted as proposed, the regulations would generally provide that (i) the amount of a deemed distribution is the excess of the fair market value of a warrant immediately after the number-of-shares or exercise-price adjustment over the fair market value of the warrant without the adjustment, (ii) the deemed distribution occurs at the earlier of the date the adjustment occurs under the terms of the warrant and the date of the actual distribution of cash or property that results in the deemed distribution, and (iii) we are required to report the amount of any deemed distributions on our website or to the IRS and all holders of warrants (including holders of warrants that would otherwise be exempt from reporting). The final regulations will be effective for deemed distributions occurring on or after the date of adoption, but holders of warrants agents may rely on them prior to that date under certain circumstances.

Distributions

As discussed above under "Dividend Policy," we do not currently expect to make distributions on our common stock. In the event that we do make distributions of cash or other property, distributions paid on common stock or pre-funded warrants, other than certain pro rata distributions of common stock or pre-funded warrants, will be treated as a dividend to the extent paid out of our current or accumulated earnings and profits, if any, and will be includible in income by the U.S. Holder and taxable as ordinary income when received. If a distribution exceeds our current and accumulated earnings and profits, the excess will be first treated as a tax-free return of the U.S. Holder's investment, up to the U.S. Holder's tax basis in the common stock or pre-funded warrant, as applicable. Any remaining excess will be treated as a capital gain. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be eligible for taxation as "qualified dividend income" and therefore may be taxable at rates applicable to long-term capital gains. U.S. Holders should consult their tax advisers regarding the availability of the reduced tax rate on dividends in their particular circumstances. Dividends received by a corporate U.S. Holder will be eligible for the dividends-received deduction if the U.S. Holder meets certain holding period and other applicable requirements.

Sale or Other Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants

For U.S. federal income tax purposes, gain or loss realized on the sale or other disposition of common stock, pre-funded warrants or common warrants will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the common stock, pre-funded warrants or common warrants, as applicable, for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the common stock, pre-funded warrants, or common warrants disposed of and the amount realized on the disposition. Long-term capital gains recognized by non-corporate U.S. Holders will be subject to reduced tax rates. The deductibility of capital losses is subject to limitations.

Tax Consequences to Non-U.S. Holders

Exercise and Expiration of Warrants

In general, a Non-U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a warrant, except to the extent the Non-U.S. Holder receives a cash payment for a fractional share that would otherwise have been issuable upon exercise of the warrant, which will be treated as a sale subject to the rules described under "Gain on Sale or Other Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants" below. The Non-U.S. Holder will take a tax basis in the shares acquired on the exercise of a warrant equal to the exercise price of the warrant. The Non-U.S. Holder's holding period in the shares of our common stock acquired on exercise of the warrant will begin on the date of exercise of the warrant, and will not include any period for which the Non-U.S. Holder held the warrant.

The expiration of a warrant will be treated as if the Non-U.S. Holder sold or exchanged the warrant and recognized a capital loss equal to the Non-U.S. Holder's tax basis in the warrant. However, a Non-U.S. Holder will not be able to utilize a loss recognized upon expiration of a warrant against the Non-U.S. Holder's U.S. federal income tax liability unless the loss is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment in the United States) or is treated as a U.S.-source loss and the Non-U.S. Holder is present 183 days or more in the taxable year of disposition and certain other conditions are met.

Certain Adjustments to the Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the warrants, or an adjustment to the exercise price of the warrants, may be treated as a constructive distribution to a Non-U.S. Holder of the warrants if, and to the extent that, such adjustment has the effect of increasing such Non-U.S. Holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of warrants made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the warrants generally should not be considered to result in a constructive distribution. Such constructive distribution would be treated as a dividend, return of capital or capital gain as described under the heading "Distributions" below. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property.

On April 12, 2016, the IRS issued proposed regulations addressing the amount and timing of deemed distributions, obligations of withholding agents and filing and notice obligations of issuers. If adopted as proposed, the regulations would generally provide that (i) the amount of a deemed distribution is the excess of the fair market value of a warrant immediately after the number-of-shares or exercise-price adjustment over the fair market value of the warrant without the adjustment, (ii) the deemed distribution occurs at the earlier of the date the adjustment occurs under the terms of the warrant and the date of the actual distribution of cash or property that results in the deemed distribution, (iii) subject to certain limited exceptions, a withholding agent is required to impose any applicable withholding on deemed distributions to a Non-U.S. Holder and, if there is no associated cash payment, may set off its withholding obligations against other payments to or funds of such holder and (iv) we are required to report the amount of any deemed distributions on our website or to the IRS and all holders of warrants (including holders of warrants that would otherwise be exempt from reporting). The final regulations will be effective for deemed distributions occurring on or after the date of adoption, but holders of warrants and withholding agents may rely on them prior to that date under certain circumstances.

Distributions

As discussed in the section entitled “Dividend Policy,” we do not anticipate paying any dividends on our common stock in the foreseeable future. If we make distributions on our common stock or pre-funded warrants, those payments will constitute dividends for U.S. federal income tax purposes to the extent we have current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce a Non-U.S. Holder’s basis in our common stock or pre-funded warrants, as applicable, but not below zero. Any excess will be treated as capital gain and will be treated as described below under the “—Gain on Sale or Other Disposition of Common Stock, Pre-Funded Warrnts or Common Warrants” section. Any such distributions would be subject to the discussions below regarding back-up withholding and the Foreign Account Tax Compliance Act, or FATCA.

Subject to the discussion below on effectively connected income, any dividend paid to a Non-U.S. Holder generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. To receive a reduced treaty rate, a Non-U.S. Holder must provide us or our agent with an IRS Form W-8BEN (generally including a U.S. taxpayer identification number), IRS Form W-8 BEN-E or another appropriate version of IRS Form W-8 (or a successor form), which must be updated periodically, and which, in each case, must certify qualification for the reduced treaty rate. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States and that are not eligible for relief from U.S. (net basis) income tax under an applicable income tax treaty, generally are exempt from the (gross basis) withholding tax described above. To obtain this exemption from withholding tax, the Non-U.S. Holder must provide the applicable withholding agent with an IRS Form W-8ECI or successor form or other applicable IRS Form W-8 certifying that the dividends are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States. Such effectively connected dividends, if not eligible for relief under a tax treaty, would not be subject to a withholding tax, but would be taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits and if, in addition, the Non-U.S. Holder is a corporation, may also be subject to a branch profits tax at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty).

If you are eligible for a reduced rate of withholding tax pursuant to a tax treaty, you may be able to obtain a refund of any excess amounts withheld if you timely file an appropriate claim for refund with the IRS.

Gain on Sale or Other Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants

Subject to the discussion below regarding backup withholding and FATCA, a Non-U.S. Holder generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock, pre-funded warrants or common warrants unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States and not eligible for relief under an applicable income tax treaty, in which case the Non-U.S. Holder will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and for a Non-U.S. Holder that is a corporation, such Non-U.S. Holder may be subject to the branch profits tax at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items;

- the Non-U.S. Holder is an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met, in which case the Non-U.S. Holder will be required to pay a flat 30% tax on the gain derived from the sale, which tax may be offset by U.S. source capital losses (even though the Non-U.S. Holder is not considered a resident of the United States) (subject to applicable income tax or other treaties); or

- we are a "U.S. real property holding corporation" for U.S. federal income tax purposes, or a USRPHC, at any time within the shorter of the five-year period preceding the disposition or the Non-U.S. Holder's holding period for our common stock, pre-funded warrants or common warrants, as applicable. We believe we are not currently and do not anticipate becoming a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock, pre-funded warrants, or common warrants will not be subject to United States federal income tax if (a) shares of our common stock are "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, such as Nasdaq, and (b) the Non-U.S. Holder owns or owned, actually and constructively, 5% or less of the shares of our common stock and pre-funded warrants throughout the five-year period ending on the date of the sale or exchange. If the foregoing exception does not apply, such Non-U.S. Holder's proceeds received on the disposition of shares will generally be subject to withholding at a rate of 15% and such Non-U.S. Holder will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Information Reporting and Backup Withholding

Information returns may be filed with the IRS in connection with distributions on common stock or pre-funded warrants, and the proceeds of a sale or other disposition of common stock or pre-funded warrants. A non-exempt U.S. Holder may be subject to U.S. backup withholding on these payments if it fails to provide its taxpayer identification number to the withholding agent and comply with certification procedures or otherwise establish an exemption from backup withholding.

A Non-U.S. Holder may be subject to U.S. information reporting and backup withholding on these payments unless the Non-U.S. Holder complies with certification procedures to establish that it is not a U.S. person (within the meaning of the Code). The certification requirements generally will be satisfied if the Non-U.S. Holder provides the applicable withholding agent with a statement on the applicable IRS Form (or a suitable substitute or successor form), together with all appropriate attachments, signed under penalties of perjury, stating, among other things, that such Non-U.S. Holder is not a U.S. Person. Applicable Treasury Regulations provide alternative methods for satisfying this requirement. In addition, the amount of distributions on common stock or pre-funded warrants paid to a Non-U.S. Holder, and the amount of any U.S. federal tax withheld therefrom, must be reported annually to the IRS and the holder. This information may be made available by the IRS under the provisions of an applicable tax treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides.

Payment of the proceeds of the sale or other disposition of common stock, pre-funded warrants or common warrants to or through a non-U.S. office of a U.S. broker or of a non-U.S. broker with certain specified U.S. connections generally will be subject to information reporting requirements, but not backup withholding, unless the Non-U.S. Holder certifies under penalties of perjury that it is not a U.S. person or an exemption otherwise applies. Payments of the proceeds of a sale or other disposition of common stock, pre-funded warrants or common warrants to or through a U.S. office of a broker generally will be subject to information reporting and backup withholding, unless the Non-U.S. Holder certifies under penalties of perjury that it is not a U.S. person or otherwise establishes an exemption.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment generally will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle the holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Accounts

The Code generally imposes a U.S. federal withholding tax of 30% on dividends and, subject to the discussion below regarding proposed regulations recently issued by the U.S. Treasury Department, the gross proceeds of a disposition of our securities paid to a "foreign financial institution" (as specifically defined for this purpose), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise qualifies for an exemption from these rules. A U.S. federal withholding tax of 30% also applies to dividends and, subject to the discussion below regarding proposed regulations recently issued by the U.S. Treasury Department, will apply to the gross proceeds of a disposition of our securities paid to a non-financial foreign entity (as defined in the Code), unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect. "United States owners" (as defined in the Code), provides information regarding each substantial United States owners of the entity, or otherwise qualifies for an exemption from these rules.

Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph.

The U.S. Treasury Department recently released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock, pre-funded warrants and common warrants. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. Prospective purchasers should consult their own tax advisors regarding the possible impact of these rules on their investment in our common stock, pre-funded warrants and common warrants, and the possible impact of these rules and the proposed regulations on the entities through which they hold our common stock, pre-funded warrants and common warrants, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of this 30% withholding tax.

EACH PROSPECTIVE PURCHASER SHOULD CONSULT ITS TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR SECURITIES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS. IN ADDITION, SIGNIFICANT CHANGES IN U.S. FEDERAL TAX LAWS WERE RECENTLY ENACTED. PROSPECTIVE PURCHASERS SHOULD ALSO CONSULT WITH THEIR TAX ADVISORS WITH RESPECT TO SUCH CHANGES IN U.S. TAX LAW AS WELL AS POTENTIAL CONFORMING CHANGES IN STATE TAX LAWS.

LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Ballard Spahr LLP, Philadelphia, Pennsylvania. Haynes and Boone, LLP, New York, New York is acting as counsel for the underwriter in connection with the securities offered hereby.

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 in this offering. 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 OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede the information in this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC (Commission File No. 001-37367):

- 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 and June 30, 2019, filed with the SEC on May 15, 2019 and August 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) and September 4, 2019 (Items 1.01 and 9.01 (except for Exhibit 99.2)) and September 18, 2019 (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

Copies of these filings are also available through the “Investor” section of our website at www.opgen.com. For other ways to obtain a copy of these filings, please refer to “Where You Can Find More Information” above.

Any information in any of the foregoing documents will automatically be deemed to be modified or superseded to the extent that information in this prospectus modifies or replaces such information.

CURETIS BUSINESS
COMBINED FINANCIAL STATEMENTS

Combined Financial Statements for the Years Ended December 31, 2018 and 2017

Unaudited Interim Condensed Combined Financial Statement for the Six Months Ended June 30, 2019 and 2018

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.

CURETIS BUSINESS
NOTES TO THE 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, I	Amended by Annual Improvements to IFRS	1 January 2019
AS 12, IAS 23	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 are 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
thereof from share-based payments equity-settled	*113*	*370*
Depreciation and Amortization	74	170
Other operating expenses	3,057	2,881
thereof marketing expenses	*1,410*	*1,138*
thereof travel expenses	*746*	*520*
thereof consulting, advisory & third party service	*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
thereof from share-based payments equity-settled	*111*	*116*
Depreciation and Amortization	90	104
Other expenses	2,224	1,964
thereof for remuneration of supervisory board	*409*	*359*
thereof consulting, advisory & third party service	*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
thereof from share-based payments equity-settled	*141*	*32*
Depreciation and Amortization	861	810
Material expenses	513	407
Other expenses	5,010	2,994
thereof IP-fees and expenses for patent lawyers	*576*	*—*
thereof external services for clinical trial	*351*	*367*
thereof costs for laboratory demand	*473*	*303*
thereof consulting, advisory & third party service	*1,999*	*—*
thereof other manufacturing expenses for cartridges used in R&D	*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
EPOSs / 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:

in kEUR	Curetis GmbH		
	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 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.):

	Tranche 1	**Tranche 2**	**Tranche 3**	**Tranche 4**	**Tranche 5**
Grant date	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	—	—	—	—	—

	Tranche 6	Tranche 7	Tranche 8	Tranche 9	Tranche 10
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 1 October 2017	Tranche 7 1 January 2018	Tranche 8 1 March 2018	Tranche 9 1 July 2018	Tranche 10 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	/s/ ppa. Andreas Schuster
Dietmar Eglauer	ppa. Andreas Schuster
Wirtschaftsprüfer	Wirtschaftsprüfer
(German Public Auditor)	(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
UNAUDITERD 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.

CURETIS BUSINESS
NOTES TO THE UNAUDTIED INTERIM CONDENDSED 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
thereof marketing expenses	*534*	*712*
thereof travel expenses	*192*	*365*
thereof consulting, advisory & 3rd party service	*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
thereof for remuneration of supervisory board	*206*	*210*
thereof consulting, advisory & 3rd party service	*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
thereof IP-fees and expenses for patent lawyers	*121*	*370*
thereof external services for clinical trial	*99*	*83*
thereof costs for laboratory demand	*115*	*278*
thereof consulting, advisory & 3rd party service	*785*	*890*
thereof other manufacturing expenses for cartridges used in R&D	*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.):

	Tranche 1	Tranche 2	Tranche 3	Tranche 4	Tranche 5	Tranche 6
Grant date	1 July 2016	1 October 2016	1 January 2017	1 April 2017	1 July 2017	1 October 2017
Granted stock options	170,000	45,000	42,500	5,000	20,000	123,500
Remaining contractual term of the option	7.00 years	7.25 years	7.50 years	7.75 years	8.00 years	8.25 years
Exercise price	6.45 Euro	6.41 Euro	6.42 Euro	5.81 Euro	4.93 Euro	4.98 Euro
Outstanding at 1 January 2019	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	—	—	—	—	—

Grant date	Tranche 7 1 January 2018	Tranche 8 1 March 2018	Tranche 9 1 July 2018	Tranche 10 1 October 2018	Tranche 11 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:

Measurement date[1]	Tranche 11 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**
Expense arising from equity-settled share-based payment transactions		
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

2,590,170 Units (each Unit contains One Share of Common Stock and One Common Warrant to purchase One Share of Common Stock)

2,109,830 Pre-funded Units (each Pre-funded Unit contains One Pre-funded Warrant to Purchase One Share of Common Stock and One Common Warrant to purchase One Share of Common Stock)

2,109,830 Shares of Common Stock Underlying the Pre-funded Warrants and

4,700,000 Shares of Common Stock Underlying the Common Warrants

H.C. Wainwright & Co.

October 23, 2019