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Registration Statement No. 333-234657

OPGEN, INC.
708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878

NOTICE OF SPECIAL MEETING OF STOCKHOLDERS
To Be Held On March 10, 2020

January 27, 2020

Dear Stockholder:

NOTICE IS HEREBY GIVEN of, and you are cordially invited to attend, a Special Meeting of Stockholders, or the Special Meeting, of OpGen, Inc., a Delaware corporation, or the Company. The Special Meeting will be held on March 10, 2020, at 10:00 a.m. local time at the offices of Ballard Spahr LLP, 1909 K Street, NW, 12th Floor, Washington DC, for the following purposes:

1. To approve the business combination transaction pursuant to an Implementation Agreement dated September 4, 2019, or the Implementation Agreement, by and among the Company, Curetis N.V., a public company with limited liability under the Laws of the Netherlands, or the Seller, and Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and wholly owned subsidiary of the Company, or the Purchaser. We refer to this proposal as the "Transaction Proposal."

2. To approve the issuance or reservation for issuance of 2,662,564 shares of the Common Stock to be issued or reserved for issuance in connection with the transaction contemplated by the Implementation Agreement, or the Transaction Shares, in accordance with the Implementation Agreement and as required by and in accordance with the applicable rules of The Nasdaq Capital Market, or Nasdaq. We refer to this proposal as the "Share Issuance Proposal."

3. To approve a proposal to adjourn the Special Meeting to a later date or dates, if necessary, to permit further solicitation and vote of proxies if, based upon the tabulated vote at the time of the Special Meeting, the Company is not authorized to consummate the transactions contemplated by Proposals No. 1 and 2. We refer to this proposal as the "Adjournment Proposal."

These items of business are more fully described in the proxy statement/prospectus accompanying this Notice. **We encourage you to read the enclosed proxy statement/prospectus carefully, including the section titled "Risk Factors" beginning on page 8**.

Stockholders of record at the close of business on January 24, 2020, or the Record Date, are entitled to notice of, and to attend and to vote at, the Special Meeting and any postponement or adjournment thereof. This Notice of Special Meeting of Stockholders and the attached proxy statement/prospectus are first being furnished to the Company's stockholders on or about January 27, 2020.

Based on the price of the OpGen common stock as of January 21, 2020 of $1.76 per share, the market value of the Transaction Shares is approximately $4.7 million. Such market value will vary with any change in the OpGen common stock price. We cannot assure you the value will remain the same. Based on the fixed number of Transaction Shares, and assuming that OpGen does not issue additional shares before the closing of the proposed Transaction, Curetis will own approximately 32% of the OpGen shares and the legacy OpGen stockholders will own approximately 68% of the OpGen shares on a fully diluted basis.

All stockholders are cordially invited to attend the Special Meeting in person. Stockholders of record as of the Record Date will be admitted to the Special Meeting and any postponement or adjournment thereof upon presentation of identification. Please note that if your shares are held in the name of a bank, broker, or other nominee, and you wish to vote in person at the Special Meeting, you must bring to the Special Meeting a statement or letter from your bank, broker or other nominee showing your ownership of shares as of the Record Date and a proxy from the record holder of the shares authorizing you to vote at the Special Meeting.

The Board of Directors unanimously recommends that you vote:

1. "**FOR**" Proposal One – the Transaction Proposal;

2. "**FOR**" Proposal Two – the Share Issuance Proposal; and

3. "**FOR**" Proposal Three – the Adjournment Proposal.

Whether or not you plan to attend the Special Meeting in person, you are encouraged to read the proxy statement/prospectus accompanying this Notice and then cast your vote as promptly as possible in accordance with the instructions contained in the proxy statement/prospectus. Even if you have given your proxy, you may still vote in person if you attend the Special Meeting and follow the instructions contained in the attached proxy statement/prospectus.

Your vote is important whether or not you expect to attend the Special Meeting. We urge you to vote by proxy to ensure your vote is counted. You are urged to vote either via the internet, or to mark, sign and date and promptly return the proxy in the stamped return envelope provided with these materials. Voting promptly will help avoid the additional expense of further solicitation to assure a quorum at the meeting.

By Order of the Board of Directors:

By: 

Timothy C. Dec
Corporate Secretary
Gaithersburg, Maryland
January 27, 2020

The accompanying proxy statement/prospectus is dated January 24, 2020 and is first being furnished to stockholders on or about January 27, 2020.

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

IMPORTANT NOTICE REGARDING THE AVAILABILITY OF PROXY MATERIALS FOR THE SPECIAL MEETING OF STOCKHOLDERS TO BE HELD ON MARCH 10, 2020

The Notice of Special Meeting and OpGen's proxy statement/ prospectus are available at: http:// www.pstvote.com/opgenspecial2020

January 24, 2020

REFERENCES TO ADDITIONAL INFORMATION

This proxy statement/prospectus incorporates important business and financial information about the Company that has been filed with the U.S. Securities and Exchange Commission and is not included in or delivered with this document. You may obtain this information without charge through the SEC website (www.sec.gov) or upon your written or oral request by contacting the Corporate Secretary of the Company, 708 Quince Orchard Road, Suite 205, Gaithersburg, MD 20878 or by calling 301.869.9683.

OpGen stockholders may also consult the website of OpGen for more information concerning the business combination with Curetis GmbH and other transactions described in the accompanying proxy statement/prospectus. The website of OpGen is www.opgen.com. Information included on this website is not incorporated by reference into the accompanying proxy statement/prospectus.

To ensure timely delivery of these documents, any request should be made no later than March 3, 2020 to receive them before the special meeting.

This proxy statement/prospectus is dated January 24, 2020. You should not assume that the information contained in this prospectus is accurate as of any date other than that date.

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 proxy statement/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 Condensed Combined Financial Information," all Curetis financial results and measures in this proxy statement/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.

For additional details about where you can find information about the Company, please see the section titled "Where You Can Find More Information" in this proxy statement/prospectus beginning on page 208.

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OPGEN, INC.
708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878

The following information is furnished to each stockholder in connection with the foregoing Notice of Special Meeting of Stockholders of OpGen, Inc., a Delaware corporation, to be held on March 10, 2020, at 10:00 a.m. local time at the offices of Ballard Spahr LLP, 1909 K Street, NW, 12th Floor, Washington DC. The enclosed proxy is for use at the special meeting of stockholders and any postponement or adjournment thereof. This proxy statement/prospectus and form of proxy are being furnished to stockholders on or about January 27, 2020. Unless the context requires otherwise, references in this proxy statement/prospectus to "OpGen," the "Company," "we," "our," and "us" refer to OpGen, Inc.

In accordance with the Amended and Restated Bylaws of the Company, or the Bylaws, the Special Meeting has been called for the following purposes:

1. To approve the business combination transaction pursuant to an Implementation Agreement, dated September 4, 2019, or the Implementation Agreement, by and among the Company, Curetis N.V., a public company with limited liability under the Laws of the Netherlands, or the Seller, and Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and wholly owned subsidiary of the Company, or the Purchaser. We refer to this proposal as the "Transaction Proposal."

2. To approve the issuance of shares of the Common Stock to be issued or reserved for issuance in connection with the transaction contemplated by the Implementation Agreement, or the Transaction Shares, in accordance with the Implementation Agreement and as required by and in accordance with the applicable rules of The Nasdaq Capital Market, or Nasdaq. We refer to this proposal as the "Share Issuance Proposal."

3. To approve a proposal to adjourn the Special Meeting to a later date or dates, if necessary, to permit further solicitation and vote of proxies if, based upon the tabulated vote at the time of the Special Meeting, the Company is not authorized to consummate the transactions contemplated by Proposals No. 1 and 2. We refer to this proposal as the "Adjournment Proposal."

Pursuant to the Bylaws of the Company, no business is proper for consideration, or may be acted upon, at the Special Meeting, except as set forth in the Notice of Special Meeting of Stockholders.

Shares represented by duly executed and unrevoked proxies will be voted at the Special Meeting and any postponement or adjournment thereof in accordance with the specifications made therein. **If no such specification is made, shares represented by duly executed and unrevoked proxies will be voted "FOR" each of Proposals 1, 2 and 3**.

PROXY STATEMENT/PROSPECTUS SUMMARY

This summary highlights selected information from this proxy statement/prospectus and may not contain all of the information that is important to you. To better understand the Transaction and the proposals being considered at the Special Meeting, you should read this entire proxy statement/prospectus carefully, including the Implementation Agreement and the other documents to which you are referred to herein. For more information, please see the section titled "Where You Can Find More Information."

The Companies

OpGen (see page 95)

OpGen, Inc.
708 Quince Orchard Road
Suite 205
Gaithersburg, Maryland 20878
(301) 869-9683

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

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

- Our molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include the Acuitas antimicrobial resistance, or AMR, Gene Panel (Urine) test in development for patients at risk for complicated urinary tract infections, or cUTI, the Acuitas AMR Gene Panel (Isolates) test in development for testing bacterial isolates, and the QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of our Acuitas AMR Gene Panel tests is currently available for sale in the United States for research use only, or RUO, and none have been granted FDA clearance to date. This means that, currently, we cannot market these tests for clinical diagnostic uses.

- Our Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that are designed to combine clinical lab test results with patient and hospital information to provide analytics and actionable insights to help manage MDROs in the hospital and patient care environment. Components of the informatics systems include the Acuitas Lighthouse Knowledgebase and the Acuitas Lighthouse Software. The Acuitas Lighthouse Knowledgebase is a relational database management system and a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens. The Acuitas Lighthouse Software system includes the Acuitas Lighthouse Portal, a suite of web applications and dashboards, the Acuitas Lighthouse Prediction Engine, which is a data analysis software, and other supporting software components. The Acuitas Lighthouse Software can be customized and made specific to a healthcare facility or collaborator, such as a pharmaceutical company. The Acuitas Lighthouse Software has not yet been cleared for marketing in the United States. It is currently available for RUO and may not be distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

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

Curetis Group (see page 123)

Curetis N.V. and Curetis GmbH
Max-Eyth-Str. 42
71088 Holzgerlingen
Germany
+49 (0)7031 49195 10

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

The Curetis business is based on two complementary business pillars:

- The Unyvero A50 high-plex polymerase chain reaction, or PCR, platform for comprehensive and rapid diagnosis of severe infectious diseases in hospitalized patients. The platform is based on proven, intelligently integrated technologies, allowing for the testing of broad panels of pathogens and antibiotic resistance markers and the processing of a large variety of native patient samples with an intuitive workflow. The Unyvero A50 high-plex PCR platform's advantage is the timely access to comprehensive, actionable and reliable data. Curetis' molecular tests for different indications are commercially available in Europe, the United States, Asia and the Middle East. The Curetis Group is also developing the Unyvero A30 *RQ* Analyzer, which is designed to serve as a platform with low-to medium-plex capabilities that it ultimately intends to commercially leverage predominantly in collaborations with one or more diagnostics industry partners.

- The ARES AMR database, or ARESdb, is a comprehensive database of the genetics of antimicrobial resistance, or AMR, which permits Curetis to increasingly utilize the proprietary biomarker content in its own assay and cartridge development, as well as to build an independent business in next-generation sequencing, or NGS, based offerings for AMR research and diagnostics in collaboration with partners in the life science, pharmaceutical and diagnostics industries. ARESdb is not commercially available in the United States for diagnostic use, as it has not been cleared by the FDA for marketing. In September 2019, Ares Genetics, a wholly owned subsidiary of Curetis, or Ares Genetics, signed a technology evaluation agreement with an undisclosed global IVD corporation. In the first phase of the collaboration, expected to take about 10 months, Ares Genetics expects to further enrich ARESdb with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication.

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

Overview of the Implementation Agreement and the Transaction (see page 70)

As announced on September 4, 2019, OpGen has entered into an Implementation Agreement with Curetis N.V., or the Seller, 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, or the Purchaser, 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 proxy statement/prospectus.

Pursuant to the Implementation Agreement, the business of the Seller and the business of the Company will be combined by the Purchaser's acquisition of (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. We refer to such acquisition, together with the other transactions contemplated by the Implementation Agreement as the "Transaction." 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, and (2) 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. OpGen had also agreed to assume 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, but since the date of the Implementation Agreement, Curetis has issued additional shares to the holders of the PSOPs, and all have been retired. The shares previously reserved to cover the PSOPs will be issued to Curetis N.V. as part of the Consideration. The Purchaser will also assume all of the liabilities of the Seller solely and exclusively related to the business being acquired, which is providing innovative solutions, through development of proprietary platforms, diagnostic content, applied bioinformatics, lab services, research services and commercial collaborations and agreements, for molecular microbiology, diagnostics designed to address the global challenge of detecting severe infectious diseases and identifying antibiotic resistances in hospitalized patients, or the Business.

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

The Transaction under the Implementation Agreement is subject to approval by the stockholders and debt holder of the Company and the shareholders and debt holders of Curetis N.V. and Curetis GmbH. The parties anticipate that, if such approvals are obtained and all other closing conditions are satisfied or waived, the Transaction will close in the first quarter of 2020.

The Implementation Agreement contains customary representations and warranties of the parties and the parties have agreed to use their commercially reasonable efforts to take all actions necessary to consummate the closing of the transactions contemplated by the Implementation Agreement.

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

On November 12, 2019, Crystal GmbH, OpGen's subsidiary, as Lender, and Curetis GmbH, as Borrower, entered into the Interim Facility Agreement, or the Interim Facility. Under the Interim Facility, the Lender shall lend to the Borrower, for the benefit of the Curetis Group, committed capital, up to $4 million, between November 18, 2019 and the closing of the Transaction. The purpose of the loans are to provide capital to fund the operations of the Curetis Business, including the discharge of current liabilities when due. Each loan under the Interim Facility bears interest at 10% per annum, and is due to be repaid on the first anniversary of the loan. The loans will be subject to mandatory pre-payment if the Implementation Agreement is terminated and the Transaction abandoned. The Interim Facility loans are deeply subordinated to the current and future indebtedness of the Borrower. The Interim Facility has identified, customary events of default. This summary of the Interim Facility is not complete. The Interim Facility is filed as an exhibit to the Registration Statement of which this proxy statement/prospectus forms a part. You are encouraged to read the Interim Facility for a complete understanding of its terms. The parties to the Interim Facility agreed that the Interim Facility meets the closing condition set forth in the Implementation Agreement.

This proxy statement/prospectus summary provides information about OpGen and Curetis and its subsidiaries (together referred to as the Curetis Group), and forward-looking, pro forma financial information about Newco 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 tests, a 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.

Reasons for the Transaction (page 45)

We believe the Transaction with Curetis represents a unique opportunity to more rapidly and cost effectively develop the OpGen business than we would have been able to on a stand-alone basis. We believe that this will enhance shareholder value compared with building the business on a stand-alone basis. We anticipate that the combined business will create a market leader positioned to capitalize on global opportunities in infectious disease and antimicrobial resistance detection, in that the combined business will have a broader portfolio of proprietary molecular diagnostic tests and platforms and premier AI-powered bioinformatics solutions for multi-drug resistance diagnostics. We believe Newco will be able to leverage the established global commercial channel capabilities and partners of OpGen and Curetis. We believe the Transaction creates financial leverage and operational synergies by eliminating overlap and avoiding new investment that would have been required by OpGen and by combining the product offerings of the two companies we believe that the combined business will have an improved growth-driven business outlook.

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.

Overview of Newco

Anticipated Headquarters:
708 Quince Orchard Road
Suite 205
Gaithersburg, Maryland 20878
(301) 869-9683

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 with a panel of pathogens that Curetis believes covers more than 90% of infection cases of hospitalized pneumonia patients. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. The Unyvero LRT automated test detects 19 pathogens within less than five hours and with approximately two minutes of hands-on time and provides clinicians with a comprehensive overview of 10 genetic antibiotic resistance markers. We believe the Unyvero LRT test has the ability to help address a significant, previously unmet medical need that causes over $10 billion in annual costs for the U.S. healthcare system, according to the Centers for Disease Control, or CDC.

- Commercializing the Unyvero LRT test for testing BAL specimens of U.S. patients with lower respiratory tract infections following FDA clearance received by Curetis in December 2019.

- The Acuitas AMR Gene Panel (Urine) test is being developed for patients at risk for cUTI, and is designed to test for up to five pathogens and up to 47 antimicrobial resistance genes. When paired with the Acuitas Lighthouse software, we believe the test will be able to help improve management of the more than one million patients in the United States with cUTI. The AMR Gene Panel (Urine) is in testing in preparation for FDA 510(k) submission. We are pursuing 510(k) clearance for the test in connection with an initial clinical indication to test bacterial isolates.

Risk Factors (see page 8)

The business of OpGen and Curetis is, and Newco's business will be, subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" in this proxy statement/prospectus. 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 the Transaction contemplated by the Implementation Agreement may not close because of failure to meet one of the conditions to closing;
- under the Interim Facility, we are obligated to lend significant funds to Curetis under a short-term subordinated loan agreement;
- if the Transaction does not close, it will be difficult for Curetis to repay funds loaned under the Interim Facility
- we will need to pursue additional financings 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;
- we may not be successful in developing commercial relationships with collaborators or partnering with additional large companies;
- 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.

Opinion of OpGen's Financial Advisor (page 59)

At a meeting of the OpGen Board on September 3, 2019, Crosstree Capital New York, LLC, or Crosstree, rendered its oral opinion to the Board that, as of such date and based upon and subject to the factors and assumptions set forth in its opinion, the Consideration to be paid in the proposed Transaction was fair, from a financial point of view, to the stockholders of OpGen.

Interests of Certain Persons in Matters to be Acted Upon (see page 205)

In considering whether to approve the proposals at the Special Meeting, OpGen's stockholders should be aware that certain of the Company's directors and executive officers, and their affiliates and certain of Curetis' directors and executive officers and their affiliates, or the Interested Parties, have interests in the Transaction that may differ from, or that are in addition to, their interests as stockholders generally. These interests may cause some of the Interested Parties to view the Transaction differently than you may view them as a disinterested stockholder of the Company, and may influence or may have influenced the Interested Parties in determining to support or approve the Transaction. See the section titled "Interests of Certain Persons in Matters to be Acted Upon."

As of the Record Date, approximately 39,000 of the issued and outstanding shares of OpGen's common stock representing less than one percent of the total voting power of stockholders entitled to vote on the Transaction, were held by the directors, executive officers, and related affiliates, of OpGen.

As of the Record Date, approximately none of the issued and outstanding shares of Curetis' common stock were held by directors, executive officers, and related affiliates, of Curetis.

Regulatory Approvals (see page 184)

In the United States, OpGen must comply with applicable federal and state securities laws and the rules and regulations of Nasdaq in connection with the issuance of shares of OpGen common stock pursuant to the Implementation Agreement and has filed this proxy statement/prospectus with the SEC and will furnish it to stockholders in compliance with such requirements. The parties are aware of no additional regulatory approvals required to effect the Transaction.

Appraisal Rights (see page 184)

Holders of shares of OpGen common stock are not entitled to appraisal rights in connection with the Transaction.

Anticipated Accounting Treatment (see page 65)

If it closes, the Transaction 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. In making this determination of the accounting treatment, we have considered, among other factors, the following: (i) the number of shares to be issued to the Seller, and reserved for issuance under the Implementation Agreement; (ii) the outstanding shares of OpGen common stock following the October 2019 Offering; (iii) whether the percentage of voting rights held by OpGen's stockholders would continue to constitute a majority of the voting rights of Newco after the October 2019 Offering and after closing under the Implementation Agreement; (iv) the contractual right held by the Seller to designate a majority of the members of the initial board of directors of Newco after the closing; and (v) the change in the chief executive officer of OpGen after the closing to be the chief executive officer of the Seller.

Considerations with Respect to U.S. Federal Income Tax Consequences (see page 184)

Tax matters are very complicated, and the tax consequences of the Transaction to a particular stockholder will depend on such stockholder's circumstances. Accordingly, you should consult your tax advisor for a full understanding of the tax consequences of the Transaction to you, including the applicability and effect of federal, state, local and foreign income and other tax laws. For more information, please see the section titled "Material U.S. Federal Income Tax Consequences."

Comparison of Stockholders Rights (see page 196)

OpGen is incorporated under the laws of the State of Delaware, and Curetis N.V., is a public company with limited liability under the laws of the Netherlands. Accordingly, the rights associated with the common stock in OpGen are different from the rights associated with Curetis N.V. shares. The material differences between the current rights OpGen stockholders and Curetis N.V. shareholders are more fully described in the section titled "Comparison of the Rights of Shareholders of Curetis N.V. and Stockholders of OpGen" on page 195 in this proxy statement/prospectus.

Nasdaq Stock Exchange Listing (see page 66)

OpGen's common stock is listed on the Nasdaq Capital Market. The Implementation Agreement requires the Transaction Shares to be listed on the Nasdaq Capital Market as a condition precedent of the Transaction, and either party may waive this condition.

Special Meeting (see page 36)

The Special Meeting will be held at the offices of Ballard Spahr LLP, 1909 K Street, NW, 12th Floor, Washington DC at 10:00 a.m. local time on March 10, 2020, unless postponed or adjourned to a later date in accordance with the Adjournment Proposal or otherwise.

Only holders of record of OpGen common stock at the close of business on January 24, 2020, the record date of the Special Meeting, or the Record Date, are entitled to notice of, attendance at and to vote at, the Special Meeting. As of the Record Date for the Special Meeting, there were 5,582,280 shares of OpGen common stock outstanding and entitled to vote at the Special Meeting, held by approximately 27 holders of record. Each holder of OpGen common stock is entitled to one vote for each share of OpGen common stock owned as of the Record Date.

There are three proposals to be presented at the Special Meeting.

- First – a proposal to approve the Transaction pursuant to the Implementation Agreement.
- Second – a proposal to approve the issuance and reservation for future issuance of the Transaction Shares to the Seller in accordance with the Implementation Agreement and as required by and in accordance with the applicable rules of Nasdaq.
- Third – to approve a proposal to adjourn the Special Meeting to a later date or dates, if necessary, to permit further solicitation and vote of proxies if, based upon the tabulated vote at the time of the Special Meeting, OpGen is not authorized to consummate the transactions contemplated by Proposals One and Two.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this proxy statement/prospectus, including our financial statements, the unaudited pro forma condensed combined financial information, the Curetis Business combined financial statements, and, in each case, the related notes included herein, before making an investment decision or voting on the proposals. 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 the Pending Transaction

We may not be successful in consummating the proposed Transaction, which failure could have a material adverse effect on us.

The proposed combination with Curetis is subject to the approval of our stockholders and debt holder, 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, we may become liable to reimburse Curetis N.V. for its expenses up to a maximum amount of $250,000. 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. 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 would have a material adverse impact on our financial condition.

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

Completion of the proposed 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 assumption by us of the obligation under the Curetis Convertible Notes, including the need to provide for the conversion of the Curetis Convertible Notes into shares of OpGen's common stock; the entry into the Interim Facility and the funding thereunder; and the receipt of the applicable consents or waivers to be received or granted by certain debt financing providers of Curetis N.V., Curetis GmbH and OpGen. Failure to satisfy any of the conditions may result in the Transaction not being closed.

We have agreed to use a significant portion of the capital raised in the October 2019 Offering to support the operations of Curetis in the period prior to the closing of the Transaction. This reduces the proceeds invested in OpGen's operations, which could have a negative impact on OpGen if the proposed Transaction is not consummated, or if the approval process takes longer than anticipated.

Pursuant to the Implementation Agreement, we have entered into the Interim Facility and agreed provide $4 million from the proceeds of the October 2019 Offering to fund and support the operations, and satisfy the current obligations, of Curetis in the period prior to closing. 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 entered into the Interim Facility, a short-term, subordinated credit facility with Curetis. The Interim Facility is unsecured, subordinated to the existing and future indebtedness of Curetis, including the EIB debt, and provides a mechanism for us to lend funds to Curetis to support its current business and pay its short-term obligations. We may 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.

The date on which the proposed Transaction will close is uncertain.

The date on which the Transaction will close depends on the satisfaction of the conditions set forth in the Implementation Agreement, or the waiver of certain of those conditions by OpGen or Curetis N.V. While OpGen expects to complete the Transaction during the first quarter of 2020, the closing date of the Transaction might be earlier or later than expected because of unforeseen events.

If the proposed Transaction does not close, 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 proposed Transaction 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. and Curetis. As of November 1, 2019, Curetis N.V. owed indebtedness of $1.4 million to lenders under the Curetis Convertible Notes and as of June 30, 2019, 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 Merck Global Health Innovation Fund, or MGHIF, under the amended and restated promissory note issued in June 2017 to MGHIF, or the MGHIF Note. Pursuant to the Implementation Agreement, OpGen will be required to assume the indebtedness of Curetis N.V. (subject to approval of the holder of the Curetis Convertible Notes) and of 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.

We will incur significant transaction costs as a result of the proposed Transaction, which could have a material adverse effect on our financial condition.

We expect to incur significant one-time transaction costs related to the proposed business combination with Curetis. These transaction costs include legal and accounting fees and expenses and filing fees, printing expenses and other related charges. We may also incur additional unanticipated transaction costs in connection with the Transaction. A portion of the transaction costs related to the proposed business combination will be incurred regardless of whether the Transaction is completed. Additional costs will be incurred in connection with integrating the two companies' businesses. Costs in connection with the Transaction and integration may be higher than expected. These costs could adversely affect OpGen's financial condition, operating results or prospects of Newco.

The proposed Transaction will significantly change the business and operations of OpGen. We may face challenges integrating the businesses.

Following the consummation of the proposed Transaction, 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 will change upon the consummation of the 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 have agreed to add a seventh director, to be recommended by OpGen, but that process has not started. The current members of the management board of Curetis N.V. have experience serving on the boards of companies listed on Euronext and German Frankfurt Stock Exchange companies, but not on U.S. publicly-listed companies and this could impact the transition of Newco.

Some executive officers and directors of OpGen and Curetis N.V. have interests in the Transaction that are different from ordinary investors and that may influence them to support or approve the Transaction without regard to the interests of ordinary investors.

Some officers and directors of OpGen and Curetis N.V. are parties to arrangements that provide them with interests in the Transaction that are different from other investors, including, among others, service as an officer or director of Newco following the closing of the Transaction, severance and retention plan benefits, the acceleration of equity award vesting, and continued indemnification.

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, operations 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.

If OpGen or Curetis receives a proposal for an alternative transaction, and one of us accepts such proposal, the Transaction will not close.

OpGen may 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 at the Special Meeting, 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. Any such alternative transaction could divert the attention of our board of directors and management team, and would, if accepted, cause the termination of the Transaction.

The opinion of OpGen's financial advisor does not reflect changes in circumstances that may have occurred or that may occur between the signing of the Implementation Agreement and the closing of the Transaction.

The opinion rendered to the OpGen Board by Crosstree was provided in connection with, and at the time of, the OpGen Board of Director's evaluation of the Transaction. This opinion was based on the financial analysis performed, which considered market and other conditions then in effect, and financial forecasts and other information made available to them, as of the date of their opinion, which may have changed, or may change, after the date of the opinion. The OpGen Board of Directors has not obtained an updated opinion from Crosstree as of the date of this proxy statement/prospectus or as of any other date, nor does it expect to receive an updated, revised or reaffirmed opinion prior to the closing of the Transaction. Changes in the operations and prospects of OpGen, general market and economic conditions and other factors that may be beyond the control of OpGen, and which changes were not taken into account by OpGen's financial advisor in rendering its opinion, may significantly alter the value of OpGen or the prices of OpGen shares by the time the Transaction closes. The opinion does not speak as of the time the Transaction will be closed or as of any date other than the date of such opinion. Because there is no plan for OpGen's financial advisor to update its opinion, the opinion does not address the fairness of the Transaction consideration, from a financial point of view, at any time other than the time such opinion was issued, even though the OpGen Board of Director's recommendation that OpGen shareholders vote "FOR" the proposals related to the Transaction is made as of the date of this proxy statement/prospectus.

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.

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 the October 2019 Offering, will own approximately 67.7%, and Curetis N.V. will own approximately 32.3% of the outstanding shares of OpGen, in each based on the sale of 2,590,170 units and 2,109,830 pre-funded units in the October 2019 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 proxy statement/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 proxy statement/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 Newco financial condition or results of operations may cause significant variations in the stock price of Newco.

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 OpGen's Business" and the consolidated financial statements of OpGen elsewhere in this proxy statement/prospectus. For a discussion of the business of Curetis and of certain factors to consider in connection with Curetis' business, see "Curetis' Business" and the financial statements of Curetis included elsewhere in this proxy statement/prospectus.

Risks Related to Newco's 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 Newco will 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 nine months ended September 30, 2019 was $9.9 million. From our inception through September 30, 2019, we had an accumulated deficit of $172.0 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 October 2019, 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 $44.2 million.

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

- commercializing 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 *RQ* platform;
- completing development and clinical evaluations, obtaining necessary regulatory approvals, and successfully commercializing the Acuitas AMR Gene Panel (Urine) for cUTIs;
- commercializing the Acuitas AMR Gene Panel tests for RUO, which started in January 2018 and for which on May 13, 2019, we filed a 510(k) submission with the FDA for clearance for the detection of antimicrobial resistance genes in bacterial isolates;
- making additional FDA 510(k) submissions for the Acuitas AMR Gene Panel (Urine) test and the Acuitas Lighthouse Software (AMR Gene Panel Prediction) anticipated during 2020;
- further advancing the development of ARESdb and the ARES Technology Platform and NGS-based development and clinical validation of infectious disease applications based on these assets;
- 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 the first quarter of 2020. If, during the first quarter of 2020 we are unable to raise additional capital 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. The failure to obtain sufficient capital to support our operations until we can achieve profitability would have an adverse effect on our business and financial condition, potentially force us to cease operations and/or liquidate.

Newco expects to make significant additional investment in the future related to its 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 the Unyvero platform, ARESdb, Acuitas AMR Gene Panel tests in development and Acuitas Lighthouse Software products 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 OpGen's acquisition of its 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.

If the Transaction closes, Newco will have significant additional indebtedness through the assumption of owed indebtedness of $1.4 million under the Curetis Convertible Notes and, as of June 30, 2019, of $20.4 million of principal (plus interest of $1.6 million) under a loan provided by the EIB. We may find it difficult to repay such indebtedness in the future, and the inability to pay such debt would have a material adverse effect on our financial condition.

The process to obtain and maintain FDA clearances or approvals for Newco's products is complex and time-consuming. If Newco fails to obtain such clearances or approvals, its 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 make a 510(k) submission 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 filed a 510(k) submission 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 submission of a complete response, which must be issued within 180 days of the date listed on the July 2019 AI Request. Questions from the July 2019 AI Request focused on the intended use of the test including the correlation between marker detection and antibiotic resistance, the level of evidence to support resistance marker/organism claims, whole genome sequencing (WGS) test validation and use as a comparator method, clinical performance of the test compared to WGS and further analysis of individual study results, in silico analysis to support test evaluations, further analysis of analytical study results, additional information regarding instrumentation for use with the test, and test reporting and labeling. We have been working interactively with the FDA to address the deficiencies and questions from the AI correspondence as well as additional questions that have arisen during the interactive response process. On January 6, 2020, OpGen filed a formal response to the FDA's July 2019 AI Request. Subsequently, the FDA issued a second AI Request on January 17, 2020 to formalize additional questions and remaining requests for information from the earlier July 2019 AI Request. OpGen will continue to work interactively with the FDA to provide responses necessary to address questions related to the submission as well as additional questions that may arise through this second interactive response review process. If we are unable to address the FDA's additional questions and remaining requests for information, we could be required to either let the submission lapse or withdraw our 510(k) submission for re-submission at such time when the requested data are available. Consequently, the refile process could add several months to the anticipated clearance timeline.

We anticipate making an additional FDA submission in the summer of 2020 for our Acuitas AMR Gene Panel (Urine) product followed by a submission for the Acuitas Lighthouse software.

If we or Curetis are not able to achieve clearance of such products and services on a timely basis, or at all, we and Curetis will not be able to pursue our business strategy on the anticipated timeline and OpGen's business, results of operations and financial condition following the Transaction will be materially adversely impacted.

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of OpGen's Acuitas AMR Gene Panel tests or Acuitas Lighthouse Software or for any future products Newco may develop, and failure to obtain necessary clearances or approvals for such future products would adversely affect our ability to grow Newco's 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. In 2019 we made one submission and we are currently in the process of completing and intend to submit two additional 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.

Newco 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 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 Newco or its 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.

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 Newco's products commercialized as medical devices, we and our suppliers are and will be 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.

OpGen's and Curetis' products have in the past been, and Newco's products may in the future be, subject to product recalls and other similar actions that could harm its 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.

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

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.

Newco's products and services may never achieve significant commercial market acceptance.

Newco's 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.

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

Curetis makes projections on the number of people who have severe disease incidences such as pneumonia, implant and tissue infections and other indications that Curetis is targeting. These projections are derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, governmental statistics and market research but are highly contingent on a number of variables that are difficult to predict and may prove to be too high, resulting in a smaller population of patients who could benefit from Curetis lead products, than Curetis currently anticipates, which would result in lower potential revenue for Newco.

Newco's future success is dependent upon its ability to expand its customer base.

The current customers OpGen is targeting for its 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.

The current customers Curetis is targeting for its Unyvero IVD test products and Ares Genetics 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, as well as pharmaceutical companies, research products and BioIT companies and large IVD companies. Curetis 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 services 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.

OpGen and Curetis are each developing new in vitro diagnostic tests for more rapid identification of MDROs and antibiotic resistance genomic information. If Newco is unable to successfully develop, receive regulatory clearance or approval for or commercialize such new products and services, Newco's 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 2020. 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.

Curetis began marketing and selling its Unyvero products in Europe in 2012. Over the years Curetis has built up its commercial channel infrastructure and distribution for the Unyvero System and Application Cartridges addressing hospitalized pneumonia, or HPN, implant and tissue infection, or ITI, bloodstream infection from positively flagged blood cultures, BCU, intra-abdominal infection, or IAI and UTI mainly in Europe and Asia, and has only recently begun to commercialize its Unyvero System and the LRT Application Cartridge by way of direct sales and marketing in the United States following the clearance by the FDA in April 2018. Thus, it has relatively limited experience in marketing and selling.

Except for the United States, in all other markets Curetis relies on a third-party distribution model. As of September 30, 2019, Curetis has entered into distribution agreements with 18 distributors covering 43 countries. Although Curetis has made progress in expanding its network of distributors, if Curetis should be unable to find suitable distributors, loses these distributors or if Curetis' distributors fail to sell its products in sufficient quantities, on commercially viable terms or in a timely manner, Newco's commercialization of the Application Cartridges and other future products could be materially delayed or harmed.

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

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

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

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

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

We believe that a significant portion of Newco's future revenue growth will come from international sources following the closing of the Transaction, including Europe, the Middle East, Asia and South America. 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, for Newco, will be in the United States, Germany and Austria. 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.

Curetis is exposed to changes in foreign currency exchange rates.

Curetis currently records its transactions, prepares its financial statements and incurs the main portion of its costs in Euro. Its results of operations and cash flows will however increasingly become subject to fluctuations due to changes in foreign currency exchange rates, in particular the U.S. dollar but potentially also other currencies such as the Swiss franc and certain Asian currencies such as the Chinese Yuan as Curetis expands its operations in China as a result of the recent signing of a distribution agreement with Beijing Clear Biotech for Greater China. Curetis' expenses are mainly denominated in Euro because Curetis' operations are located in Germany and in U.S. dollars (e.g. for the costs incurred in clinical trials in the United States). Curetis currently does not apply any currency-hedging strategies. If the value of the Euro increases relative to foreign currencies in the future, and Curetis does not otherwise increase the prices of its products in such local markets, Newco's future revenues could be adversely affected as it converts future revenues from local currencies to Euro.

Newco will face the risk of potential liability under the FCPA for past international distributions of products and to the extent it distributes products or otherwise operate internationally in the future.

In the past, we have distributed certain of our products internationally, and in the future Newco will distribute products internationally and 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.

We may enter into agreements with United States 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.

Curetis GmbH and Ares Genetics have received, currently receive or expect to receive grant funding and subsidies including but not limited to two De-minimis Grants by the German Federal Government for Curetis GmbH in 2019. Grants for Ares Genetics include the ARES&CO Pharma Partnering Program and the ongoing TRIPLE A project both co-funded by the Vienna Business Agency, and the ongoing project, The Digital Microbe, co-funded by the Austrian Research Promotion Agency (FGG). Further, Ares Genetics is eligible for a research premium by the Austrian Government of 14% on all research and development expenses not funded or subsidized otherwise. Overall, over EUR 3 million of research and development costs of Ares Genetics were co-funded or are expected to be co-funded by grants and subsidies. If these grants or subsidies do not continue, or the programs are terminated, it could have a material adverse effect on Newco's financial condition.

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 OpGen's and Curetis' current products and products in development are not supported by studies published in peer-reviewed medical publications, the rate of adoption of Newco's 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, and the Curetis products 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.

The sales cycle for Newco's marketed products and services is lengthy and variable, which makes it difficult for Newco to forecast revenue and other operating results.

We believe the sales cycles for Newco's 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. For example, sales of Newco's products often involve purchasing decisions by large public and private institutions and any purchases can require multiple levels of pre-approval. In addition, those large institutions, such as public universities, frequently depend on government grants or public funding themselves, indirectly making Newco's sales dependent on those funding sources.

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.

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

Newco's future success depends on its ability to recruit, train, retain and motivate key personnel, including Newco's research and development, science and engineering, manufacturing and sales and marketing personnel. In particular, Curetis N.V. is highly dependent on the technology expertise of its Chief Technology Officer, Chief Operating Officer, and the Ares Genetics Chief Executive Officer, as well as certain key R&D employees. As competition for qualified sales personnel is intense in the United States and Europe, Newco's growth will depend, in particular, on retaining, or attracting and retaining and motivating highly trained sales personnel with the necessary scientific background and ability to understand Newco's products at a technical level. In addition, Newco may need additional employees at its manufacturing facilities to meet the demand for its products as Newco scales up its sales and marketing operations. Because of the complex and technical nature of Curetis' products and the dynamic market in which it will compete, any failure to attract, train, retain and motivate qualified personnel could materially harm Newco's growth prospects and could have a material adverse effect on Newco's business, financial position, cash flows and results of operations.

OpGen and Curetis are each currently party to, and Newco may enter into additional, collaborations with third parties to develop product and services candidates. If these collaborations are not successful, Newco's business could be adversely affected.

Curetis is party to a number of collaborations and OpGen is currently party to a few collaborations. We anticipate that Newco will enter into additional collaborations, related to its 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.

Newco 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.

Newco 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.

Newco will be an early commercial stage company and may never be profitable.

Newco will rely principally on the commercialization of the QuickFISH and Acuitas Gene Panel (RUO) test products and Acuitas Lighthouse Software (RUO) as well as the Unyvero IVD test kits and ARESdb based services and licenses to generate future revenue growth. To date, such products and services have delivered only minimal revenue. Also, Unyvero test sales and Ares Genetics service offerings and partnering revenues are in their very early stages. 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 as well as partners that use our products and services. 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.

Newco will have limited experience in marketing and selling products, and if it is unable to adequately address its customers' needs, it could negatively impact sales and market acceptance of Newco's products and it 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. Curetis sells its Unyvero products directly in the United States and via distributors in EMEA and Asia as well as ROW. Ares Genetics sells its services and collaborations and licenses directly in a business to business model. 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' and collaborators' 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 services, and adequately address our customers' and collaborators' needs, it could negatively impact sales and market acceptance of our products and services, and we may never generate sufficient revenue to achieve or sustain profitability.

If Newco's manufacturing facilities becomes inoperable, Newco's business will be harmed.

OpGen manufactures its Acuitas, QuickFISH and PNA FISH products in its facility in Gaithersburg, Maryland. Curetis manufactures its Unyvero test kits and cartridges at its manufacturing facility in Bodelshausen, Germany. Neither has redundant facilities. The 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. A 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 certification procedures and inspection by the FDA and other regulatory bodies. If we fail to maintain our certification(s) or if our certification(s) are 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.

Curetis has entered into a lease agreement for a manufacturing plant in which its laboratory facilities are located. The unexpected termination or non-renewal of this lease agreement could have a significant adverse effect on Newco's business, financial position and results of operations.

Curetis entered into a lease agreement with Joma-Polytec GmbH for 1,600 square meters of manufacturing and logistics space for its manufacturing plant in which its Bodelshausen laboratory facilities are located. The lease term was extended until June 30, 2025. Curetis has invested significantly in the installation of tailored clean rooms, automated Application Cartridge manufacturing equipment and laboratory facilities in the buildings located at this plant. As a consequence, untimely termination or failure to renew its lease agreement with Joma-Polytec GmbH would force Curetis to invest significant monetary and managerial resources to move to an alternative manufacturing facility and Curetis may have difficulty in meeting deadlines for customer orders due to the significant production downtime such relocation would cause. As a result, the unexpected termination or non-renewal of this lease agreement could have a significant adverse effect on Curetis' business, financial position and results of operations.

Newco may be unable to successfully manage its growth.

During the past few years, Curetis has significantly expanded its operations with regard to sales and the manufacturing of a greater variety of product offerings, especially in the DACH region (Germany, Austria and Switzerland) as well as in Eastern and Western Europe and the Middle East. It recently expanded into the Asian market by entering into distribution agreements for certain ASEAN markets and Greater China and, after receiving FDA clearance, commercially launched its Unyvero System in the United States beginning in June 2018. Curetis expects this expansion to continue as its Ares Genetics business line continues to expend it offerings in the DACH.

Curetis' growth has placed on Curetis, and is expected to continue to place, a significant strain on Newco's management, operating and financial systems and Newco's sales, marketing and administrative resources. As a result of Newco's growth, operating costs may escalate even faster than planned, and some of Newco's internal systems and processes, including those related to manufacturing Newco's products, may need to be enhanced, updated or replaced. If Newco cannot effectively manage its expanding operations, manufacturing capacity and costs, including scaling to meet increased demand, Newco may not be able to continue to grow or may grow at a slower pace than expected.

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

OpGen relies on several sole suppliers and manufacturers, including Thermo Fisher Scientific, QIAGEN, and Fluidigm Corporation, for supplying certain reagents, raw materials, supplies and substances that it uses to manufacture its products. Curetis relies on a number of key suppliers for critical product components, including Zollner El-ektronik AG for the manufacture of its Unyvero Systems, Contexo GmbH and Scholz HTIK GmbH for the application-specific cartridges and consumables plastic parts as well as certain single source suppliers for specific Unyvero amplification primers, detection probes and the mastermix, which is the enzyme required to start any PCR, and thus is one of the critical components of any PCR based molecular diagnostic test. An interruption in Newco's operations could occur if it encounters delays or difficulties in securing these items or manufacturing its products, if any one of these suppliers were to terminate its business relationship with Newco, or if we are unable to obtain an acceptable substitute in the event of such delays or difficulties. Any such interruption could significantly affect Newco's business, financial condition, results of operations and reputation.

For example, during the first half of 2013, Curetis encountered unexpected issues with its Original Equipment Manufacturer supplier of the Unyvero System, Zollner El-ektronik AG, which had significant problems supplying Curetis with the ordered quantities at the required quality. While Newco may technically be able to modify product candidates to utilize a new source of such critical reagents, raw materials, supplies and substances it uses to manufacture its products, Newco would need to secure CE-IVD-marking and regulatory clearance from the FDA and any other relevant regulatory body in other markets for the modified product, and it could take considerable time and necessitate significant expenses to perform the requisite tasks prior to and in connection with petition for renewed market clearance.

Additionally, OpGen purchases the QuantStudio 5 (QS5) Real Time PCR instrument system from Thermo Fisher Scientific. Although the QS5 was designed and developed to be a Research Use Only (RUO) system, OpGen has been working with the FDA to receive clearance for use of the QS5 as part of the Acuitas AMR Gene Panel product offering. We are in discussions with Thermo Fisher and the FDA regarding required labeling, software and quality system support for the QS5 instrument. If Thermo Fisher should fail to cooperate or oppose OpGen's agreed-upon regulatory pathway with the FDA, OpGen could be required to identify an alternative instrument to the QS5 resulting in potential delays and additional costs to OpGen.

If Newco has issues or faces delays in delivery of materials from a supplier, Newco's commercialization plans and financial condition could be significantly harmed.

If Newco cannot compete successfully, it may be unable to increase or sustain its revenue or achieve and sustain profitability.

Newco's 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.

Newco's 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 Luminex.

Newco also faces 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.

The selling price level in the molecular diagnostics market could decrease in the future which would adversely affect Newco's business, financial position and results of operations.

The molecular diagnostic market is relatively young and Curetis competes with a large number of commercial diagnostics companies in this market. Curetis expects that, with the molecular diagnostic market becoming more mature, the use of scale effects and continuous technological improvements, the prices for molecular diagnostic products and Curetis' products are likely to decline over the course of time. If Newco is not able to offset a decrease in product prices by a corresponding reduction of its costs of goods sold, this could have a material adverse effect on Newco's business, financial position, cash flows and results of operations.

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

Successful commercialization of certain of Newco's diagnostic products will depend, in large part, on the extent to which the costs of Newco's products are reimbursed to its customers, either separately or through bundled payment, by third-party private and governmental payers, private health insurances as well as public health systems. Coverage and reimbursement will also depend on the applicable healthcare policy framework in the relevant jurisdiction. For example, in the EU and the United States, there is significant uncertainty surrounding third-party coverage and reimbursement for the use of tests that incorporate new technology, such as the Unyvero Platform, as it is uncertain whether and to which extent third-party payers will reimburse Newco's customers for the use of the Unyvero Platform under current legal frameworks

Hospitals, clinical laboratories and other healthcare providers generally bill various third-party payers to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of products. Curetis current products are used in a hospital inpatient setting, where in most geographic areas governmental payers, health insurances or funds and other national equivalents in the respective countries, generally reimburse hospitals a single bundled payment per patient case. However, third-party payers may deny coverage if they determine that Newco's products are not cost-effective compared to the use of alternative testing methods or deem them to be experimental or medically unnecessary. Even if third-party payers make coverage and reimbursement available, such reimbursement may not be adequate, which could have an adverse effect on Newco's business, financial position, cash flows and results of operations.

Certain of Newco's 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.

Certain of Newco's 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, or HHS, Centers for Medicare and Medicaid Services, or 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 Newco's information technology, storage systems, Curetis' ARESdb or our Acuitas Lighthouse Software could significantly disrupt Newco's operations and our research and development efforts, which could adversely impact its revenues, as well as research, development and commercialization efforts.

Newco's ability to execute it 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 the ARESdb and 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 the ARESdb and Acuitas Lighthouse Software, could adversely affect our ability to operate our business. Any interruption in the operation of the ARESdb or 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 Newco's business or prevent it from accessing critical information and expose us to liability, which could adversely affect its business and 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.

Newco will be 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 its 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.

If Newco is unable to protect its intellectual property effectively, its 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.

Newco may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect its 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.

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

A key element of Newco's 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.

OpGen's insurance policies are expensive and protect it only from some business risks, which could leave Newco exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter, and do not anticipate that Newco will carry additional insurance. 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 Newco uses hazardous materials in a manner that causes injury, it 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 Newco is 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.

Newco 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 OpGen's Securities

We received deficiency notices from the Nasdaq Capital Market. Although we have regained compliance with the ongoing listing requirements of the Nasdaq Capital Market, if we are unable to maintain compliance with the ongoing listing requirements, we could be delisted from the Nasdaq Capital Market, which would negatively impact the trading of our common stock.

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 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. We effected the 2019 Reverse Stock Split of our common stock on August 28, 2019, with the primary intent of increasing the price of our common stock in order to meet the price criteria for continued listing on the Nasdaq Capital Market. There can be no assurance that the market price per share of our common stock after the Reverse Stock Split will remain above the Minimum Bid Price Rule requirement.

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. We believe we regained compliance with this listing requirement as a result of the closing of the October 2019 Offering. However, if we cannot maintain compliance with such continuing listing standard through December 31, 2019, our common stock will be delisted.

Maintaining compliance with the Nasdaq listing requirements is a closing condition under the Implementation Agreement. If we do not maintain our compliance, the Transaction may not close.

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.

You will experience immediate dilutions as a result of the proposed issuance of the Transaction Shares and may experience future dilution as a result of future equity offerings or other equity issuances.

The issuance of the Transaction Shares and the resale of the Transaction Shares, or even the potential of such issuance and resale, may have a depressive effect on the market price of our common stock and the issuance of such Transaction Shares will cause dilution to our stockholders. In addition, 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 offering at a price per share that is equal to or greater than the price per share paid by existing investors, and investors purchasing other securities in the future could have rights superior to existing stockholders.

In addition, we have a significant number of stock options, restricted stock units and warrants outstanding, have agreed to assume the outstanding stock option awards of Curetis N.V. in the Transaction, and anticipate that we will grant additional equity awards following the closing of the 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 January 21, 2020, the market price of our common stock fluctuated from a high of $2,720.00 per share to a low of $0.92 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 September 30, 2019, we had outstanding warrants to acquire 175,982 shares of our common stock, and stock options to purchase 9,936 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.

In addition, we issued 4,700,000 common warrants in the October 2019 Offering at an exercise price of $2.00 per share, and issued 235,000 underwriter warrants at an exercise price of $2.60 per share. The term of these warrants is five years from issuance. If a significant number of such warrants are exercised by the holders, the percentage of our common stock owned by our existing stockholders will be diluted.

We have agreed to assume all outstanding stock options issued by Curetis N.V. As of July 1, 2019, 1,771,500 stock options have been granted since the start of the Curetis stock option program, 359,390 of those have been forfeited, as at the date of this proxy statement/prospectus, which is expected to leave 1,412,110 stock options outstanding. OpGen has agreed to assume the stock option awards using the .0959 conversion factor set forth in the Implementation Agreement and, therefore, these stock options are expected to convert into up to 135,421 OpGen shares upon exercise. If a significant number of such equity awards 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.

OpGen's Certificate of Incorporation will govern Newco following the closing of the proposed Transaction and provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between Newco and its stockholders, which could limit its stockholders' ability to obtain a favorable judicial forum for disputes with Newco or its directors, officers or other employees.

OpGen's Certificate of Incorporation will govern Newco following the closing of the proposed Transaction and provides that, unless Newco consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of Newco, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of Newco or its stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or the Company's Certificate of Incorporation or Bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision is intended to apply to claims arising under Delaware state law and would not apply to claims brought pursuant to the Securities Act or Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. The exclusive forum provision in OpGen's Certificate of Incorporation will not relieve Newco of its duties to comply with the federal securities laws and the rules and regulations thereunder, and stockholders of Newco will not be deemed to have waived Newco's compliance with these laws, rules and regulations.

This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with Newco or its directors, officers or other employees, which may discourage lawsuits against Newco and its directors, officers and other employees. In addition, stockholders who do bring a claim in the Court of Chancery of the State of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery of the State of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder would otherwise choose to bring the action, and such judgments or results may be more favorable to Newco than to its stockholders. However, 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 find this type of provision to be inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings. If a court were to find the exclusive forum provision contained in OpGen's Certificate of Incorporation to be inapplicable or unenforceable in an action, Newco might incur additional costs associated with resolving such action in other jurisdictions.

Risks Related to OpGen's 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 December 31, 2020. 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.

QUESTIONS AND ANSWERS ABOUT THE TRANSACTION AND SPECIAL MEETING

Q: What is the date and time of the Special Meeting and where is it being held?

A: We will hold the Special Meeting at the offices of Ballard Spahr LLP, 1909 K Street, NW, 12th Floor, Washington DC at 10:00 a.m. local time on March 10, 2020, unless postponed or adjourned to a later date in accordance with the Adjournment Proposal or otherwise.

Q: Why am I receiving these materials?

A: We sent you this proxy statement/prospectus and enclosed proxy card because the OpGen Board of Directors is soliciting your proxy to vote at the Special Meeting. We intend to distribute this proxy statement/prospectus and accompanying proxy card on or about January 27, 2020 to all stockholders of record entitled to vote at the Special Meeting. This document serves as:

- a proxy statement of OpGen used to solicit proxies for the Special Meeting; and
- a prospectus of OpGen used to offer the shares of Common Stock to be issued to the Seller, or reserved for future issuance in connection with the Transaction, or the Transaction Shares.

This document contains important information about the proposed Transaction and the Special Meeting and you should read it carefully.

Q: What is the purpose of the Special Meeting?

A: At the Special Meeting, OpGen's stockholders will act upon the following matters outlined in the Notice of Special Meeting of Stockholders and discussed in this proxy statement/prospectus:

- ***Proposal One – The Transaction Proposal***. Approval of the Transaction pursuant to the Implementation Agreement whereby OpGen will acquire all of the outstanding shares of Curetis and the related business assets of the Seller to create a combined business within OpGen.
- ***Proposal Two – The Share Issuance Proposal***. Approval of the issuance and reservation for future issuance of the Transaction Shares to the Seller in accordance with the Implementation Agreement and as required by and in accordance with the applicable rules of Nasdaq.
- ***Proposal Three*** – ***The Adjournment Proposal***. Approval of a proposal to adjourn the Special Meeting to a later date or dates, if necessary to permit further solicitation and vote of proxies if, based upon the tabulated vote at the time of the Special Meeting, OpGen is not authorized to consummate the transactions contemplated by Proposals No. 1 and 2.

This transaction must be approved by the shareholders of Curetis N.V.

Q: What are the recommendations of the OpGen Board of Directors?

A: The OpGen Board of Directors unanimously recommends that you vote:

1. "**FOR**" Proposal One – the Transaction Proposal;
2. "**FOR**" Proposal Two – the Share Issuance Proposal; and
3. "**FOR**" Proposal Three – the Adjournment Proposal.

Q: What is the Record Date?

A: Holders of record of our common stock as of the close of business on January 24, 2020, the Record Date, will be entitled to notice of and to vote at the Special Meeting and at any adjournments or postponements thereof. Holders of record of shares of common stock are entitled to vote on all matters brought before the Special Meeting.

As of the Record Date, there were 5,582,280 shares of common stock outstanding and entitled to vote on each proposal presented at the Special Meeting. Holders of common stock will vote on all matters as a class. Holders are entitled to one vote for each share of common stock outstanding as of the Record Date.

You do not need to attend the Special Meeting to vote your shares. Instead, you may vote your shares by marking, signing, dating and returning the enclosed proxy card or voting through the internet.

Q: What shares may I vote?

A: You may vote all shares of common stock of the Company that you owned as of the close of business on the Record Date.

These shares include:

1. those held directly in your name as the stockholder of record; and

2. those held for you as the *beneficial owner* through a bank, broker or other financial intermediary at the close of business on the Record Date.

Each share of common stock is entitled to one vote.

Q: What is the difference between holding shares as a stockholder of record and as a beneficial owner?

A: Most stockholders hold their shares through a bank, broker or other financial intermediary rather than directly in their own name. As summarized below, there are some distinctions between shares held of record and shares held beneficially.

Stockholder of Record: If your shares are registered directly in your name with OpGen's transfer agent, Philadelphia Stock Transfer, Inc., or the Transfer Agent, you are considered, with respect to those shares, the stockholder of record. As the stockholder of record, you have the right to grant your proxy directly to OpGen or to vote your shares in person at the Special Meeting.

Beneficial Owner: If you hold shares in a stock brokerage account or through a bank or other financial intermediary, you are considered the *beneficial owner* of shares held *in street name*.

- Your bank, broker or other financial intermediary is considered, with respect to those shares, the stockholder of record.

- As the beneficial owner, you have the right to direct your bank, broker or other financial intermediary on how to vote your shares, but because you are not the stockholder of record, you may not vote these shares in person at the Special Meeting unless you obtain a signed proxy from the stockholder of record giving you the right to vote the shares.

- As a beneficial owner, you are, however, welcome to attend the Special Meeting.

Q: How do I vote?

A: If you are a stockholder of record, you may vote in person at the Special Meeting, vote by proxy through the internet or vote by proxy using the enclosed proxy card. To vote through the internet, go to **http://www.pstvote.com/opgenspecial2020** and complete an electronic proxy card. You will be asked for a Control Number, which has been provided with the Notice of Internet Availability.

Whether you plan to attend the Special Meeting or not, we urge you to vote by proxy to ensure your vote is counted. Voting by proxy will not affect your right to attend the Special Meeting and vote. If you vote via the internet or properly complete your proxy card and submit it to us in time, the "proxy" (one of the individuals named on the proxy card) will vote your shares as you have directed. If you sign the proxy card but do not make specific choices, the proxy will vote your shares as recommended by the Board of Directors and, as to any other matters properly brought before the Special Meeting, in the sole discretion of the proxy.

If you are a beneficial owner of shares registered in the name of your broker, bank, or other agent, you should have received a voting instruction form with these proxy materials from that organization rather than from us. Simply complete and mail the voting instruction form to ensure that your vote is counted. Alternatively, you may vote over the internet as instructed by your broker, bank or other agent. To vote in person at the Special Meeting, you must obtain a valid proxy from your broker, bank or other agent. Follow the instructions from your broker, bank or other agent included with these proxy materials, or contact your broker, bank or other agent to request a proxy form.

Q: Can I change my vote after submitting my proxy?

A: Yes. You may change your proxy instructions or revoke your proxy at any time prior to the vote at the Special Meeting. For shares held directly in your name, you may accomplish this by: (a) delivering a written notice of revocation to the Secretary of the Company or the Secretary's designated agent bearing a later date than the proxy being revoked, (b) signing and delivering a later dated written proxy relating to the same shares, or (c) attending the Special Meeting and voting in person (although attendance at the Special Meeting will not in and of itself constitute a revocation of a proxy). For shares held in street name, you may change your vote by submitting new voting instructions to your broker, trustee or nominee.

Q: What constitutes a quorum at the Special Meeting?

A: The presence in person or by proxy of the holders of a majority of the issued and outstanding common stock and entitled to vote at the Special Meeting is necessary to constitute a quorum at the Special Meeting. As of the Record Date, there were 5,582,280 shares of our common stock issued and outstanding, representing the same number of votes. Accordingly, the presence of the holders of at least 2,791,141 shares of our common stock will be required to establish a quorum. Both abstentions and broker non-votes, if any, are counted as present for determining the presence of a quorum. If there is no quorum, the chairman of the meeting may adjourn the meeting to another date.

Q: What is the vote required to approve each proposal?

A: The vote required for the proposals to be considered at the Special Meeting are as follows:

Proposal One - ***The Transaction Proposal***. Approval of this proposal requires the affirmative vote of a majority of the shares present in person or represented by proxy at the Special Meeting and entitled to vote.

Proposal Two - ***The Share Issuance Proposal***. Approval of this proposal requires the affirmative vote of a majority of the shares present in person or represented by proxy at the Special Meeting and entitled to vote.

Proposal Three - ***The Adjournment Proposal***. Approval of this proposal requires the affirmative vote of a majority of the shares present in person or represented by proxy at the Special Meeting and entitled to vote.

Q: What is the effect of abstentions and broker non-votes?

A: An "abstention" occurs when a stockholder sends in a proxy with explicit instructions to decline to vote regarding a particular matter or attends the Special Meeting and elects not to vote or fails to cast a ballot. Abstentions are treated as shares present in person or by proxy and entitled to vote, so abstaining has the same effect as a negative vote for purposes of determining whether the Transaction Proposal, the Share Issuance Proposal and the Adjournment Proposal are adopted.

A "broker non-vote" occurs when a broker has not received voting instructions from the beneficial owner and the broker does not have discretionary authority to vote the shares because the proposal is non-routine. Brokers do not have discretionary authority to vote on the Transaction Proposal, the Share Issuance Proposal or on the Adjournment Proposal. Broker non-votes have no effect on the votes on the Transaction Proposal, the Share Issuance Proposal or on the Adjournment Proposal.

Q: Are there any federal or state regulatory requirements that must be complied with or federal or state regulatory approvals or clearances that must be obtained in connection with the Transaction?

A: In the United States we must comply with applicable federal and state securities laws and Nasdaq rules and regulations in connection with the issuance of the Transaction Shares, including the filing with the SEC of this proxy statement/prospectus and receipt of the required stockholder approvals under Nasdaq rules.

Q: How can I find out the results of the voting at the Special Meeting?

A: Preliminary voting results will be announced at the Special Meeting. In addition, final voting results will be published in a Current Report on Form 8-K that we expect to file within three business days after the completion of the Special Meeting. If final voting results are not available to us in time to file a Form 8-K within three business days after the Special Meeting, we intend to file a Form 8-K to publish preliminary results and, within three business days after the final results are known to us, file an additional Form 8-K to publish the final results of the Special Meeting.

Q: Am I entitled to appraisal rights?

A: No appraisal rights are available under the General Corporation Law of the State of Delaware, our Amended and Restated Certificate of Incorporation, as amended, or our Bylaws to any stockholder with respect to any of the matters proposed to be voted on at the Special Meeting.

Q: What is the proposed Transaction with Curetis?

A: As announced on September 4, 2019, OpGen has entered into an Implementation Agreement with the Seller. Under the Implementation Agreement, OpGen has agreed to purchase, through the Purchaser, the Transferred Shares and the Transferred Assets to create a combined business of OpGen and Curetis within OpGen.

We have also agreed to assume (1) the 2016 Stock Option Plan and the outstanding awards thereunder, and (2) the outstanding indebtedness of Curetis N.V. under the Curetis Convertible Notes, including providing for conversion of such notes into shares of OpGen 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. Since the date of the Implementation Agreement, Curetis has issued additional shares to the holders of the PSOPs, and all have been retired. The shares previously reserved to cover the PSOPs will be issued to Curetis N.V. as part of the Consideration.

Under the Implementation Agreement, we have 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) up to 135,421 shares of OpGen common stock reserved for its assumption of the 2016 Stock Option Plan and (b) up to 500,000 shares of common stock reserved for future issuance upon the conversion, if any, of the Curetis Convertible Notes. 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 Seller's ordinary shares on a fully diluted basis. The number of shares of common stock to be reserved for the Consideration represents 32.3% of the outstanding common stock of OpGen if issued on the date of this proxy statement/prospectus. The number of shares included in the Consideration is fixed, therefore, the percentage ownership of the Company as of the date of closing will be different.

For a more complete description of the Transaction and the Implementation Agreement, please see the section titled "Proposal One: The Transaction Proposal" in this proxy statement/prospectus.

Q: What will happen to OpGen if, for any reason, the proposed Transaction does not occur?

A: If we or Curetis N.V. cannot meet all of the conditions to close under the Implementation Agreement, and the proposed Transaction does not close, we will be in a difficult financial position. We have loaned, and will continue to loan, 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 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.

Q: What are the reasons for the proposed Transaction with Curetis?

A: We believe the proposed Transaction represents a unique opportunity to more rapidly and cost effectively develop the OpGen business than we would have been able to on a stand-alone basis. We believe that this will enhance shareholder value compared with building the business on a stand-alone basis. The combined business will create a leading position in the market to capitalize on global opportunities in infectious disease and antimicrobial resistance detection. We believe the combined business will have a broader portfolio of proprietary molecular diagnostic tests and platforms and premier AI-powered bioinformatics solutions for multi-drug resistance diagnostics. OpGen will be able to leverage the established global commercial channel capabilities and partners of Curetis. The combination creates financial leverage and operational synergies by eliminating overlap and avoiding new investment that would have been required by OpGen and by combining the product offerings of the two companies we believe that the combined business will have an improved growth-driven business outlook. The OpGen and Curetis N.V. boards of directors considered a number of factors that supported their respective decision to approve the Transaction in the course of deliberations. The OpGen and Curetis N.V. boards of directors also considered a variety of risks and other countervailing factors related to entering into the Implementation Agreement.

For a more complete description of the reasons for the proposed Transaction, please see the section titled “Proposal One: The Transaction Proposal – Reasons for the Transaction” on page 45 in this proxy statement/prospectus.

Q: What do you anticipate will be the focus of Newco’s business after the closing of the Transaction?

A: 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 LRT test, which is the first FDA cleared test that has a panel that covers more than 90% of infection cases of hospitalized pneumonia patients. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. The Unyvero LRT automated test detects 19 pathogens within less than five hours and with approximately two minutes of hands-on time and provides clinicians with a comprehensive overview of 10 genetic antibiotic resistance markers. We believe the Unyvero LRT test has the ability to help address a significant, previously unmet medical need that causes over $10 billion in annual costs for the U.S. healthcare system, according to the Centers for Disease Control, or CDC.

- The Acuitas AMR Gene Panel (Urine) test, which 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.

For a more complete description of the expected focus of Newco, please see the section titled “Proxy Statement/Prospectus Summary - Overview of Newco” in this proxy statement/prospectus.

Q: What risks should I consider in deciding whether to vote in favor of the Transaction Proposal or the Stock Issuance Proposal?

A: Our business is subject to numerous risks and uncertainties. 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;
- the Transaction may not close because of failure to meet one of the conditions to closing;
- we have lent, and will need to lend additional money to Curetis during the period between the October 2019 financing and closing, and if the Transaction fails to close, it may be difficult for Curetis to repay such funds;
- we will need to pursue additional financings 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.

You should carefully review the section of this proxy statement/prospectus titled "Risk Factors," which sets forth certain uncertainties and risks relating to the Transaction, our business, our securities and other matters.

Q: What are the risks of the Interim Facility to OpGen?

A: OpGen entered into the Interim Facility with Curetis as required under the Implementation Agreement to provide Curetis with capital, from the October 2019 Offering, to operate the Curetis business and stay current on its obligations during the period between November 2019 and the closing of the Transaction. The loans to be made under the Interim Facility will be deeply subordinated to existing and future indebtedness of Curetis. If the Transaction does not close for any reason, and the Implementation Agreement is terminated, Curetis will be obligated to repay the Interim Facility loans. However, there is substantial doubt as to the ability of Curetis to repay the loans. In addition, any funds lent to Curetis under the Interim Facility will not be available to fund OpGen's operations. Finally, depending on the length of time to prior to the closing of the Transaction, if it occurs, the proceeds from the October 2019 Offering may be depleted and OpGen may need to raise additional capital.

Q: Who are expected to be the directors of Newco following the Transaction?

A: Currently, the OpGen Board of Directors consists of four directors. Following the closing of the proposed Transaction, we expect that the Newco Board of Directors will include a total of seven directors. Pursuant to the terms of the Implementation Agreement, four of the directors are designated by Curetis N.V. and two of the directors are designated by OpGen. The parties have agreed to include a seventh director, who will be recommended by OpGen. As of the date of this proxy statement/prospectus, the expected directors of Newco are as follows:

Name	Age	Expected Positions with Newco	Recommended by:
William Rhodes	65	Director and Chair of the Board	Curetis
Oliver Schacht, Ph.D.	49	Director and Chief Executive Officer	Curetis
Mario Crovetto	66	Director	Curetis
R. Donald Elsey	66	Director and Audit Committee Chair	OpGen
Prabhavathi Fernandes, Ph.D.	70	Director	Curetis
Evan Jones	62	Director	OpGen

Q: Who are expected to be the executive officers of Newco following the Transaction?

A Following the closing of the proposed Transaction, Evan Jones, the current Chairman, President and Chief Executive Officer of OpGen will continue on the Newco Board of Directors in a non-executive role. Oliver Schacht, the current Chief Executive Officer of Curetis N.V. will serve as the Chief Executive Officer, and Timothy C. Dec, the current Chief Financial Officer of OpGen, will continue to serve in that role. As of the date of this proxy statement/prospectus, the expected executive officers of Newco are as follows:

Name	Age	Expected Position with Newco
Oliver Schacht, Ph.D.	49	Chief Executive Officer
Timothy C. Dec	60	Chief Financial Officer and Corporate Secretary
Johannes Bacher	51	Chief Operating Officer
Vadim Sapiro	48	Chief Information Officer

Q: What are the challenges involved in combining a German/Austrian company and a U.S. company?

A: Following the closing of the proposed Transaction, 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 and culturally 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 business 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 business 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. We could have difficulty integrating the assets, personnel, operations and business of OpGen and Curetis.

Q: When do you expect the Transaction to be consummated?

A: Assuming that we can hold the Special Meeting of stockholders in February 2020 to approve the Transaction and the Transaction Shares issuance, and Curetis N.V. can hold its extraordinary general meeting in February 2020 to approve the Transaction, and all other closing conditions are satisfied or waived, we anticipate the Transaction will close in the first quarter of 2020. We cannot guarantee the closing of the proposed Transaction will occur in this time frame.

Q: What is required to consummate the Transaction?

A: In addition to approval of the Transaction Proposal, Share Issuance Proposal and Adjournment Proposal by OpGen stockholders, the closing of the proposed Transaction is subject to the satisfaction or waiver by OpGen and Curetis N.V. of a number of other conditions, including the assumption by OpGen of the obligations under the Curetis Convertible Notes, including the need to provide for the conversion of the Curetis Convertible Notes into shares of OpGen's common stock; the entry into the Interim Facility and the funding thereunder; and the receipt of the applicable consents or waivers to be received or granted by certain debt financing providers of Curetis N.V., Curetis GmbH and OpGen. Each of OpGen and Curetis N.V. may waive any or all of the conditions to the closing of the proposed Transaction that are for its benefit to the extent permitted by applicable law. OpGen and Curetis N.V. do not believe that applicable law would permit them to waive (i) the condition for obtaining approval of the Transaction Proposal and Share Issuance Proposal from OpGen's stockholders or (ii) the condition for obtaining approval of the proposed Transaction from Curetis N.V.'s shareholders and debt holders. See "The Implementation Agreement" beginning on page 70 of this proxy statement/prospectus.

Q: What are the material U.S. federal income tax consequences of the Transaction to us and our stockholders?

A: The proposed Transaction consists of the issuance of the Consideration by OpGen in exchange for the acquisition by Crystal GmbH, its wholly owned German subsidiary, of all of the capital stock of Curetis GmbH and assumption of certain liabilities of Curetis N.V. by OpGen or Crystal GmbH. A corporation does not recognize gain or loss when it issues stock in exchange for property under Section 1032(a) of the U.S. Internal Revenue Code of 1986, as amended, or the Code. OpGen therefore believes that neither OpGen nor its stockholders will recognize taxable gain or loss on OpGen's issuance of shares in the proposed Transaction. OpGen has not sought a tax opinion regarding the U.S. federal income tax consequences of the proposed Transaction, and it provides no information regarding the tax treatment of the proposed Transaction to OpGen or its stockholders in jurisdictions other than the United States. The foregoing summary is for general information only and does not discuss any state, local, foreign or other tax consequences.

The U.S. federal income tax consequences described above may not apply to all stockholders. Your tax consequences will depend on your individual situation. Accordingly, we strongly urge you to consult your tax advisor for a full understanding of the particular tax consequences of the Transaction to you.

Q: Who is paying for this proxy solicitation?

A: OpGen is paying for this proxy solicitation. Our officers and other regular employees may solicit proxies by mail, in person or by telephone or telecopy. These officers and other regular employees will not receive additional compensation. The Company has retained a third party proxy solicitor for the Special Meeting and estimates cost of $5,000.00. We will reimburse banks, brokers, nominees, custodians and fiduciaries for their reasonable out-of-pocket expenses incurred in sending the proxy materials to beneficial owners of the shares.

INFORMATION REGARDING FORWARD-LOOKING INFORMATION

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

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. These risks should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to the risk factors described in this proxy statement/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 proxy statement/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.

PROPOSAL ONE
THE TRANSACTION PROPOSAL

Reasons for the Transaction

There are multiple reasons for contemplating and implementing the Transaction between OpGen and Curetis. The business combination with represents a unique opportunity for both companies to more rapidly and cost effectively develop their businesses than they would have been able to on a stand-alone basis. We believe that this will enhance shareholder value compared with building the individual businesses on a stand-alone basis. We believe the combined business will:

- establish a leading AMR precision medicine business with the goal of becoming a market leader positioned to capitalize on global opportunities in infectious disease and rapid AMR detection;
- possess a broad portfolio of proprietary molecular diagnostics tests and platforms with high impact rapid diagnostics;
- have premier AMR bioinformatics and premier AI powered bioinformatics solutions for multi-drug resistance diagnostics;
- capitalize financial leverage, operational synergies, and positive growth-driven business opportunities; and
- combine sales, distribution, bioinformatics and operating infrastructure.

We believe that OpGen will be able to leverage the established global commercial channel capabilities and partners of Curetis. We also believe that the combined business will have improved access to the U.S. capital markets as a result of the larger scale of the business and the Company's Nasdaq stock exchange listing.

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 distributing the OpGen products through the Curetis international distribution channels. Potential 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 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 main products we expect Newco to focus on are for lower respiratory infection and urinary tract infection, which specifically include:

- The Unyvero Lower Respiratory Tract, or LRT, test is the first FDA cleared test with a panel of pathogens that Curetis believes covers more than 90% of infection cases of hospitalized pneumonia patients. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. The Unyvero LRT automated test detects 19 pathogens within less than five hours and with approximately two minutes of hands-on time and provides clinicians with a comprehensive overview of 10 genetic antibiotic resistance markers. We believe the Unyvero LRT test has the ability to help address a significant, previously unmet medical need that causes over $10 billion in annual costs for the U.S. healthcare system, according to the Centers for Disease Control, or CDC.
- 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 40,000 sequenced isolate strains and phenotypic correlation data against over 100 antibiotics. In September 2019, Ares Genetics signed a technology evaluation agreement with an undisclosed global IVD corporation. In the first phase of the collaboration, expected to take about 10 months, Ares Genetics expects to further enrich ARESdb with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication. We anticipate that Newco will utilize the proprietary biomarker content in these databases, as well as to build an independent business in NGS- and AI-based offerings for AMR research and diagnostics in collaboration with partners in the life science, pharmaceutical and diagnostics industries.

The Unyvero A50 tests for up to 130 diagnostic targets (pathogens and resistance genes) in under five hours with approximately two minutes of hands-on time. The system was first CE Marked in 2012 and was FDA cleared in 2018 along with the LRT test through *de novo* clearance. As of September 30, 2019, an installed base of 165 Unyvero A50 Analyzers globally. The Unyvero A30 *RQ* is a new device designed to address the low to mid-plex testing market for 5 to 30 DNA targets and to provide 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. Curetis has been executing a partnering strategy for the Unyvero A30 *RQ*, 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, as of September 30, 2019, Curetis had a network consisting of 18 distributors covering 43 countries.

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

Pursuant to the Implementation Agreement, we have agreed to assume the Curetis Convertible Notes from Curetis N.V. and outstanding indebtedness of Curetis GmbH under a loan provided by the European Investment Bank, or EIB. As of November 1, 2019, the outstanding indebtedness under the Curetis Convertible Notes was $1.4 million. 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.

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;
- further advancing the development of ARESdb and the ARES Technology Platform and NGS-based development and clinical validation of infectious disease applications based on these assets;
- 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.

Newco's Strategy

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

- continue to gain regulatory approvals and establish a market position for proprietary molecular diagnostic tests and platforms;
- capitalize on unique AMR bioinformatics solutions based on the Acuitas Lighthouse Software and ARESdb to help differentiate Newco's molecular diagnostic offerings and establish stand-alone product offerings directly or through strategic partners;
- leverage global commercial channel capabilities and partners to help accelerate growth and establish a global footprint for Newco's tests and informatics;

- pursue partner relationships to help fund product development and to support commercialization of products and services; and

- capitalize on the financial leverage, operational and research synergies to help improve return on capital and achieve future profitability.

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

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

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

- **Rapid diagnostics** – The two lead products for Newco's rapid diagnostics business are for lower respiratory infection and urinary tract infection. The LRT test is based on the Unyvero A50 and was FDA cleared in 2018 for use with tracheal aspirates as a sample type. In July 2019, Curetis filed for the 510(k) clearance of an LRT application cartridge optimized for use with BAL as an additional sample type. BAL is another common sample type for the diagnosis of lower respiratory tract infections. In response to its July 2019 510(k) submission, Curetis received an AI request from the FDA in September 2019. After resolving the deficiencies identified in the AI request, FDA clearance was received in December 2019. Curetis believes that receipt of FDA clearance of an Unyvero LRT Application Cartridge for this additional sample type will significantly increase the total addressable market for Unyvero in the United States. Newco plans to continue to expand the commercial opportunity for the Unyvero products by developing new tests, running additional clinical trials, pursuing expanded regulatory approvals and through sales and marketing activities intended to help increase commercial adoption and test usage. OpGen is developing OpGen-branded Acuitas AMR Gene Panel tests for use on the Thermo Fisher Scientific Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System. The first of these new tests will be for antibiotic resistance testing of bacterial isolates. The second indication for the Acuitas AMR Gene Panel is for management of patients with UTI.

- **ARESdb and Acuitas Lighthouse informatics and services** – Newco plans to pursue commercial opportunities to provide bio-informatics and companion genomic testing services to pharmaceutical companies, CROs, health systems, third party *in vitro* diagnostic companies, and government agencies based on the Acuitas Lighthouse and ARESdb. 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 solutions based on the Acuitas Lighthouse and ARESdb bioinformatics platforms in the United States and internationally.

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

- commercializing the Unyvero A50 LRT test for BAL specimens and expand the base of commercial customers following FDA clearance in December 2019;
- entering into strategic partnering and licensing agreements to provide funding and support further development of the Unyvero A30 *RQ* platform;
- obtaining FDA clearance to market the Acuitas AMR Gene Panel test for the detection of antimicrobial resistance genes in bacterial isolates and expand the base of commercial customers;
- 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;
- progressing the development of ARESdb-based solutions for AMR prediction for public health, pharma, and diagnostics in collaboration with and partially funded by established *in vitro* diagnostic and pharmaceutical companies;
- 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.

Background of the Transaction

Highlighted below is a detailed chronology of events leading up to and subsequent to the execution of the Implementation Agreement.

In summer of 2017, the Management Board, or Curetis MB, and Supervisory Board, or Curetis SB, of Curetis N.V. met and discussed the strategic and commercial future as well as financial aspects of Curetis N.V. as a stand-alone company. The Curetis SB approved retaining a banking advisor to run a structured process to determine whether there would be any interested parties in acquiring Curetis N.V., as a whole. Following a structured process where several banks presented to the Curetis MB and Curetis SB in August 2017, RW Baird was chosen to run the process. Following the preparation of certain non-confidential pitch materials, an outreach was conducted from the fourth quarter of 2017 through the first quarter of 2018. Following a series of meetings and telephone conference calls around the JP Morgan healthcare conference in January 2018, it became obvious that Curetis N.V. would be unable to attract meaningful bids from global IVD companies prior to receipt of FDA clearance of Unyvero LRT in the United States and some significant amount of commercial traction. Also, during a meeting between representatives of H.C. Wainwright & Co., LLC, or HC Wainwright, and the Curetis MB during the 2018 JP Morgan conference, the idea of having an informal discussion about possible areas of mutual interest and providing an introduction to the OpGen management team were floated.

Around that time, Curetis N.V. ran a dual track process of preparing Curetis N.V. for a possible future Nasdaq listing. PwC was retained to audit the IFRS IASB or U.S. GAAP financial statements. The project was initiated in the fall 2017 and ran into the first quarter of 2018.

At a meeting of the Curetis SB on February 22, 2018 the feedback and status of both of these projects were discussed in depth. Given the estimated required time and resource commitment towards a possible Nasdaq IPO by Curetis pursuant to a Form F-1 filing, a decision was made to abandon the idea of a Nasdaq IPO and instead focus on capital raising measures using the existing Euronext listing. The primary reason at the time was that it was believed that a Euronext follow-on offering might be possible to complete in the second or third quarter of 2018. It was decided to retain Goetzpartners and Trout Capital for a private placement financing, or PIPE, to be completed in the first half of 2018. In addition, several of the potential leads and discussions from the strategic outreach track process put on hold, to be pursued independently by Curetis management directly.

Once the decision to not pursue the Nasdaq IPO track further was made, RW Baird determined that it would not be best positioned to support a Euronext follow-on offering. The bank ended its engagement letter and waived any tail obligations that Curetis would have otherwise had.

On April 27, 2018, Curetis successfully closed a PIPE financing raising EUR 4.1 million by issuing 854.166 new shares at EUR 4.80 per share. A new anchor investor was found with Milaya Capital, the family office of a well-known Belgium life science and diagnostics investor.

On May 2, 2018, as part of a regularly scheduled Board meeting, the OpGen Board of Directors, or the OpGen Board, discussed OpGen's strategic focus, planned regulatory and business activities and short and long-term financing needs. As part of such discussion, the Board reviewed information regarding a number of companies with a business focus similar to OpGen's, including Curetis N.V. and companies in OpGen's general industry with which OpGen could potentially collaborate. The OpGen Board determined that it was advisable to consider all strategic alternatives available to OpGen, including entry into collaboration agreements, licensing transactions, or a business combination transaction, either as an acquirer or a seller.

Over the ensuing months in the spring and summer of 2018 Curetis N.V. completed a number of non-deal road shows in China with both institutional investors as well as potential strategic collaboration partners. Special emphasis was put on opportunities that could leverage some of the assets in the Curetis N.V. R&D pipeline such as the Unyvero A30 *RQ* platform as well as ARESdb.

At the Curetis SB meetings in May 2018 and June 2018, as well as several Curetis SB conference calls in the third quarter of 2018 an intensive dialogue was held between the Curetis MB and Curetis SB to determine the best possible course of action. Also over the course of several months from May 2018 until September 2018, various banking syndicate alternatives were evaluated and discussed and following significant re-structuring of engagements and composition of syndicates after evaluating a total of six banking and advisory firms, final engagement letters were signed with Baader Bank and Goetzpartners, respectively, to complete the process for a prospectus driven Euronext follow-on offering. The financing successfully closed on November 7, 2018 raising EUR 8.9 million in gross proceeds. Given that these gross proceeds were significantly below the desired target, the Curetis MB and Curetis SB discussed and implemented significant re-organization and strategic re-direction in December 2018 and January 2019 with a significant reduction in force, putting all EMEA direct sales territories into the hands of Menarini Diagnostics, down-sizing the U.S. commercial team and operations and optimizing R&D programs for partnering and third party commercialization rather than internal IVD development and commercialization e.g. of the Unyvero A30 *RQ* platform.

During June and July 2018, the OpGen Board reviewed information provided by management regarding potential industry partners and competitors, and determined that it would be helpful to engage banking advisors to assist the Board with its determinations. On June 8, 2018, the OpGen Board retained John Kuzmishin, a consultant with knowledge of the industry, to assist the Board in evaluating the alternatives available to the Board. In July 2018, OpGen entered into non-disclosure agreements with a number of investment banking firms to seek advice regarding next steps. The OpGen Board, with John Kuzmishin's assistance, spoke with representatives of seven banking firms during July and August 2018.

During July and August 2018, the OpGen Board considered a number of alternatives available to the Company, including capital-raising transactions, business collaboration transactions with pharmaceutical companies or other, larger companies with complimentary diagnostic and platform product offerings, or some combination of such alternatives. The Board also discussed the interplay of these considerations with the potential collaboration being negotiated among the Company, 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.

In a parallel track over the summer and fall of 2018 a series of informal discussions and meetings were held between the management teams of OpGen and Curetis N.V, after an informal introductory meeting during ASM Microbe in Atlanta in late June 2018. A strategic brainstorming session about possible areas of mutual interest and collaboration opportunities was held in Chicago in July 2018 ahead of the American Association of Clinical Chemistry annual conference. All of these discussions were held under a non-disclosure agreement between OpGen and Curetis N.V. signed on June 25, 2018.

In addition, during the period from June through September 2018, the Compensation Committee of the Board engaged in an analysis of OpGen's executive compensation and the need to implement a retention plan to assist in the retention of OpGen leadership to assist with the potential process. The Compensation Committee approved a number of retention-related compensation changes including: restoring Mr. Jones' base salary to $425,000/year in July 2018; providing four executive officers, including Mr. Jones, with a Change in Control/Severance Agreement (approved in September 2018) that provided all four executive officers with six months' base salary severance on a termination outside of a change in control period and increased to 12 months' base salary, plus acceleration of outstanding equity awards on a termination related to a change in control; and putting in place a retention plan that reserved 5% of the acquisition value of OpGen in a consummated change in control transaction to be paid by the acquiring company, in cash, if any of the four executive officer's employment was terminated without cause or for "good reason" in the six months before or two years after a change in control. The retention plan, approved and disclosed in September 2018, was an addition to the severance to be paid, if any, under the Change in Control/Severance Agreements. The retention plan also provided that if any of the four executive officers are retained by the acquiring company for two years after a change in control, the payment would be made at the end of that period, and severance would not be paid.

At a regularly scheduled OpGen Board meeting held on August 1, 2018, the Board received presentations from two investment bankers and advice from a third relayed by management. During such presentations the advisors provided information regarding their experience, advice regarding market activity, the possibilities for a successful transaction and the types of strategic transactions they believed were available to the Company, include sale transactions and collaborations. After discussion, the Board determined that it would engage Crosstree as a financial advisor and authorized management to work with counsel to negotiate an engagement letter with Crosstree.

On August 21, 2018, the Transaction Committee of the OpGen Board met to discuss the Company's financial position and anticipated cash reach over the remainder of calendar 2018 and into the first quarter of 2019. The financing alternatives discussed included use of the Company's existing at-the-market offering, or the implementation of a public offering of securities, private placement with an investor or industry participant, a warrant exchange transaction or a rights offering. The Transaction Committee authorized management to secure financing through the at-the-market offering to the extent appropriate and possible over the next month.

The engagement letter with Crosstree was executed on August 27, 2018. The fee structure included a transaction fee and, if requested, a separate fee for the issuance of a fairness opinion. Crosstree representatives were given access to an electronic data room and due diligence commenced.

During the ongoing discussions the Curetis MB determined that there might be significant value in exploring a more strategic nature of the collaboration with OpGen and possibly also a business combination. In late August 2018, Curetis N.V. was informed by OpGen management of the formal and structured bidding process that OpGen and its board had implemented. Curetis was invited by Crosstree to submit an initial non-binding indicative offer for OpGen by December 2018.

During late August, September and October 2018, Crosstree, John Kuzmishin and OpGen management worked to develop introductory materials describing OpGen and its strategic interests and developing a list of potential financing sources, collaborators, targets and potential acquirors. Crosstree, John Kuzmishin and OpGen management also drafted and refined a Confidential Information Memorandum, or CIM, regarding the Company. The OpGen Board was kept informed of the progress of such activities with weekly updates and approved the introductory materials and CIM in October 2018.

On September 17, 2018, the Compensation Committee of the OpGen Board met to review and finalize the executive officer Change in Control/Severance Agreements and the Retention Plan for Senior Executives. The agreements and plan were approved by the full OpGen Board on September 21, 2018. A Current Report Form 8-K disclosing the agreements and retention plan was filed by the Company on September 25, 2018.

Beginning on October 4, 2018, OpGen's management and counsel worked with representatives of Aegis Capital Corp. to effect a public offering of common stock using OpGen's existing shelf registration statement. On October 22, 2018, OpGen closed a public offering, or the October 2018 Public Offering, of 111,000 shares of common stock at a public offering price of $29.00 per share. The offering raised gross proceeds of approximately $3.2 million and net proceeds of $2.8 million.

On October 18, 2018, Crosstree circulated to the OpGen Board a presentation of potential strategic and financial partnering opportunities for OpGen, ranked by business focus, potential interest, and deal capacity, as well as information on alternative candidates. Crosstree representatives were available to the OpGen Board members to discuss the materials over the next week. On October 23, 2018, the OpGen Board met and discussed the materials in detail. Mr. Kuzmishin also updated the OpGen Board regarding ongoing conversations with a global pharmaceutical company regarding a potential business combination or collaboration transaction with a subsidiary. After discussion, the Board authorized Crosstree to contact a designated number of companies and financing sources to provide the approved OpGen materials and enter into confidentiality agreements with the companies who expressed interest in receiving additional information. The OpGen Board also authorized Mr. Kuzmishin to continue conversations with the pharmaceutical company.

Over the next month, Crosstree contacted 62 strategic buyers and 40 financial buyers. Of such companies, 19 executed non-disclosure agreements with the Company and received the CIM. Other than Curetis, none of such 19 companies delivered an indication of interest or term sheet to OpGen. On November 7, 2018, at a regularly scheduled Board meeting, Crosstree provided an update on the process, and management provided an update on conversations and evaluation of potential transactions with the subsidiary of a global pharmaceutical company, a large medical equipment supplier and a multi-national diagnostic testing and device manufacturer regarding potential collaboration and/or financing transactions.

On November 16, 2018, Harry D'Andrea, the Chair of the Audit Committee and the Chair of the Transaction Committee resigned from the OpGen Board and Committee membership. He confirmed that his resignation was not due to disagreements with management. Tina Nova was appointed to the Audit Committee and Misti Ushio was appointed as Chair of the Transaction Committee.

In September through December 2018 the Curetis MB and Curetis SB held several meetings and conference calls and determined that it would be in the best interest of Curetis N.V. to submit such a non-binding and initial indicative offer letter to OpGen, This was done in the light of a smaller than anticipated equity capital raise in November 2018 when actual gross proceeds of EUR 8.9 million fell significantly short of a targeted amount in the range of EUR 16 to 18 million, and the need to gain more critical mass and commercial traction especially in the United States faster than otherwise possible as a stand-alone company.

On December 17, 2018, Curetis N.V. provided a non-binding indicative letter outlining some key terms under which Curetis N.V. would be willing to further explore the idea of a business combination with OpGen. These indicative terms included a relative share exchange ratio of 2:1 to 3:1 in favor of Curetis N.V. and required sufficient financing becoming available for the business combination prior to proceeding, leading to relative share ownership of between 67% and 75% for the Curetis N.V. shareholders. The indication of interest also noted that an important component of any deal was the ability to adequately finance both companies and the potential business combination, either before or after the negotiation of any transaction. The ability of OpGen to maintain its Nasdaq listing was mentioned as a material consideration for Curetis N.V.

The Curetis SB held a meeting on December 5, 2018 and authorized the Curetis MB to proceed with discussions and negotiations towards a more detailed view on a potential business combination.

During JP Morgan healthcare conference in January 2019, an informal meeting was held between the OpGen chairman Evan Jones, OpGen Chief Financial Officer Timothy Dec, Curetis SB's chairman William Rhodes and Curetis N.V.'s Chief Executive Officer Oliver Schacht. Following the discussion Curetis N.V. signaled to OpGen that it would await formal feedback on whether, based on the terms outlined in the non-binding letter, there would be merit in continuing the discussions.

The first regularly scheduled OpGen Board meeting of 2019 was held on January 9, 2019. The focus of the meeting was the strategic combination project, including a detailed discussion of the Curetis N.V. proposal, due diligence to date and potential transaction issues. The OpGen Board also discussed an update from Mr. Kuzmishin and representatives of Crosstree on the ongoing collaboration and potential business combination transaction discussions with other interested parties.

During the period from mid-February 2019 until May 2019 the Curetis MB and Curetis SB discussed various financial and business scenario analyses on a possible business combination with OpGen. In addition, the strategic decision to put pan European commercial activities into the hands of one single larger distributor was implemented. Curetis, in late March 2019, signed an exclusive multiyear distribution agreement for all of its Unyvero A50 product portfolio covering 11 countries initially. At a Curetis SB meeting on February 24, 2019, the progress to date with the interactions with OpGen were discussed and the Curetis MB was given the green light to proceed with the idea of a potential business combination. The progress was discussed in regular bi-weekly telephone calls between Curetis SB chairman Bill Rhodes and Curetis N.V. Chief Executive Officer Oliver Schacht.

The OpGen Board was provided with updates on the process every one-to-two weeks over the next month. On February 13, 2019, the OpGen Board met to evaluate the alternatives available for OpGen, including continuing to negotiate with Curetis, N.V., engaging with other companies, expanding the strategic alternatives process, pursuing the future on a stand-alone basis, and the projected financing needs of the Company and the combined business with Curetis in the short- and long-term. Crosstree representatives and management provided analyses of each scenario and the pros and cons of each approach, including the finance-ability of each alternative, timing considerations and the potential impact on OpGen's stockholders. The OpGen Board discussed OpGen's stand-alone transaction in detail, including a discussion of the financing needs, the likelihood of financing OpGen on a stand-alone basis, and the anticipated product development timeline and length and expense of the related regulatory process. After a lengthy discussion, the OpGen Board asked the Crosstree representatives to secure Curetis N.V.'s thoughts on the viability of a business combination process, and the ability to develop a solid financial forecast for the proposed business combination and financing plan, while OpGen took the steps necessary to secure financing for OpGen.

On February 19, 2019, the OpGen Board elected R. Donald Elsey to the Board and appointed him as Chair of the Audit Committee of the Board.

OpGen management concentrated on finalizing and filing OpGen's Annual Report on Form 10-K for the year ended December 31, 2018. On management's recommendation, management and the Board suspended all management participation in discussions with Curetis N.V. and other potential parties while OpGen focused on financing the Company. During March 2019, Crosstree representatives and Mr. Kuzmishin continued to address questions and provide information without input or further assistance from OpGen.

On March 28, 2019, OpGen closed a common stock financing, raising net proceeds of $4.8 million through the sale of 450,000 shares at $12.00 per share. The over-allotment option granted to the underwriter was not exercised.

On April 2, 2019, and again on April 11, 2019, OpGen management and representatives of Crosstree provided the OpGen Board with an update on the strategic alternatives process over the prior six weeks. The update focused on the financial viability of a transaction with Curetis N.V. and a potential collaboration or going private transaction with the subsidiary of a global pharmaceutical company to meld OpGen's diagnostics tests and informatics products with software technology of another company with funding provided by third party investors in the industry. The expense of the March 2019 public offering, coupled with the small amount of capital raised was discussed. The OpGen Board also received an update on a potential business transaction with a multi-national diagnostic testing and medical device manufacturer. OpGen management notified the OpGen Board that the focus of each of these efforts was finding financing sources needed to finance any business combination or other transaction, and that the business combination with Curetis was increasingly viewed as the most attractive alternative available to OpGen.

At the OpGen Board meeting held on May 1, 2019, Mr. Kuzmishin and representatives of Crosstree updated the Board on a joint investor presentation being developed by OpGen and Curetis N.V. to present the proposed business combination financing needs to investors to gauge potential interest. Mr. Jones also reported that conversations with investors for the potential transaction with a subsidiary of a global pharmaceutical company had revealed that the timeline for any such transaction was too extended for OpGen to pursue given its then-current financial condition.

On May 6, 2019, the Listing Qualifications Staff of The Nasdaq Stock Market LLC notified the Company that the closing bid price of the Company's 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). OpGen had until November 4, 2019 to regain compliance with the Minimum Bid Price Rule.

During May and June 2019, the efforts of each of OpGen and Curetis focused on investor meetings for a potential combination, and considerations by each party of stand-alone strategies and likelihood of success. Representatives of HC Wainwright and Crosstree, and counsel from Linklaters LLP and Ballard Spahr LLP, counsel to the parties, participated in a few calls regarding possible transaction structure alternatives for a business combination between Curetis N.V. and OpGen. The analyses considered the complexity of the proposed transaction, various structuring alternatives, the anticipated time-lines and the approval requirements associated with each possible transaction structure.

At the Curetis SB meeting held on May 15, 2019, the Curetis MB updated the Curetis SB on a joint investor presentation being developed by OpGen and Curetis N.V. to present the proposed business combination financing needs to investors to gauge potential interest. The entire Curetis SB reviewed the status once again in detail at this meeting. Other key topics discussed at that Curetis SB meeting included the commercial progress in the United States, hand-over of European customers and business to Menarini, other strategic business development and partnering opportunities for Unyvero A30 *RQ* platform and ARESdb. Regular conversations were also held between the Curetis MB and Crosstree as well as the OpGen team to fine tune ideas of possible business combination scenarios.

During May 2019, OpGen determined that the proposed time frame for a potential transaction with a global pharmaceutical company was too long to consider this as a viable alternative in the near term. The consulting agreement with Mr. Kuzmishin was terminated by OpGen in May 2019.

Following receipt of the information that the OpGen Board had decided to continue discussions with Curetis N.V., the Curetis MB and Curetis SB discussed retaining a bank as an advisor and also for any potentially associated capital raise. On May 29, 2019, Curetis signed an engagement letter with HC Wainwright to become its M&A advisor and, on June 6, 2019, in a separate engagement letter also to serve as its investment bank for capital raising. Furthermore, PwC as auditors and Linklaters LLP as legal counsel were retained for the project. In a Curetis SB meeting on June 27, 2019 a detailed strategic discussion was held on prioritization and possible next steps of the discussions.

Representatives of OpGen, including Mr. Jones, attended the ASM Microbe 2019 conference from June 20-24, 2019. Mr. Jones engaged in a number of conversations with companies and investment banking firms regarding potential collaboration or transaction alternatives. He reported these conversations to the OpGen Board on June 25, 2019.

During May and June 2019, the efforts of each of OpGen and Curetis focused on investor meetings for a potential business combination, and considerations by each party of stand-alone strategies and likelihood of success. Representatives of HC Wainwright and Crosstree, and counsel to the parties, participated in a few calls regarding possible transaction structure alternatives for a business combination between Curetis N.V. and OpGen. The analyses considered the complexity of the proposed transaction, the anticipated time-lines and the approval requirements associated with each possible transaction structure. In June 2019, in a series of meetings and conference calls HC Wainwright had reached out to multiple institutional investors, and the prevailing feedback that HC Wainwright provided to the Curetis MB and Curetis SB during a conference call on June 27, 2019 was that an up-front commitment by one or multiple investors to invest $20 million or more would not likely be obtainable as investors would only consider an investment closer to or following the closing of a business combination.

The Curetis SB during the June 27, 2019 meeting also requested that the Curetis MB prepare a detailed analysis of various alternative scenarios including various asset monetization and licensing or partnering scenarios for the Unyvero A30 *RQ* platform, for Ares Genetics and a scenario under which Curetis N.V. would wind down its operations into a hibernation mode in order to maximize cash reach and determine asset selling activities in parallel. Such scenarios were prepared by the Curetis MB and provided to the Curetis SB by July 19, 2019. These analyses included status updates provided by the Curetis MB to the Curetis SB on various ongoing strategic licensing and partnering discussions. Amongst those were several Unyvero A30 *RQ* platform-related negotiations and discussions with three parties from China, one from Asia Pacific, two from Europe and one from the United States. Furthermore, a pipeline of strategic business development negotiations around ARESdb and Ares Genetics assets were discussed. These included strategic discussions with a big pharmaceutical company, a strategic biotechnology transaction, a major global leading IVD corporation, existing partners QIAGEN and Sandoz and several other parties.

The input management of the companies received from the investor outreach process by the end of June 2019 was that a pre-business combination financing transaction was unlikely to raise sufficient funds within the time frame required by OpGen and Curetis N.V., and the boards and management of each party determined that a business combination of the two companies was the best alternative available to their respective shareholders and stockholders.

Based upon this analysis, a formal decision was taken by Curetis N.V. to focus its energies on a potential business combination transaction with OpGen and to abandon remaining alternatives, such as asset sales, monetization deals and the like. Curetis N.V. decided to proceed with next steps and have Linklaters LLP draft certain implementation plans for selection by the wider working group towards preparing a non-binding letter of intent and subsequently a definitive implementation agreement. The Curetis SB was kept informed throughout the process by means of regular bi-weekly calls between William Rhodes as chairman of the Curetis SB and Chief Executive Officer Oliver Schacht, as well as regular email updates and calls where needed.

Effective June 30, 2019, each of Timothy Harris and David Rubin resigned from the Board of OpGen due to other commitments. Neither director communicated any disagreement with management of the Company.

The OpGen Board determined in late June 2019 to abandon pursuit of any alternatives and to focus OpGen's activities on securing a business combination transaction with Curetis.

On July 8, 2019, Curetis N.V. provided OpGen and its counsel, Ballard Spahr LLP, with a term sheet that proposed an asset acquisition transaction in which OpGen would acquire 100% of the assets and liabilities of Curetis N.V. and its subsidiaries in exchange for the issuance of OpGen common stock to Curetis N.V. shareholders, with OpGen surviving as a Nasdaq-listed company. The proposed ownership ratio for Curetis was 72.5% of the outstanding OpGen stock, as the closing of the transaction, to be held by Curetis N.V. shareholders, with 27.5% to be held by OpGen stockholders on a fully diluted basis. These percentages were based on the relative market capitalizations of Curetis N.V. and OpGen over 30, 60, 90, 180 and 360 day periods prior to the term sheet date. At this point, no additional valuation work was conducted. The proposal included corporate governance provisions related to the post-closing Board and management team of OpGen consisting of representative of each of Curetis and OpGen. The term sheet included the need for an interim financing of OpGen, to be used to fund the operations of both companies during the period between signing and closing of the definitive agreement, and a 45-day exclusivity period. The proposed ownership ratio discussed in the term sheet did not include any adjustment for the dilutive impact of the proposed interim financing. As noted in this proxy statement/prospectus, the actual ratio will be closer to 32.3% for Curetis N.V. and 67.7% for OpGen's stockholders following the Interim Financing.

The executive teams of Curetis and OpGen, along with their respective advisors and counsel (HC Wainwright and Linklaters LLP for Curetis, and Crosstree and Ballard Spahr LLP for OpGen) negotiated the non-binding term sheet. The deal structure was refined to be an acquisition of the business of Curetis N.V., which consisted of the business of its subsidiaries, notably Curetis GmbH and its down-stream subsidiaries, Ares Genetics GmbH and Curetis USA Inc. The term sheet was revised to reflect the issuance of the OpGen stock consideration to Curetis N.V. with the understanding that Curetis N.V. would ask its shareholders at an EGM to resolve to move to dissolve shortly after the closing of the transaction and liquidate in order to distribute the maximum number of OpGen shares available for distribution under Dutch law to its shareholders.

Management of Curetis N.V. and OpGen, based in large part on the anticipated ownership percentages post-closing without consideration of the impact of the Interim Financing, determined that the proposed transaction structure would be likely treated as a reverse acquisition of the carved out business of Curetis GmbH and its subsidiaries, necessitating the need for an evaluation of the financial statements that would be required for the transaction.

Over the next two weeks the chief executive officers of the companies, along with counsel and advisors negotiated the term sheet provisions and determined whether the required carved-out financial statements could be developed, audited and delivered within the time frame needed by the companies. In addition, the parties negotiated the impact on the ownership ratio of the required interim financing transaction, and the cash needs of the two companies over the next three months. The final non-binding term sheet was executed on July 29, 2019. The principal terms of the term sheet were, subject to completion of due diligence:

- OpGen to acquire all of the assets and liabilities of the Curetis business through the purchase of all of the equity interests of Curetis GmbH from Curetis N.V.;

- OpGen would file, as soon as possible after announcement of the transaction, a registration statement for an interim financing of at least $10 million, the proceeds of which would be used to support the business operations of the two companies prior to the closing, and Newco after the closing;

- The number of shares to be issued by OpGen (or reserved for issuance by OpGen to cover stock option exercises under the 2016 Stock Option Plan and conversion of the Curetis Convertible Notes), would be a fixed number of shares that would, as of the date of the Implementation Agreement, result in 72.5% of the equity of Newco being held by Curetis N.V. or reserved for future issuance as described above, and 27.5% of the equity held by OpGen legacy stockholders on a fully diluted basis; such ratios not to be adjusted to reflect the Interim Financing, the dilutive impact of which could not be reasonably estimated;

- the shares to be issued to Curetis N.V. or reserved for issuance under the Curetis 2016 Stock Option Plan and conversion of Curetis Convertible Notes would be registered on a Form S-4 Registration Statement;
- retention of an independent registered public account firm by Curetis N.V. to audit the required financial statements;
- post-closing governance would include a six-member Newco Board of Directors with two members named by OpGen, including Evan Jones, and four, including Board chair William Rhodes, named by Curetis N.V., all in compliance with Nasdaq requirements;
- Oliver Schacht, Ph.D. would become Chief Executive Officer of Newco and Timothy C. Dec would continue as Chief Financial Officer of Newco;
- standard due diligence, confidentiality, access to information and a commitment for the definitive agreement to contain customary representations, warranties, covenants and indemnification language for a transaction of the type contemplated; and
- agreement to a 20-day exclusivity period.

Counsel to the parties commenced legal due diligence and the parties continued business due diligence promptly after execution of the non-binding term sheet. On August 16, 2019, Linklaters LLP, counsel to Curetis N.V. provided a first draft of the Implementation Agreement to the working group. Working group conference calls were held on August 20, 2019 and August 27, 2019 with each company and their advisors and counsel. Legal calls occurred on August 27, 29 and 30, 2019. Drafts of the Implementation Agreement were exchanged between Linklaters LLP and Ballard Spahr LLP, counsel to OpGen, during this period.

Oliver Schacht was the principal negotiator for Curetis N.V. and Evan Jones for OpGen, Inc. Each of OpGen and Curetis kept their respective board members updated regarding negotiations as negotiations progressed between August 16, 2019 and September 2, 2019. OpGen was represented by attorneys from Ballard Spahr LLP, for United States, securities and M&A purposes, and from Weidema van Tol (Switzerland) GmbH for Dutch and German-related matters. Curetis was represented by attorneys from Linklaters LLP and its affiliates. Linklaters took the lead on document drafting.

The principal points of negotiation related to the Implementation Agreement, a discussion summary, and the resolution of such points were:

Negotiating Point	Discussion	Resolution
The number of shares to be issued to Curetis N.V. and, the impact, if any, of the Interim Financing on the actual ownership of OpGen common stock by Curetis N.V. upon closing of the proposed Transaction	After much discussion, it was determined that it was impractical to attempt to adjust the Consideration for the Interim Financing.	The Consideration is a fixed number of shares - no adjustment was to be made to reflect the Interim Financing. The overall percentage ownership cannot be determined until closing.
How the assumption of the outstanding equity awards of Curetis N.V. under the 2016 Stock Option Plan and PSOP would be handled	Negotiations focused on the relative in-the-money value of the stock options and PSOPs, the tax implications to the PSOP holders and the difficulty of adding additional shares to Curetis N.V.	A conversion factor of 0.0959 (based on the number of fully diluted Curetis N.V. shares and fully diluted OpGen shares) was agreed upon to be used in such calculations. Since the date of the Implementation Agreement, Curetis has issued additional shares to the holders of the PSOPs, and all have been retired. The shares previously reserved to cover the PSOPs will be issued to Curetis N.V. as part of the Consideration.
The extent to which OpGen would assume all liabilities of Curetis N.V. related to the Curetis business	Curetis N.V. took the position that all liabilities must be transferred to Curetis GmbH or otherwise assumed by OpGen because of Curetis' dissolution plans. The potential for some sort of indemnification from Curetis N.V. and/or certain Curetis N.V. shareholders was discussed and rejected. The fact that the businesses were combining and would be operated together was an important discussion point	OpGen agreed to assume the Curetis Convertibles Notes and the EIB Finance Agreement, and to forego any indemnification for known or unknown, accrued or unaccrued liabilities.
The timing of the Interim Financing and the amount of capital to be raised; and the potential reverse acquisition accounting for the Transaction	The timing of the availability of carved out financial statements for the Curetis Business, and the need for such financial statements in order to progress the Interim Financing and, therefore, the overall transaction, was a vital point discussed during the negotiations. Accountants from PricewaterhouseCoopers GmbH Wirtschaftsprüfungsgesellschaft, or	The availability of the Curetis Business financial statements were the principal gating item to the filing of the Form S-1 registration statement for the Interim Financing.

PwC, were retained to audit and review the carved-out financial statements.

In addition, the OpGen Finance team researched and evaluated the accounting for the proposed transaction and CohnReznick LLP, OpGen's independent auditors, provided oversight of such review.

During the negotiations, and, until the Interim Financing was consummated, the parties operated under the assumption that the Transaction would be accounted for as a reverse acquisition of OpGen by Curetis GmbH.

Negotiating Point	Discussion	Resolution
The anticipated cash needs of the parties prior to the closing and the method by which OpGen would provide funds to the Curetis business from the Interim Financing in order to operate the Curetis business prior to the closing	Both parties identified the need for capital financing to operate its business in the period prior to the closing of the proposed Transaction as the most important aspect of continuing discussions. Curetis N.V. noted that once the proposed Transaction was announced, it would not be able to raise capital independently to support the Curetis Business. OpGen noted that it needed to regain and then maintain compliance with the Nasdaq Capital Markets listing requirements.	OpGen agreed to conduct the Interim Financing and to share the proceeds with Curetis GmbH through a subordinated credit facility that was subordinated to the existing and future indebtedness of Curetis in order to allow the parties to continue operations during the period prior to the closing of the proposed Transaction.
The extent of the representations and warranties made by each party and whether any indemnification would be available to support such representations and warranties post-closing	The representations and warranties were heavily negotiated, particularly once it was clear, early in the process, that Curetis N.V. would not provide indemnification. The representations and warranties were used as additional diligence inquiries as well.	
The anticipated timing of the filing of the Form S-4, the Special Meeting of OpGen stockholders and extraordinary general meeting of the Curetis N.V. shareholders	The parties discussed the impact of the Interim Financing and its timing on the Form S-4 filing, and the approval needs. Aside from discussions regarding the implementation of the proposed Transaction pursuant to a Form S-4 registration statement, there were no other thorough discussions of alternative methods.	

Negotiating Point	Discussion	Resolution
The termination rights of each party during the period between signing and closing if the Interim Financing did not occur, if an unsolicited third-party offer was received, if the necessary consents and approvals were not received, and a drop dead date for the closing of the proposed Transaction	In addition to standard termination rights, the parties negotiated a tight time frame for completion of the Interim Financing and the amount of the Financing. Each party requested the right to interact with any unsolicited third-party offer, given the anticipated timeline for the closing of the proposed Transaction. The parties negotiated a tight timeline for closing the proposed Transaction to try and minimize the expense of operating as separate businesses.	Standard termination rights for breach by the other party (with a cure) are included. Each party had the right to terminate if the Interim Financing was not consummated by October 31, 2019. The parties have subsequently agreed that closing condition has been met. Each party has the right to respond to unsolicited third party offers, but must follow a process of notification to the other. Either party can terminate if the proposed Transaction does not close by January 31, 2020.

On August 19, 2019, OpGen received written notification from The Nasdaq Stock Market LLC that the Company failed to comply with Nasdaq's 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.

On August 22, 2019, OpGen held its annual meeting of stockholders at which the four continuing directors were re-elected to one-year terms and the stockholders authorized the OpGen Board to effect a reverse stock split of the Company's common stock to assist the Company in regaining compliance with the Nasdaq Minimum Bid Price Rule. The OpGen Board authorized a twenty-for-one reverse stock split, which was effected on August 28, 2019. On September 13, 2019, the Company regained compliance with the Nasdaq Minimum Bid Price Rule.

Negotiations and discussions continued over the Labor Day weekend to resolve all remaining issues. On September 2, 2019, the OpGen Board met with representatives of Ballard Spahr LLP and Crosstree in attendance. The representatives of Crosstree made a presentation to the OpGen Board regarding Crosstree's assessment of whether the proposed transaction was fair, from a financial point of view to the OpGen stockholders, including a review of the valuation methodologies used, the alternatives available to the Company, and the conclusions. The valuation methods included selected comparable companies, including the limitations using this method, selected transaction analysis, discounted cash flow analysis, and M&A premium analysis. Crosstree representatives also discussed its assumptions, qualifications and limiting conditions, including the current cash position of OpGen and the fact that budgeted positive cash flow and EBITDA estimates provided by OpGen did not occur until the final year in the five year projections. Following its analysis Crosstree noted that the valuation analysis showed the proposed transaction provided a premium to the OpGen stockholders. The representatives of Crosstree noted it was able to provide the OpGen Board with an opinion that the proposed transaction was fair to the stockholders from a financial point of view. Following such presentation, and a presentation by counsel of the principal terms of the Implementation Agreement and the contemplated transactions, including the Interim Financing, and after discussion, the OpGen Board unanimously approved the Implementation Agreement, the filing of the Form S-1 for the Interim Financing, the filing of the Form S-4 and the matters related to the approval of the Implementation Agreement.

The Curetis MB and Curetis SB discussed the status of the negotiations, and all critical issues with regards to the draft implementation agreement. The Curetis MB and Curetis SB engaged HC Wainwright to provide the Curetis MB and Curetis SB with an opinion as to the fairness, from a financial point of view, to Curetis N.V. of the consideration to be paid by OpGen pursuant to the terms of the proposed implementation agreement. HC Wainwright delivered the fairness opinion to the Curetis MB and Curetis SB which was received on September 3, 2019. In arriving at its opinion, HC Wainwright (i) reviewed the draft implementation agreement; (ii) reviewed certain information, including financial forecasts, relating to the business, earnings, cash flow, assets liabilities and prospects of Curetis N.V. and OpGen that were furnished to HC Wainwright by management of Curetis N.V. and OpGen, respectively; (iii) conducted discussions with members of senior management and representatives of Curetis N.V. and OpGen concerning the information provided; (iv) reviewed publicly available information relating to the respective businesses of Curetis N.V. and OpGen; (v) reviewed the pro forma ownership structure of the combined entity resulting from the transaction; (vi) discussed the past and current operations and financial condition and the prospects of Curetis N.V. and OpGen with members of senior management of Curetis N.V. and OpGen, respectively; and (vii) performed such other analyses and considered such other factors as HC Wainwright deemed appropriate for the purpose of rendering its opinion. The opinion was prepared solely for the information of the Curetis MB and Curetis SB for their use in connection with the consideration of the transaction and was not intended to be and did not constitute a recommendation to any shareholder of Curetis N.V. as to how such shareholder should vote on any matter relating to the transactions contemplated by the implementation agreement or any other matter. HC Wainwright disclosed to the Curetis MB and Curetis SB that it had been engaged by OpGen pursuant to an engagement letter dated September 2, 2019 to assist OpGen with financing for a term of six months after the consummation of the Transaction. HC Wainwright obtained signed conflict waivers from both Curetis N.V. and OpGen in connection with this financing engagement by OpGen. In the light of the fairness opinion delivered by HC Wainwright, as well as any other alternative and options discussed in terms of other scenarios such as asset sales, licensing deals, hibernation mode or a potential taking private of Curetis N.V., all of which prior to signing the term sheet and letter of intent had not led to any immediately available option that would have been superior, the Curetis SB on September 4, 2019 approved the Curetis MB decision and resolution to sign the definitive Implementation Agreement and issue corresponding public announcements.

OpGen and Curetis N.V. executed the Implementation Agreement on September 4, 2019, and announced the entry into the Implementation Agreement on September 4, 2019. The management of OpGen and Curetis N.V. held a conference call on September 4, 2019 to provide information about the Implementation Agreement and the plans for Newco. OpGen filed a Current Report on Form 8-K on September 4, 2019.

Opinion of OpGen's Financial Advisor

Pursuant to an engagement letter dated August 27, 2018, the OpGen Board retained Crosstree, to deliver a fairness opinion, or the Opinion, in connection with the proposed Transaction.

At a meeting of the OpGen Board on September 3, 2019, Crosstree rendered its oral opinion to the Board that, as of such date and based upon and subject to the factors and assumptions set forth in its opinion, the Consideration to be paid in the proposed Transaction was fair, from a financial point of view, to the stockholders of OpGen. Crosstree confirmed its September 3, 2019 oral opinion by delivering the Opinion.

The full text of the Opinion, dated September 3, 2019, which sets forth the assumptions made, matters considered, and limits on the review undertaken, is attached as Appendix B to this proxy statement/prospectus and is incorporated herein by reference. The summary of the Opinion set forth in this proxy statement/prospectus is qualified in its entirety by reference to the full text of the Opinion. OpGen stockholders are urged to read the Opinion in its entirety.

The Opinion was addressed to the OpGen Board in connection with and for the purposes of their evaluation of the proposed Transaction, was directed only to the Consideration to be issued by OpGen in the proposed Transaction and did not address any other aspect of the proposed Transaction. Crosstree expressed no opinion as to the fairness of the Consideration to the holders of any class of securities, creditors, or other constituencies of the Company. The issuance of the Opinion was approved by a fairness committee of Crosstree. The Opinion does not constitute a recommendation to any stockholder of the Company as to how such stockholder should vote with respect to the proposed Transaction or any other matter.

In arriving at the Opinion, Crosstree, among other things:

- reviewed a draft Implementation Agreement as of September 3, 2019;
- reviewed certain financial and other information about the Company that was publicly available;
- reviewed information furnished to us by the Company's management, including certain internal financial analyses, budgets, reports, and other information;
- held discussions with various members of senior management of the Company concerning historical and current operations, financial conditions, and prospects, including recent financial performance;
- reviewed the recent share trading price history of the Company;
- reviewed the valuation of the Company implied by the Consideration;
- reviewed the valuations of publicly- traded companies that we deemed comparable in certain respects to the Company;
- reviewed the financial terms of selected acquisition transactions involving companies in lines of business that we deemed comparable in certain respects to the business of the Company;
- reviewed the premiums paid in selected acquisition transactions;
- prepared a discounted cash flow analysis of the Company on a stand- alone basis;
- assessed the general economic, market, and financial conditions;
- took into consideration our experience in other similar transactions and securities valuations; and
- performed such other analyses and considered such other factors as we deemed appropriate.

In giving the Opinion, Crosstree relied upon and assumed the accuracy and completeness of all information that was publicly available or was furnished to or discussed with Crosstree by OpGen or otherwise reviewed by or for Crosstree. Crosstree did not independently verify any such information or its accuracy or completeness and, pursuant to Crosstree's engagement letter with OpGen, Crosstree did not assume any obligation to undertake any such independent verification. Crosstree did not conduct and was not provided with any valuation or appraisal of any assets or liabilities, nor did Crosstree evaluate the solvency of OpGen under any state or federal laws relating to bankruptcy, insolvency, or similar matters. In relying on financial analyses and forecasts provided to Crosstree or derived therefrom, Crosstree assumed that they were reasonably prepared based on assumptions reflecting the best currently available estimates and judgments by management as to the expected future results of operations and financial condition of OpGen to which such analyses or forecasts relate. Crosstree expressed no view as to such analyses or forecasts or the assumptions on which they were based. Crosstree also assumed that the Transaction contemplated by the Implementation Agreement will be consummated as described in the Implementation Agreement. Crosstree also assumed that the representations and warranties made by OpGen in the Implementation Agreement and related agreements were and will be true and correct in all respects material to its analyses. Crosstree is not a legal, regulatory, or tax expert and relied on the assessments made by advisors to OpGen with respect to such issues.

The Opinion was necessarily based on economic, market, and other conditions as in effect on, and the information made available to Crosstree, as of the date of the Opinion. The Opinion noted that subsequent developments may affect the Opinion and that Crosstree does not have any obligation to advise any person of any change in any fact or matter affecting the Opinion. The Opinion is limited to the fairness, from a financial point of view, of the Consideration to be issued in the Transaction, and Crosstree has expressed no opinion as to the fairness of any consideration paid in connection with the Transaction other than the Consideration. Furthermore, Crosstree expressed no opinion with respect to the amount or nature of any compensation to any officers, directors, or employees of any party to the Transaction, with respect to the fairness of any such compensation.

The terms of the Implementation Agreement were determined through arm's-length negotiations between OpGen and Curetis N.V., and, with respect to the Company, the decision to enter into the Implementation Agreement was solely that of the Board. The Opinion and financial analyses were only one of the many factors considered by the Board in their evaluation of the proposed Transaction and should not be viewed as determinative of the Board or the Company's management with respect to the proposed Transaction or the Consideration.

In accordance with customary investment banking practice, Crosstree employed generally accepted valuation methodologies in: (1) rendering the Opinion to the Board; and (2) the presentation delivered to the Board in connection with the rendering of the Opinion. This does not purport to be a complete description of the analyses or data presented by Crosstree. Some of the summaries of the financial analyses include information presented in tabular format. The tables are not intended to stand alone, and in order to understand more fully the financial analyses used by Crosstree, the tables must be read together with the full text of each summary. Considering the data set forth below without considering the full narrative description of the financial analyses, including the methodologies and assumptions underlying the analyses, could create a misleading or incomplete view of Crosstree's analyses.

The projections furnished to Crosstree for OpGen were prepared by OpGen's management.

Public Trading Multiples Analysis

Using publicly available information, Crosstree compared selected financial data of OpGen with similar data for the following selected publicly-traded companies engaged in businesses that Crosstree judged to be sufficiently analogous to OpGen:

- QIAGEN N.V.;
- GenMark Diagnostics, Inc.;
- Quidel Corporation;
- Accelerate Diagnostics, Inc.;
- Luminex Corporation;
- bioMerieux S.A.;
- Genomic Health, Inc.;
- T2 Biosystems, Inc.; and
- Curetis N.V.

These companies were selected, among other reasons, because they are publicly- traded companies with operations and businesses that, for purposes of Crosstree's analysis, may be considered similar to those of OpGen based on business- sector participation, operational characteristics, and financial metrics. None of the selected companies were excluded from the analysis. However, none of the selected companies reviewed is identical to OpGen and certain of these companies may have financial and operating characteristics that are materially different from those of OpGen. For the companies included in the public trading multiples analysis, the following table discloses employees (worldwide) and number of products or services offered or sold, based on information collected by CapIQ as of December 2019:

Comparable Company	Employees Worldwide	Products or Services Offered
QIAGEN N.V.	5,200	154
GenMark Diagnostics, Inc.	477	8
Quidel Corporation	1,224	86
Accelerate Diagnostics, Inc.	287	3
Luminex Corporation	988	98
bioMérieux S.A.	11,200	234
Genomic Health, Inc.	829	7
T2 Biosystems, Inc.	153	10
Curetis N.V.	80	17
OpGen, Inc.	47	23*

* Includes four future products and products currently awaiting clearance by the FDA. Also includes legacy AdvanDx products.

Using publicly available information, Crosstree calculated, for each selected company, the multiple of enterprise value as of September 3, 2019 to historical standardized data that Crosstree obtained from S&P Capital IQ for revenue for the trailing twelve months from latest reported period (June 30, 2018 in most cases) ("EV/Revenue TTM-latest"); and the multiple of share price as of September 3, 2019 to historical standardized data obtained from S&P Capital IQ for tangible book value as reported in the latest period available ("P/Tangible BV- latest"). A multiple of enterprise value to EBITDA was not used for the analysis because OpGen is not currently profitable and has incurred substantial losses since inception.

Company Name	EV/Revenue TTM-latest	P/Tangible BV- latest
QIAGEN N.V.	5.9x	n.m.
GenMark Diagnostics, Inc.	4.8x	26.4x
Quidel Corporation	5.3x	221.2x
Accelerate Diagnostics, Inc.	150.3x	39.4x
Luminex Corporation	2.8x	3.7x
bioMerieux S.A.	3.7x	10.8x
Genomic Health, Inc.	6.2x	9.0x
T2 Biosystems, Inc.	10.4x	n.m.
Curetis N.V.	15.6x	n.m.

Based on the results of this analysis and other factors that Crosstree considered appropriate, Crosstree selected multiple reference ranges:

- for EV/Total Revenue TTM- latest of 5.6x – 6.5x; and
- for Price/Tangible BV- latest of 10.8x – 17.9x.

These multiple ranges were then applied to OpGen's trailing twelve months' revenue from June 30, 2019 and Tangible Book Value as reported on June 30, 2019, which indicated an implied enterprise value range for OpGen, rounded to the nearest $0.1 million, of $19.2 million to $27.2 million.

Transaction Multiples Analysis

Using both publicly available and proprietary internal information, Crosstree examined selected transactions involving companies in lines of business that we deemed comparable in certain respects to the business of OpGen. Based upon the availability of relevant data, Crosstree calculated the enterprise value to be paid for the target company in such transaction as a multiple of Revenue. The transactions considered are as follows:

Deal Date	Target	Buyer	Revenue Multiple
07/29/2019	Genomic Health, Inc.	Exact Sciences (NAS: EXAS)	6.3x
03/01/2019	Medical Neurogenetics, LLC	Laboratory Corporation of America Holdings (NYSE:LH)	n.a.
12/10/2018	Genoptix	NeoGenomics Laboratories (NAS: NEO)	n.a.
08/01/2018	Exosome Diagnostics	Bio-Techne (NAS: TECH)	n.a.
06/19/2018	Foundation Medicine (NAS: FMI)	Roche (SWX: RO)	31.3x
05/28/2018	Counsyl	Myriad Genetics (NAS: MYGN)	2.8x
10/18/2017	Cleveland HeartLab, LLC	Quest Diagnostics Inc.	n.a.
07/31/2017	Good Start Genetics, Inc.	InVitae Corporation	1.8x
07/31/2017	CombiMatrix Corporation	InVitae Corporation	1.9x
07/06/2017	Ambry Genetics Corp.	Konica Minolta Healthcare Americas, Inc. and Innovation Network Corporation of Japan	3.5x
06/12/2017	Med Fusion LLC	Quest Diagnostics Inc.	n.a.
06/06/2017	Genetics of Memphis, Inc.	Poplar Healthcare	n.a.
12/21/2016	Yourgene Bioscience Co., Ltd.	Premaitha Health PLC	n.a.
07/27/2016	Sequenom Inc.	Laboratory Corp. of America Holdings	3.2x
06/23/2016	IMUGEN, Inc.	Oxford Immunotec Ltd.	2.0x
05/25/2016	Recombine, Inc.	CooperSurgical, Inc.	4.3x
10/21/2015	Clarient, Inc.	NeoGenomics Laboratories, Inc.	2.4x
10/13/2015	DNA Diagnostics Center, Inc.	Ardian and GHO Capital Partners LLP	n.a.
06/29/2015	Emory Genetics Laboratory (majority stake)	Eurofins Scientific SA	3.6x
06/22/2015	Biomnis	Eurofins Scientific SA	1.4x
06/01/2015	DIATHERIX Laboratories, Inc.	Eurofins Scientific SA	1.3x
01/11/2015	Foundation Medicine, Inc. (majority stake)	Roche Holdings, Inc.	39.3x
01/06/2015	Diagnovus, LLC	Aegis Sciences Corporation	n.a.
08/12/2014	Boston Heart Diagnostics	Eurofins Scientific SA	2.1x
05/09/2014	Viracor-IBT Laboratories	Eurofins Scientific SA	3.2x
02/19/2014	Centogene (Canadian Business)	LifeLabs	n.a.

Based on the results of this analysis and other factors that Crosstree considered appropriate, Crosstree selected a multiple reference range for EV/Revenue of 3.0x – 6.9x. The EV/ Revenue multiples were then applied to OpGen's historical LTM revenue at June 30, 2019, which indicated an implied enterprise value range for OpGen, rounded to the nearest $0.1 million, of $10.0 million to $23.1 million.

Discounted Cash Flow Analysis

Crosstree conducted a discounted cash flow, or DCF, analysis for the purpose of calculating a range of theoretical enterprise values for OpGen.

A DCF analysis is a method of evaluating an asset by estimating the future unlevered free cash flows generated by an asset and taking into consideration the time value of money with respect to those future cash flows by calculating their "present value." The "unlevered free cash flows" refers to a calculation of the future cash flows generated by an asset without including in such calculation any debt- servicing costs. "Present value" refers to the current value of the cash flows generated by the asset and is obtained by discounting those cash flows back to the present using a discount rate that takes into account macro- economic assumptions, estimates of risk, the opportunity cost of capital, and other appropriate factors. "Terminal value" refers to the present value of all future cash flows generated by the asset for periods beyond the projection period, and is often calculated as a multiple of EBITDA.

Crosstree calculated the unlevered free cash flows that OpGen is expected to generate during the remainder of fiscal year 2019 through fiscal year 2023. Crosstree also calculated a range of terminal values by applying a terminal growth rate range of 5.0% to 10.0% at the end of fiscal year 2023. The unlevered free cash flows and the range of terminal values were then discounted to present values using a range of discount rates from 13.0% to 15.0%, which was chosen by Crosstree based upon an analysis of the weighted average cost of capital of OpGen. The DCF analysis indicated an implied enterprise value for OpGen, rounded to the nearest $0.1 million, of $(6.7) million to $27.7 million.

OpGen does not make public long-term projections as to future revenues, earnings or other results due to, among other reasons, the uncertainty of the underlying assumptions and estimates. However, in connection with OpGen's evaluation of the proposed Transaction, OpGen made available to Crosstree, its financial advisor, certain unaudited prospective financial information of OpGen on a stand-alone, pre-transaction basis. The unaudited prospective financial information was not prepared with a view toward public disclosure and the inclusion of this information should not be regarded as an indication that any of OpGen or any other recipient of this information considered, or now considers, it to be necessarily predictive of actual future results.

The unaudited prospective financial information was, in general, prepared solely for internal use and is subjective in many respects and thus subject to interpretation. While presented with numeric specificity, the unaudited prospective financial information reflects numerous estimates and assumptions, including risk adjustments, made by management of OpGen to the proposed Transaction with respect to industry performance and competition, general business, economic, market and financial conditions and matters specific to its business, all of which are difficult to predict and many of which are beyond its control. In particular, the unaudited prospective financial information assumed, among other things, that the then-current macro-economic outlook would remain constant and that OpGen's strategic growth plan, in particular in regulatory approval of products, would be successfully executed. Many of these assumptions are subject to change, including among other factors, clinical trial results and regulatory approval out of OpGen's control, and the unaudited prospective financial information does not reflect revised prospects for its business, changes in general business or economic conditions or any other transaction or event that has occurred or that may occur and that was not anticipated at the time such financial information was prepared. As a result, there can be no assurance that the results reflected in the unaudited prospective financial information will be realized or that actual results will not materially vary from this unaudited prospective financial information. In addition, since the unaudited prospective financial information covers multiple years, such information by its nature becomes less predictive with each successive year. Therefore, the inclusion of the unaudited prospective financial information in this proxy statement/prospectus should not be relied on as necessarily predictive of actual future events nor construed as financial guidance. OpGen and Curetis' stockholders are urged to review OpGen's risk factors with respect to OpGen's business located elsewhere in this proxy statement/prospectus.

The unaudited prospective financial information was not prepared with a view toward complying with the published guidelines of the SEC regarding projections or the guidelines established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information, but, in the view of OpGen's management, was prepared on a reasonable basis, reflects the best available estimates and judgments at the time of preparation, and presents, to the best of management's knowledge and belief at the time of preparation, the expected course of action and the expected future risk adjusted financial performance of each such party. Neither OpGen's independent registered public accounting firm nor any other independent accountants have compiled, examined, or performed any procedures with respect to the unaudited prospective financial information contained herein (including the unaudited prospective financial information presented below), nor have they expressed any opinion or any other form of assurance on such information or the achievability of the results reflected in such information, and assume no responsibility for, and disclaim any association with, the unaudited prospective financial information. Accordingly, neither OpGen's independent registered public accounting firm nor any other independent accountants provide any form of assurance with respect thereto for the purpose of this proxy statement/prospectus.

Readers of this proxy statement/prospectus are cautioned not to unduly rely on the unaudited prospective financial information. Some or all of the assumptions which have been made regarding, among other things, the timing or probability of certain occurrences or impacts, may have changed since the date such information was prepared. OpGen has not updated and does not intend to update or otherwise revise the unaudited prospective financial information to reflect circumstances existing after the date when such information was prepared or to reflect the occurrence of future events, except to the extent required by applicable law. OpGen has not made any representation to Curetis or any other person involved with the proposed Transaction or otherwise concerning the unaudited prospective financial information.

The unaudited prospective financial information set forth below does not give effect to the proposed Transaction.

OpGen Income Statement Projections

	YTD 12/31/2018	YTD 12/31/2019	YTD 12/31/2020	YTD 12/31/2021	YTD 12/31/2022	YTD 12/31/2023
Revenue:						
Product Revenue	$ 2,400,000	$ 2,300,000	$ 7,300,000	$14,700,000	$24,200,000	$35,400,000
Collaboration revenue	400,000	1,300,000	2,500,000	1,800,000	1,000,000	1,000,000
Total revenue	**2,800,000**	**3,600,000**	**9,800,000**	**16,500,000**	**25,200,000**	**36,400,000**
Gross profit	**1,000,000**	**2,100,000**	**4,900,000**	**10,600,000**	**17,200,000**	**25,000,000**
Gross margin	*33.3%*	*58.3%*	*50.0%*	64.2%	68.3%	68.7%
Operating expenses						
Research and development	5,700,000	6,500,000	6,000,000	6,200,000	6,400,000	6,600,000
General and administrative	7,100,000	6,700,000	6,900,000	7,500,000	8,200,000	8,500,000
Sales and marketing	1,500,000	1,600,000	2,200,000	4,000,000	4,600,000	5,400,000
Total operating expenses	**14,300,000**	**14,800,000**	**15,100,000**	**17,700,000**	**19,200,000**	**20,400,000**
Operating income (loss)	**(13,300,000)**	**(12,700,000)**	**(10,200,000)**	**(7,100,000)**	**(2,100,000)**	**4,600,000**
Other income (expense)						
Total other income (expense)	(200,000)	(700,000)	(100,000)	—	—	—
Provision for income taxes	—	—	—	—	—	1,800,000
Net loss	**$ (13,300,000)**	**$ (13,400,000)**	**$ (10,300,000)**	**$ (7,100,000)**	**$ (2,100,000)**	**$ 2,800,000**

Premiums Paid Analysis

Crosstree conducted a premiums paid analysis for the purpose of calculating a range of premiums to the price of OpGen's common stock as of September 3, 2019.

Crosstree reviewed the premiums paid for M&A transactions involving public healthcare companies in North America over the last 24 months from August 29, 2019. Transactions were limited to deal sizes below $100 million and were further segmented as $0-50 million and $50-100 million. Crosstree calculated the premium per common share paid by the acquirer for each representative transaction compared to the closing unaffected common share price of the target, in order to determine a baseline price per common share on which to calculate the implied premium per share of common stock. Based upon the results of this analysis, Crosstree applied a range of premiums paid of 10.0% to 22.5% to the historical share price of OpGen to calculate an implied enterprise value for OpGen, rounded to the nearest $0.1 million, of $8.0 million to $8.7 million.

Miscellaneous

The foregoing summary of certain material financial analyses does not purport to be a complete description of the analyses or data presented by Crosstree. The preparation of a fairness opinion is a complex process and is not necessarily susceptible to partial analysis or summary description.

Crosstree believes that the foregoing summary and its analyses must be considered as a whole, and that selecting portions of the foregoing summary and these analyses, without considering all of its analyses as a whole, could create an incomplete view of the processes underlying the analyses and the Opinion. As a result, the ranges of valuations resulting from any particular analysis, or combination of analyses, described above were utilized merely to create points of reference for analytical purposes and should not be taken to be the view of Crosstree with respect to the actual value of OpGen.

The order of analyses described does not represent the relative importance or weight given to those analyses by Crosstree. In arriving at the Opinion, Crosstree did not attribute any particular weight to any analyses or factors considered by it and did not form an opinion as to whether any individual analysis or factor (positive or negative), considered in isolation, supported, or failed to support, the Opinion. Rather, Crosstree considered the totality of the factors and analyses performed in determining the Opinion. Analyses based upon forecasts of future results are inherently uncertain, as they are subject to numerous factors or events beyond the control of the parties and their advisors. Accordingly, forecasts and analyses used or made by Crosstree are not necessarily indicative of actual future results, which may be significantly more or less favorable than suggested by those analyses. Moreover, Crosstree's analyses are not and do not purport to be appraisals or otherwise reflective of the prices at which businesses actually could be acquired or sold. None of the selected companies reviewed as described in the above summary are identical to OpGen, and none of the selected transactions reviewed were identical to the Transaction. However, the companies selected were chosen because they are publicly- traded companies with operations and businesses that, for purposes of Crosstree's analyses, may be considered similar to those of OpGen. The transactions selected were similarly chosen because their participants, transaction structures, sizes, and other factors, for purposes of Crosstree's analyses, may be considered similar to the Transaction. The analyses necessarily involve complex considerations and judgments concerning differences in financial and operational characteristics of the companies involved and other factors that could affect the companies compared to OpGen and the transactions compared to the Transaction.

As a part of its investment banking business, Crosstree and its affiliates are continually engaged in the valuation of businesses and their securities in connection with M&A, investments for passive and control purposes, private placements, and valuations for corporate and other purposes. Crosstree was selected to advise OpGen with respect to the Transaction and deliver a fairness opinion to the Board with respect to the Transaction on the basis of, among other things, such experience and its qualifications and reputation in connection with such matters, and its familiarity with OpGen and the industries in which it operates.

For services rendered in connection with the Transaction and the delivery of the Opinion, OpGen has agreed to pay Crosstree fees of approximately $475,000, of which $50,000 has been paid in the form of retainer payments and of which $200,000 has been paid or became payable upon delivery of the Opinion. The remainder will be payable only upon the completion of the Transaction. In addition, OpGen has agreed to reimburse Crosstree for its reasonable expenses incurred in connection with its services, including reasonable fees and disbursements of counsel, and will indemnify Crosstree against certain liabilities arising out of Crosstree's engagement.

The Implementation Agreement

Please refer to the description of the Implementation Agreement beginning on page 70 of this proxy statement/prospectus.

Closing of the Transaction

The Transaction will be completed as promptly as practicable after all the conditions to closing of the Transaction are satisfied or waived, including the approval of the stockholders of OpGen and Curetis N.V. OpGen and Curetis are working to complete the Transaction as quickly as practicable. OpGen and Curetis N.V. estimate that the Transaction will close in the first quarter of 2020, but cannot predict the exact timing of the closing of the Transaction because it is subject to various conditions.

Anticipated Accounting Treatment

If it closes, the Transaction 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. In making this determination of the accounting treatment, we have considered, among other factors, the following: (i) the number of shares to be issued to the Seller, and reserved for issuance under the Implementation Agreement; (ii) the outstanding shares of OpGen common stock following the October 2019 Offering; (iii) whether the percentage of voting rights held by OpGen's stockholders would continue to constitute a majority of the voting rights of Newco after the October 2019 Offering and after closing under the Implementation Agreement; (iv) the contractual right held by the Seller 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 the Seller. This anticipated accounting treatment differs from the anticipated accounting treatment as of the date of the execution of the Implementation Agreement, primarily as a result of the dilution caused by the October 2019 Offering.

Nasdaq Stock Market Listing

OpGen's common stock currently is listed on the Nasdaq Capital Market under the symbol "OPGN".

The Implementation Agreement provides that the approval for the listing on the Nasdaq Capital Market of the Transaction Shares to be issued in connection with the Transaction is a condition precedent of the Transaction, and either party may waive this condition.

Vote Required

The affirmative vote of a majority of the shares present in person or represented by proxy at the Special Meeting and entitled to vote is required to approve the Transaction Proposal.

THE OPGEN BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE "FOR" THE TRANSACTION PROPOSAL

PROPOSAL TWO
THE SHARE ISSUANCE PROPOSAL

The Share Issuance Proposal is a proposal to approve, under the listing rules of Nasdaq, the issuance the Transaction Shares in connection with the Transaction to be voted on in the Transaction Proposal.

The Company's Common Stock is listed on the Nasdaq Capital Market and, as such, the Company is subject to the Nasdaq listing rules.

Under Nasdaq listing rules, a company whose stock is listed on Nasdaq, such as the Company, is required to obtain stockholder approval prior to certain issuances of common stock or securities convertible into or exchangeable for common stock, in connection with an acquisition, if such issuance (i) equals 20% or more of the common stock or voting power of the company outstanding before the transaction or (ii) in connection with the acquisition of assets of another company where any director, officer or a "substantial shareholder" (generally defined as a 5% or greater shareholder) has a 5% or greater interest (or such persons collectively have a 10% or greater interest), directly or indirectly, in the consideration to be paid in the transaction, and the present or potential issuance of common shares could result in an increase in outstanding common shares or voting power of 5% or more.

Immediately after the completion of the Transaction, the number of outstanding shares of Common Stock and the outstanding voting power of the Company will exceed 20% of the shares of Common Stock outstanding before such issuance and issuances to certain stockholders will result in an increase in such stockholders' outstanding common shares or voting power of 5% or more. For this reason, OpGen must obtain the approval of its stockholders, in accordance with the Nasdaq listing rules, for the issuance of the Transaction Shares in connection with the Transaction. Accordingly, the Company is asking its stockholders to approve the issuance of the Transaction Shares in the Transaction.

Effects of the Share Issuance Proposal on Stockholders

The issuance of the Transaction Shares will result in an additional 2,662,564 shares of OpGen Common Stock being issued or reserved for issuance of up to 135,421 shares under the 2016 Stock Option Plan to be assumed and up to 500,000 for the Curetis Convertible Notes. After giving effect to all shares of Common Stock issued in or reserved for future issuance in connection with the Transaction, Company stockholders immediately before completion of the Transaction will hold approximately 67.7% of the issued and outstanding Common Stock and the Seller or its equity awards and debt holders will hold approximately 23.3% of the issued and outstanding OpGen Common Stock.

Curetis N.V. intends to dissolve promptly after the Transaction closes and distribute the Transaction Shares to its shareholders. See "Distribution of OpGen Shares and Winddown of Curetis N.V." beginning on page 184 of this proxy statement/prospectus.

Because the shares of Common Stock issued to the Seller will be issued in a transaction registered under the Securities Act, the Seller may be able to resell the shares issued to it at the Closing. Subsequent resales of such shares of Common Stock may cause the market price of our Common Stock to decline. The issuance would also increase the number of shares of Common Stock outstanding, which may have the effect of reducing the Company's loss per share.

Consequences if Stockholder Approval is Not Obtained

If the Company's stockholders do not approve the Share Issuance Proposal, the Transaction Shares will not be issued unless the Company's stockholders subsequently approve the Share Issuance Proposal by the required vote under the Nasdaq listing rules.

The Share Issuance Proposal is conditioned upon and subject to the approval of the Transaction Proposal. If the Transaction Proposal is not approved, the Share Issuance Proposal will have no effect, even if approved by our stockholders.

Federal Securities Laws Consequences

The Transaction Shares to be issued in connection with the Transaction will be registered under the Securities Act of 1933. The Transaction Shares will be distributed by Curetis N.V. to its shareholders in a dissolution of Curetis N.V. See “Distribution of OpGen Shares and Winddown of Curetis N.V.” on page 184 of this proxy statement/prospectus.

Vote Required

The affirmative vote of a majority of the shares present in person or represented by proxy at the Special Meeting and entitled to vote is required to approve the Share Issuance Proposal.

THE OPGEN BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE
“FOR” THE SHARE ISSUANCE PROPOSAL

PROPOSAL THREE
THE ADJOURNMENT PROPOSAL

The Adjournment Proposal allows OpGen's Board of Directors to submit a proposal to adjourn the Special Meeting to a later date or dates, if necessary, to permit further solicitation of proxies in the event, based on the tabulated votes, there are not sufficient votes at the time of the special meeting to approve Proposals No. 1 and 2. In no event will OpGen solicit proxies to adjourn the Special Meeting or consummate the Transaction beyond the date by which it may properly do so under Delaware law. The purpose of the adjournment proposal is to provide more time for OpGen to solicit proxies in favor of the proposals.

In addition to an adjournment of the Special Meeting upon approval of an Adjournment Proposal, the OpGen Board of Directors is empowered under Delaware law to postpone the meeting at any time prior to the meeting being called to order. In such event, OpGen will issue a press release and take such other steps as it believes are necessary and practical in the circumstances to inform its stockholders of the postponement.

Consequences if the Adjournment Proposal is not Approved

If the Adjournment Proposal is presented at the Special Meeting and such proposal is not approved by its stockholders, OpGen's Board of Directors may not be able to adjourn the Special Meeting to a later date in the event, based on the tabulated votes, there are not sufficient votes at the time of the Special Meeting to approve Proposals No. 1 and 2.

Vote Required

The affirmative vote of a majority of the shares present in person or represented by proxy at the Special Meeting and entitled to vote is required to approve the Adjournment Proposal.

THE OPGEN BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE
"FOR" THE ADJOURNMENT PROPOSAL

THE IMPLEMENTATION AGREEMENT

This description of the Implementation Agreement is only a summary and is qualified in its entirety by reference to the complete text of the Implementation Agreement, which is attached as Appendix A to this proxy statement/prospectus and incorporated by reference herein. The Implementation Agreement is not intended to provide any factual information about the Company, the Purchaser or the Seller. In particular, the representations, warranties and covenants of each party set forth in the Implementation Agreement have been made only for the purposes of, and were and are solely for the benefit of the parties to, the Implementation Agreement, may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosure schedules delivered by the parties, and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to investors. Accordingly, the representations and warranties may not describe the actual state of affairs at the date they were made or at any other time, and investors should not rely on them as statements of fact. The confidential disclosure schedules contain information that modifies, qualifies and creates exceptions to the representations and warranties and certain covenants set forth in the Implementation Agreement.

On September 4, 2019, the Company entered into a business combination transaction pursuant to an Implementation Agreement by and among the Company, Curetis N.V., a public company with limited liability under the Laws of the Netherlands, or the Seller, and Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and wholly owned subsidiary of the Company, or the Purchaser.

Pursuant to the Implementation Agreement, the business of the Seller and the business of the Company will be combined by the Purchaser's acquisition of (i) all of the Transferred Shares of Curetis GmbH, and (ii) the Transferred Assets. The Company has agreed to assume (i) the Seller's Stock Option Plan , (ii) the obligation to issue equity to the holders of awards under the Seller's PSOP, and (iii) the outstanding indebtedness of the Seller under the Curetis Convertible Notes, including providing for conversion of such notes into shares of the Company's Common Stock. The Purchaser will also assume all of the liabilities of the Seller solely and exclusively related Business.

At the closing of the transaction, the Company will pay, as the sole consideration for the Business, 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 (i) its assumption of the Seller's Stock Option Plan, (ii) any future issuance of shares of Common Stock under the PSOP, and (iii) 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, or the Conversion Ratio, which is the ratio of the Consideration as contrasted with the number of Seller's ordinary shares on a fully diluted basis. The Consideration is equal to 32.2% of the common stock of the Company as of October 28, 2019, the date OpGen closed the October 2019 Offering. Since the date of the Implementation Agreement, Curetis has issued additional shares to the holders of the PSOPs, and all have been retired. The shares previously reserved to cover the PSOPs will be issued to Curetis N.V. as part of the Consideration.

The Company has agreed to file this Registration Statement on Form S-4 to register the Consideration. The Transaction is subject to approval by the stockholders of the Company and the shareholders and debt holders of the Seller.

Representations and Warranties

The Implementation Agreement contains representations and warranties made by the parties to such agreement. Certain of the representations and warranties in the Implementation Agreement are subject to knowledge qualifications, which means that those representations and warranties would not be deemed untrue, inaccurate or incorrect as a result of matters of which specified representatives and certain members of key management of the parties do not have actual knowledge (provided such key management has made due inquiries with certain individuals reporting to such key management). In addition, the representations and warranties contained in the Implementation Agreement are subject to specified exceptions and qualifications and the disclosure schedules that the parties have provided in connection with signing the Implementation Agreement. The representations and warranties should not be read alone but, instead, should be read only in conjunction with the information provided elsewhere in this proxy statement/prospectus. The parties' representations and warranties will not survive the closing of the Transaction.

For purposes of the Implementation Agreement, a "Material Adverse Effect" means any fact, circumstance, change, event, occurrence, development or effect, or a Change, that, individually or in the aggregate with all other Changes, has, or could reasonably be expected to have (with or without notice or the passage of time, or both), a material adverse effect on the business, assets, properties, financial condition, or results of operations of Curetis and its subsidiaries, taken as a whole, or the Company and its subsidiaries, taken as a whole, as the case may be; provided, however, that Material Adverse Effect will not be deemed to include:

- any Changes in general United States or global economic conditions, including any Changes affecting financial, credit, foreign exchange or capital market conditions;
- any Changes in economic conditions generally affecting the industry or industries in which such party operates;
- any Changes in political conditions, including any prolonged federal government furlough, shutdown or lack of funding;
- any Changes after the date of the Implementation Agreement in applicable Laws, GAAP, IFRS or the interpretation thereof;
- any Changes in geopolitical conditions, acts of terrorism or sabotage, war (whether or not declared), the commencement, continuation or escalation of a war, acts of armed hostility, weather conditions, natural disasters or other force majeure events, including any material worsening of such conditions threatened or existing as of the date of the Implementation Agreement;
- any Changes caused by the public announcement or pendency of the transactions contemplated by the Implementation Agreement; and
- the effects of any action required to be taken by the Implementation Agreement by one of the parties of the Implementation Agreement or actions taken (including any adverse Change that results from the other party's unreasonable refusal to permit the applicable party, upon request to the other party, to take any of the actions set forth in Section 6.1 of the Implementation Agreement, as described below under "Conduct of Business Prior to Closing,") or omitted to be taken by one of such parties with the written consent of the other party hereto;

provided, however, that the effect of any of the Changes described above will not be excluded from the definition of "Material Adverse Effect" to the extent they have a disproportionate impact on Curetis or its subsidiaries as a whole, on the one hand, or the Company and its subsidiaries as a whole, on the other hand, as measured relative to companies operating in the industry or industries in which such party operates.

Representations and Warranties of the Seller

The Implementation Agreement contains representations and warranties made by the Seller to the Company and the Purchaser relating to a number of matters, including, among other things, the following:

- organization, good standing and qualification of Seller, Curetis and each of its subsidiaries;
- authority of the Seller with respect to the execution and delivery of the Implementation Agreement and the consummation of the transactions contemplated by the Implementation Agreement;
- consents and approvals relating to the execution and delivery of the Implementation Agreement and the consummation of the transactions contemplated by the Implementation Agreement;
- capitalization of Curetis;
- financial statements of the Seller;
- absence of certain changes in the business of the Seller, Curetis and its subsidiaries;
- matters with respect to certain material contracts;
- real property of the Seller, Curetis and its subsidiaries;
- intellectual property matters;
- absence of litigation or governmental proceedings;
- compliance with applicable laws and permits;
- environmental matters;
- labor and employment matters;
- employee benefit plans and related matters;
- tax matters;
- insurance matters;
- sufficiency of assets;
- the fairness opinion received by the Seller;
- the absence of any broker, investment banker or financial advisor to the Seller; and
- with respect to information supplied by the Seller for inclusion in the Form S-4, the absence of any untrue statement of a material fact or omission to state any material fact required or necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

Representations and Warranties of the Company

The Implementation Agreement also contains representations and warranties by the Company and the Purchaser, jointly and severally, to the Seller relating to a number of matters, including, among other things, the following:

- organization, good standing and qualification of the Company and the Purchaser;
- authority of the Company and the Purchaser with respect to the execution and delivery of the Implementation Agreement and the consummation of the transactions contemplated by the Implementation Agreement;
- consents and approvals relating to the execution and delivery of the Implementation Agreement and the consummation of the transactions contemplated by the Implementation Agreement;
- capitalization of the Company;
- the Company's filings with the SEC;
- financial statements of the Company;
- internal controls of the Company;
- absence of certain changes in the business of the Company and its subsidiaries;
- matters with respect to certain material contract;
- real property of Company and its subsidiaries;
- intellectual property matters;
- absence of litigation or governmental proceedings;
- compliance with applicable laws and permits;
- environmental matters;
- labor and employment matters;
- employee benefit plans and related matters;
- tax matters;
- insurance matters;
- the absence of any broker, investment broker or financial advisor to the Company;
- the common stock of the Company to be issued in connection with the Transaction;
- with respect to the Form S-4, the absence of any untrue statement of a material fact or omission to state any material fact required or necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and
- the fairness opinion received by the Company.

Conduct of Business Prior to Closing

Each of the Purchaser, the Company and the Seller has agreed that, during the period from the date of the Implementation Agreement to the closing or the termination of the Transaction:

- it will conduct its operations in the ordinary course of business consistent with past practice;
- it will use commercially reasonable efforts to preserve its business organization and goodwill and maintain satisfactory relationships with those having business relationships with it;
- it will not, and will not permit any of its subsidiaries, to:
    - adopt or propose amendments to its governing documents;
    - issue or sell any of its equity securities;
    - acquire or redeem any of its equity securities;
    - recapitalize its capital stock;
    - make any material change to its accounting methods;
    - make certain changes with respect to taxes;
    - make certain changes with respect to its employees' compensation or arrangements;
    - enter into any loan transaction with any officer, director or employee;
    - enter into any material new line of business outside its existing business;
    - commence any legal proceeding or settle any material legal proceeding;
    - sell, pledge, mortgage, dispose of, transfer, lease, license or encumber any property or assets other than sales of inventory in the ordinary course of business;
    - maintain inventory other than in the ordinary course of business;
    - incur, modify or assume any indebtedness;
    - adopt a plan of liquidation or acquire any other business organization;
    - incur any liabilities other than in the ordinary course of business;
    - amend, extend, renew or terminate any real property lease or enter into any new leases;
    - write up, write down or write off the book value of any material amount of assets;
    - enter into any material contract, or modify, amend, terminate or cancel any material contract;
    - enter into any transaction or take any action that would reasonably be expected to prevent or materially delay the completion of the Transaction;
    - fail to timely file any SEC filing required to be filed by the Company;
    - enter into or materially amend a contract with any of its affiliates, officers or directors;
    - enter into a collective bargaining agreement;
    - transfer or license to any person any intellectual property;
    - take certain actions with respect to its intellectual property; or
    - authorize, commit or agree to take any of the foregoing actions,

except (i) as required or contemplated under the Implementation Agreement, (ii) as required by applicable law, or (iii) with the written consent of the Seller (in the case of the Company and the Purchaser) or the Company (in the case of the Seller).

No Solicitation Covenants

From the date of the Implementation Agreement until the closing or the termination of the Transaction no party will, directly or indirectly:

- solicit, initiate or knowingly encourage or facilitate (including by way of furnishing information) the submission of any inquiries, proposals or offers that constitute or could reasonably be expected to lead to, any Acquisition Proposal or engage in any discussions or negotiations with respect thereto or otherwise cooperate with or assist or participate in, or facilitate any such inquiries, proposals, discussions or negotiations or provide access to its books, records, properties or employees or furnish any nonpublic or confidential information or data with respect to any Acquisition Proposal; or

- approve or recommend, or publicly propose to approve or recommend, an Acquisition Proposal or any agreement, arrangement or understanding relating to an Acquisition Proposal (or resolve or authorize or propose to agree to do any of the foregoing), or enter into any merger agreement, letter of intent, confidentiality agreement (other than as specified in the Implementation Agreement), agreement in principle, share purchase agreement, asset purchase agreement or share exchange agreement, option agreement or other similar agreement, understanding or arrangement relating to an Acquisition Proposal or enter into any agreement, understanding or arrangement, whether or not in writing or binding on any party, requiring the party to abandon, terminate or fail to consummate the transactions contemplated by the Implementation Agreement or breach its obligations under the Implementation Agreement.

An “Acquisition Proposal” is defined as any inquiry, proposal or offer from any person (other than a party to the Implementation Agreement or any of its affiliates) relating to any direct or indirect acquisition, in one transaction or a series of transactions, including by way of any merger, consolidation, tender offer, exchange offer, binding share exchange, business combination, sale of substantially all assets, recapitalization, restructuring, investment, liquidation, dissolution or similar transaction, of (i) assets that constitute or represent 25% or more of the total assets or total revenues of the party in question, taken as a whole, or (ii) 25% or more of the common equity then outstanding.

If a party is approached prior to obtaining the applicable stockholder vote, if and the either the Seller’s management board and supervisory board or Company’s Board of Directors, as applicable, the Board, party’s Board determines in good faith (after consultation with its outside financial and legal advisors and after taking into account the person making the Acquisition Proposal and all legal, financial, regulatory and other aspects of such Acquisition Proposal, including the financing terms thereof), that such Acquisition Proposal constitutes or would reasonably be expected to result in a “Superior Proposal” (meaning a bona fide Acquisition Proposal for assets comprising more than 50% of the total assets or total revenue of the party in question or more than 50% of the common equity then-outstanding of the party in question), then, subject to compliance with the Implementation Agreement, the party may (i) furnish information (including non-public information) to the person making such Acquisition Proposal and (ii) participate in discussions or negotiations with the person making such Acquisition Proposal regarding such Acquisition Proposal; provided that the person making the Acquisition Proposal must have provided a waiver under any non-disclosure agreement entered into with the applicable party to permit the party that was approached to make any disclosures to the other party to the Implementation Agreement and must enter into a confidentiality agreement that is acceptable under the Implementation Agreement. The Implementation Agreement sets forth the requirements of any party that receives an Acquisition Proposal must follow, including notification to the other party to the Implementation Agreement, in order to continue discussions with any person making an Acquisition Proposal.

The Board receiving an Acquisition Proposal may, at any time prior to obtaining the required vote of its stockholders or shareholders, withdraw, modify, qualify, or propose publicly to withdraw, modify or qualify in a manner adverse to the other party, the Board's recommendation, or a Change of Board Recommendation, if (i) in each case, the Board concludes in good faith, after taking into consideration the advice of its outside legal advisors, that taking such action is required for the Board to comply with its fiduciary obligations under applicable law, and (ii) (A) in the case of a Change of Board Recommendation in respect to an Acquisition Proposal made after the date hereof, the Board determines in good faith (after consultation with its outside financial and legal advisors and after taking into account the person making the Acquisition Proposal and all legal, financial, regulatory and other aspects of such Acquisition Proposal, including the financing terms thereof) that such Acquisition Proposal constitutes a Superior Proposal, or (B) in the case of a Change of Board Recommendation in the absence of an Acquisition Proposal, solely in response to a material event, fact, development, circumstance or occurrence that affects the business, assets or operations of the party that was not known to the party prior to the execution of the Implementation Agreement and occurs after the execution of the Implementation Agreement and prior to the time that the applicable stockholder or shareholder vote is obtained, or an Intervening Event.

The Implementation Agreement provides further requirements to be followed prior to terminating the Implementation Agreement to accept a Superior Proposal or because of an Intervening Event. If either party terminates the Implementation Agreement as a result of the foregoing, it is obligated to pay a termination fee of $500,000 to the other party.

Other Covenants Between Signing and Closing; Post-Closing Covenants

In addition, each of the parties has covenanted to comply with the following covenants between the signing of the Implementation Agreement and the closing of the Transaction to:

- provide the other party with access to information;
- cooperate to develop, file and disseminate this registration statement on Form S-4;
- hold an extraordinary general meeting of the shareholders of each of the Seller and the Company for the purpose of obtaining the requisite shareholder vote to approve the Transaction;
- use commercially reasonable efforts to obtain approval of such party's stockholders or shareholders;
- use commercially reasonable efforts to obtain all governmental and third party consents and approvals;
- provide notification if designated events occur, including litigation;
- provide further assurances to progress the Transaction; and
- provide an opportunity to review press releases and other public disclosures by the parties.

The Company has agreed to assume the Seller 2016 Stock Option Plan and each option outstanding thereunder immediately prior to the Closing, each a Seller Stock Option. Immediately prior to the closing of the Transaction, each Seller Stock Option, whether vested or exercisable, will be converted into an option to purchase Common Stock, or a Company Stock Option granted under any of the 2008 Stock Option and Restricted Stock Plan, as amended (under which no further grants can be made) or the Amended and Restated 2015 Equity Incentive Plan. Each Company Stock Option so converted and granted pursuant to the assumption of the Seller 2016 Stock Option Plan will be equal to the number of whole shares of Common Stock, rounded down to the nearest whole share, equal to the number of shares of the Seller subject to such Seller Stock Option multiplied by the Conversion Ratio, at an exercise price per share of Common Stock so converted and granted equal to the exercise price per share of the Seller's shares subject to such Seller Stock Option divided by the Conversion Ratio. The Company has additionally agreed to reserve for future issuance a number of shares of Common Stock at least equal to the number of shares of Common Stock that will be subject to, assumed, or granted equity awards to the holders of options under the Seller 2016 Stock Option Plan.

The Implementation Agreement contains additional covenants related to the composition of the OpGen Board of Directors following the closing of the Transaction, the integration of the companies' employees and employee benefit plans, the treatment of stock options and other stock-based compensation, the treatment of outstanding indebtedness, tax matters, transitional agreements, including changing of the name of OpGen following the closing of the Transaction.

Corporate Governance Following the Transaction

The parties have agreed that the Board of Directors following the completion of the Transaction is expected to be comprised of seven members. Four members will be appointed by the Seller, including William E. Rhodes III to serve as the Chairman of the Board of Directors, and the remaining three members are expected to be comprised by Evan Jones and R. Donald Elsey, who currently serve as members of the OpGen Board of Directors, and a third director to be recommended by OpGen.

As soon as practicable after the completion of the Transaction, the Board of Directors will appoint Oliver Schact, Ph.D. as the Chief Executive Officer of the Company and Tim Dec as the Chief Financial Officer of the Company. Johannes Bacher is expected to become the Chief Operating Officer of the Company and Vadim Sapiro is expected to be the Chief Information Officer. The other officers and senior management of the Company will be appointed with the recommendation of Oliver Schact, Ph.D.

Conditions to Each Party's Obligations

The respective obligations of the parties to effect the Transaction are subject to the satisfaction or waiver at or prior to the closing of the Transaction of the following conditions:

- the Implementation Agreement and the transactions contemplated thereby has been adopted by the vote of the stockholders of the Seller and the Company;
- there is no stay, injunction or decree of any court or governmental authority making the Transaction illegal or prohibiting the consummation of the Transaction;
- the Form S-4 has been declared effective by the SEC and no stop order shall have been issued by the SEC;
- the shares of common stock to be issued by the Company to the Seller shall has been approved for listing on Nasdaq Capital Market;
- the registration, sale and issuance of the Company's common stock with gross proceeds to the Company of at least $10,000,000, or the Interim Financing, has been completed;
- the documentation implementing the assumption by the Company of the Curetis Convertible Notes, including providing for the conversion of the Curetis Convertible Notes into shares of the Company's common stock, or the Convertible Debt Rollover, has executed by the Seller, the Company and the relevant investors; and
- the Seller has received all required consents, authorizations, qualifications and orders of all third parties.

Conditions to Obligations of the Company and the Purchaser

The obligations of the Company and the Purchaser to effect the Transaction are subject to the satisfaction or waiver at or prior to the closing of the Transaction of the following conditions:

- the representations and warranties of the Seller in the Implementation Agreement shall be true and correct as of the closing date;
- the Seller shall have performed in all material respects its covenants and agreements in the Implementation Agreement;
- the Company shall have received an officer's certificate from the Seller certifying as to certain matters;
- the Seller shall have executed and delivered to the Purchaser the share transfer agreement to assign the Transferred Shares to the Purchaser, or the German Transfer Agreement;
- the Seller shall have executed and delivered to the Purchaser the assignment and assumption agreement to assign the Transferred Assets to the Purchaser, or the Assignment and Assumption Agreement;
- since the date of the Implementation Agreement, there shall not have occurred any Material Adverse Effect with respect to Curetis; and
- the Company shall have received each other document reasonably requested by the Company.

Conditions to Obligations of the Seller

The obligations of the Seller to effect the Transaction is subject to the satisfaction or waiver at or prior to the closing of the Transaction of the following conditions:

- the representations and warranties of the Company and the Purchaser in the Implementation Agreement are true and correct as of the closing date;
- the Company and the Purchaser has performed in all material respects the covenants and agreements in the Implementation Agreement;
- the Seller has received an officer's certificate from the Company certifying as to certain matters;
- the credit facility agreement pursuant to which the Company or the Purchaser will make available to Curetis funds necessary to operate the Business until the closing date shall have been put in place within five business days of the completion of the Interim Financing;
- the Seller has received the Consideration in the form of book-entry shares of the Company's common stock from the Company's transfer agent;
- the Purchaser has executed and delivered to the Seller the German Transfer Agreement;
- the Purchaser has executed and delivered to the Seller the Assignment and Assumption Agreement;
- since the date of the Implementation Agreement, no Material Adverse Effect with respect to the Company has occurred; and
- the Seller has received each other document reasonably requested by the Seller.

Each of OpGen and Curetis N.V. may waive any or all of the foregoing conditions to the closing of the proposed Transaction that are for its benefit to the extent permitted by applicable law. OpGen and Curetis N.V. do not believe that applicable law would permit them to waive (i) the condition for obtaining approval of the Transaction Proposal and Share Issuance Proposal from OpGen's stockholders or (ii) the condition for obtaining approval of the proposed Transaction from Curetis N.V.'s shareholders and debt holders.

Termination of the Implementation Agreement

The Implementation Agreement may be terminated and the Transaction may be abandoned at any time prior to the closing of the Transaction:

- by mutual written consent of the Seller and the Company;
- by the Seller or the Company if the Interim Financing has not been completed on or before October 15, 2019;
- by the Seller if the Interim Facility has not been put in place within five business days of completion of the Interim Financing;
- by either the Seller or the Company, if the Transaction has not been consummated on or before January 31, 2020;
- by either the Seller or the Company, if the meeting of the Seller's shareholders has been convened and the approval of the Transaction has not been obtained;
- by either the Seller or the Company, if the meeting of the Company's stockholders shall have been convened and the approval of the Transaction has not been obtained;
- by the Seller, if there has been a breach of any covenants or agreements or any of the representations or warranties of the Purchaser or the Company, which breach is not cured within the period set forth in the Implementation Agreement;
- by the Company, if there has been a breach of any of the covenants or agreements or any of the representation or warranties on the part of the Seller, which breach is not cured within the period set forth in the Implementation Agreement;
- by the Seller or the Company in order to effect a Change of Board Recommendation, and substantially concurrently enter into a definitive agreement providing for a Superior Proposal; or
- by the Seller if the Company's Board, or the Company if the Seller's Board, as the case may be, effects a Change of Board Recommendation.

Effect of Termination

If the Implementation Agreement is terminated prior to the closing and the Transaction is abandoned, the Implementation Agreement shall, subject to certain exceptions, immediately become null and void and have no effect, provided that no party shall be relieved from any liability for any willful breach of a representation or warranty or the breach of any covenant in the Implementation Agreement arising prior to termination.

Termination Fees and Expenses

If the Implementation Agreement is terminated by either the Seller or the Company, if the meeting of the Seller's shareholders was convened and did not result in approval of the Transaction, or if the meeting of the Company's stockholders was convened and did not result in approval of the Transaction, then the party whose shareholders or stockholders did not approve the Transaction will pay certain expenses incurred in connection with the authorization, preparation, negotiation, execution and performance of the Implementation Agreement up to an amount not to exceed $250,000.

If the Implementation Agreement is terminated (i) by the Company if the Seller's shareholders do not vote to approve the Transaction and (x) any person has made or announced an intention to make an Acquisition Proposal for the Curetis Group companies or equity interests in Curetis that becomes public after the date of the Implementation Agreement and (y) within 12 months of such termination the Seller enters into a definitive agreement with respect to, or consummates such an, Acquisition Proposal, (ii) by the Seller to effect a Change of Board Recommendation and substantially concurrently enter into a definitive agreement providing for a Superior Proposal, or (iii) by the Company if the Seller's Board effects a Change of Board Recommendation or publicly announces any intention to do so, then the Seller will pay the Company an amount in cash equal to $500,000.

If the Implementation Agreement is terminated (i) by the Seller if the Company's stockholders do not vote to approve the Transaction and (x) any person has made or announced an intention to make an Acquisition Proposal that becomes public after the date of the Implementation Agreement and (y) within 12 months of such termination the Company enters into a definitive agreement with respect to, or consummates such an, Acquisition Proposal, (ii) by the Company to effect a Change of Board Recommendation and substantially concurrently enter into a definitive agreement providing for a Superior Proposal, or (iii) by the Seller if the Company's Board effects a Change of Board Recommendation or publicly announces any intention to do so, then the Company will pay the Seller an amount in cash equal to $500,000.

In the event that either the Seller or the Company are entitled to be paid both a reimbursement for its expenses following the failure of the other party's shareholders or stockholders to approve the Transaction and a termination fee pursuant to the foregoing, the amount of such reimbursement will be deducted from the termination fee.

Amendment of the Implementation Agreement

The Implementation Agreement may be amended by the parties at any time before or after the Seller's shareholders and the Company's stockholders approve the Transaction but, after any such Seller Stockholder Vote or the Company Stockholder Vote, no amendment may be made that requires the approval of the stockholders of the Seller or the Company without the approval of such stockholders under applicable Law. Further, the Implementation Agreement may not be amended, changed, supplemented or otherwise modified except by an instrument in writing signed on behalf of all of the parties.

Expenses of the Parties

Except for the costs and expenses incurred by the Seller and the Company in connection with the preparation, review, filing, printing and mailing of the Company's Form S-1 Registration Statement and this Form S-4 Registration Statement, which will be borne in equal proportion by the Seller and the Company, each party to the Implementation Agreement will pay all costs and expenses incurred by itself in connection with the Transaction.

OPGEN SUMMARY FINANCIAL DATA

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

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

(1) Includes stock-based compensation as follows:

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

CURETIS BUSINESS SUMMARY FINANCIAL DATA

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

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

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2017	2019	2018
Statements of Operations:	(In thousands of USD (1))			
Revenue	$ 1,623	$ 1,422	$ 1,237	$ 940
Cost of sales	(1,558)	(1,582)	(1,525)	(1,275)
Gross loss	**65**	**(160)**	**(288)**	**(335)**
Distribution costs	(9,318)	(8,632)	(3,717)	(4,903)
Administrative expenses	(4,092)	(3,815)	(1,832)	(2,175)
Research & development expenses	(12,085)	(8,786)	(4,752)	(5,451)
Other income	715	206	130	220
Operating loss	**(24,715)**	**(21,187)**	**(10,459)**	**(12,644)**
Finance income	39	13	8	58
Finance costs	(1,374)	(835)	(846)	(575)
Finance result – net	**(1,335)**	**(822)**	**(838)**	**(517)**
Loss before income taxes	**(26,050)**	**(22,009)**	**(11,297)**	**(13,161)**
Income tax expense	(41)	65	(64)	30
Loss for the period	**$ (26,091)**	**$ (21,944)**	**$ (11,361)**	**$ (13,131)**
(1) Convenience translation performed from Euros to U.S. Dollars using the following exchange rate in effect as of each period end:	1.14379	1.19786	1.13667	1.16478

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

(1) Convenience translation performed from Euros to U.S. Dollars using the following exchange rate in effect as of June 30, 2019: 1.13667

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

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

	OpGen	Curetis Business	Pro Forma Adjustments	Notes	Pro Forma Combined
Assets					
Current assets					
Cash and cash equivalents	$ 626	$ 1,451	$ 8,336	G	$ 10,413
Accounts receivable, net	377	889	—		1,266
Due from parent	—	538	—		538
Inventory, net	468	5,225	—		5,693
Contractual assets	—	180	—		180
Prepaid expenses and other current assets	533	547	—		1,080
Total current assets	**2,004**	**8,830**	**8,336**		**19,170**
Property and equipment, net	202	4,215	—		4,417
Finance lease right-of-use assets, net	1,097	—	—		1,097
Operating lease right-of-use assets	1,215	1,305	—		2,520
Goodwill	601	—	9,922	E	10,523
Intangible assets, net	885	7,992	—	E	8,877
Deferred tax assets	—	11	—		11
Other noncurrent assets	427	175	—		602
Total assets	**$ 6,431**	**$ 22,528**	**$ 18,258**		**$ 47,217**
Liabilities and Stockholders' Equity					
Current liabilities					
Accounts payable	$ 1,873	$ 2,219	$ —		$ 4,092
Due to parent	—	203	—		203
Accrued compensation and benefits	1,387	—	—		1,387
Accrued and other current liabilities	1,041	808	1,566	A,B,H	3,415
Deferred revenue	10	—	—		10
Short-term notes payable	508	2,166	—		2,674
Short-term finance lease liabilities	628	—	—		628
Short-term operating lease liabilities	988	478	—		1,466
Total current liabilities	**6,435**	**5,874**	**1,566**		**13,875**
Notes payable	329	21,642	—		21,971
Long-term finance lease liabilities	411	—	—		411
Long-term operating lease liabilities	813	839	—		1,652
Other noncurrent liabilities	—	48	—		48
Total liabilities	**7,988**	**28,403**	**1,566**		**37,957**
Stockholders' equity					
Common stock	9	6,074	(6,000)	C,D,G	83
Additional paid-in capital	170,449	179,819	(167,510)	C,D,G	182,758
Accumulated deficit	(172,007)	(191,709)	190,143	A,B,C,H	(173,573)
Accumulated other comprehensive loss	(8)	(59)	59	C	(8)
Total stockholders' equity (deficit)	**(1,557)**	**(5,875)**	**16,692**		**9,260**
Total liabilities and stockholders' equity	**$ 6,431**	**$ 22,528**	**$ 18,258**		**$ 47,217**

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

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

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

	OpGen	Curetis Business	Pro Forma Adjustments (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	$ (44.50)				$(5.15)
Weighted average shares outstanding - basic and diluted	300,453		7,362,564	D,G	7,663,017

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of Transaction

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

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

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

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

2. Curetis Business

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

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

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

(1) Convenience translation performed using the following exchange rate in effect as of September 30, 2019: 1.09368

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

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

(1) Convenience translation performed using the following exchange rate in effect as of September 30, 2019: 1.09368

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

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

(1) Translation performed using the following exchange rate in effect as of December 31, 2018: 1.14379

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

Curetis Business Statement of Operations Descriptions	OpGen Consolidated Statements of Operations and Comprehensive Loss Descriptions
Revenue	Revenue
Cost of sales	Cost of products sold
Distribution costs	Sales and marketing
Administrative expenses	General and administrative
Research & development expenses	Research and development
Transaction costs	Transaction costs
Other income	Other income
Operating loss	Operating loss
Finance income	Other income
Finance costs	Interest expense
Income tax expense	Provision for income taxes
Loss for the period	Net loss

Curetis Business Statement of Financial Position Descriptions	OpGen Balance Sheet Descriptions
Cash and cash equivalents	Cash and cash equivalents
Trade receivables	Accounts receivable, net
Other receivables, related party	Due from parent
Contractual assets	Contractual assets *
Inventories	Inventory, net
Prepaid Expenses and other current assets	Prepaid expenses and other current assets
Total current assets	Total current assets
Intangible assets	Intangible assets, net
Property, plant and equipment	Property and equipment, net
Right of use assets	Operating lease right-of-use assets
Other non-current assets	Other noncurrent assets
Other non-current financial assets	Other noncurrent assets
Deferred tax assets	Deferred tax assets
Total assets	Total assets
Liabilities and Stockholders' Equity	Liabilities and Stockholders' Equity
Current liabilities	Current liabilities
Trade and other payables	Accounts payable
Other liabilities, related party	Due to parent
Provisions current	Provisions current
Tax liabilities	Accrued and other current liabilities
Other current liabilities	Accrued and other current liabilities
Other current financial liabilities	Accrued and other current liabilities
Current lease liabilities	Short-term operating lease liabilities
Total current liabilities	Total current liabilities
Provisions non-current	Other noncurrent liabilities*
Other non-current financial liabilities	Notes payable
Non-current lease liabilities	Long-term operating lease liabilities
Total liabilities	Total liabilities
Equity	Equity
Subscribed capital	Common stock
Capital reserve	Additional paid-in capital
Currency translation differences	Accumulated other comprehensive loss
Accumulated deficit	Accumulated deficit
Total stockholders' equity	Total stockholders' equity (deficit)
Total liabilities and stockholders' equity	Total liabilities and stockholders' equity

* Denotes Curetis description added to proforma balance sheet

3. Estimated Purchase Price

The accompanying unaudited pro forma condensed combined financial statements reflect an estimated acquisition price of approximately $4.0 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 $405 thousand.

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

Number of shares to be issued under the implementation agreement (i)		2,662,564
Multiplied by the fair market value per share of OpGen's common stock (ii)	$	1.52
Total	$	4,047

(i) Under the Implementation Agreement, OpGen will issue, as the sole consideration, 2,662,564 shares of common stock, less the number of shares of common stock the issuance of which shall be reserved by OpGen in connection with (a) up to 135,421 shares of common stock reserved for its assumption of the 2016 Stock Option Plan, and (b) up to 500,000 shares of common stock reserved for future issuance upon the conversion of the Curetis Convertible Notes.

(ii) The estimated purchase price was based on the closing price as reported on the Nasdaq Capital Market on January 13, 2020. The final purchase price arising from the actual fair market value of OpGen common stock outstanding immediately prior to the closing of the business combination could result in a total purchase price different from that assumed in this unaudited pro forma condensed combined financial information, and that difference may be material. Therefore, the estimated consideration expected to be transferred reflected in this unaudited pro forma condensed combined financial information does not purport to represent what the actual consideration transferred will be when the business combination is completed. The actual purchase price will fluctuate until the closing date of the business combination, and the final valuation of the purchase consideration could differ significantly from the current estimate.

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

Net assets as of September 30, 2019	$	(5,875)
Goodwill		9,922
Total	$	4,047

4. Pro Forma Adjustments

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

The pro forma adjustments relate to the following:

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

F. To reflect transaction costs incurred by OpGen and the Curetis Business during the nine months ended September 30, 2019.
G. To record the receipt of $9,400,000 in gross proceeds, and $8,336,000 estimated net proceeds, in cash for the issuance of 2,590,170 units and 2,109,830 pre-funded units in the October 2019 Offering, based on an offering price of $2.00 per unit and $1.99 per pre-funded unit.
H. To record retention payments to be made to OpGen executives with change in control.

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

	September 30, 2019
OpGen's estimated transaction costs (A)	$ 650
Curetis Business estimated transaction costs (B)	492
Retention benefits to be paid to OpGen executives (H)	424
Total	$ 1,566

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

	September 30, 2019
Eliminate Curetis Business' historical additional paid-in-capital balance (C)	$ (179,819)
To reflect shares to be issued under the implementation agreement (D)	4,020
To reflect shares to be issued to investors in a $10 million public offering, net of offering costs (G)	8,289
Total	$ (167,510)

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

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

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

	September 30, 2019
OpGen's estimated transaction costs (A)	$ (650)
Curetis Business estimated transaction costs (B)	(492)
Eliminate Curetis Business' historical accumulated deficit balance (C)	191,709
Retention benefits to be paid to OpGen executives (H)	(424)
Total	$ 190,143

OPGEN'S BUSINESS

Overview

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.

Our molecular diagnostics and informatics products, product candidates and services combine our Acuitas® molecular diagnostics and Acuitas Lighthouse® informatics platform for use with our proprietary, curated MDRO knowledgebase. We are working to deliver our products and services, some in development, to a global network of customers and partners.

- Our molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include the Acuitas antimicrobial resistance, or AMR, Gene Panel (Urine) test in development for patients at risk for complicated urinary tract infections, or cUTI, the Acuitas AMR Gene Panel (Isolates) test in development for testing bacterial isolates, and the QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of our Acuitas AMR Gene Panel tests is currently available for sale in the United States for research use only, or RUO, and none have been granted FDA clearance to date. This means that, currently, we cannot market these tests for clinical diagnostic uses.

- Our Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that are designed to combine clinical lab test results with patient and hospital information to provide analytics and actionable insights to help manage MDROs in the hospital and patient care environment. Components of the informatics systems include the Acuitas Lighthouse Knowledgebase and the Acuitas Lighthouse Software. The Acuitas Lighthouse Knowledgebase is a relational database management system and a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens. The Acuitas Lighthouse Software system includes the Acuitas Lighthouse Portal, a suite of web applications and dashboards, the Acuitas Lighthouse Prediction Engine, which is a data analysis software, and other supporting software components. The Acuitas Lighthouse Software can be customized and made specific to a healthcare facility or collaborator, such as a pharmaceutical company. The Acuitas Lighthouse Software has not yet been cleared for marketing in the United States. It is currently available for RUO and may not be distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

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

We have established a number of commercial arrangements to support execution of our business strategy as we work to address the more than $2 billion potential market for precision medicine MDRO solutions. Our 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 Health Solutions, LLC, an entity created by Merck's Healthcare Services and Solutions division, whereby ILÚM Health Solutions provided us with 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.

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.

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.

Lead Rapid Diagnostics and Acuitas Lighthouse Software

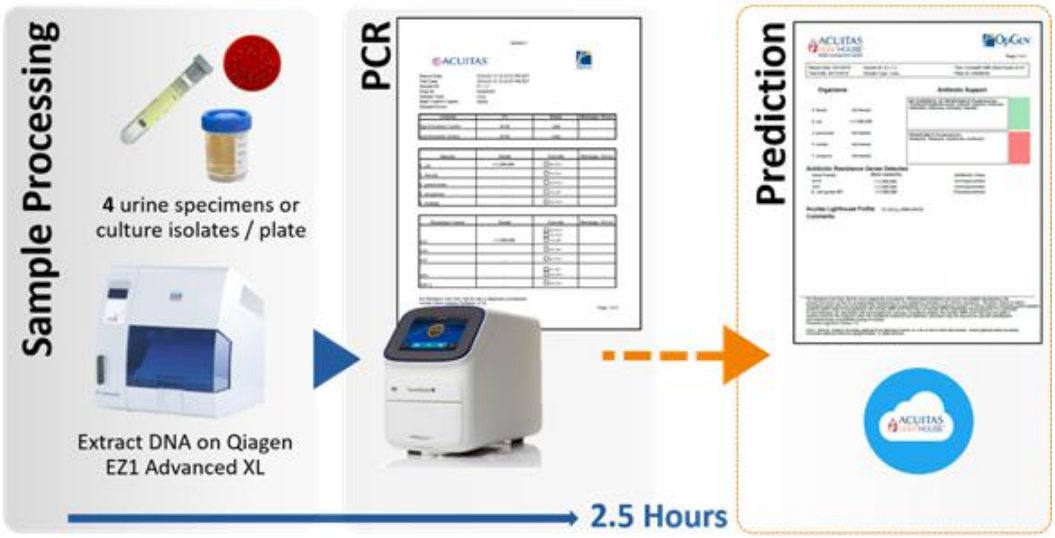
We believe more rapid genetic identification methods will reduce morbidity from MDROs, reduce healthcare costs through reduced length of stay, and assist in the identification of targeted antibiotic therapy. Current conventional microbiology, largely unchanged in 50 years, requires one to two days for growth and phenotypic analysis and often leads to the use of broad spectrum antibiotic therapy in the early stages of infection.

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.



FISH Products

We have commercialized 12 QuickFISH and PNA FISH diagnostic test products in the United States and Europe for the identification of various infectious pathogens. The pathogens identified and differentiated by our FISH products are:

QuickFISH	PNA FISH
Staphylococcus	Staphylococcus
Enterococcus	Enterococcus
Gram-negative bacteria	Gram-negative bacteria
Candida	Candida

Our FISH products can provide pathogen identification and differentiation within 20 to 90 minutes of positive blood culture results. The tests provide actionable information that can be used by the healthcare provider to determine appropriate antibiotic therapy.

Approximately 70 U.S. hospital customers purchased our FISH products over the past twelve months, and we sell our FISH products to hospitals in 8 countries with antibiotic stewardship programs. Our hospital customers include academic medical centers, tertiary care hospitals and community hospitals.

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.

Other Business Initiatives

In October 2017, the Company announced that it was awarded a contract from the Centers for Disease Control and Prevention, or CDC, to develop smartphone-based clinical decision support solutions for antimicrobial stewardship, or AMS, and infection control in low- and middle-income countries. The one-year $860,000 award began September 30, 2017 and funded development and evaluation of cloud-based mobile software. The Company worked with partners ILÚM and Universidad El Bosque, or UEB, of Bogota, Colombia. The Company's teaming partner ILÚM provided its cloud- and mobile-based software platform, which integrates electronic patient data and local empiric treatment guidelines to support antimicrobial stewardship. The ILÚM platform is state-of-the-art mobile AMS software that is commercially available and in use in major medical centers. The mobile platform was translated into Spanish and was extended to quickly identify patients requiring infection control precautions, assist with the implementation of appropriate precautions, and assist with the collection and tracking of indicators for monitoring implementation of infection control precautions. During 2018 we deployed the software in three medical sites in Colombia to assess the effectiveness of the effort. Through the initial pilot, we gained experience and positive results to support the expansion of this important initiative further. The three sites from the project are using the Acumen software tool, to help develop outcomes data to support further implementation of the software.

Molecular Information Business

We are working to build a unique and highly proprietary molecular information business. Our approach combines FDA-cleared and CE-marked rapid diagnostics with our Acuitas Lighthouse Software. We are developing an integrated solution based on a genomic knowledgebase of drug-resistant pathogens. Our approach involves sourcing thousands of pathogens from hospitals worldwide and completing genomic analysis including DNA sequencing and drug susceptibility testing of each individual pathogen. These data are combined along with hospital patient data and other information in our Acuitas Lighthouse Knowledgebase. We anticipate using this information and insights we derive from it to help power our rapid diagnostic products, healthcare management solutions and new applications to support pharmaceutical companies.

Market Overview

Antibiotic Resistance – An Urgent Global Issue

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 September 2014, 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 have been estimated 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,” 300 million people are expected to die prematurely because of drug resistance over the next 35 years, which could result in $60 to $100 trillion worth of lost economic output if the problem of antimicrobial drug resistance is not resolved.

Over the last decade, multidrug-resistant Gram-negative bacteria, frequently referred to as Superbugs, have been implicated in severe HAIs and their occurrence has increased steadily. For example, Klebsiella pneumoniae, or K. pneumoniae, is responsible for roughly 15% of Gram-negative infections in hospital intensive care units. Infections caused by KPC strains have few treatment options and are associated with a mortality rate upwards of 50%.

Exacerbating the problems associated with the emergence of these highly resistant KPC strains is their propensity to cause outbreaks in healthcare institutions. These pathogens persist both in the flora of hospitalized patients and in the hospital environment, and they have the capacity to silently colonize patients or hospital personnel by establishing residence in the gastrointestinal tract without causing any signs of infection. Individuals can be silently colonized or become asymptomatic carriers for long periods of time, with detection of these carriers often proving difficult. These silent carriers act as reservoirs for continued transmission, which makes subsequent spread difficult to control and outbreaks difficult to stop. In addition, KPC strains can survive for several hours on the hands of hospital personnel, which likely facilitates the spread of organisms from patient to patient. Effective control of KPC outbreaks requires a detailed understanding of how transmission occurs, but current technologies do not allow healthcare providers to routinely perform these investigations on a timely basis.

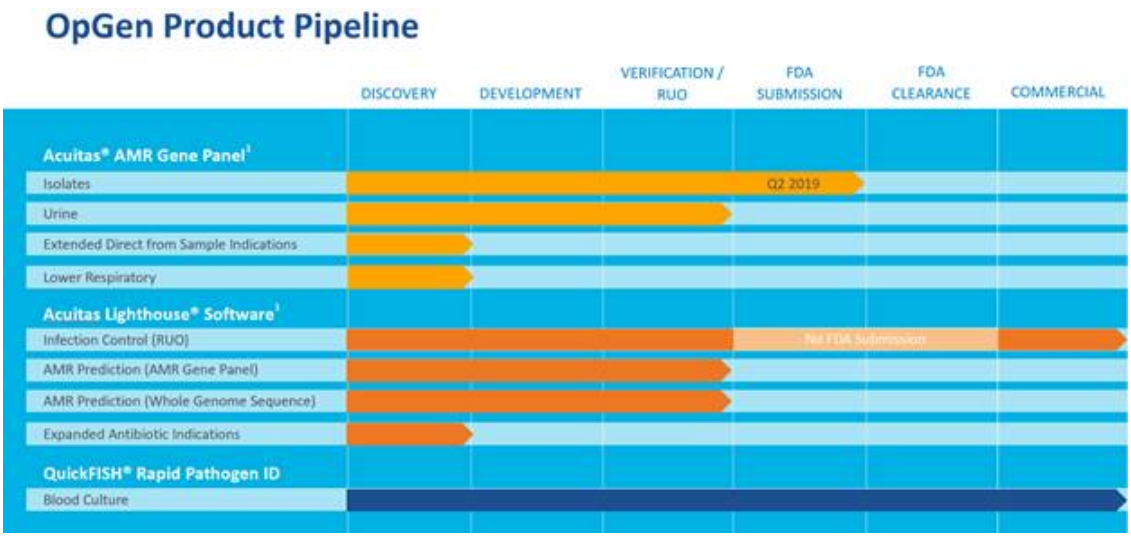
The lack of currently available treatment options and scarcity of new treatment options in development are compounding the emerging Superbug problem. It has been close to 30 years since a new class of antibiotics was developed and successfully introduced. As a result, we believe that rapid, accurate identification of the pathogen and its genetic make-up, screening, infection control and antibiotic stewardship have become one of the most powerful weapons in the fight to contain this threat.

The emergence of multidrug resistant pathogens has made the treatment of patients with UTIs a growing problem in the United States and internationally. There are approximately 10 million patients each year in the United States with UTIs and more than one million of these patients have cUTI often requiring hospitalization intravenous antibiotic therapy. Among these patients E.Coli represents the most common pathogen, and recent data indicate that 18.3% of U.S. E. Coli isolates extended spectrum β-lactamase (ESBL) resistant. These patients present complicated therapeutic choices for clinicians and often require last resort carbapenem antibiotics. The rate of ESBL resistant E. Coli increased 34% annually between 2010 – 2014. Therapy with carbapenem antibiotics has contributed to growing Carbapenem resistance (CRE) rates and high patient treatment costs. A large outcomes study recently completed by the Company indicated that average cost to treat an ESBL E. Coli patient was $25,000 while patients with ESBL K. pneumonia infections cost over $60,000.

Based on industry analyses, we believe the global HAI market is a $2 billion dollar market with the molecular diagnostic segment representing a fast growing segment of such market with multiple high acuity patients and significant infectious sites, including UTIs, surgical site infections, pneumonia and bloodstream infections.

Research and Development

We intend to continue to invest in the development of additional Acuitas AMR Gene Panel tests and our Acuitas Lighthouse informatics platform, and to support commercial sales of our QuickFISH rapid identification tests. Our current focus is on completing the development of the Acuitas AMR Gene Panel (Urine) and our other product offerings to provide actionable, precise diagnostics powered by our Acuitas Lighthouse Software for rapid diagnostics of pathogens, determination of the appropriate antibiotics to treat the infection and accumulation of actionable surveillance data to provide information useful for monitoring and controlling outbreaks and promoting antibiotic stewardship. The figure below highlights our current products, products under development, and their regulatory status.



Our ongoing and anticipated research and development efforts include:

- development of the Acuitas AMR Gene Panel tests for additional indications and sample types; clinical trial work to support FDA submissions for commercial launch of the Acuitas AMR Gene Panel tests;

- continued investments in our Acuitas Lighthouse informatics platform, focused on (i) data warehouse and portal for MDRO data and (ii) antibiotic analysis;

- expanding our clinical decision support capabilities by completing the work under the CDC contract to develop smartphone-based clinical decision support solutions for antimicrobial stewardship and infection control in low- and middle-income countries; and

- working with pharmaceutical companies to add new or recently FDA approved antibiotics to the Acuitas Lighthouse Software.

The following summarizes our regulatory approach for commercializing the initial Acuitas AMR Gene Panel tests and the Acuitas Lighthouse Software. We filed the 510(k) application for the Acuitas AMR Gene Panel (Isolates) in May 2019. We anticipate completing clinical trials and filing two additional 510(k) submissions during 2020. Details and final labeling are subject to change during the FDA review process and negotiation with the FDA upon actual instruction for use labeling.

Acuitas AMR Gene Panel (Isolates) – 510(k), FDA Class II (filed May 2019)

- Indication: Identification of bacterial nucleic acids and gene sequences associated with antimicrobial resistance in pure bacterial colonies and detection of forty-seven gene sequences associated with antimicrobial resistance to nine antibiotic classes. In vitro diagnostics and infection control.

- Sample type: Isolates from any primary sample (blood, urine, lung, wounds, other)

- Clinical trial: ~900 stock isolates, 75 fresh isolates, 4 sites

Acuitas AMR Gene Panel (Urine) – *De Novo* 510(k), FDA Class II

- Indication: Aid in the diagnosis of specific agents of UTIs for patients at risk of cUTI. Semi-quantitation of *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa* and *Enterococcus faecalis* and forty-seven gene sequences associated with antimicrobial resistance to nine antibiotic classes.

- Sample type: Urine

- Clinical trial: 1,500 fresh urine samples, ~300 contrived urine samples, 9 sites

Acuitas Lighthouse Software – *De Novo* 510(k), Class II

- Indication: Evaluation of data from the Acuitas AMR Gene Panel (Urine) test using a series of predictive models and, based on species identified to predict resistance for nine classes of antibiotics.

- Clinical trial: 2,000 globally and phenotypically representative stock isolates, 1,500 urine samples and resulting isolates, ~300 contrived urine samples.

Commercial Sales

We currently sell and market our products and services directly in the United States through a dedicated sales and marketing support team. Internationally, we sell our products through a network of distributors in eight countries. We operate a subsidiary in Denmark that provides support for our European customers and to distributors. In 2018, we established OpGen Colombia SAS to commercialize our products in Colombia and to support sales on a direct basis and through distributors in South America and Central America. We anticipate expanding our commercial organization in conjunction with the anticipated FDA clearance to commercialize our Acuitas AMR Gene Panel and Acuitas Lighthouse Software products. Our strategy to build demand for our products following receipt of such regulatory clearance includes completing clinical verification studies, sales of the Acuitas AMR Gene Panel tests for RUO, and in conjunction with such FDA clearance entering into channel partner co-marketing and distribution agreements.

We are generating data to support the commercialization of our Acuitas AMR Gene Panel (Urine) and Acuitas Lighthouse Software products through a structured clinical verification program including academic medical centers and clinical collaborators. In November 2018 we announced that we have completed specimen accrual and testing of urine specimens for the clinical verification study with the Acuitas AMR Gene Panel (Urine) test and Acuitas Lighthouse Software. The three participating clinical sites were Beth Israel Deaconess Medical Center, Geisinger Health System, and Intermountain Healthcare. The results of the study, which tested 670 remnant urine specimens from patients at increased risk for cUTI, will be summarized and discussed in a peer-reviewed manuscript anticipated to be published in 2020.

In the first quarter of 2018, we introduced the Acuitas AMR Gene Panel (RUO) for infection control purposes and pharmaceutical surveillance research as research use only tests. The Acuitas AMR Gene Panel (RUO) tests will be available while the Company completes clinical trials and regulatory submissions to support FDA clearance to commercialize such products for broader clinical use. We anticipate that customers who use the products as RUO tests for infection control and clinical research will serve as a potential installed base for the FDA cleared products. Our rapid pathogen identification FISH products are used by approximately 65 customers in the United States and internationally. Many of these customers are potential customers for our FDA-cleared Acuitas AMR Gene Panel tests. We are working to expand our market reach by entering into strategic co-marketing relationships with larger diagnostic and pharmaceutical companies and by expanding our network of distributors globally.

We operate in one segment. Substantially all of our operations are in the United States.

Competition

We are developing a molecular information business focused on leading a transformation in microbiology and infectious disease through precision medicine products and services that combine genomic data and informatics. Our approach combines proprietary, FDA cleared DNA tests developed for use with our Acuitas Lighthouse informatics and data warehouse offerings. 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 Luminex. We believe our focus on identifying antibiotic-resistant genes, rather than primarily organisms, the genes and associated diseases included in our gene tests, and our Acuitas Lighthouse informatics offerings distinguish us from such competitors.

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

Competitors may develop their own versions of our product offerings in countries where we do not have patents 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 products and services, or offer products and services at prices designed to promote market penetration, which could force us to lower our list prices 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.

Manufacturing

During 2018, we manufactured our FDA-cleared and CE-marked QuickFISH and PNA FISH products in our Gaithersburg, Maryland facility.

Manufacturing of our FDA-cleared products is performed under the current Good Manufacturing Practices – Quality System Regulation as required by the FDA for the manufacture of IVD labeled products. These regulations carefully control the manufacture, testing and release of IVD products as well as raw material receipt and control. We also have ongoing postmarket surveillance and vigilance responsibilities under FDA regulations, and are subject to periodic inspections by the FDA to determine compliance with the FDA's requirements, including primarily the quality system regulations and medical device reporting regulations. The results of these inspections can include inspectional observations on FDA's Form 483, warning letters, or other forms of enforcement.

Seasonality of Business

We do not believe our business is subject to seasonality. However, our business can be subject to and affected by the business practices of our business partners. To the extent that the availability of inventory or materials from or development practices of our partners is seasonal, our sales may be subject to fluctuations quarter to quarter or year over year.

Quality Assurance

Our quality assurance function oversees the quality of our laboratory and our FDA-cleared and CE-marked diagnostic products as well as the quality systems used in research and development, client services, billing operations and sales and marketing. We have established a quality assurance system across our entire business, including implementation and maintenance, document control, supplier qualification, corrective or preventive actions, oversight, and employee training processes. We monitor and seek to improve our quality over time in compliance with all applicable regulations.

Raw Materials and Suppliers

We procure PCR amplification reagents and the QuantStudio 5 Real-Time PCR System from Thermo Fisher Scientific. DNA purification reagents and the EZ1 DNA Purification System are procured from QIAGEN, NV. We purchase the PNA probes, glass slides and specialty consumables for our QuickFISH products from third party manufacturers who have long lead times and who manufacture several of these products for us on a sole source basis. We also purchase our collection kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors. While we have developed alternative sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective or whether alternative sources will be available when we need them. If these suppliers can no longer provide us with the materials we need to manufacture our Acuitas AMR Gene Panel products or our QuickFISH products, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, our business would be negatively affected.

Payments and Reimbursement

Our Acuitas AMR Gene Panel (RUO) tests and QuickFISH tests are, and other future products and services will be, sold to hospitals and public health organizations as products and on a fee-for-service basis. When hospital and health system clients purchase our QuickFISH tests we bill them directly for the purchase of test kits and consumables. In the future, we envision selling our Acuitas Lighthouse Software to health systems, hospitals and long-term care facilities under capitated, flat-rate contracts. We believe that hospitals will recoup costs of our products and services by obtaining reimbursement from the government or private insurance companies for in-bed occupancies, which traditionally includes all testing required for admitted patients. When our tests are used prior to hospital admission, hospitals, clinical laboratories, and other healthcare provider customers that purchase our products may bill various third-party payers to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our products.

Intellectual Property

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. To that end, in order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. To that end, we rely on a combination of patents, copyrights and trademarks, as well as contracts, such as confidentiality, invention assignment and licensing agreements. We also rely upon trade secret laws to protect unpatented know-how and continuing technological innovation. In addition, we have what we consider to be reasonable security measures in place to maintain confidentiality. Our intellectual property strategy is intended to develop and maintain our competitive position.

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.

In October 2019, the U.S. Patent and Trademark Office allowed an OpGen patent covering the Lighthouse Profiling technology used in the Company's software for tracking antimicrobial resistant pathogens. The patent covers the use of the Company's Acuitas Lighthouse® Software for real-time monitoring of superbug infections and other multi-drug resistant infections.

We intend to file additional patent applications in the United States and abroad to strengthen our intellectual property rights; however, our patent applications (including the patent applications listed above) may not result in issued patents in a timely fashion or at all, and we cannot assure investors that any patents that have issued or might issue will protect our technology.

We require all employees and technical consultants working for us to execute confidentiality agreements, which provide that all confidential information received by them during the course of the employment, consulting or business relationship be kept confidential, except in specified circumstances. Our agreements with our research employees provide that all inventions, discoveries and other types of intellectual property, whether or not patentable or copyrightable, conceived by the individual while he or she is employed by us are assigned to us. We cannot provide any assurance, however, that employees and consultants will abide by the confidentiality or assignment terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our technology or obtain and use information that we regard as proprietary.

Regulation

The following is a summary of the regulations materially affecting our business and operations.

Federal Oversight of Research-Use-Only Products

We currently offer for sale and sell our Acuitas AMR Gene Panel (RUO) tests to CROs, pharmaceutical companies, hospitals and other health care facilities for research use only. RUO and investigational use only, or IUO, products are not intended for human clinical use and must be properly labeled in accordance with FDA guidance. Claims for RUOs and IUOs related to safety, effectiveness, or clinical utility or that are intended for human diagnostic or prognostic use are prohibited. In November 2013, the FDA issued guidance titled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only – Guidance for Industry and Food and Drug Administration Staff." This guidance sets forth the requirements to utilize such designations, labeling requirements and acceptable distribution practices, among other requirements.

Some products are for RUO or for investigational use only, or IUO. RUO and IUO products are not intended for human clinical use and must be properly labeled in accordance with FDA guidance. Claims for RUOs and IUOs related to safety, effectiveness, or clinical utility or that are intended for human diagnostic or prognostic use are prohibited. In November 2013, the FDA issued guidance titled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only – Guidance for Industry and Food and Drug Administration Staff." This guidance sets forth the requirements to utilize such designations, labeling requirements and acceptable distribution practices, among other requirements.

Mere placement of an RUO or IUO label on an IVD product does not render the device exempt from otherwise applicable clearance, approval or other requirements. The FDA may determine that the device is intended for use in clinical diagnosis based on other evidence, including how the device is marketed.

Our Acuitas AMR Gene Panel (Urine) test was launched for RUO purposes in January 2018. We cannot predict the potential effect the FDA's current and forthcoming guidance IUOs/RUOs will have on our product offerings or materials used to perform our diagnostic services. We cannot be certain that the FDA might not promulgate rules or issue guidance documents that could affect our ability to purchase materials necessary for the performance of our diagnostic services. Should any of the reagents obtained by us from vendors and used in conducting our diagnostic services be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of service or delaying, limiting or prohibiting the purchase of reagents necessary to perform the service.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our surveillance and diagnostic services, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. On November 17, 2015, the House Committee on Energy and Commerce held one such hearing entitled "Examining the Regulation of Diagnostic Tests and Laboratory Operations." We expect that new legislative proposals will be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA, which may result in new or increased regulatory requirements for us to continue to offer our diagnostic services or to develop and introduce new services.

FDA's Premarket Clearance and Approval Requirements

The FDA also has broad authority over the regulation of medical devices marketed for sale in the United States. The FDA regulates the research, clinical testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, promotion, distribution and production of medical devices. The FDA also regulates the export of medical devices manufactured in the United States to international markets.

Under the Food, Drug, and Cosmetic Act, or FDC Act, the FDA classifies medical devices into one of three classes: Class 1, Class 2 or Class 3. Devices deemed to pose lower risk are placed into either Class 1 or Class 2.

Class 1 devices are deemed to pose the lowest risk to the patient. Accordingly, Class 1 devices are subject to the lowest degree of regulatory scrutiny and need only comply with the FDA's General Controls. The General Controls include compliance with the registration, listing, adverse event reporting requirements, and applicable portions of the Quality System Regulation, or QSR as well as the general misbranding and adulteration prohibitions. Unless specifically exempted in the regulations, general controls require a company that intends to market a Class 1 device, like us, to gain clearance for marketing through the 510(k) process. Many Class 1 devices, however, are exempt from 510(k) clearance because the level of risk is low.

Class 2 devices are considered higher risk devices than Class 1 devices. Class 2 devices are subject to General Controls as well as additional Special Controls. Special Controls may include labeling requirements, mandatory performance standards, and post market surveillance. Generally companies that intend to market Class 2 devices, like us, must comply with applicable regulations and submit a 510(k) premarket submission for review to receive clearance to list and market their devices. The 510(k) must establish substantial equivalence to a predicate device. Some Class 2 devices are exempt from filing a 510(k) but in some instances, Class 2 devices may be required to file a Premarket Approval, or PMA, application.

Class 3 devices are deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared device, and require a PMA before commercialization.

All medical device manufacturers must register their establishments with the FDA; such registrations require the payment of user fees. In addition, both 510(k) premarket submissions and PMA applications are subject to the payment of user fees, paid at the time of submission for FDA review.

510(k) Clearance Pathway

We are currently working to submit our Acuitas AMR Gene Panel tests for clearance under Section 510(k) of the FDC Act. Such tests are classified as medical devices, and we have to submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of premarket approval applications. FDA's 510(k) clearance pathway usually takes from three to twelve months. On average the review time is approximately six months, but it can take significantly longer than twelve months in some instances, as the FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, require a PMA. The FDA requires each manufacturer to determine whether the proposed change requires submission of a new 510(k) notice, or a premarket approval, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. If the FDA requires us to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties. We have made and plan to continue to make additional product enhancements to products that we believe do not require new 510(k) clearances, but we cannot guarantee that the future enhancements, should they occur, will be exempt from new 510(k) clearances.

De Novo Classification Request

The Food and Drug Administration Modernization Act of 1997, or FDAMA, added the De Novo classification option as an alternate pathway to classify novel medical devices that had automatically been placed in Class III after receiving a not substantially equivalent determination in response to a premarket notification 510(k) submission. The FDAMA allows a sponsor to submit a De Novo classification request to the FDA for a product otherwise requiring a PMA application without first being required to submit a 510(k) application.

Premarket Approval Pathway

A PMA application must be submitted if a device cannot be cleared through the 510(k) process. The PMA application process is generally more costly and time consuming than the 510(k) process. A PMA application must be supported by extensive data including, but not limited to, analytical, preclinical, clinical trials, manufacturing, statutory preapproval inspections, and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use.

After a PMA application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application can take between one and three years, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The preapproval inspections conducted by the FDA include an evaluation of the manufacturing facility to ensure compliance with the QSR, as well as inspections of the clinical trial sites by the Bioresearch Monitoring group to evaluate compliance with good clinical practice and human subject protections. New premarket approval applications or premarket approval application supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. Significant changes to an approved PMA require a 180-day supplement, whereas less substantive changes may utilize a 30-day notice, or the 135-day supplement. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and may not require as extensive clinical data or the convening of an advisory panel. None of our products are currently approved under a premarket approval.

Clinical Trials

Clinical trials are almost always required to support a PMA application and are usually required to support non-exempt Class 1 and Class 2 510(k) premarket submissions. Clinical trials may also be required to support certain marketing claims. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an investigational device exemption, or IDE application with the FDA and obtain IDE approval prior to conducting the human clinical trials. The IDE application must be supported by appropriate data, such as analytical, animal and laboratory testing results, manufacturing information, and an Investigational Review Board, or IRB approved protocol showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA prior to initiation of enrollment of human subjects. Clinical trials for a significant risk device may begin once the investigational device exemption application is approved by the FDA. If the clinical trial design is deemed to be "non-significant risk," the clinical trial may eligible for the "abbreviated" IDE requirements; in some instances IVD clinical trials may be exempt from the more burdensome IDE requirements if certain labeling requirements are met. All clinical trials conducted to support a premarket submission must be conducted in accordance with FDA regulations and Federal and state regulations concerning human subject protection, including informed consent, oversight by an IRB and healthcare privacy requirements. A clinical trial may be suspended by the FDA or the IRB review board at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the study. Even if a study is completed, the results of our clinical testing may not demonstrate the safety and efficacy of the device, or may be equivocal or otherwise not be sufficient to obtain approval of our product. Similarly, in Europe the clinical study must be approved by the local ethics committee and in some cases, including studies of high-risk devices, by the Ministry of Health in the applicable country.

Pervasive and Continuing FDA Regulation

Numerous regulatory requirements apply to our products classified as devices would continue to apply. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our cleared devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

OpGen's Gaithersburg, Maryland facility is currently registered as a manufacturer with the FDA to manufacture our products. We and any third-party manufacturers are subject to announced and unannounced inspections by the FDA to determine our compliance with quality system regulation and other regulations.

Failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, which might include any of the following sanctions: (1) untitled letters, Form 483 observations, 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.

After a medical device is placed on the market, numerous regulatory requirements apply. These include: all of the relevant elements of the QSR, labeling regulations, restrictions on promotion and advertising, the medical device reporting (which requires the manufacturer to report to the FDA if its 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 recur), the Reports of Corrections and Removals regulations (which requires manufacturers to report certain recalls and field actions to the FDA), and other post-market requirements.

Health Insurance Portability and Accountability Act

Under HIPAA, the Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information used or disclosed by healthcare providers, such as us, and by certain vendors of ours, also known as our business associates. The regulations include limitations on the use and disclosure of protected health information and impose notification requirements in the event of a breach of protected health information. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties.

We have developed and implemented policies and procedures designed to comply with these regulations. The requirements under these regulations may change periodically and could have an effect on our business operations if compliance becomes substantially more costly than under current requirements.

In addition to Federal privacy regulations, there are a number of state laws governing confidentiality of health information that are applicable to our business. If our business expands internationally, we would be subject to compliance with other laws regarding confidentiality of health information and privacy.

New laws governing privacy may be adopted in the future as well. We have taken steps to comply with health information privacy requirements to which we are aware that we are subject. However, we can provide no assurance that we are or will remain in compliance with diverse privacy requirements in all of the jurisdictions in which we do business. Failure to comply with privacy requirements could result in civil or criminal penalties, which could have a materially adverse effect on our business.

Federal and State Physician Self-referral Prohibitions

As a manufacturer and seller of diagnostic tests, we are subject to the Federal physician self-referral prohibitions, commonly known as the Stark Law, and to similar restrictions under the Maryland Physician Self-Referral Law. Together, these restrictions generally prohibit us from billing a patient or any governmental or private payor for any clinical laboratory services when the physician ordering the service, or any member of such physician's immediate family, has an investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Both the Stark Law and the Maryland Physician Self-Referral Law contain an exception for compensation paid to a physician for personal services rendered by the physician. We have compensation arrangements with a number of physicians for personal services, such as clinical advisory board services, speaking engagements and other consulting activities. We have structured these arrangements with terms intended to comply with the requirements of the personal services exception to the Stark Law and the Maryland Physician Self-Referral Law.

However, we cannot be certain that regulators would find these arrangements to be in compliance with the Stark Law, the Maryland Physician Self-Referral Law, or similar state laws. We would be required to refund any payments we receive pursuant to a referral prohibited by these laws to the patient, the payor or the Medicare program, as applicable.

Sanctions for a violation of the Stark Law include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- a civil penalty of up to $15,000 for each service arising out of the prohibited referral;
- possible exclusion from Federal healthcare programs, including Medicare and Medicaid; and
- a civil penalty of up to $100,000 against parties that enter into a scheme to circumvent the Stark Law's prohibition.

These prohibitions apply regardless of the reasons for the financial relationship and the referral. No finding of intent to violate the Stark Law is required for a violation. In addition, knowing violations of the Stark Law may also serve as the basis for liability under the Federal False Claims Act, which prohibits knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to the U.S. Government.

Further, if we submit claims in violation of the Maryland Physician Self-Referral Law, we can be held liable to the payer for any reimbursement received for the services by us. Finally, other states have self-referral restrictions with which we have to comply that differ from those imposed by Federal and Maryland law. While we have attempted to comply with the Stark Law and the Maryland Physician Self-Referral Law, it is possible that some of our financial arrangements with physicians could be subject to regulatory scrutiny at some point in the future, and we cannot provide assurance that we will be found to be in compliance with these laws following any such regulatory review.

Federal and State Anti-Kickback Laws

The Federal healthcare program Anti-Kickback Law makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any Federal healthcare program. A violation of the Anti-Kickback Law may result in imprisonment for up to five years and fines of up to $250,000 in the case of individuals and $500,000 in the case of organizations. Convictions under the Anti-Kickback Law result in mandatory exclusion from Federal healthcare programs for a minimum of five years. In addition, HHS has the authority to impose civil assessments and fines and to exclude healthcare providers and others engaged in prohibited activities from Medicare, Medicaid and other Federal healthcare programs. Actions which violate the Anti-Kickback Law also incur liability under the Federal False Claims Act.

Although the Anti-Kickback Law applies only to Federal healthcare programs, a number of states, including Maryland, have passed statutes substantially similar to the Anti-Kickback Law pursuant to which similar types of prohibitions are made applicable to all other health plans and third-party payers. Violations of Maryland's anti-kickback law are punishable by tiered criminal penalties based on the crime with a maximum penalty of life imprisonment and fines of up to $200,000, or both. Civil penalties include three times the amount of any overpayment made in violation of the statute.

Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of particular products or services. The law enforcement authorities, the courts and Congress have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between healthcare providers and actual or potential referral sources. Generally, courts have taken a broad interpretation of the scope of the Anti-Kickback Law, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases.

In addition to statutory exceptions to the Anti-Kickback Law, regulations provide for a number of safe harbors. If an arrangement meets the provisions of a safe harbor, it is deemed not to violate the Anti-Kickback Law. An arrangement must fully comply with each element of an applicable safe harbor in order to qualify for protection. There are no regulatory safe harbors to the Maryland anti-kickback law.

Among the safe harbors that may be relevant to us is the discount safe harbor. The discount safe harbor potentially applies to discounts provided by providers and suppliers, including laboratories, to physicians or institutions. If the terms of the discount safe harbor are met, the discounts will not be considered prohibited remuneration under the Anti-Kickback Law. Maryland does not have a discount safe harbor.

The personal services safe harbor to the Anti-Kickback Law provides that remuneration paid to a referral source for personal services will not violate the Anti-Kickback Law provided all of the elements of that safe harbor are met. One element is that if the agreement is intended to provide for the services of the physician on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

Our personal services arrangements with some physicians may not meet the specific requirement of this safe harbor that the agreement specify exactly the schedule of the intervals of time to be spent on the services because the nature of the services, such as speaking engagements, does not lend itself to exact scheduling and therefore meeting this element of the personal services safe harbor is impractical. Failure to meet the terms of the safe harbor does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances.

While we believe that we are in compliance with the Anti-Kickback Law and the Maryland anti-kickback law, there can be no assurance that our relationships with physicians, academic institutions and other customers will not be subject to investigation or challenge under such laws. If imposed for any reason, sanctions under the Anti-Kickback Law and the Maryland anti-kickback law could have a negative effect on our business.

Other Federal and State Fraud and Abuse Laws

In addition to the requirements discussed above, several other healthcare fraud and abuse laws could have an effect on our business. For example, provisions of the Social Security Act permit Medicare and Medicaid to exclude an entity that charges the Federal healthcare programs substantially in excess of its usual charges for its services. The terms "usual charge" and "substantially in excess" are ambiguous and subject to varying interpretations.

Further, the Federal False Claims Act prohibits a person from knowingly submitting a claim, making a false record or statement in order to secure payment or retaining an overpayment by the Federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the Federal government by a private party having knowledge of the alleged fraud, also known as qui tam lawsuits. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. It is not uncommon for qui tam lawsuits to be filed by employees, competitors or consultants.

Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Violation of these provisions may result in fines, imprisonment or both, and possible exclusion from Medicare or Medicaid programs. Maryland has an analogous state false claims act applicable to state health plans and programs, as do many other states.

International Regulation

Sales of diagnostic tests like our QuickFISH and PNA FISH products outside the United States would be subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we would need to obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. OpGen currently distributes its QuickFISH and PNA FISH products in the European Union through its Denmark office. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ significantly. If we elect to, or are required to, seek clearance of or approval for any of our products from the FDA, we may be able to commercialize such products with shorter lead time in international markets, but would need to establish international operations in order to do so.

Environmental Matters

Our operations require the use of hazardous materials (including biological materials) which subject us to a variety of Federal, state and local environmental and safety laws and regulations. Some of these regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or new regulations will affect our business, operations or the cost of compliance.

Employees

As of September 30, 2019, we had 44 employees worldwide, with 42 employed in the United States, 1 employed in Denmark and 1 employed in Colombia. There are 42 full-time employees. The 42 employees in the United States primarily work in our Gaithersburg, Maryland location. None of our employees are the subject of collective bargaining arrangements, and our management considers its relationships with employees to be good.

Properties

The Company leases 20,939 square feet of office and laboratory space at our headquarters in Gaithersburg, Maryland. Pursuant to this lease agreement, as amended, our lease will continue in effect until January 31, 2021 and may be renewed for one additional five-year period at the Company's election. Additionally, the Company leases 2,967 square feet of office space in Denmark; this lease is currently on a month-to-month basis.

We believe that our existing facilities are, or any such new facilities will be, adequate to meet our business requirements for at least the next 18 months and that additional space will be available on commercially reasonable terms, if required.

Legal Proceedings

From time to time, we may be party to lawsuits in the ordinary course of business. We are currently not a party to any material legal proceedings.

Corporate 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. The Company's headquarters and principal operations are in Gaithersburg, Maryland. The Company also has operations in Copenhagen, Denmark and Bogota, Colombia.

Market Price and Dividend Information

Market Information

Our common stock and 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 January 21, 2020, the last reported sale price of our common stock on the Nasdaq Capital Market was $1.76 per share. As of January 21, 2020, 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.

OPGEN'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our audited consolidated financial statements and the accompanying notes thereto and the unaudited condensed consolidated financial statements and the accompanying notes thereto included elsewhere in this proxy statement/prospectus. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth in the section titled "Risk Factors" of this proxy statement/prospectus.

Overview

OpGen was incorporated in Delaware in 2001. On July 14, 2015, OpGen completed the Merger with AdvanDx. Pursuant to the terms of a Merger Agreement, Velox Acquisition Corp., OpGen's wholly-owned subsidiary formed for the express purpose of effecting the Merger, merged with and into AdvanDx with AdvanDx surviving as OpGen's wholly-owned subsidiary. OpGen and AdvanDx are collectively referred to hereinafter as the "Company." The Company's headquarters and principal operations are in Gaithersburg, Maryland. The Company also has operations in Copenhagen, Denmark, and Bogota, Colombia. The Company operates in one business segment.

OpGen is a precision medicine company using molecular diagnostics and informatics to help combat infectious disease. The Company is 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. The Company's 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.

The Company'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. The Company is working to deliver products and services, some in development, to a global network of customers and partners.

- The Company's molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include its Acuitas antimicrobial resistance, or AMR, Gene Panel (Urine) test in development for patients at risk for complicated urinary tract infections, or cUTI, its Acuitas AMR Gene Panel (Isolates) test in development for testing bacterial isolates, and its QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of its Acuitas AMR Gene Panel tests is available for sale for research use only, or RUO.

- The Company's Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that 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 is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

In May 2019, the Company filed a 510(k) application with the FDA seeking clearance of its Acuitas AMR Gene Panel (Isolates) diagnostic test. In July 2019, the Company received correspondence from the FDA detailing a number of questions related to this filing. The Company is currently evaluating the FDA correspondence and preparing its responses.

The Company's operations are subject to certain risks and uncertainties. The risks include rapid technology changes, the need to manage growth, the need to retain key personnel, the need to protect intellectual property and the need to raise additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop and commercialize its proprietary technology as well as raise additional capital.

Results of operations for the nine months ended September 30, 2019 and 2018

Revenue

	Nine Months Ended September 30,	
	2019	2018
Product sales	$ 1,597,505	$ 1,805,877
Laboratory services	5,435	22,155
Collaboration revenue	1,075,000	359,316
Total revenue	$ 2,677,940	$ 2,187,348

Total revenue for the nine months ended September 30, 2019 increased approximately 22%, with a change in the mix of revenue, as follows:

- Product sales: a decrease in revenue of approximately 12% in the 2019 period compared to the 2018 period is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products partially offset by an increase in the sales of our Acuitas AMR products;
- Laboratory services: a decrease in revenue of approximately 75% in the 2019 period compared to the 2018 period is a result of our ceasing sales of our Acuitas MDRO test products in 2019; and
- Collaboration revenue: an increase in revenue of approximately 199% in the 2019 period compared to the 2018 period is primarily the result of revenue from our contract with the New York State Department of Health.

Operating expenses

	Nine Months Ended September 30,	
	2019	2018
Cost of products sold	$ 681,568	$ 939,479
Cost of services	592,647	446,144
Research and development	4,069,335	3,821,117
General and administrative	4,901,136	5,365,221
Sales and marketing	1,142,755	1,117,380
Transaction costs	538,061	—
Impairment of right-of-use asset	520,759	—
Total operating expenses	$ 12,446,261	$ 11,689,341

The Company's total operating expenses for the nine months ended September 30, 2019 increased approximately 6% when compared to the same period in 2018. This increase is primarily attributable to $538 thousand of transaction costs incurred in connection with our business combination with Curetis and the impairment of our Woburn, Massachusetts ROU asset recorded as part of the Company's adoption of ASU 2016-02, *Leases (Topic 842)*. In addition, operating expenses changed as follows:

- Cost of products sold: cost of products sold for the nine months ended September 30, 2019 decreased approximately 27% when compared to the same period in 2018. The change in costs of products sold is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products;
- Cost of services: cost of services for the nine months ended September 30, 2019 increased approximately 33% when compared to the same period in 2018. The change in costs of services is primarily attributable to an increase in costs associated with our collaboration contracts;

- Research and development: research and development expenses for the nine months ended September 30, 2019 increased approximately 6% when compared to the same period in 2018, primarily due to R&D related costs associated with our isolate submission expenses related to our 510(k) submission for the Acuitas AMR Gene Panel for use with bacterial isolates;
- General and administrative: general and administrative expenses for the nine months ended September 30, 2019 decreased approximately 9% when compared to the same period in 2018, primarily due to decreased outside service and payroll related costs; and
- Sales and marketing: sales and marketing expenses for the nine months ended September 30, 2019 increased approximately 2% when compared to the same period in 2018, primarily due to the increased headcount of our marketing team.

Other income (expense)

	Nine Months Ended September 30,	
	2019	**2018**
Interest expense	$ (142,672)	$ (140,453)
Foreign currency transaction losses	(9,426)	(6,556)
Other income (expense)	(8,213)	5,210
Change in fair value of derivative financial instruments	67	8,070
Total other expense	$ (160,244)	$ (133,729)

The Company's total other expense for the nine months ended September 30, 2019 increased primarily due to an increase in other expenses.

Sources and uses of cash the nine months ended September 30, 2019 and 2018

The Company's principal source of liquidity is from financing activities, including issuances of equity and debt securities. The following table summarizes the net cash and cash equivalents provided by (used in) operating activities, investing activities and financing activities for the periods indicated:

	Nine Months Ended September 30,	
	2019	**2018**
Net cash used in operating activities	$ (8,055,962)	$ (8,376,394)
Net cash used in investing activities	(43,357)	(31,470)
Net cash provided by financing activities	4,169,371	11,230,780

Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2019 consists primarily of our net loss of $9.9 million, reduced by certain noncash items, including impairment of ROU asset of $0.5 million, depreciation and amortization expense of $0.7 million, and stock-based compensation expense of $0.3 million. Net cash used in operating activities for the nine months ended September 30, 2018 consists primarily of our net loss of $9.6 million, reduced by certain noncash items, including depreciation and amortization expense of $0.5 million and stock-based compensation expense of $0.7 million.

Net cash used in investing activities

Net cash used in investing activities in the nine months ended September 30, 2019 and 2018 consisted solely of purchases of property and equipment offset by proceeds from the sale of equipment.

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2019 of $4.2 million consisted primarily of the net proceeds from the March 2019 Public Offering. Net cash provided by financing activities for the nine months ended September 30, 2018 of $11.2 million consisted primarily of the net proceeds from the February 2018 Public Offering and net proceeds from the at the market offering.

Results of Operations for the Years Ended December 31, 2018 and 2017

Revenues

	Year Ended December 31,	
	2018	**2017**
Revenue		
Product sales	$ 2,395,626	$ 2,771,869
Laboratory services	34,665	41,960
Collaboration revenue	516,016	397,178
Total revenue	$ 2,946,307	$ 3,211,007

Our total revenue for the year ended December 31, 2018 decreased 8%, to $2.9 million from $3.2 million, when compared to the same period in 2017. This decrease is primarily attributable to:

- Product Sales: the decrease in revenue of 14% in 2018 as compared to 2017 is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products (QuickFISH and PNA FISH) and the discontinuance of our legacy whole genome mapping business;
- Laboratory Services: the decrease in revenue of 17% in 2018 as compared to 2017 is a result of decreases in sales of our Acuitas test products; and
- Collaboration Revenue: the increase in collaboration revenue of 30% in 2018 as compared to 2017 is primarily the result of increased revenue associated with our CDC contract.

Operating expenses

	Year Ended December 31,	
	2018	**2017**
Cost of products sold	$ 1,222,919	$ 1,612,838
Cost of services	625,516	520,338
Research and development	5,677,243	6,883,293
General and administrative	7,069,315	6,692,659
Sales and marketing	1,531,556	2,767,670
Total operating expenses	$ 16,126,549	$ 18,476,798

The Company's total operating expenses for the year ended December 31, 2018 decreased 13%, to $16.1 million from $18.5 million, when compared to the same period in 2017. This decrease is primarily attributable to:

- Costs of products sold: expenses for the year ended December 31, 2018 decreased approximately 24% when compared to the same period in 2017. The change in costs of products sold is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products;
- Costs of services: expenses for the year ended December 31, 2018 increased approximately 20% when compared to the same period in 2017. The change in costs of services is primarily attributable to increased costs of services associated with our CDC contract;
- Research and development: expenses for the year ended December 31, 2018 decreased approximately 18% when compared to the same period in 2017, primarily due to a decrease in costs related to the automated rapid pathogen identification project that was suspended in 2017, offset by increased costs related to clinical studies;

- General and administrative: expenses for the year ended December 31, 2018 increased approximately 6% when compared to the same period in 2017, primarily due to increased payroll and consultant costs; and
- Sales and marketing: expenses for the year ended December 31, 2018 decreased approximately 45% when compared to the same period in 2017, primarily due to the reductions in the size of our commercial organization in 2017.

Other income (expense)

	Year Ended December 31,	
	2018	**2017**
Interest expense	$ (191,195)	$ (233,505)
Foreign currency transaction (losses)/gains	(10,431)	23,179
Change in fair value of derivative financial instruments	8,386	144,064
Interest and other income/(expense)	5,384	(87,255)
Total other expense	$ (187,856)	$ (153,517)

Other expense for the year ended December 31, 2018 increased to a net expense of $187,856 from a net expense of $153,517 in the same period of 2017. The increase was primarily a result of decreased gains due to the change in fair value of warrant liabilities offset by the expense of the unamortized discount on the outstanding Bridge Financing Notes at repayment in the prior year.

Sources and uses of cash for the years ended December 31, 2018 and 2017

The following table summarizes the net cash and cash equivalents provided by (used in) operating activities, investing activities and financing activities for the periods indicated:

	Year Ended December 31,	
	2018	**2017**
Net cash used in operating activities	$ (11,073,997)	$ (14,303,880)
Net cash used in investing activities	(137,327)	(276,950)
Net cash provided by financing activities	13,845,102	12,348,194

Net cash used in operating activities

Net cash used in operating activities in 2018 consists primarily of our net loss of $13.4 million, reduced by certain non-cash items, including depreciation and amortization expense of $0.7 million, share-based compensation of $0.9 million, and the net change in operating assets and liabilities of $0.6 million. Net cash used in operating activities for 2017 consists primarily of our net loss of $15.4 million, reduced by certain non-cash items, including depreciation and amortization expense of $0.7 million, share-based compensation expense of $0.9 million, partially offset by the net change in operating assets and liabilities of $0.6 million.

Net cash used in investing activities

Net cash used in investing activities in 2018 and 2017 consisted solely of the purchase of property and equipment offset by proceeds from the sale of equipment.

Net cash provided by financing activities

Net cash provided by financing activities in 2018 of $13.8 million consisted primarily of net proceeds from the October 2018 Public Offering, February 2018 Public Offering and the ATM offering. Net cash provided by financing activities in 2017 of $12.3 million consisted primarily of net proceeds from the July 2017 Public Offering, the ATM offering and from the issuance of Bridge Financing Notes.

Liquidity and capital resources

As of September 30, 2019, the Company had cash and cash equivalents of $0.6 million compared to $4.6 million at December 31, 2018. At December 31, 2018, the Company had cash and cash equivalents of $4.6 million, compared to $1.8 million at December 31, 2017. The Company believes that current cash on hand will be sufficient to fund operations into the first quarter of 2020. The Company has funded its operations primarily through external investor financing arrangements and has raised significant funds in 2019, 2018 and 2017, including:

On October 28, 2019, the Company closed the October 2019 Offering, a firm commitment underwritten public offering of (i) 2,590,170 units, with each unit being comprised of one share of the Company's Common Stock, and one common warrant to purchase one share of Common Stock and (ii) 2,109,830 pre-funded units, with each pre-funded unit being comprised of one pre-funded warrant to purchase one share of common stock and one warrant. The offering price to the public was $2.00 per unit and $1.99 per pre-funded unit. The total number of warrants included in the units and pre-funded units was 4,700,000. The warrants are immediately exercisable at a price of $2.00 per share of common stock and expire five years from the date of issuance. The offering raised gross proceeds of $9.4 million and net proceeds of approximately $8.3 million.

On March 28, 2019, the Company closed a firm commitment underwritten public offering of 450,000 shares of the Company's Common Stock at a public offering price of $12.00 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million.

On October 22, 2018, we closed a public offering, or the October 2018 Public Offering of 111,000 shares of common stock at a public offering price of $29.00 per share. The offering raised gross proceeds of approximately $3.2 million and net proceeds of $2.8 million.

On June 11, 2018, the Company executed an Allonge to its Second Amended and Restated Senior Secured Promissory Note, dated June 28, 2017, with a principal amount of $1,000,000 issued to MGHIF. The Allonge provided that accrued and unpaid interest of $285,512 due as of July 14, 2018, the original maturity date, would be paid through the issuance of shares of OpGen's common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021. On July 30, 2018, the Company issued 7,212 shares of common stock to MGHIF in a private placement transaction for $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

On February 6, 2018, the Company closed a public offering, or the February 2018 Public Offering, of 2,841,152 units at $3.25 per unit, and 851,155 pre-funded units at $3.24 per pre-funded unit, raising gross proceeds of approximately $12 million and net proceeds of approximately $10.7 million. Each unit included one twentieth of a share of common stock and one common warrant to purchase one fortieth of a share of common stock at an exercise price of $65.00 per share. Each pre-funded unit included one pre-funded warrant to purchase one twentieth of a share of common stock for an exercise price of $0.20 per share, and one common warrant to purchase one fortieth of a share of common stock at an exercise price of $65.00 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance.

On May 31, 2017, the Company entered into a Note Purchase Agreement with jVen Capital, under which jVen Capital agreed to provide bridge financing in an aggregate principal amount of up to $1,500,000 to the Company in up to three separate tranches of Bridge Financing Notes. The interest rate on each Bridge Financing Note was ten percent (10%) per annum (subject to increase upon an event of default). In connection with the Bridge Financing Notes, the Company issued jVen Capital stock purchase warrants to acquire 281 shares with an exercise price of $390.00 per share, and stock purchase warrants to acquire 317 shares at an exercise price of $345.00 per share. On June 14, 2017, the Company drew down on the first of three Bridge Financing Notes, with $1 million remaining capacity available. The Company drew down on the second Bridge Financing Note on July 5, 2017 and the third Bridge Financing Note was never issued. The outstanding Bridge Financing Notes were repaid in full upon the closing of the July 2017 Public Offering.

As a condition to the receipt of the bridge financing, the Company issued the Second Amended & Restated Senior Secured Promissory Note, or the MGHIF Note, to MGHIF, which extended the maturity date of the promissory note from July 14, 2017 to July 14, 2018. In return for MGHIF's consent to such extension, the Company increased the interest rate of the MGHIF Note to 10% per annum and issued warrants to purchase shares of common stock to MGHIF equal to 20% of the principal balance of the MGHIF Note, plus interest accrued thereon, as of June 28, 2017.

On July 18, 2017, the Company closed a public offering, or the July 2017 Public Offering, of 18,164,1959 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million, or the July 2017 Public Offering. jVen Capital was one of the investors participating in the offering. Each unit included 0.0025 of a share of common stock and one common warrant to purchase 0.0025 of a share of common stock at an exercise price of $212.50 per share. Each pre-funded unit included one pre-funded warrant to purchase 0.0025 of a share of common stock for an exercise price of $5.00 per share, and one common warrant to purchase 0.0025 of a share of common stock at an exercise price of $212.50 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. Approximately $1 million of the gross proceeds was used to repay the outstanding Bridge Financing Notes to jVen Capital in July 2017.

In early June 2017, the Company commenced a restructuring of its operations to improve efficiency and reduce its cost structure. Under the restructuring plan, the Company is consolidating its operations for FDA-cleared and CE marked QuickFISH and PNA FISH products and research and development activities for the Acuitas AMR Gene Panel in Gaithersburg, Maryland, and reducing the size of its commercial organization while the Company works to complete the development of its Acuitas AMR Gene Panel and Acuitas Lighthouse Knowledgebase products and services in development. As part of this restructuring, the Company decommissioned its CLIA laboratory operations in the third quarter of 2018 to provide incremental resources in support of efforts to gain FDA clearance for the Company's Acuitas AMR Gene Panel products in development.

There were approximately $121,000 of one-time termination benefits that were recognized during the year ended December 31, 2017 related to the restructuring. The Company incurred total retention expense of approximately $68,000 during the year ended December 31, 2017. The future minimum lease payments for the Woburn facility were approximately $1.4 million as of December 31, 2018. A liability for costs that will continue to be incurred under a contract for its remaining term without economic benefit to the entity was recognized at the cease-use date in the three months ended June 30, 2019.

Critical accounting policies and use of estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our audited consolidated financial statements and on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires us 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 revenues and expenses during the reporting period. In our audited consolidated financial statements, estimates are used for, but not limited to, liquidity assumptions, revenue recognition, share-based compensation, allowances for doubtful accounts and inventory obsolescence, and valuation of derivative financial instruments measured at fair value on a recurring basis, deferred tax assets and liabilities and related valuation allowance, depreciation and amortization and estimated useful lives of long-lived assets. Actual results could differ from those estimates.

A summary of our significant accounting policies is included in Note 3 to the accompanying audited consolidated financial statements and in Note 3 “Summary of significant accounting policies” to the accompanying unaudited condensed consolidated financial statements. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain.

Revenue Recognition

Subsequent to the Adoption of Accounting Standards Codification Revenue from Contracts with Customers (“ASC 606”) on January 1, 2018

The Company derives revenues from (i) the sale of QuickFISH and PNA FISH diagnostic test products and Acuitas AMR Gene Panel (Urine) RUO test products, (ii) providing laboratory services, and (iii) providing collaboration services including funded software arrangements, and license arrangements.

The Company analyzes contracts to determine the appropriate revenue recognition using the following steps: (i) identification of contracts with customers, (ii) identification of distinct performance obligations in the contract, (iii) determination of contract transaction price, (iv) allocation of contract transaction price to the performance obligations and (v) determination of revenue recognition based on timing of satisfaction of the performance obligation.

The Company recognizes revenues upon the satisfaction of its performance obligation (upon transfer of control of promised goods or services to our customers) in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services.

The Company defers incremental costs of obtaining a customer contract and amortizes the deferred costs over the period that the goods and services are transferred to the customer. The Company had no material incremental costs to obtain customer contracts in any period presented.

Deferred revenue results from amounts billed in advance to customers or cash received from customers in advance of services being provided.

For details about the Company's revenue recognition policy prior to the adoption of ASC 606, refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Impairment of Long-Lived Assets

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets.

Definite-lived intangible assets include trademarks, developed technology and customer relationships. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any.

Goodwill represents the excess of the purchase price for AdvanDx over the fair values of the acquired tangible or intangible assets and assumed liabilities. The Company will conduct an impairment test of goodwill on an annual basis as of October 1 of each year, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value.

Share-Based Compensation

Share-based payments to employees, directors and consultants are recognized at fair value. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option. The estimated fair value of equity instruments issued to nonemployees is recorded at fair value on the earlier of the performance commitment date or the date the services required are completed.

For all time-vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. Share-based compensation expense recognized is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period. The fair value of share-based payments is estimated, on the date of grant, using the Black-Scholes model. Option valuation models, including the Black-Scholes model, require the input of highly subjective estimates and assumptions, and changes in those estimates and assumptions can materially affect the grant-date fair value of an award. These assumptions include the fair value of the underlying and the expected life of the award.

See additional discussion of the use of estimates relating to share-based compensation, and a discussion of management's methodology for developing each of the assumptions used in such estimates, in Note 3 to the accompanying consolidated financial statements.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") and International Accounting Standards Board ("IASB") jointly issued a new revenue recognition standard, Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASC 606") that is designed to improve financial reporting by creating common recognition guidance for GAAP and International Financial Reporting Standards ("IFRS"). This guidance provides a robust framework for addressing revenue issues, improves the comparability of revenue recognition practices across industries, provides useful information to users of financial statements through improved disclosure requirements and simplifies the presentation of financial statements. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. From March to December 2016, amendments to the new revenue recognition standard were issued to clarify numerous accounting topics, including, but not limited to (i) the implementation guidance on principal versus agent considerations, (ii) the identification of performance obligations, (iii) the licensing implementation guidance, (iv) the objective of the collectability criterion, (v) the application of the variable consideration guidance and modified retrospective transition method, (vi) the way in which impairment testing is performed and (vii) the disclosure requirements for revenue recognized from performance obligations. This guidance permits the use of either a full retrospective method or a modified retrospective approach. The modified retrospective approach is applied only to the most current period presented along with a cumulative-effect adjustment at the date of adoption. This guidance became effective for annual reporting periods beginning after December 15, 2017.

On January 1, 2018, the Company adopted ASC 606, using the modified retrospective method. Results for reporting periods beginning subsequent to December 31, 2017 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting policies prior to adoption. In adopting the guidance, the Company applied the guidance to all contracts and used available practical expedients including assessing contracts with similar terms and conditions on a "portfolio" basis. The adoption of this new guidance did not have a material impact on the Company's condensed consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows: Restricted Cash*, which addresses classification and presentation of changes in restricted cash on the statement of cash flows. The standard requires that restricted cash and restricted cash equivalents be included as components of total cash and cash equivalents as presented on the statement of cash flows. The Company adopted ASU 2016-18 using a retrospective transition method effective January 1, 2018 and applied to the periods presented on the condensed consolidated statements of cash flows. Restricted cash includes cash and cash equivalents that is restricted through legal contracts, regulations or the Company's intention to use the cash for a specific purpose. The Company's restricted cash primarily related to funds held as collateral for letters of credit.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASC 842"), which amends the existing accounting standards for leases. The new standard requires lessees to record a right-of-use ("ROU") asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases), whereas under current accounting standards, the Company's lease portfolio consists of operating leases and is not recognized on its consolidated balance sheets. The new standard also requires expanded disclosures regarding leasing arrangements. The new standard is effective for the Company beginning January 1, 2019. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842)*: *Targeted Improvements*, which provides an alternative modified transition method. Under this method, the cumulative-effect adjustment to the opening balance of retained earnings is recognized on the date of adoption with prior periods not restated.

The new standard provides a number of optional practical expedients in transition. The Company expects to elect: (1) the 'package of practical expedients', which permits it not to reassess under the new standard its prior conclusions about lease identification, lease classification, and initial direct costs; (2) the use-of-hindsight; and (3) the practical expedient pertaining to land easements. In addition, the new standard provides practical expedients for an entity's ongoing accounting that the Company anticipates making, such as the (i) the election for certain classes of underlying asset to not separate non-lease components from lease components and (ii) the election for short-term lease recognition exemption for all leases that qualify.

The Company adopted this guidance effective January 1, 2019 using the modified retrospective transition method and the following practical expedients:

- The Company did not reassess if any expired or existing contracts are or contain leases.
- The Company did not reassess the classification of any expired or existing leases.

Additionally, the Company made ongoing accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12 months or less) and (ii) combines lease and non-lease elements of our operating leases.

Upon adoption of the new guidance on January 1, 2019, the Company recorded an operating lease right of use asset of approximately $2.2 million (net of existing deferred rent) and recognized a lease liability of approximately $2.5 million.

In June 2018, the FASB issued ASU 2018-07: *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, early adoption is permitted but no earlier than an entity's adoption date of ASC 606. The adoption of this new guidance did not have a material impact on the Company's condensed consolidated financial statements.

In August 2018, the SEC issued a final rule that amends certain disclosure requirements that were duplicative, outdated or superseded. In addition, the final rule expanded the financial reporting requirements for changes in stockholders' equity for interim reporting periods. The Company adopted the new guidance on January 1, 2019 with no material impact to the condensed consolidated financial statements.

The Company has evaluated all other issued and unadopted ASUs and believes the adoption of these standards will not have a material impact on its results of operations, financial position or cash flows.

Off-Balance Sheet Arrangements

As of September 30, 2019, December 31, 2018 and 2017, the Company did not have any off-balance sheet arrangements.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows it to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, the Company's financial statements may not be comparable to companies that comply with public company effective dates.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," the Company intends to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. The Company will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which it has total annual gross revenues of $1.07 billion or more; (ii) December 31, 2020; (iii) the date on which the Company has issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which the Company is deemed to be a large accelerated filer under the rules of the SEC.

Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

CURETIS' BUSINESS

Overview

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

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

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

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

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

As of September 30, 2019, Curetis' total installed base comprised 165 Unyvero A50 Analyzers. There are currently six commercially available Application Cartridges, which include:

- the HPN Application Cartridge, which addresses severe forms of pneumonia,
- the ITI Application Cartridge, which addresses severe cases of implant and tissue infections,
- the BCU Application Cartridge, which addresses severe blood stream infections,
- the IAI Application Cartridge, which addresses intra-abdominal infections,

- the UTI Application Cartridge, which addresses severe urinary tract infections, all of which are CE-IVD-marked, and
- the LRT Application Cartridge, which is technically similar to the HPN Application Cartridge and also addresses severe forms of pneumonia, which was cleared by the FDA in April 2018 for use with tracheal aspirates and is now being marketed in the United States.

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

To date, more than 90 clinical studies and evaluations with over 12,800 patient samples have been completed to validate these Application Cartridges and more than 40 clinical and scientific publications have been produced since the beginning of 2016. Additional trials with several thousand additional samples are ongoing or planned in the coming years. This includes clinical studies to obtain FDA clearance for the LRT Application Cartridge for use with BAL specimens, cleared in December 2019, in addition to the tracheal aspirate samples for which the Unyvero LRT Application Cartridge was cleared by the FDA in April 2018, and the IJI Application Cartridge, which addresses invasive joint infections, as well as Chinese NMPA trials for the Unyvero System and the HPN Application Cartridges.

In addition to the current Unyvero System, Curetis also develops its Unyvero A30 *RQ* Analyzer module designed to offer a rapid time-to-result (potentially as fast as 45 to 90 minutes), qualitative and, where needed, quantitative real-time PCR testing in a cartridge format that can provide up to 11 parallel multiplex (i.e. simultaneously running multiple assays in one reaction) PCR reactions from one sample, with up to three assays per reaction (for a total of up to 33 assays per cartridge). It is expected to be operated on a stand-alone basis or fully integrated into the Unyvero System suite of products with respect to system architecture, design, software and handling, thereby expanding the Unyvero Platform to include low- and mid-plex capabilities. A further advantage of the Unyvero A30 *RQ* Analyzer is that the costs of the Analyzer and cartridges are expected to be lower than those for the current Unyvero System and Application Cartridges, potentially opening up commercial opportunities in the medium multiplexing infectious disease testing market segment. Initially developed as an expansion of the Unyvero platform complementing the Unyvero A50 high-plex Application Cartridges with low- to mid-plex Unyvero A30 *RQ* Application Cartridges for infectious diseases, Curetis in December 2018 changed its strategy and now also seeks partners in the global IVD industry that want to license the Unyvero A30 *RQ* for commercialization of their own assays on this platform as legal manufacturer under their own branding.

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

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

In addition to its out-licensing strategy, Ares Genetics offers next-generation molecular AMR testing services out of its NGS service lab opened in mid-2019 in Vienna, Austria, with initial focus on infection control, AMR epidemiology and surveillance, clinical research and pharmaceutical anti-infectives R&D.

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

2019 Business Updates

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

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

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

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

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

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

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

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

Financing Arrangements to be Assumed by Newco

EIB Finance Contract

Curetis, as borrower, and the European Investment Bank, or EIB, as lender, entered into a finance contract, originally dated December 12, 2016 (where applicable, as amended or restated), as amended by an amendment letter dated April 20, 2018, or the Amendment Letter, and by an amended and restated finance contract dated May 20, 2019, or the Amended and Restated EIB Finance Contract and collectively referred to as the EIB Finance Contract, providing for two term loan tranches in the aggregate principal amount of €25 million for the purpose of financing the development of novel test panels, e.g. for intra-abdominal infections and sepsis host response as well as urinary tract infection, cardiology associated infection and extended respiratory panels, as well as future panels on platforms such as the Unyvero Platform, including the necessary clinical trials to obtain the relevant regulatory approvals for market authorization and reimbursement, and capex for manufacturing expansion. The loan amount is split into two tranches, a first tranche of €10 million which was drawn down in April 2017 and a second tranche of up to an additional €15 million, in respect of which a disbursement of €3 million was drawn down and received on June 22, 2018 following the fulfillment of the key condition in April 2018 that the FDA clear the Unyvero System and the LRT Application Cartridge. Pursuant to the Amendment Letter, following the disbursement of €3 million as described above, the disbursement of the balance of the second tranche, with an aggregate commitment of up to €12 million, has been amended as follows: (i) first, a disbursement of up to €5 million would become available subject to Curetis N.V. having raised cumulative new equity of at least €13.5 million, which was partly accomplished through the issuance of shares raising €4.1 million in an equity offering in May 2018 and partially by a follow-on equity offering in November 2018 which raised €8.9 million; and (ii) the remaining distribution amount of up to €7 million would become available subject to Curetis having installed 350 Unyvero Analyzers globally as well as Curetis' consolidated revenues being at least €10 million over the 12 months preceding the request for the loan disbursement are not expected to be met. In regards to (i), in return for EIB waiving certain conditions precedent to disbursing this aforementioned €5 million tranche, the parties agreed pursuant to the Amended and Restated EIB Finance Contract on a 2.1% participation percentage interest, or PPI. Upon maturity of this 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. All other terms and conditions of the EIB financing contract with Curetis remain unchanged. In regards to (ii), the conditions referred to therein are not expected to be met and Curetis, therefore, does not anticipate having access to any further tranches under the EIB Finance Contract going forward.

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

Each loan under the EIB Finance Contract matures on the fifth anniversary of the disbursement of that loan and is to be repaid as a single installment on its maturity date. Each loan bears interest in the form of (i) a cash interest element at a floating rate of EURIBOR plus a cash pay margin and (ii) a deferred interest element of a fixed interest rate to be paid on the maturity date of the relevant loan. As of June 30, 2019, €18 million plus deferred interest in the amount of €1.32 million was outstanding under the EIB Finance Contract.

The obligations and liabilities of Curetis under the EIB Finance Contract are secured by a guarantee of Curetis N.V. as initial guarantor as well as guarantees by Ares Genetics and Curetis USA as additional guarantors. OpGen will need to assume and replace the guarantee of Curetis N.V. as a condition to closing of the proposed Transaction. This will require a further amendment and/or restatement of, or the entry into of a new finance contract, between OpGen, EIB and Curetis. On October 15, 2019, EIB confirmed in writing that they have approved the Transaction, subject to (i) the guarantee of Curetis N.V. being replaced by a new guarantee from OpGen and (ii) upon completion of the Transaction, the EIB Finance Contract and ancillary documentation (if any) being amended accordingly, inter alia, in respect of amending the PPI calculation and any other references to Curetis N.V.

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

The EIB Finance Contract contains undertakings on the part of the borrower to use the funds drawn down under the contract to finance the Financed Project and to maintain and insure the Financed Project, as well as certain restrictions, including restrictions on the borrower's ability to dispose of assets, engage in hedging activities, violate applicable law, dispose of the shares of its material subsidiaries, engage in certain acquisitions, grant guarantees and security other than certain types of permitted guarantees and security, and incur additional financial indebtedness other than certain types of permitted indebtedness. The borrower is required to repay the loan together with accrued interest and any deferred interest upon demand by the EIB in the event of events of default, including payment defaults subject to a three-day grace period, certain insolvency or bankruptcy events, or the inability of the borrower or guarantor to fulfill its other obligations under the EIB Finance Contract or the guarantees.

Yorkville Financing

Under the terms of the agreement entered into on October 2, 2018 by Curetis N.V. and Yorkville, or the Yorkville Agreement, Yorkville has committed to subscribe for up to 2,000 Curetis Convertible Notes with a principal amount of €10,000 per note, divided into multiple tranches, over a period of 36 months from the date of the agreement. Share subscription warrants, or the Warrants, are issued with each tranche of Curetis Convertible Notes, except for the first tranche of 500 Curetis Convertible Notes with an aggregate principal amount of €5 million. As of October 2, 2018, Curetis N.V. had issued €3.5 million and has issued the remaining €1.5 million in principal amount of Curetis Convertible Notes of the first tranche in June 2019. As of November 8, 2019, a total of €1.3 million of unconverted Curetis Convertible Notes was outstanding. OpGen has committed to assuming the Curetis Convertible Notes and changing the conversion feature to relate to shares of OpGen stock.

The principal amount of subsequent tranches of Curetis Convertible Notes, if and to the extent that the Yorkville facility were to be continued by OpGen in Newco post-closing of the Transaction, will be equal to the lower of either (a) €5 million and (b) ten times the combined average daily value of the Curetis N.V. shares, or the Curetis Shares traded on Euronext in Amsterdam and Euronext in Brussels during the ten days preceding Curetis N.V.'s tranche request (up to a maximum of €5 million). Curetis N.V. is restricted from submitting a request to fund a subsequent tranche of Curetis Convertible Notes under the Yorkville Agreement until after the tenth calendar day following the conversion into Curetis Shares and/or redemption of all the outstanding Curetis Convertible Notes issued under the previous tranches. The commitment by Yorkville under the Yorkville Agreement to subscribe for subsequent tranches of the Curetis Convertible Notes is subject to certain conditions, described below.

After the initial tranche of €3.5 million received upon signing of the Curetis Convertible Notes agreement, in the second quarter of 2019, Curetis N.V. received access to another €1.5 million gross in funding in June 2019. Net proceeds from this tranche were €1.36 million. As with the prior tranche, Yorkville is expected from time to time to convert such notes into equity and Curetis N.V. will then issue new Curetis Shares. However, as of November 8, 2019, Curetis N.V. no longer has any Curetis Shares available for Yorkville to convert any of the remaining outstanding unconverted Curetis Convertible Notes of €1.3 million. It is expected that these unconverted Curetis Convertible Notes will be assumed by OpGen and the conversion feature will be changed to a conversion into OpGen stock post-closing of the Transaction, subject to OpGen, Yorkville and Curetis N.V. entering into a new facility agreement reflecting the same. As at the date of this proxy statement/prospectus, no such new facility agreement has been entered into between OpGen, Yorkville and Curetis N.V. Details between OpGen, Yorkville and Curetis N.V. are, therefore, yet to be determined.

As of November 8, 2019, Yorkville has converted a total of EUR 3.7 million in notes into equity. A total of 4,780,552 new Curetis Shares have been issued as of November 9, 2019. Under the terms of the Yorkville Agreement, the number of Curetis Shares to be issued upon conversion of all Curetis Convertible Notes of the first tranche should initially not exceed 2.75 million Curetis Shares. Any excess entitlement on the basis of the conversion ratio will be settled in cash unless Curetis N.V. elects to settle such excess in Curetis Shares. On July 31, 2019 the limit of 2.75 million Curetis Shares was exceeded by a further conversion note by Yorkville. On August 1, 2019 Curetis N.V. opted to settle its obligations resulting from this conversion notices fully in Curetis Shares, thereby exercising its right under the Yorkville Agreement to settle the excess beyond the First Tranche Share Issue Cap in Curetis Shares. Any Curetis Shares issued by Curetis N.V. upon conversion of the first tranche of Curetis Convertible Notes subscribed for by Yorkville to settle any excess beyond the First Tranche Share Issue Cap will be issued pursuant to the 10% authorization granted at Curetis N.V.'s 2019 AGM, which designated Curetis N.V.'s management board, subject to the approval of Curetis N.V.'s supervisory board, as the corporate body authorized to issue shares and/or grant rights to subscribe for shares in relation to general capital raising(s) and to limit or exclude pre-emption rights relating thereto. The Company may thereafter be required to seek from its shareholders further authorizations to issue additional shares upon conversion of subsequent tranches of notes and exercise of Warrants prior to the funding of such subsequent tranches, based upon certain coverage requirements specified in the Yorkville Agreement.

Under the Yorkville Agreement, the number of Warrants issued with subsequent tranches of Curetis Convertible Notes shall be equal to 25% of the aggregate principal amount of such Curetis Convertible Notes divided by the relevant Warrant exercise price, as described below. Each Warrant entitles the holder to one share of Curetis N.V. at the specified exercise price. Accordingly, if all Warrants issued with a tranche of Curetis Convertible Notes are exercised, the aggregate proceeds of such Warrants would be equal to approximately 25% of the aggregate principal value of the related Curetis Convertible Notes.

The key terms of the Curetis Convertible Notes and Warrants under the Yorkville Agreement as currently in place between Curetis N.V. and Yorkville are described below, as well as conditions to the funding of a tranche of Curetis Convertible Notes, information about certain undertakings made by Yorkville, and certain other information.

Curetis Convertible Notes

The Curetis Convertible Notes are issuable at a subscription price per note equal to 96% of their principal amount. A commitment fee of 4% of the aggregate principal amount of the relevant Curetis Convertible Notes is payable to Yorkville by deducting such fee from the aggregate subscription price of those notes.

Each Curetis Convertible Note has a maturity of 12 months from its date of issuance. Curetis N.V. has the right to extend such maturity by an additional 12-month period, while paying a cash fee equal to 5% of the principal amount of the relevant Curetis Convertible Notes. The maturity period can be extended up to four times, provided that the resulting extended maturity date shall exceed the maturity of the indebtedness of Curetis under the EIB Finance Contract and the extension fee is paid.

The Curetis Convertible Notes shall not accrue interest, except in the case of an event of default under the notes, in which case the Curetis Convertible Notes shall accrue default interest at a rate of 15% per annum until the earlier of the date that the event of default is cured or the date on which the Curetis Convertible Notes have been fully converted or redeemed.

Curetis Convertible Notes may be converted at any time until they are fully redeemed. Conversion rights are limited to the number of Curetis Shares that are authorized, available and approved for issuance during the period from the moment it has insufficient Curetis Shares authorized, available and approved for issuance for one time coverage for the conversion or exercise of the outstanding Notes and Warrants until the extraordinary General Meeting at which the additional authorizations to issue Curetis Shares are requested. Upon conversion of one or more Curetis Convertible Notes into Curetis Shares, the number of Curetis Shares will be calculated by dividing the aggregate principal amount of the relevant Curetis Convertible Notes by 93% of the lowest daily volume weighted average price of the Curetis Shares on Euronext in Amsterdam over the 10 trading days prior to the conversion date. The number of Curetis Shares to be issued upon a conversion of Curetis Convertible Notes is subject to a maximum specified by Curetis N.V. in its request to Yorkville for the disbursement of the tranche of such Curetis Convertible Notes. Any excess entitlement on the basis of the conversion ratio will be settled in cash unless Curetis N.V. elects to settle such excess in Curetis Shares.

Curetis Convertible Notes may be freely transferred, except to retail investors, and subject to compliance with applicable securities laws. The Curetis Convertible Notes contain anti-dilution protection, which protects the holder of the security from equity dilution resulting from later issues of shares at a lower price or value than that provided for in the security. The protection in the Curetis Convertible Notes takes the form of tying the conversion price of the Curetis Convertible Notes to the prevailing market price of the underlying Curetis Shares, as described above, so that changes to the Share price due to Share issuances, Share splits or other potentially dilutive events will result in a corresponding change in the number of Curetis Shares issuable upon conversion of a Curetis Convertible Note.

The Curetis Convertible Notes are not and will not be listed or admitted to trading on any financial market.

Conditions to the issue of a tranche of Curetis Convertible Notes

The issuance of a tranche of Curetis Convertible Notes is subject to certain conditions:

- no material adverse change shall have occurred in the assets or financial or trading position of Curetis N.V. with a net adverse impact of €5 million;
- no event of default or event or circumstance constituting an event of default if not cured within the applicable cure period is in existence;
- no suspension of trading of the Curetis Shares on Euronext in Amsterdam shall have occurred during the 90 days preceding the request for the disbursement of a tranche;
- the closing price of the Curetis Shares on the day prior to it sending the request for the disbursement of a tranche shall be €3.00 per Share or greater;
- the combined average daily value of the Curetis Shares on Euronext in Amsterdam and Euronext in Brussels during the week prior to the request for the disbursement of a tranche shall be €150 thousand or greater; and
- upon each disbursement request, Curetis N.V. shall have at least (a) two times coverage of Curetis Shares authorized, available and approved for issuance upon conversion of the maximum amount of Curetis Convertible Notes of the tranche to be issued and any other outstanding Curetis Convertible Notes (calculated as if the conversion occurred on the date of the request for disbursement of the tranche); and (b) one time coverage of Curetis Shares authorized, available and approved for issuance upon exercise of the maximum number of Warrants to be issued.

A holder of Curetis Convertible Notes may require Curetis N.V. to redeem all or any of its notes if Curetis N.V. fails to issue new Curetis Shares in accordance with the terms of the Yorkville Agreement or if an event of default, as described below, occurs which has not been cured within 10 calendar days. Unless converted or previously redeemed, Curetis Convertible Notes will be redeemed at 100% of their principal amount plus interest, if any, on their maturity date.

Restrictions

The Yorkville Agreement provides for certain covenants applicable to Curetis N.V., including most importantly in relation to: (i) compliance with applicable law, (ii) the maintenance of corporate existence, insurance of assets and payment of taxes, (iii) not engaging in mergers whereby Curetis N.V. is the disappearing entity without prior approval, (iv) not effecting major asset disposals, (v) not declaring dividends, (vi) not granting security for indebtedness (subject to certain exceptions) when Curetis Convertible Notes are outstanding, (vii) incurring further indebtedness (subject to certain exceptions, including for incurring indebtedness under the EIB Finance Contract), (viii) participating in variable rate equity financing transactions (such as an issue of Curetis Shares under the GCF Equity Facility) from 30 days prior to the request for the disbursement of a tranche of Curetis Convertible Notes until the 20th business day following the redemption or conversion of such Curetis Convertible Notes.

Events of default

The Yorkville Agreement further provides for certain events of default in respect of Curetis N.V., including most importantly in relation to: (i) failure to repay principal under the Curetis Convertible Notes when due; (ii) failure to comply with the covenants, (iii) failure to pay for the cash settlement of Warrants when due; (iv) the impossibility for any Curetis Convertible Notes to be converted; (v) the delisting or suspension of the Curetis Shares from Euronext in Amsterdam (except for temporary suspensions); (vi) representations or warranties of Curetis N.V. (to the effect that it is in compliance with applicable money laundering, sanctions, anti-bribery and similar laws, is not in violation of its contractual obligations or its by-laws, that its financial statements give a true and fair view of its financial position, and similar matters) being materially incorrect or misleading; (vii) failure to pay other indebtedness when due; (viii) voluntary discontinuance or liquidation of the business or insolvency proceedings being instituted; (ix) the failure to comply with judgements for the payment of money; and (x) failure to issue Curetis Shares upon conversion of Curetis Convertible Notes when due under the Yorkville Agreement.

Investor's commitments

Pursuant to the Yorkville Agreement, from the date of the agreement until the full conversion and / or redemption of all outstanding Curetis Convertible Notes, Yorkville covenants and undertakes:

- not to request any seat on Curetis N.V.'s management board or the Curetis N.V.'s supervisory board;
- either alone or acting in concert, not to hold at any time a number of shares higher than 4.99% of the outstanding number of Curetis Shares; and
- not to send any conversion notice or exercise notice for any Curetis Convertible Notes or Warrants if a prospectus would be required for the admission to listing and trading of the Curetis Shares to be issued upon such conversion or exercise, until such prospectus has been approved by the Dutch Authority for the Financial Markets.

Assumption by OpGen

OpGen has agreed to assume the Curetis Convertible Notes as a condition to closing the Transaction, and to replace the conversion feature of the Curetis Convertible Notes to be convertible into OpGen Common Stock. This, however, remains subject to OpGen, Yorkville and Curetis N.V. entering into a new facility agreement reflecting the same. As at the date of this proxy statement/prospectus, no such new facility agreement has been entered into between OpGen, Yorkville and Curetis N.V.

Curetis' Products

Unyvero Platform

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

Unyvero Platform and System Components

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

Figure 1: Unyvero Platform

The Unyvero L4 Lysator

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

The Unyvero C8 Cockpit

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

The Unyvero A50 Analyzer

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

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

Workflow

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

Unyvero A50 Application Cartridge Portfolio

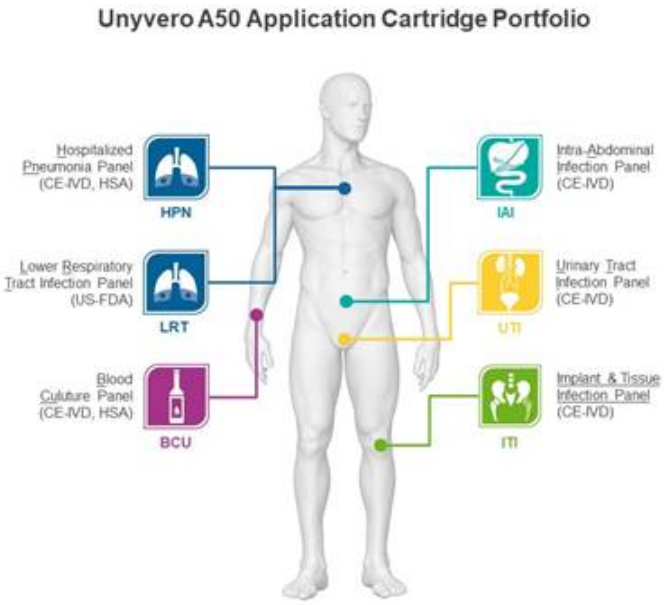


Figure 3: Current available Application Cartridges

The HPN and LRT Application Cartridges

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

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

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

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

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

The LRT Application Cartridge was launched in the United States in April 2018. It is an FDA cleared Application Cartridge for the fully automated detection of 46 targets, consisting of 36 microorganisms and 10 antibiotic resistance markers, for lower respiratory tract infections and severe cases of pneumonia with a total of 29 PCR assays combined in eight multiplexed PCR reactions. Although similar in most respects to the HPN Application Cartridge, the LRT differs from the HPN in its pathogen reporting due to FDA reporting requirements. In accordance with *De Novo* request that was granted by the FDA in April 2018, the initial label claim covers the use of LRT with tracheal aspirate samples only and has cleared 19 pathogens as well as 10 antibiotic resistance marker assays. The LRT BAL Application Cartridge for BAL samples was cleared by FDA in December 2019.

The ITI Application Cartridge

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

The BCU Application Cartridge

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

The IAI Application Cartridge

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

The UTI Application Cartridge

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

Ares Genetics' NGS and Bioinformatics Services for Molecular Microbiology

In August 2019, Ares Genetics opened a specialized service laboratory offering next-generation AMR testing services with an initial focus on infection control, AMR epidemiology and surveillance, clinical research and pharmaceutical anti-infectives R&D. All services are based on NGS and Curetis' proprietary, AI-powered antimicrobial resistance database ARESdb and the ARES Technology platform for data interpretation.

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

Industry & Market

Overview

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

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

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

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

The Molecular Diagnostics Market

Size of the Molecular Diagnostics Market

Based on market research reports, the global molecular diagnostics market is projected to reach $11.5 billion by 2023 and presents a significant share of the total IVD market. Other segments in the IVD market include immunoassays, diabetes, clinical chemistry, point of care, hematology, (culture-based) microbiology, or coagulation. According to Marketsandmarkets: Molecular Diagnostics Market (2018), the MDx market is growing rapidly and it is expected to grow from $7.7 billion in 2018 with a CAGR of 8.4% globally to $11.5 billion in 2023, North America represents the largest part of the market with 44% of the total, followed by Europe with 26% and Asia Pacific with 22% of the total.

Molecular Diagnostics Market by Application

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

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

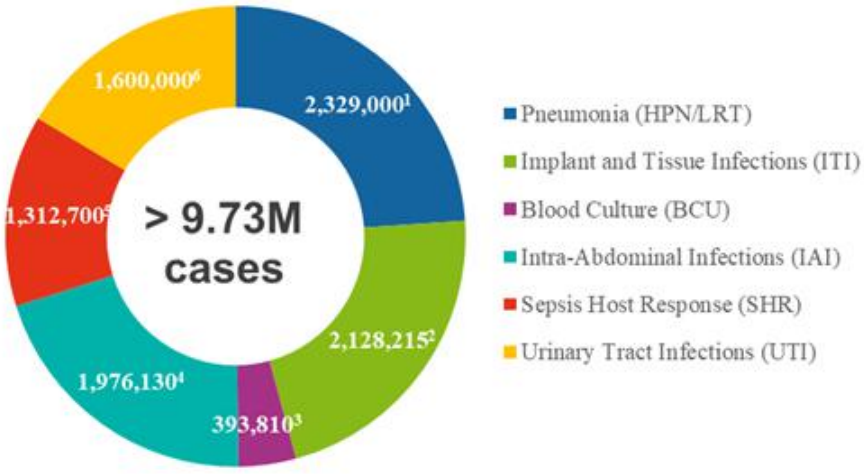


Figure 4: Total addressable market (United States and Europe) by Unyvero Products on the market or in the R&D pipeline

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

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

The Molecular Diagnostics Market by Customer

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

The Molecular Diagnostics Market by Technology

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

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

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

Competition

Unyvero System

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

- Based on its corporate market analysis, Curetis believes that due to the proprietary lysis technology its Unyvero Platform is able to process a broader variety of sample types than competing platforms. In most cases, no labor or time intensive manual sample preparation is necessary and even difficult and blood-contaminated native samples can be processed. Furthermore, the Unyvero Platform is CE-IVD-marked for a variety of samples including sputum, bronchoalveolar lavage, tracheal aspirate, exudate, catheter tip, pus, sonication fluid, synovial fluid, swab and tissue. Further samples such as blood, urine, stool and formalin-fixed paraffin embedded tissues present further options for extending the variety of samples for future applications. Fresh or frozen samples and also samples that have been stored in different media can be processed easily on the Unyvero Platform. As the lysis is integrated into the workflow, hands-on time and potential handling errors are significantly reduced.

- What also sets apart Curetis' Unyvero Platform is its high multiplexing capability based on end-point PCR, which allows for the execution of eight independent multiplex PCR reactions simultaneously. Therefore, Curetis can identify a broad range of microorganisms and in addition a large variety of antibiotic resistance markers in a single run.

- Focusing on severe infectious diseases and having developed a HPN Application Cartridge, an ITI Application Cartridge, a BCU Application Cartridge, an IAI Application Cartridge and a UTI Application Cartridge and planning to develop further Application Cartridges in the severe infectious disease area, Curetis has a highly differentiated positioning in the market.

- Although several direct competitors have in the past three years started to develop and / or commercialize their own infectious disease tests, Curetis believes that the variety and breadth of its menu of cartridges targeting different infection areas positions it favorably to answer patient and customer needs.

- With the acquisition of the GEAR database from Siemens and its further development into ARESdb, Curetis also believes that it can increasingly differentiate its test panels through proprietary biomarkers for antibiotic resistance.

Unyvero Application Cartridges

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

Ares Genetics

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

Conventional Microbiology

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

Molecular Diagnostics – PCR

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

Molecular Diagnostics – NGS

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

AMR Databases & Bioinformatics Solutions

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

Curetis' Strategic Partnering, Collaboration and License Agreements

Collaboration Agreements with Pharmaceutical Companies (Curetis GmbH)

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

Acumen (Curetis GmbH)

In October 2015, Curetis and Acumen Research Laboratories Pte Ltd., Singapore, or Acumen, entered into two separate collaboration agreements. First, a non-exclusive patent license and research collaboration agreement, under which Curetis has obtained a limited, royalty-bearing, non-exclusive, non-transferrable, non-sublicensable license to Acumen's proprietary sepsis biomarker panel for detection of sepsis host response in blood samples. Under this agreement the parties further agree to a research and development collaboration, in which Acumen is expected to further develop its technology underlying the license and Curetis is expected to develop products based on such technology and develop a novel sepsis host response Application Cartridge that the parties will jointly validate in a series of clinical studies in Singapore, Germany and possibly the UK. It is envisaged that Curetis becomes the manufacturer of the sepsis host response Application Cartridge, subject to an up-front one-time payment €480,000 by Curetis to Acumen and a high single-digit royalty percentage on net sales to be paid to Acumen for all such sepsis host response sales except for the territories where Acumen is the exclusive distributor of Unyvero products. (For further information, see below the section titled " *Indirect Sales"*). The agreement is set to expire upon the expiration of the last claim of any of the relevant patents, provided that it is not terminated by one of the parties with 12 months prior written notice.

Second, a distribution agreement under which Acumen has become the exclusive distributor of Unyvero Systems and HPN, BCU and ITI Application Cartridges and possibly future Application Cartridges in Singapore, Malaysia, Thailand and Indonesia. Both parties at a later point may mutually agree to amend the agreement to include additional territories of the ASEAN region. Under the terms of the agreement, Acumen is subject to certain minimum purchase commitments for the Unyvero Systems and the Application Cartridges per year and currently terminates on February 6, 2021. The agreement provides an initial three-year term, which shall be automatically extended for one year, and currently terminates on February 6, 2021, provided that it is not terminated by one of the parties with six months prior written notice. During that period, Acumen has exclusive rights to market, sell and distribute all Unyvero products in the respective territories. In return, Acumen needs to commit to annual minimum purchases of Unyvero systems as well as Application Cartridges. Transfer prices for the Unyvero Systems and Application Cartridges are defined and reflect typical MDx industry 30% to 40% distributor margins on the consumable sales. In case Acumen fails to meet its annual minimum commitments fixed in the contract, Curetis has the right to either terminate the agreement in its entirety, or to terminate Acumen's territorial exclusivity. The agreement also includes a standard change of control provision, allowing for termination of the agreement in the event of a change in control of either party.

Beijing Clear Biotech (Curetis GmbH)

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

Under the agreement with Curetis, BCB is responsible for conducting and implementing, as well as fully funding, comprehensive NMPA clinical trials of the Unyvero System and the HPN and ITI Application Cartridges according to NMPA guidelines. Beijing Clear Biotech shall act as direct contact for the Beijing NMPA and is obligated to file the Unyvero Platform NMPA registration as Curetis' Chinese representative. Curetis is obligated to fully support Beijing Clear Biotech in obtaining NMPA clearance by providing its expert knowledge. Further, Curetis shall compensate Beijing Clear Biotech for certain milestone achievements, consisting of (1) initiation of up to three clinical trial sites as marked by first patient enrolment and (2) regulatory approval by NMPA of the Unyvero System and the HPN and ITI Application Cartridges. Curetis shall be responsible for the labelling of instruments and consumables according to the requirements of the NMPA during the clinical trial and after the approval.

BCB will become the exclusive distributor for Unyvero Systems and HPN and ITI Application Cartridges in greater China. BCB is responsible for the local marketing which is to correspond with Curetis' global marketing strategy. The marketing activities of Beijing Clear Biotech shall include marketing with hospitals as well as with physicians and microbiology laboratories and/or core laboratory marketing. Curetis shall, upon BCB's request, provide support services, including technical and scientific training for the promotion, marketing and distribution of the products as well as the provision of second-level technical support. BCB has committed to annual minimum purchases of Unyvero Systems as well as Application Cartridges. Transfer prices for the Unyvero Systems and Application Cartridges are defined and reflect typical MDx industry 30% to 40% distributor margins with certain further volume discounts on the consumable sales. The agreement may be terminated upon written notice by either party in the event of a breach by the other party under the terms of the agreement and its failure to remedy that breach within 30 days. If BCB fails to meet its annual minimum commitments fixed in the contract, Curetis has the right to either terminate the agreement in its entirety, or to terminate BCB's territorial exclusivity.

On April 1, 2016, Technomed (Hong Kong) Ltd assumed the role of BCB as Curetis' distributor in Hong Kong.

Under the agreement, BCB committed to a minimum purchase, over an eight year period from the first NMPA approval, of more than 360 Unyvero A50 Systems as well as over 1.5 million Unyvero Application A50 Cartridges for the duration of the agreement. This commitment would, based on agreed transfer price levels, lead to potential revenues to Curetis of over €30 million annually in years six to eight of commercialization in China in addition to potential cumulative revenues of more than €60 million for years one to five of commercialization in China, as had been agreed previously.

Further, the parties agreed to waive certain milestone payments otherwise payable by Curetis to BCB, consisting of payments due upon (1) initiation of up to three clinical trial sites as marked by first patient enrolment and (2) regulatory approval by NMPA of the Unyvero System and the HPN and ITI Application Cartridges. These waivers represent a total savings to Curetis of €600 thousand over the next one to three years. The contract also contains certain termination provisions upon a change in control of Curetis, with capped termination payments that will gradually reduce over years 5 through 7 of the agreement, since its original effectiveness.

MGI (Curetis GmbH & Ares Genetics)

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

Under the terms of the MoU, MGI would provide hardware and chemistry integration and develop an automated workflow as well as manufacture the targeted NGS assays. MGI would also be in charge of validating the assay and seeking regulatory approval as needed. Curetis and Ares Genetics would provide expertise in sample preparation technologies, panel design and NGS sequencing assay design using its ARES*db*. Ares Genetics would also develop a data interpretation application that automates the bioinformatics analysis of the NGS data and supports the interpretation and visualization of NGS results on pathogens and antibiotic resistance markers detected by the assay to facilitate the deployment of the assay in the clinical routine.

On January 10, 2018, Curetis entered into a supply and authorization agreement with MGI to advance its strategic alliance in NGS-based infectious disease testing. Curetis and MGI aim to integrate Curetis' patented Unyvero L4 Lysator-based sample preparation technology and MGI's NGS next generation sequencing technology to develop a fully automated workflow that allows the processing of any type of native clinical sample with the subsequent NGS-based detection of microbial pathogens and genetic markers for antibiotic resistances. Under the terms of the agreement and subject to certain conditions, including the first commercial order for the products to be supplied by Curetis, as described above, and specific agreement on pricing and the relevant commercial terms, MGI reimbursed Curetis for supporting the workflow integration and transferring this advanced technology, in a total amount of less than €100,000. No further amounts are expected under this agreement in the foreseeable future.

Sandoz (Ares Genetics)

In December 2018, Ares Genetics entered into a collaboration agreement with Sandoz International GmbH, or Sandoz, to leverage Ares Genetics' database on the genetics of antibiotic resistance, ARES*db*, and the ARES Technology Platform for Sandoz' anti-infective portfolio.

Under the terms of the agreement, which has an initial term of 36 months and is currently scheduled to terminate December 31, 2021, Ares Genetics and Sandoz intend to develop a digital anti-infectives platform, combining established microbiology laboratory methods with advanced bioinformatics and artificial intelligence methods to support drug development and life-cycle management. The collaboration, in the short- to mid-term, aims to both rapidly and cost-effectively re-purpose existing antibiotics and design value-added medicines with the objective of expanding indication areas and to overcome antibiotic resistance, in particular with regards to infections with bacteria that has already developed resistance against multiple treatment options. In the longer-term, the platform is expected to inform the development of novel anti-infectives that are less prone to encounter resistance and thereby preserve antibiotics as an effective treatment option.

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

Qiagen (Ares Genetics)

On February 18, 2019, Ares Genetics and Qiagen GmbH, or Qiagen, entered into a strategic licensing agreement for Ares*db* and ARESтools, in the area of antimicrobial resistance (AMR) research. The agreement has a term of 20 years and may be terminated by Qiagen for convenience with 180 days written notice.

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

Under the terms of the agreement, Qiagen, in exchange for a moderate six figure up-front licensing payment, has received an exclusive license to develop and commercialize general bioinformatics offerings and services for AMR research, based on Ares Genetics' database on the genetics of antimicrobial resistance, Ares*db*, as well as on the ARES bioinformatics AMR toolbox, ARESтools. Under the agreement, the parties agreed to a mid-single digit percentage royalty rate on Qiagen net sales, which is subject to a minimum royalty rate that steps up upon certain achieved milestones, which is payable to Ares Genetics. The parties also agreed to further modest six figure milestone payments upon certain product launches.

Global leading IVD corporation (Ares Genetics)

On September 16, 2019, Ares Genetics entered into a multi-phase partnership with an undisclosed leading global in vitro diagnostics corporation, the Partner, to jointly develop diagnostic solutions for infectious disease testing, based on next-generation sequencing, or NGS, technology. Ares Genetics and the Partner also entered into and R&D option agreement for the first phase of the partnership. Ares Genetics received a €500,000 option fee. The initial term of the R&D collaboration is 10 months, ending July 13, 2020. The Partner may terminate, at any time and for any reason, with 30 days' written notice.

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

Under the initial agreement, the Partner will fully fund Ares Genetics' R&D activities for the genotypic and phenotypic characterization of additional bacterial strains to augment ARESdb and the development of optimized algorithms for predicting antibiotic resistance. Furthermore, in return for an undisclosed up-front option fee, the Partner obtained a three-month right for first negotiation for an exclusive human clinical diagnostic use license to ARES*db* and the ARES Technology Platform. The option can be exercised during the term of the agreement plus three months.

Acquisition Agreements

The Gyronimo Acquisition (Curetis GmbH)

In December 2016, Curetis acquired the real-time qPCR-based Gyronimo platform from joint owners Carpegen GmbH, Muenster, Germany, or Carpegen, and Systec GmbH, Muenster, Germany, or Systec. Integrating Gyronimo into the Unyvero Platform as the Unyvero A30 *RQ* analyzer module for infectious disease testing allows Curetis to expand its product portfolio as well as partner with companies with appropriate multiplex assay menus in infectious diseases, cancer or other indications that are in need for such platform. Under the terms of the agreement, Curetis acquired all Gyronimo platform assets, including fully functional prototype systems and the entire intellectual property portfolio comprised of several patent families pending and a key patent granted in the United States, Canada and China, and allowed in Europe. Curetis obtained exclusive license to Gyronimo know-how and a non-exclusive license to general background know-how of Carpegen and Systec. Curetis was granted exclusive worldwide rights to the platform, including the right to sublicense, partner or sell it, with an exemption for Carpegen and Systec in dental testing as well as in environmental and food safety testing. In exchange for these assets, Curetis made a one-time up-front cash payment of €5 million. In addition, Carpegen and Systec are eligible for two discrete, one-time milestone payments upon platform and first cartridge CE marking and FDA clearance, respectively, totaling up to €2.5 million. There will also be the potential for a royalty-based earn-out at an industry-typical mid-single digit percentage rate, up to a cumulative maximum amount of €9.0 million. In the case of a non-commercialization decision by Curetis, the Gyronimo platform (now Unyvero A30 *RQ* platform) would need to be offered to Carpegen and Systec at the current value.

GEAR Asset Acquisition (Curetis GmbH, Ares Genetics GmbH)

In September 2016, Curetis GmbH as acquirer entered into an asset acquisition agreement with Siemens Technology Accelerator GmbH, Munich, Germany, or STA, pursuant to which Curetis acquired sole commercial rights from STA to the GEAR platform and database with all its content, numerous GEAR-related patents and patent applications, as well as all corresponding know-how. Curetis received sole worldwide product development and commercial rights, including the right to sublicense in the fields of human and animal diagnostics as well as food safety testing. As a result of this transaction, Curetis secured the sole rights to leverage the GEAR assets in collaboration with pharmaceutical companies for the development of novel antimicrobial drugs for human and animal health. As consideration for these assets, STA received a low single digit million euro upfront payment from Curetis, and Curetis shall make milestone payments for products including GEAR biomarkers upon first CE-IVD-marking and first FDA approval (or similar regulatory clearance), respectively as well as royalty payments to STA in industry-typical low to mid-single digit percentage ranges on future products based on use of the GEAR platform or GEAR biomarkers and double digit percentages on sub licensing income. The aggregate future potential milestone payments for the first CE-marked and FDA-approved products based on the GEAR assets is a maximum amount of €750,000. Following the acquisition of GEAR from STA, Curetis in 2017 transferred all assets to Ares Genetics. Ares Genetics since then has integrated GEAR into ARESdb, Ares Genetics' proprietary database on the genetics of AMR with significantly increased pathogen and drug coverage and significantly expanded functionality compared to the original GEAR platform and database.

Marketing and Sales

Customers

In 2016, Curetis' commissioned an EU commercial team of direct sales, marketing and customer service personnel to market the Unyvero System. Additionally, in the United States, Curetis hired an executive core team in 2016 and between the second half of 2017 and the second quarter of 2018 has built out its commercial organization to a total of 25 staff by June 30, 2018. In December 2018, Curetis revised its sales channel strategy for ex-U.S. markets and switched to an indirect distributor driven sales model. The commercial team at Curetis GmbH was streamlined accordingly to provide optimal support for distribution partners and as of today consist of six experts for marketing, customer service and support, and business development. The general sales approach does not substantially differ between direct and indirect selling and Curetis trains its distribution partners accordingly.

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

Sales Process

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

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

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

In the more developed markets of the EU and the RoW, additional customer segmentation reflects the business opportunity per customer / institution and is linked to size of the hospital reflected in the number of beds available at the institution. In the IVD market, hospitals with more than 500 beds generate approximately 80% of the Curetis' revenues but represent only 20% of the Curetis' customer base in any given period. Therefore, the sales strategy is based on a key account management approach, initially only targeting large hospitals with clear focus on departments like pneumology, large ICUs or orthopedics wards depending on the particular Application Cartridge being promoted.

Accordingly, the sales activities target university or teaching hospitals and hospital chains with more than 300 beds and greater in the United States. In the United States, Curetis intends to target 700-1,000 relevant hospitals. In RoW Curetis via its distribution partners currently aims to address about 2,000 relevant target hospitals with 500 beds and greater or is striving for future indirect channels. The focus is on high-volume consumable orders (Application Cartridges and other consumables) instead of driving revenues and profits through hardware placements (Unyvero System installations). Consequently, Curetis and its distribution partners aim to optimize the utilization of each placed hardware unit rather than solely maximizing the installed base of instruments. Therefore, Curetis, with its tests primarily targeting in-patients (hospitalized) with severe infections, is focusing its sales and commercialization efforts on laboratories in hospitals and independent laboratories serving larger hospitals.

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

Investment in brand awareness

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

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

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

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

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

Distribution Channels

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

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

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

Direct Sales Markets

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

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

Direct Sales U.S. Market

Curetis USA completed trial enrolment for the LRT Application Cartridge in June 2016. Top line data was reported in October 2016 and the FDA *De Novo* request was submitted on January 5, 2017. This was followed by a submissions issue meeting with the FDA in April 2017 as well as interactive review ongoing with the FDA, culminating with FDA clearance on April 3, 2018. Curetis launched the Unyvero System and the LRT Application Cartridge at the ASM Microbe 2018 Congress in the United States in June 2018.

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

Despite the revised strategy communicated in December 2018 and the re-organization Curetis USA Inc. in January 2019, which has reduced the size of the team in the United States to 10 full time staff as of November 8, 2019, with the majority being based in the field, Curetis USA Inc. has built a solid funnel of target accounts and opportunities that spans numerous thoroughly vetted accounts and several near-term opportunities for additional evaluations and some near-term commercial account conversion opportunities. As of September 30, 2019, Curetis USA Inc. had an installed base of 15 Unyvero Analyzers across the United States and in different types of hospitals and labs plus an additional 20 Analyzers for FDA trials and clinical studies. Clinical and commercial evaluations are ongoing at multiple of these accounts and first evaluations have concluded in late 2019. The expectation for 2020 is to increase the installed base of Unyvero Analyzers further with a continuously growing proportion of installations at commercial accounts towards the end of 2019 and into 2020.

Curetis plans to further develop its commercial organization in the United States in line with available funds, the market adoption of the Unyvero Platform and its growing product portfolio.

Indirect Sales Markets

Curetis uses its standard distribution agreement template for most of its Unyvero distributors, which specifies the particular Unyvero product and the respective distribution territory. The distribution agreements typically contain provisions for exclusive distribution within a particular territory and provide for a three to five-year term. During that period, the distributor has exclusive rights to market, sell and distribute all Unyvero products under this agreement. In return, each distributor needs to commit to annual minimum purchases of Unyvero Systems as well as Application Cartridges. Transfer prices for the Unyvero Systems and Application Cartridges are defined and reflect typical MDx industry distributor margins on consumable sales. If a distributor fails to meet its annual minimum commitments fixed in the contract Curetis has the right to either terminate such agreement in its entirety, or to terminate said distributor's territory exclusivity in such country. Each of these agreements can be extended by mutual agreement between the parties. Furthermore, the agreements also contain typical change of control provisions which comprise a merger of the company, the sale of all assets or the liquidation of the company.

As of October 31, 2019, Curetis has entered into distribution agreements with 18 distributors covering 43 countries. There are several distribution agreements in place for the following European countries:

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

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

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

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

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

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

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

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

After-sales support and maintenance

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

Reimbursement

In the IVD market, sales volumes and prices of innovative products will depend in large part on the availability of coverage and reimbursement from third-party payers, which includes depending on public funding through governmental programs, private insurance plans and workers' compensation plans. In most healthcare settings, reimbursement schemes are complex, processes to achieve reimbursement for new technologies is tedious and time consuming and payers may deny coverage or reimbursement. As a result, even though a new product may have been cleared for commercial distribution, it may find limited demand for the product until reimbursement approval has been obtained from governmental and private third-party payers. However, specific reimbursement codes for laboratory tests are in most countries only applicable for out-patients healthcare. In addition, some public funding is already available in most countries for certain established tests and is often technology specific, thus code stacking or cross-walking and using corresponding codes is quite usual to overcome challenging reimbursement situations.

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

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

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

Scientific Advisory Boards

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

Manufacturing

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

Unyvero System

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

So far, no decision has been made on the selection of the OEM provider for the series production of the Unyvero A30 *RQ* systems.

Application Cartridges

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

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

Manufacturing Agreements (Curetis GmbH)

Zollner

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

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

Scholz

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

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

Under the framework agreement with Scholz , Curetis in 2018 also commissioned several single- and multi-cavity injection models for parts of the Unyvero A30 *RQ* cartridge, namely molds for 'Frame bottom', 'Frame top', 'PCR Disc', 'Drive Ring', 'Switching Wheel bottom', 'Switching Wheel top', 'Sealing Ring switching wheel' und 'Sealing Ring PCR disc'. These injection molds were developed, manufactured and put into service by Scholz over the course of 2018 and 2019 under the same terms as described above for the injection molds for the Unyvero A50 cartridges.

Contexo

On April 30, 2010, Curetis and Contexo entered into a collaboration and contract manufacturing agreement for the manufacturing of a pilot line and the automated Application Cartridge manufacturing line modules. Under the terms of the agreement, Curetis receives drawings as well as comprehensive documentation of the automated manufacturing line modules and components. Curetis has acquired ownership in all of the construction documents of the pilot line whereas the copyright rights and all rights related to the Contexo index machine base technologies (“Rundtakt- und Längstakt-Basistechnologien”) remain with Contexo.

Supply Agreements (Curetis GmbH)

PCR Master Mix Supply Agreement

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

Supply Agreements (Ares Genetics GmbH)

Qiagen GmbH (Qiagen) – Laboratory Devices and Reagents

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

MGI Tech Co. Ltd. (MGI) – Laboratory Devices and Reagents

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

Curetis' Product Development & R&D Pipeline

Unyvero Product development phases

Curetis' Unyvero product development follows a systematic stage-gated process, as shown in the figure below, of five phases under its ISO 13485:2016 certified Quality Management System:

Figure 5: Curetis product development process

The time to develop and market a molecular diagnostics product varies and depends on many factors such as the multiplexing level, amount of different sample types, the targeted clinical indication and expected performance in terms of clinical sensitivity, as well as clinical specificity. On average, the development of a new Application Cartridge through to market launch as CE-IVD-marked Application Cartridge in the EU takes 12 months or longer. Development costs are to some degree dependent on the Application Cartridge complexity and regulatory pathway. Once the new IVD Regulation repealing the IVD Directive and the Commission Decision 2010/227/EU will have become applicable in 2022, such processes are expected to take even longer, e.g. from 12 to 18 months.

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

Curetis' commitment to clinical evaluation is reflected in several additional clinical projects targeting a total of several thousand patient samples, which are either currently enrolling or in preparation:

- a new FDA clearance study for the IJI Application Cartridge;
- geographic expansion of studies into France, the UK, China, the ASEAN region and other countries;
- companion diagnostic clinical trial with Biotest AG, or Biotest, for PEPPER Pentaglobin® trial;
- a systematic evaluation of the properties and effects of Curetis' Unyvero System, also known as a health technology assessment, or HTA, in the UK; and
- an interventional multi-center study using the HPN Application Cartridge in Switzerland (Basel, FLAGSHIP Study).

Application Cartridges for the Unyvero A50 Analyzer

The Unyvero LRT BAL Application Cartridge

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

The Unyvero IJI Application Cartridge

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

The SHR Application Cartridge

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

Curetis' management expects that an Application Cartridge for the early diagnosis of sepsis will make a difference in a significant proportion of cases and, as it can be performed within the first hours of hospital admission, may also help to save significant costs. Curetis estimates the sepsis host response market to be larger than the microorganism ID in blood cultures addressed by its BCU Application Cartridge. Based on CDC and ECDC data from 2018 regarding market potential, around 2.3 million patients would be eligible for a SHR test representing a total available market in the United States and EU of several hundred million Euros depending on price points. As Sepsis Host Response testing is a complementary application, major cannibalization of the BCU Application Cartridge is not anticipated at the outset.

The Unyvero A30 RQ Analyzer

Figure 6: latest design concept of Unyvero A30 *RQ* Analyzer and its Application Cartridge; final product may differ

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

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

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

With its unique features, the Unyvero A30 RQ will lend itself to numerous applications in infectious disease testing but also in numerous indications that are beyond the commercial focus of Curetis, including cancer, genetic testing and companion diagnostics, as well as veterinary or food and environmental testing. Following its strategic shift to a more partnering-based strategy in December 2018, Curetis hence is seeking diagnostics industry partners to collaborate in the late stage development and commercialization of Unyvero A30 *RQ* and expects the platform to ready for partnering in 2020, funding permitting.

Ares Genetics – ARESupa – Universal Pathogenome Assay

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

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

Funding permitting, Ares Genetics further aims at developing and launching an ARESupa laboratory-developed test, or LDT, on native patient samples for human diagnostic use in indications in which current culture-based diagnostic practice is inherently challenging. The test would be offered through Ares Genetics own laboratories in in Vienna and potentially the United States and potentially partner laboratories in other geographies. Eventually, the development of an ARESupa IVD solution is envisaged. To this end, Ares Genetics in September 2019 entered into a multi-phase partnership with an undisclosed leading global in vitro diagnostics corporation to jointly develop diagnostic solutions for infectious disease testing based on next-generation sequencing technology. The companies signed an R&D and option agreement for the first phase of the partnership. In this phase, expected to take about 10 months, the partner will fully fund Ares Genetics' research and development activities for the genotypic and phenotypic characterization of additional bacterial strains to augment ARESdb and the development of optimized algorithms for predicting antibiotic resistance. Furthermore, in return for an up-front option fee of €500,000, the partner obtained a right of first negotiation for an exclusive human clinical diagnostic use license to ARESdb and the ARES Technology Platform for the term of the agreement plus three months.

Ares Genetics' R&D programs for the development of ARESupa are co-funded by non-dilutive public grants provided by the Vienna Business Agency, the Austrian Research Promotion Agency (FFG), and other institutions with a total co-funded volume of up to more than EUR 3 million in the period 2017-2021.

Regulation

In each of the countries in which Curetis markets its products, it must comply with local regulations affecting, among other things, design and product standards, packaging and labelling requirements and clinical validation. A summary of the most important regulations is set out below.

European Union

In the EU, Curetis is currently required to comply with the local rules and regulations, which implement the IVD Directive. The IVD Directive provides the regulatory framework for manufacturers who place IVD devices on the EU market. Each member state of the EU, each a Member State, is required to implement the IVD Directive into its national legislation.

Additional European Directives, Regulations and local rules have to be followed to be in compliance with the regulations. This includes the Directive Waste Electrical and Electronic Equipment (WEEE 2012/19/EC), the Directive on Packaging and Waste (2013/2/EC), Regulation of Registration, Evaluation and Restriction of Chemicals (REACH 1907/2006) and others.

CE Conformity Mark

In order to demonstrate compliance with the essential requirements of the IVD Directive and to obtain the right to bear the CE-conformity mark (without which Curetis' products could not be marketed as IVDs in Europe), each of Curetis' products must undergo a conformity assessment procedure, which procedure varies according to the type of device and its classification. For IVD devices not intended for self-testing and not covered in Annex II of the IVD Directive, the conformity procedure involves the manufacturer issuing an EC Declaration of Conformity, or a Conformity Declaration, based on a self-assessment of the conformity of its products with the relevant essential requirements of the IVD Directive and registering such Conformity Declaration with the governmental or regulatory body that is responsible for regulating medical devices in the relevant Member State, or the Competent Authority. The relevant Member State is usually the manufacturer's place of incorporation. For IVD devices covered in Annex II of the IVD Directive, a conformity assessment procedure requires notification to a Notified Body in the relevant Member State who must audit and examine the quality system of the manufacturer, and, in case of an IVD device covered by Annex II List A, also an examination of the design and validation of the device before approving the manufacturer's issuing of a certification demonstrating compliance with the relevant essential requirements of the IVD Directive.

Curetis' Unyvero Platform and all Unyvero Application Cartridges therefore were eligible for CE-IVD self-certification by Curetis. The only application which required a notification of Curetis' Notified Body (mdc medical device certification GmbH, Stuttgart) was the HPN Application Cartridge, as it includes Chlamydophila pneumonia, an Annex II List B organism. Based on a self-assessment of the conformity of these products with the relevant essential requirements of the IVD Directive, Curetis issued the respective Conformity Declarations and has registered its products with the German Competent Authority (DIMDI; German Institute for Medical Documentation and Information) as CE-IVD-marked IVDs for distribution in the EU over time, starting with the Unyvero Platform and the P50 Application Cartridge back in May 2012. With its ISO 13485 certification in good standing, Curetis is therefore entitled to bear the CE-conformity mark to the Unyvero Platform and the Unyvero Application Cartridges, which allows Curetis to market these products in the EU, as well as in additional countries recognizing CE-IVD-marked IVD devices. As part of its strategy, Curetis intends, in general, to seek CE-IVD-mark status for each of its assays so that they can be marketed in the EU and the key countries where the CE-IVD-mark is accepted.

The IVD Regulation entered into force on May 25, 2017 and will replace the IVD Directive after a transition period of five years after entry into force. CE-IVD-marking of Curetis products will remain valid until the end of this transitional period, after which both new and existing devices will need to comply with the requirements of the IVD Regulation. This also includes new clinical evidence requirements specific to the IVD sector which are also expected with respect to the way a device works to provide a diagnosis. Curetis' quality management system has already taken these requirements into account in its development process in principle, and Curetis therefore believes it is unlikely that the additional requirements for clinical evidence would significantly impact the Unyvero Platform or Curetis' Application Cartridges which are currently on the market or under development other than with a likely increase in time and resources needed to bring a product to market in the EU.

Under the IVD Regulation, all of Curetis' Application Cartridges products will require a conformity assessment by its Notified Body, as they are not considered a low risk class A device. The IVD Regulation also includes new labelling requirements, such as the deployment of unique device identification (UDI) labelling to allow and improve traceability of devices, e.g. to enhance the effectiveness of post-market safety related activities. As UDI labelling has already been implemented for the commercial launch of the Unyvero System and the LRT Application Cartridge in the United States, management believes that these new labelling requirements will have minimal impact on Curetis' other products.

As a manufacturer of CE-IVD-marked medical devices sold on the European market, Curetis must also maintain a vigilance system that enables it to notify relevant regulatory authorities of incidents which may lead to (or may have led to) death or serious injury/health consequences for individuals, or a recall of the relevant product. This includes obligations to submit reports to the relevant national Competent Authority (or Authorities) for recording and evaluation when incidents (comprising any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health) occur, for the dissemination of information which could be used to prevent a recurrence of the incident or to alleviate the consequences of such incidents, and where appropriate, by the implementation of a "Field Safety Corrective Action" to reduce the risk of death or serious injury associated with the use of the device (such as a product recall).

Research Use and Clinical Investigations

In the EU, subject to certain restrictions set out in the Active Implantable Medical Devices Directive (Directive 90/385/EC), the Medical Devices Directive (Directive 93/42/EC), the In-Vitro Diagnostic Medical Devices (Directive 98/79/EC) and its successor, on in-vitro diagnostic medical devices (Regulation (EU) 2017/746), respectively, and the local laws and regulations implementing these Directives in each Member State, devices without the CE-conformity mark may be used for clinical investigations, for example for the purposes of determining whether the particular device will meet the requirements of the IVD Directive (and when applicable the IVD Regulation) and the Medical Devices Directive.

United States

In the United States, IVDs are medical devices as defined in section 201(h) of the FD&C Act, and may also be biological products subject to section 351 of the Public Health Service Act 1944. Like other medical devices, IVDs are subject to premarket and post market controls as defined in the U.S. Code of Federal Regulations, including 21CFR820, Quality System Regulation. Clinical laboratories running IVDs are subject to the Clinical Laboratory Improvement Amendments of 1988, or CLIA.

Requirement for Premarket Notification or Approval

IVDs are classified in one of three classes (Class I, II or III) depending on risk and the extent of controls the FDA determines are necessary to reasonably ensure their safety and efficacy. The classification of an IVD determines the appropriate premarket process.

- Class I: general controls, such as registration, listing, labelling and adherence to quality system regulations; generally, exempt from the premarket notification (510(k)) requirement;

- Class II: general controls, and special controls such as performance standards, patient registries and/or post-market surveillance; generally subject to 510(k) requirements; and

- Class III: general controls; generally subject to PMA requirements.

Pursuant to the 510(k) process, a person who wants to market certain Class I, most Class II (or some Class III) devices intended for human use in the United States must submit a 510(k)-premarket notification to the FDA at least 90 days before marketing the device (unless the device is exempt from the 510(k) requirements). The FDA will then review the 510(k) premarket notification and determine whether the proposed device is "substantially equivalent" to a previously cleared 510(k) device, a device which has been reclassified from Class III to Class II or I, or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of PMA applications, referred to as a "predicate" device. The type of studies required to demonstrate substantial equivalence may include the following:

- in the majority of cases, analytical studies using clinical samples (sometimes supplemented by carefully selected artificial samples) will suffice;

- for some IVDs, the link between analytical performance and clinical performance is not well defined. In these circumstances, clinical information may be required. Where clinical information is required, the producer must (unless a relevant exemption applies) apply for an investigational device exemption ("IDE"), which would allow the investigational device to be used in a clinical study in order to collect safety and effectiveness data; and

- for microbiological multiplexed PCR based tests like the LRT application, the FDA issued a guidance document on August 27, 2014 (Guidance for Industry and Food and Drug Administration Staff: Highly Multiplexed Microbiological / Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices). Following this guidance, the sample set for the Curetis LRT application requires at least 1,500 prospective clinical patient samples to determine specificity.

In making its determination, the FDA compares the proposed device to the predicate device. If the two devices have the same intended use and the same technological characteristics, or the same intended use and different technological characteristics, but the information submitted to FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the predicate, the device may be cleared for marketing. 510(k) Submissions generally include, among other things, a description of the device, its intended use and its manufacturing, device labelling, medical devices to which the device is substantially equivalent, safety and biocompatibility information and the results of performance testing. Marketing may commence only when the FDA issues a clearance letter finding the proposed device to be substantially equivalent to the predicate. If the device is not found to be substantially equivalent, a reclassification process could be requested by the applicant. After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or any product modification that would constitute a significant change in intended use, requires a new 510(k) clearance or PMA. If the FDA determines that the non-exempt product does not qualify for 510(k) clearance the FDA must approve a PMA before the product can be marketed in the United States.

The FDA has implemented more stringent clinical investigation and PMA requirements for devices that are classified as Class III. Pursuant to the PMA process, the relevant person who wants to market the device in the United States would be required to provide clinical and laboratory data that establishes that the new device is safe and effective using clinical outcome measures rather than proving substantial equivalence to another legally marketed product or pre-amendment device. Information about the device and its components, device design, manufacturing and labelling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will inspect the device manufacturer's facilities for compliance with quality system regulation, or QSR, requirements, which govern design, testing, control, documentation and other aspects of quality assurance with respect to manufacturing. The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The PMA can include post-approval conditions including, among other things, restrictions on labelling, promotion, sale and distribution, or requirements to do additional clinical studies post approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labelling or its manufacturing process. After a device is cleared, or approved for marketing by the FDA, numerous and pervasive regulatory requirements continue to apply. These include compliance with, but are not limited to:

- regulation on registration of the manufacturer and listing of the IVD devices in the FDA database when starting commercial distribution;
- the QSR, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over and document manufacturing of their products;
- Part 11 compliance with FDA required e-records of documents in the manufacturer's quality system defined as "in scope";
- labelling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labelling;
- advertising and promotion in accordance with the requirements of the FD&C Act and its implementing regulations and FDA guidance, including FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- Medical Device Reporting regulation, which requires reporting to the FDA certain adverse experiences associated with the use of the product;
- complaint handling regulations designed to track, monitor and resolve complaints related to the Company's products;
- in some cases, on-going monitoring of the Company's products' performance and periodic reporting to the FDA of such performance results; and
- the federal Physician Sunshine Payment Act and various state laws on reporting remunerative relationships with healthcare customers.

If a relevant person wants to market a device in the United States and wants to test it in a clinical study in the United States prior to obtaining 510(k) or PMA approval, that person will have to obtain an approved IDE unless the device is exempt. An approved IDE allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data to support a PMA or 510(k) clearance application.

As new devices not equivalent to existing Class I or II devices will be classified into Class III regardless of risk, the FDCA was modified to establish the so called *De Novo* classification process for those cases where no suitable predicate device is available.

After submission of the *De Novo* request for classification, this process allows FDA to decide whether such new device should be classified as Class I, Class II without requiring a prior 510(k) submission. In case the FDA determines there is a suitable predicate device, or that the device falls under Class III and thus a PMA is required, the *De Novo* request will be declined and the submitting entity may subsequently submit a 510(k) or a PMA. If not, and if FDA comes to the conclusion that the new device meets the requirements for a Class I or Class II product with general or with special controls, it will then grant the *De Novo*, informing about the regulatory class, regulation name and product code, and the device may be legally marketed.

The FDA has granted Curetis' *De Novo* request for the Unyvero System and the Unyvero LRT Application on April 3, 2018 as a Class II device under product code QBH as a "Device to detect and identify microorganisms and associated resistance marker nucleic acids directly in respiratory specimens".

Curetis expects that future additional Unyvero Application Cartridges may be filed with the FDA as 510(k) submissions, however FDA may also require additional *De Novo* requests for new Application Cartridges. Although Curetis considers it unlikely, it cannot be excluded that future products have to undergo PMA approval processes. The FDA makes such determinations on a case-by-case basis. Curetis intends to request pre-submission meetings for future submissions if needed to, for example, discuss the appropriate regulatory pathway or clinical study details with the FDA.

Research Use Only in the United States, or RUO

In the United States, certain IVD products may also be sold (subject to certain restrictions) as research use only (RUO) products, without 510(k) clearance or PMA approval. Producers selling RUO IVD products must prominently label them: *For Research Use Only. Not for use in diagnostic procedures*.

Investigational Use Only, or IUO

In the United States, certain IVD products may also be sold (subject to certain restrictions) as IUO products, without 510(k) clearance or PMA approval. Certain IUO-labelled products are exempt from the IDE regulation. Any IUO product that is being shipped or delivered for product testing prior to full commercial marketing must be prominently labelled: "*For Investigational Use Only. The performance characteristics of this product have not been established*.".

Emergency Use Authorization, or EUA

Under section 564 of the FD&C Act, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological and nuclear (CBRN) threat agents when there are no adequate, approved, and available alternatives.

CLIA

CLIA establishes quality standards for laboratory testing and a certification program for clinical laboratories in the United States CLIA requirements vary according to the technical complexity in the testing process and risk of harm in reporting erroneous results. These regulations established three categories of testing on the basis of the complexity of the testing methodology:

- waived tests (these are tests that can be operated outside of specialized, dedicated laboratory environments and without the need for technically specialized and highly trained staff);
- tests of moderate complexity, and
- tests of high complexity.

Producers of IVDs apply for CLIA categorization of their IVDs during the premarket process. Under CLIA, laboratories performing only waived tests are subject to less regulation, whereas laboratories performing moderate or high complexity tests are subject to more stringent laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections, among other requirements.

Effective on April 13, 2018, FDA has categorized the LRT Application Cartridges for aspirate samples as well as the LRT BAL Application Cartridges for BAL samples as tests of moderate complexity.

Other Territories

In accordance with Curetis' commercialization strategy, Curetis will develop a country specific regulatory strategy for countries outside of the EU and the United States (including but not limited to China, Hong Kong, Taiwan, Singapore, Thailand, Indonesia, Malaysia, Russia, and the Middle East as well as potential further RoW markets going forward). Some of these target countries require samples from their local population to be included in clinical studies used to support product registration applications. Curetis with potential future collaboration and distributors, therefore, intends to conduct either individual national or even multinational clinical studies (which look at samples from each of the target countries, where possible) and multi-country regulatory auditing to gain maximum efficiency in product registrations in countries outside of the EU and the United States.

Regulation of End Users

In general, users of any diagnostic platform are required to respect local laws and regulations when providing healthcare services, including performing diagnostic activities. For example, in a number of jurisdictions an ISO15189 accreditation needs to be obtained on a test-by-test basis to qualify for reimbursement. The norm requires laboratories to have a Quality Management System. As most laboratories have a Quality Management System in place, the amount of work to obtain ISO15189 accreditation for Unyvero is considered limited given the sample-to-result nature of the platform. However, Curetis will provide guidelines to customers to allow then to be able to comply with the internal and external laboratory standards based on the feedback by the German Medical association.

Properties

Curetis or another member of the Curetis Group is party to a lease agreement for each of the Curetis facilities. Curetis' headquarters are located at Holzgerlingen, Germany, where it leases approximately 1,500 square meters of office space pursuant to a lease agreement most recently amended on September 27, 2013. Pursuant to the exercise of an extension option in November / December 2017, the term of the lease has been extended until August 31, 2021. After that term, the lease agreement is automatically extended for an indefinite period of time unless terminated with nine months' prior notice by either lessor or lessee. The Curetis Group is party to four additional leases in Germany, the United States and Austria. Curetis believes that existing facilities are, or any such new facilities will be, adequate to meet its business requirements for at least the next 18 months and that additional space will be available on commercially reasonable terms, if required.

Intellectual Property

It is essential for Curetis to achieve and ensure a sustainable and reliable protection of the intellectual property rights related to the Unyvero Platform products and the underlying proprietary technology and manufacturing processes. To this end, Curetis have sought and will continue to seek to obtain and maintain patents and other applicable forms of protection for inventions, know-how, as well as proprietary technology and manufacturing processes of commercial relevance.

Curetis utilizes different methods to achieve the desired protection, including patents, design registrations, trademarks, copyrights and trade secrets. Where necessary, Curetis may also rely on third parties to develop, complement and maintain its proprietary position. Curetis' success will furthermore depend on its ability to defend and enforce its intellectual property rights, to maintain its licenses, to use third-party intellectual property rights, to preserve the confidentiality of its trade secrets and to operate without infringing the valid and enforceable patents and other proprietary rights of third parties.

Patents

Curetis' granted and filed patents focus on protecting critical elements of the instrumentation of the Unyvero Platform and the proprietary Application Cartridges, specifically related to sample preparation and homogenization and to DNA amplification and detection. The principal patents are further described below. All patent inventors are Curetis' employees or members of its Management Board, except for the patents acquired as part of the Gyronimo assets and as part of the GEAR assets as described below.

- A patent titled "Universally Applicable Lysis Buffer and Processing Methods for the Lysis of Bodily Samples" relates to sample preparation and homogenisation. The patent is used in the Unyvero Sample Tube, used in the L4 Lysator in conjunction with the Unyvero A50 Analyzer for all current Unyvero Applications. It is intended to be used with the Unyvero A30 *RQ* system too. The utility patent has been issued (in Singapore grant date May 13, 2015), has been granted in Australia (term: twenty years from May 9, 2011), has been issued in the US (March 21, 2017), has been granted in Japan (March 3, 2017), has been nationalized in CH, DE, ES, FR, GB, IT and NL, has been granted in Hong Kong, has been granted in Canada (April 9, 2019) and is pending in India.

- A patent titled "Reaction Vessel For PCR Device and Method of Performing PCR", relating to the Unyvero PCR Chamber, describes a method to perform an integrated PCR and detection in one integrated reaction vessel. The patent is used in the Unyvero Cartridge for all current Unyvero applications. The utility patent has been filed and has been granted in Australia (term: 20 years from May 19, 2011), has been granted in the United States (March 14, 2017), has been granted in China (August 15, 2015), has been granted in Japan (August 26, 2016), has been granted in Canada (April 24, 2018) has been granted in Singapore (September 25, 2015) and is pending in the EU, Hong Kong and India.

- A patent titled “Apparatus and Method for a Lysis of a Sample, in particular for an Automated and/or Controlled Lysis of a Sample”, relating to the instrumentation for and sample preparation and homogenisation. The patent is used in the L4 Lysator in conjunction with the Unyvero A50 Analyzer for all current Unyvero Applications and is expected to be used with selected Unyvero A30 *RQ* Applications. The utility patent has been filed and has been granted in Australia (June 16, 2016), has been granted in the United States (May 8, 2018), has been granted in China (June 30, 2017), has been granted in Japan (April 21, 2017), has been granted in Canada (November 7, 2018) and is pending in the EU. In the United States a divisional application has been filed, that is published and still pending.

- With the acquisition of the Gyronimo assets, four additional patents were acquired. All inventors of these patents are outside of Curetis. The Gyronimo patents have only limited coverage for the Unyvero A30 *RQ* design. Therefore, these patents have been discontinued in certain regions.

- A utility patent “Method for determining a property of a starting sample” describes an algorithm for the determination of the initial concentration of an analyte in a sample. It has been granted in Europe, but has not been allowed in the United States. The patent has been discontinued in United States, Canada, China and Japan.

- With the acquisition of the GEAR assets several patent applications have been acquired. Curetis is still evaluating the utility of such patents.

- Use of all of the 94 ARES patents relate to ARESdb and ARESupa. These patents are utility patents that are filed in United States, China, EP, Australia and Canada.

As of October 23, 2019, Curetis had total ownership rights in 148 issued patents and patent applications (including any non-provisional applications) in Australia, Canada, EP, Switzerland, Germany, Spain, France, UK, Hong Kong, Italy, Netherlands, India, Japan, Singapore, United States, and China.

Of these, 33 relate to the Unyvero A50 System, the L4 Lysator and the C8 Cockpit and A50 Application Cartridges, 17 relate to the Unyvero A30 *RQ* System and Application cartridges or algorithms, and 98 relate to GEAR, ARESdb and the ARES Technology Platform.

These patents begin to expire in 2029 and will be fully expired by 2039.

The opposition proceedings against the European Patent EP 2 571 976 B1 held by Curetis GmbH were held on Friday November 22, 2019 and lost by Curetis GmbH. The patent was revoked. The revocation is not expected to have any material business impact, as it does not limit Curetis’ ability to make, use or commercialize its Unyvero sample tubes that are used with the Unyvero L4 Lysator. No license fees or royalties have been collected related to this patent.

Designs

Curetis has registered designs for certain shapes of its products such as the Column Adaptor or the sample handling tool, as well as the design of the Unyvero C8 Cockpit, Unyvero L4 Lysator and the Unyvero A50 Analyzer. The “Column Adaptor” has been published in the EU, Japan, United States and Switzerland; “Sample Handling Tool” has been published in the EU, United States and Switzerland; and “Unyvero System”, “Unyvero L4 Lysator”, “Unyvero A50 Analyzer” and “Unyvero C8 Cockpit” have been published in the EU.

In-Licenses and supplier agreements

Curetis collaborates with several external patent attorneys across the globe to assess, evaluate and implement its intellectual property protection strategy. Curetis does not own the intellectual property for reagents and markers and their use, including the spin column, the PCR Master Mix and the fluorophore labels. These are used for pre-lysis, sample preparation, amplification, detection and quality control purposes. The detailed reagent composition is not disclosed by the suppliers. A license is required to become a legitimate user for some of the reagents. Under its existing supplier agreement with the supplier for the reagents and the spin column used for sample preparation and the PCR Master Mix, Curetis has been granted the worldwide distribution rights for the sample preparation reagents. For the PCR Master Mix reagents, distribution rights cover all countries where Curetis is planning to become commercially active including the United States.

Supplier agreements have furthermore been concluded for the supply of labelled primers and probes, including the necessary license governing the use of fluorophore dyes that are incorporated in the Unyvero products.

The markers selected by Curetis for incorporation into the current Unyvero Platform are either in the public domain, are no longer protected by a patent or have been newly developed by Curetis. In the future, Curetis may decide to obtain a license for one or more targets to complement Application Cartridge coverage with one or more specific markers that are protected.

Furthermore, as the functionality of future products has not yet been defined, it is not yet clear whether Curetis might need any other licenses for one or more of the functions, methods, reagents or processing steps of such future products.

Standard software licenses are required for the Unyvero instruments, including but not limited to a Microsoft operating system, image processing, database driver and other proprietary driver libraries. Certain open source software used in the Unyvero product requires publishing a corresponding disclaimer notice.

Ares Genetics has obtained a research use license to the Comprehensive Antibiotic Resistance Database, or CARD, from McMaster University, Hamilton, Canada.

Proprietary Rights and Processes

In addition to the filed patents and registered designs, Curetis relies on proprietary technology and processes (including trade secrets) to protect the Unyvero products and technology. All full-time and temporary employees, scientific advisers, contractors and consultants working for Curetis who have access to confidential information of Curetis are therefore required to execute confidentiality agreements in order to safeguard Curetis' proprietary technologies, methods, processes, know-how, and trade secrets. This is complemented by preserving the integrity and confidentiality of Curetis' proprietary technology and processes by maintaining physical security of Curetis' premises and physical and electronic security of its information technology systems. All its full-time and temporary employees and where applicable, Curetis' independent contractors, manufacturing partners and consultants, are also bound by invention assignment obligations, pursuant to which rights to all inventions and other types of intellectual property conceived by them during the course of their employment are assigned and licensed to Curetis.

Trademarks and domain names

Curetis has secured trademark protection for its corporate name “Curetis” and its product platform “Unyvero” in Germany, Switzerland, the EU and the United States Both trademarks have been filed and published in China. Curetis has also obtained trademark protection for the marks “Univero” and “Trovero” in Germany, Switzerland and the EU and for the trademarks “IGENTIFYER” and “ANYLYSER” in Germany and the trademark “Gyronimo” in the EU. Curetis has also obtained trademark protection for the “ARES Genetics” trademark in Switzerland, the EU and the United States and has filed applications to register the “ARES Genetics” trademark in China and the “ARES” trademark in the United States and the EU, which are currently pending.

Employees

Since it was founded in 2007, Curetis has grown from six employees to a total full-time equivalent headcount of 80 as of September 30, 2019 (not including temporary employment). Curetis’ employees are located worldwide, with 59 employed in Germany at its headquarters in Holzgerlingen near Stuttgart, 11 employed in Austria at Ares Genetics in Vienna and 10 employed in the United States at Curetis USA Inc. in San Diego, California. There are 76 full-time employees.

None of the Curetis GmbH employees are the subject of collective bargaining arrangements. Employees of Ares Genetics are subject to mandatory Austrian collective bargaining agreements. Management considers its relationships with employees to be good.

Approximately 20% of Curetis’ employees have a Ph.D. and approximately 45% of employees hold a Master’s degree or equivalent. Curetis’ team members have many years of relevant industry experience and have worked in a regulated industry.

Insurance

Curetis maintains insurance to cover its potential exposure for a number of claims and losses, including public liability, product liability, transportation and business interruption insurance.

In addition, Curetis has obtained directors’ and officers’ liability insurance, which covers expenses, capped at a certain amount, that Curetis’ board members may incur in connection with their conduct as members of Curetis’ board of directors. Management believes that the insurance coverage Curetis has is adequate in light of the risks Curetis faces.

Legal Proceedings

There are no and there have been no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which Curetis is aware), during the previous 12 months which may have, or have had in the recent past, significant effects on Curetis and/or Curetis’ financial position or profitability.

CURETIS' MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the Curetis Business financial statements included in this proxy statement/prospectus.

Overview

Curetis was incorporated in Holzgerlingen (near Stuttgart, Germany) in 2007. It became the operating subsidiary of Curetis N.V. at the IPO in November 2015. Curetis and its subsidiaries Ares Genetics GmbH and Curetis USA Inc. as well as closed subsidiaries in the UK, Netherlands, France and Switzerland comprise the Curetis business (collectively referred to as "Curetis," the "Curetis Group" or the "Curetis Business"). The Curetis Group's headquarters and principal operations are in Holzgerlingen, Germany with manufacturing site in Bodelshausen Germany, Ares Genetics in Vienna Austria and Curetis USA Inc. in San Diego, CA, USA. The Curetis Group operates in one business segment.

Curetis is a company using molecular diagnostics and informatics to help diagnose and fight severe infectious disease. The Curetis Group is developing platforms such as Unyvero A50 and Unyvero A30 RQ, as well as BioIT products and services for pharmaceutical, biotech, IVD and BioIT companies. The aim is to help guide clinicians with more rapid and actionable information about life threatening infections, antimicrobial resistance (AMR) in order improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. The Curetis Group's proprietary DNA based Unyvero cartridges and bioinformatics address the ever increasing threat of AMR by helping physicians and other healthcare providers optimize treatment decisions for patients with acute life threatening infections.

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; and

- The ARES AMR database, or ARESdb, is a comprehensive database of the genetics of antimicrobial resistance, or AMR, which permits Curetis to increasingly utilize the proprietary biomarker content in its own assay and cartridge development, as well as to build an independent business in next-generation sequencing, or NGS, based offerings for AMR research and diagnostics in collaboration with partners in the life science, pharmaceutical and diagnostics industries. ARESdb is not commercially available in the United States for diagnostic use, as it has not been cleared by the FDA for marketing.

In July 2019, Curetis filed a 510(k) application with the FDA seeking clearance of its Unyvero LRT diagnostic test for use with BAL specimen, which clearance was subsequently received in December 2019. In September 2019, Curetis received correspondence from the FDA detailing a number of questions related to this filing. Curetis has completed its responses to the FDA and is currently addressing additional remaining few questions the agency has asked.

The Curetis Group's operations are subject to certain risks and uncertainties. The risks include rapid technology changes, the need to manage growth, the need to retain key personnel, the need to protect intellectual property and, if the Transaction with OpGen does not close, the need to raise additional capital financing on terms acceptable to the Curetis Group. The Curetis Group's success depends, in part, on its ability to develop and commercialize its proprietary technology.

Recent developments

Since inception, the Curetis Group has incurred, and continues to incur, significant losses from operations. The Curetis Group has funded its operations primarily through external investor financing arrangements. The Curetis Business has been funded by way of several contributions into capital reserves of Curetis GmbH by its parent Curetis N.V. These capital contributions amounted to EUR 3.0 million in H1-2019, EUR 19.0 million in 2018 and EUR 3.0 million in 2017. An additional capital contribution into reserves of Curetis GmbH has been made recently in H2-2019 totaling EUR 1.6 million in September and October 2019.

Results of Operations for the Years Ended December 31, 2018 and 2017

Revenues

In k EUR	Year Ended December 31, 2018	2017
Revenue		
Sale of Unyvero-Systems	546	448
Sale of cartridges	811	722
Sale of services	62	17
Total	**1,419**	**1,187**

Curetis' total revenue for the year ended December 31, 2018 increased 20%, to EUR 1.4 million from EUR 1.2 million, when compared to the same period in 2017. This increase is primarily attributable to:

- Sales of Unyvero Systems: the increase in revenue of 22% in 2018 as compared to 2017 is primarily attributable to more Unyvero systems being sold to distribution partners compared to the prior year;
- Sales of cartridges: the increase in revenue of 12% in 2018 as compared to 2017 is a result of increases in Application Cartridge utilization at commercial accounts as well as an increased number of commercial accounts; and
- Sale of services: the significant increase of 265% year over year is primarily attributable to a collaboration with a pharmaceutical company at Ares Genetics in 2018.

Operating expenses

In k EUR	Year Ended December 31, 2018	2017
Cost of sales	(1,362)	(1,321)
Research and development	(10,566)	(7,335)
General and administrative	(3,578)	(3,185)
Distribution	(8,147)	(7,206)
Total operating expenses	(23,653)	(19,047)

The Curetis Group's total operating expenses for the year ended December 31, 2018 increased 24%, to EUR 23.7 million from EUR 19.1 million, when compared to the same period in 2017. This increase is primarily attributable to:

- Costs of sales: increase by a modest 3% mainly driven by volume increases and product mix;
- Research and development: expenses for the year ended December 31, 2018 increased approximately 44% when compared to the same period in 2017, primarily due to an increase in personnel and advisory/consulting costs related to the Unyvero A30 *RQ* platform development as well as clinical studies and R&D related to Unyvero LRT and ramp up of R&D at Ares Genetics;

- General and administrative: expenses for the year ended December 31, 2018 increased approximately 12% when compared to the same period in 2017, primarily due to increased staffing levels and legal as well as other service costs related to financing activities; and

- Distribution: expenses for the year ended December 31, 2018 increased approximately 13% when compared to the same period in 2017, primarily due to costs associated with the build out of the U.S. commercial team and U.S. marketing expenses related to the launch of Unyvero LRT in the United States.

Other income & finance result

In k EUR	Year Ended December 31, 2018	2017
Other income	625	172
Interest expense	(1,079)	(621)
Foreign currency transaction gains/(losses)	6	(69)
Interest and finance expenses for convertible notes	(93)	—
Interest and other expense	(1)	4
Total other expense	(542)	(514)

Other income and finance result for the year ended December 31, 2018 increased to a net of EUR (542) from a net expense of EUR (514) in the same period of 2017. The increase was primarily a result of higher interests for the EIB loan due to additional draw-downs made in 2018 and finance expenses for the newly implemented convertible note facility in 2018, partially offset by higher other income primarily related to grant- funded projects by Ares Genetics.

Sources and uses of cash

The following table summarizes the net cash and cash equivalents provided by (used in) operating activities, investing activities and financing activities for the periods indicated:

In k EUR	Year Ended December 31, 2018	2017
Net cash used in operating activities	(21,161)	(16,541)
Net cash used in investing activities	(789)	(433)
Net cash provided by financing activities	23,188	14,199

Net cash used in operating activities

Net cash used in operating activities in 2018 consists primarily of our net loss of EUR (22.8) million, reduced by certain non-cash items, including depreciation and amortization expense of EUR 1.3 million, net finance costs of EUR 1.2 million, share-based compensation of EUR 0.4 million, partially offset by the net change in operating assets and liabilities of EUR (0.8) million and paid interests of EUR (0.4) million. Net cash used in operating activities for 2017 consists primarily of our net loss of EUR 18.3 million, reduced by certain non-cash items, including depreciation and amortization expense of EUR 1.3 million, net finance costs of EUR 0.7 million, share-based compensation expense of EUR 0.5 million, and the net change in operating assets and liabilities of EUR (0.7) million.

Net cash used in investing activities

Net cash used in investing activities in 2018 and 2017 consisted predominantly of the purchase of property and equipment with the increase primarily driven by capital expenditures required for Unyvero A30 *RQ*, tooling and manufacturing.

Net cash provided by financing activities

Net cash provided by financing activities in 2018 of EUR 23.2 million consisted primarily of contributions by the sole shareholder Curetis N.V. to Curetis GmbH. Net cash provided by financing activities in 2017 of EUR 14.2 million consisted primarily of contributions by the sole shareholder Curetis N.V. to Curetis GmbH, and a EUR 10 million tranche from EIB.

Results of operations for the six months ended June 30, 2019 and 2018

Revenue

	Six Months Ended June 30,	
In k EUR	**2019**	**2018**
Sale of Unyvero-Systems	146	369
Sale of cartridges	425	435
Sale of services	517	3
Total Revenue	**1,088**	**807**

Total revenue for the six months ended June 30, 2019 increased approximately 34.8%, with a change in the mix of revenue, as follows:

- Sale of Unyvero Systems: a decrease in revenue of approximately 60% in the 2019 period compared to the 2018 period is primarily attributable to a reduction in the sale of our Unyvero instrument systems to distribution partners in the period;
- Sale of Application Cartridges: a slight decrease in revenue of approximately 2.3% in the 2019 period compared to the 2018 period as a result of the transfer from direct sales model at full end customer prices to an exclusive pan European distribution partner model Menarini at significantly lower transfer prices; and
- Sale of services: a 172% increase in revenue from R&D services and collaborations in the 2019 period compared to the 2018 period, primarily as a result of revenue from our Ares Genetics contracts with Sandoz, Qiagen and an undisclosed IVD corporation.

Operating expenses

	Six Months Ended June 30,	
In k EUR	**2019**	**2018**
Cost of products sold	1,302	1,095
Cost of services	40	—
Research and development	4,181	4,680
General and administrative	1,612	1,867
Distribution	3,270	4,209
Impairment of right-of-use asset	—	—
Total operating expenses	10,405	11,851

The Curetis Group’s total operating expenses for the six months ended June 30, 2019 decreased approximately 12% when compared to the same period in 2018. This decrease is primarily attributable to:

- Cost of products sold: cost of products sold for the six months ended June 30, 2019 increased approximately 19% when compared to the same period in 2018. The change in costs of products sold is primarily attributable to higher obsolescence reserves on Unyvero Systems;

- Research and development: research and development expenses for the six months ended June 30, 2019 decreased approximately 11% when compared to the same period in 2018, primarily due to expenses related to our de novo 510(k) submission for the Unyvero LRT incurred in 2018 as well as cost reduction as a result of the restructuring and slowing of investment in R&D, or putting programs on hold (e.g. Unyvero IJI);

- General and administrative: general and administrative expenses for the six months ended June 30, 2019 decreased approximately 14% when compared to the same period in 2018, primarily due to decreased payroll related costs following the re-organization; and

- Distribution: distribution costs such as sales and marketing expenses for the six months ended June 30, 2019 decreased approximately 22% when compared to the same period in 2018, primarily due to the change in commercial channel strategy from direct sales to a distribution model and a reduction in force at Curetis USA Inc.

Other income (expense) and financial result

	Six Months Ended June 30,	
In k EUR	**2019**	**2018**
Interest expense	(628)	(471)
Foreign currency transaction gains (losses)	1	27
Other finance income (finance expense)	(13)	—
Interest and finance expenses for convertible notes	(97)	—
Other income	114	189
Total other expense	(623)	(255)

Other income (expense) and finance result for the six months ended June 30, 2019 decreased primarily due to higher interests for EIB loan facility as a result from additional drawn down financing tranches and interest for the Yorkville facility implemented in the second half of 2018.

Liquidity and capital resources

Since inception, Curetis' 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 June 30, 2019, Curetis 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 June 30, 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, Curetis 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 June 30, 2019 and year ended December 31, 2018, respectively, and Curetis had an accumulated deficit of EUR 170.4 million as of June 30, 2019. As of June 30, 2019, the Curetis Group had cash and cash equivalents of EUR 4.8 million compared to EUR 4.8 million at December 31, 2018. The Curetis Group 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;

- Curetis Convertible Notes facility withdrawal of EUR 1.5 million; and

- Capital contribution from Curetis N.V. of EUR 1.6 million.

The Curetis Group believes that current cash on hand will be sufficient to fund operations into the fourth quarter of 2019. OpGen and Curetis have entered into the Interim Facility to fund operations of Curetis and its subsidiaries for the period between November 18, 2019 and closing of the Transaction. If the Transaction does not close, the Curetis Group will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. This has led management to conclude that there is substantial doubt, if the Transaction with OpGen does not close, about the Curetis Group's ability to continue as a going concern. Accordingly, in such circumstances the Curetis Group would be compelled to immediately reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, 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 Curetis Group 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.

In addition, if the Transaction closes later in 2020 than as anticipated, or even if the Transaction does close, the parties expect that Newco will require additional capital beyond the October 2019 Offering to fund Newco's operations. If such capital cannot be obtained on reasonable terms, it is possible that Newco will not have sufficient cash flows and liquidity to finance its business operations, which may mean that substantial doubt may exist as to its ability to continue as a going concern.

Sources and uses of cash

The Curetis Group's principal source of liquidity has been from financing activities, including issuances of equity and debt securities. The following table summarizes the net cash and cash equivalents provided by (used in) operating activities, investing activities and financing activities for the periods indicated:

	Six Months Ended June 30,	
In k EUR	**2019**	**2018**
Net cash used in operating activities	(7,230)	(10,453)
Net cash provided by investing activities	(1,080)	(230)
Net cash provided by financing activities	8,275	13,725

Net cash used in operating activities

Net cash used in operating activities for the six months ended June 30, 2019 consists primarily of our net loss of EUR 10.0 million, reduced by certain noncash items, including depreciation and amortization expense of EUR 0.8 million, net finance income of EUR 0.7 million, changes in working capital of EUR 1.4 million and stock-based compensation expense of EUR 0.2 million, partly compensated by interests paid of EUR (0.5) million. Net cash used in operating activities for the six months ended June 30, 2018 consists primarily of our net loss of EUR 11.3 million, reduced by certain noncash items, including depreciation and amortization expense of EUR 0.6 million, net finance income of EUR 0.4 million and stock-based compensation expense of EUR 0.3 million, partly compensated by interests paid of EUR (0.4) million.

Net cash provided by investing activities

Net cash provided by investing activities in the six months ended June 30, 2019 and 2018 consisted solely of purchases of intangible assets, property and equipment offset by proceeds from the sale of equipment. The increase in H1-2019 versus prior year was primarily driven by investments in tooling and manufacturing equipment for the Unyvero A30 platform

Net cash provided by financing activities

Net cash provided by financing activities for the six months ended June 30, 2019 of EUR 8.3 million consisted primarily of the net proceeds from the EIB and Yorkville debt financings and capital contributions from Curetis NV into Curetis GmbH on an as needed basis. Net cash provided by financing activities for the six months ended June 30, 2018 of EUR 13.7 million consisted primarily of net proceeds from the capital contributions by Curetis NV into Curetis GmbH following the equity and debt financings by Curetis on an as needed basis.

Contractual Obligations and Commitments

in kEUR		Payments Due by Period			
	Total	Less than 1 Year	1-2 Years	3-5 Years	More than 5 Years
Lease obligations	**1,343**	454	432	384	73
Purchase obligations	**4,951**	1,704	3,247	0	0
Financing obligations	**29,421**	3,740	720	24,961	0
Total contractual obligations	**35,715**	5,898	4,399	25,345	73

Lease obligations include the payments for car lease and facility lease contracts for our Holzgerlingen headquarters, Bodelshausen manufacturing facility (both Germany) Ares Genetics office and lab space (Vienna Austria) and Curetis USA Inc. offices in San Diego, CA, USA.

Purchase obligations include the total committed purchase orders, including the long-term framework-orders for the delivery of Unyvero-Systems at our OEM supplier Zollner, as well as other orders and framework-orders for development services, toolings for Unyvero A30 *RQ* manufacturing, and raw materials to ensure manufacturing of Unyvero Application Cartridges and to be able to execute R&D programs.

Financing obligations include all payments for principal and interest for the EIB debt financing facility, including the projected PPI-tranche amounting to EUR 321 thousand which becomes due at maturity of the EUR 5 million PPI tranche in June 2024, as well as the current outstanding amount for the Yorkville Convertible Notes amounting to a combined total of EUR 3,020 thousand. It is expected that these unconverted Yorkville Convertible Notes will be assumed by OpGen and the conversion feature will be changed to a conversion into OpGen stock post-closing of the Transaction, subject to OpGen, Yorkville and Curetis N.V. entering into a new facility agreement reflecting the same. As at the date of this proxy statement/prospectus, no such new facility agreement has been entered into between OpGen, Yorkville and Curetis N.V.

Critical accounting policies and use of 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, 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.

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

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 Curetis 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, IAS11, 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 of these would 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 Curetis Group are 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 Curetis Group is the lessor.

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

Previously, the Curetis Group 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 Curetis Group 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 Curetis Group'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 k EUR 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 Curetis Group foresees no impact of the adoption of IFRS 16 on compliance with debt covenants.

Leases previously accounted for as operating leases

The Curetis Group 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 k EUR	
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 Curetis Group 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 Curetis Group is reasonably certain that 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 Curetis Group 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 Curetis Group 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 Curetis Group 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 judgment in determining the lease term of contracts with renewal options.

The Curetis Group 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.

Off-balance sheet arrangements

As of June 30, 2019 and December 31, 2018, the Curetis Group did not have any off-balance sheet arrangements.

MANAGEMENT OF NEWCO

The following table sets forth the names and ages of all individuals who are expected to be directors and executive officers of Newco after completion of the Transaction as of the date of this proxy statement/prospectus and their expected positions with Newco after completion of the Transaction:

Name	Age	Expected Positions with Newco	Recommended by:
William Rhodes	65	Director and Chair of the Board	Curetis
Oliver Schacht, Ph.D.	49	Director and Chief Executive Officer	Curetis
Mario Crovetto	66	Director	Curetis
R. Donald Elsey	66	Director and Audit Committee Chair	OpGen
Prabhavathi Fernandes, Ph.D.	70	Director	Curetis
Evan Jones	62	Director	OpGen

Newco Board of Directors

The following information summarizes, for each of Newco's expected directors, his or her principal occupations and other public company directorships for at least the last five years and information regarding the specific experiences, qualifications, attributes and skills of such person:

William E. Rhodes, III. Mr. Rhodes has served as the chairman of the Supervisory Board of Curetis N.V. since its IPO in 2015. Mr. Rhodes is a healthcare executive with more than 30 years of experience in the healthcare industry. During his 14-year career at Becton, Dickinson and Company (BD, 1998-2012), Mr. Rhodes held several senior leadership positions, including such roles as Worldwide President of BD Biosciences (2009-2011), a greater than U.S.$ 1 billion revenue segment of BD. He was also an Executive Officer of BD, and was responsible for corporate strategy and merger and acquisition functions for all of BD's businesses. Furthermore, he founded BD Ventures, the venture capital arm of Becton, Dickinson and Co. Prior to Becton Dickinson, he served in senior business development positions at Johnson & Johnson and Pfizer Inc. Mr. Rhodes also served as president at The William-James Co. and has a track record of over 20 successful acquisitions and divestitures. He was director of Andor Technologies plc (2013-2014), and has served on the boards of Novocell Inc., Conticare Medical, Vitagen Inc., the California Healthcare Institute, BIO, San Jose State University Research Foundation and Silicon Valley Leadership Group. He currently serves as director of Third Day Advisors LLC (since 2013), as director of Omega Group plc (since 2013), Paramit Corporation LLC (since 2014) and Cellector Corporation (since 2015), and as a member of the Advisory Board of Cayuga Venture Fund (since 2013). Mr. Rhodes has a number of advisory roles with Cornell University, including serving on the Advisory Councils of Mc Govern Family Center of Life Sciences (since 2013) and Entrepreneurship at Cornell (since 2015). He also was appointed to the Cornell College of Agriculture and Life Sciences Dean's Council (2016) and serves as a Venture Consultant for Cornell's Blackstone Launchpad (2016). Moreover, he is on the Editorial Board of the journal Clinical and Translational Medicine. Mr. Rhodes holds a Master's degree in International Business from Seton Hall University and a BSc degree from Cornell University. He originated eleven U.S. patents for novel topical drugs and has been a lecturer on entrepreneurship in life sciences, innovation technology and M&A at Cornell University, Seton Hall University and San Jose State University. Mr. Rhodes will be Chair of the Board of Newco after the Transaction closes, and we believe his extensive experience, familiarity with the Curetis Group and his board experiences qualify him for such position.

Oliver Schacht, Ph.D. Mr. Schacht is a corporate finance professional and expert in the molecular diagnostics industry. He has been CEO of Curetis N.V. since April 2011 and prior to that was a Supervisory Board Member of Curetis AG from mid-2010 to end of the first quarter in 2011. He was a co-founder and CFO of Epigenomics AG (Berlin, Germany) and the CEO of Epigenomics Inc. (Seattle, USA). Mr. Schacht has extensive experience in developing and implementing commercial strategies and financing measures (including two IPOs), as well as corporate finance, investor relations, PR, marketing and business development. Mr. Schacht also serves on the Board of BIO Deutschland e.V. as President (since 2019) and previously as treasurer (since 2013) and on the Supervisory Board of Protagen AG (Dortmund, Germany). Mr. Schacht obtained his Diploma in European Business Administration at the European School of Business in Reutlingen and London in 1994 as well as a Master's degree and a Ph.D. at the University of Cambridge (UK). During his time at Mercer Management Consulting (now Oliver Wyman) from 1995 to 1999, he worked on projects in M&A, growth strategies and re-organization in the pharmaceutical, biotechnology and other industries. He has co-founded several start-up companies in biotech, IT and education in Europe and the United States. We believe his experience with Curetis, as well as his past experience with start-up and other companies in the industry position him well to be Chief Executive Officer of Newco following the closing of the Transaction.

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

R. Donald Elsey. Mr. Elsey has served on OpGen's board of directors since February 2019. Mr. Elsey is a biotechnology, life sciences and high technology industries veteran with extensive experience in international financial management and operations with both large cap and small cap companies. Most recently he served as Chief Financial Officer of Senseonics, Inc., a position he has held from February 2015 to January 2019. Prior to Senseonics, he was chief financial officer of Regado Biosciences Corporation. He has also served as chief financial officer of LifeCell Corporation, a privately held regenerative medicine company, and as chief financial officer of Emergent Biosolutions, a biodefense company. He also has held senior financial positions at BioVeris Corporation, Igen, Inc. and PE Corporation (Applera). Mr. Elsey currently serves on the board of directors and audit committee for RegeneRx Biopharmaceuticals, Inc. and on the board of directors and treasurer for Cancer Support Community. He holds a B.A. degree in Economics and an M.B.A. in Finance from Michigan State University and is a Certified Management Accountant. Mr. Elsey's significant in senior financial positions at both public and privately held companies, and his experience as a board and audit committee member of a public reporting company qualifies him for service on the Board and as Chair of the Audit Committee.

Prabhavathi Fernandes, Ph.D. Dr. Fernandes has been a member of the Curetis N.V. Supervisory Board since 2016. Until her retirement in December 2016, she was President and Chief Executive Officer and a member of the board of directors of Cempra Pharmaceuticals, a company she has founded. In 2012, she led the initial public offering and listing on Nasdaq for Cempra, and has successfully raised over half a billion dollars to date for the company. Her career of more than four decades has focused on anti-infectives, first in clinical microbiology and infectious diseases and then in pharmaceutical discovery and development. Prior to Cempra, Dr. Fernandes held executive leadership positions at pharmaceutical corporations including Bristol-Myers Squibb Pharmaceutical Research Institute, Abbott Laboratories and The Squibb Institute for Medical Research. She founded and led three biotechnology and CRO companies. She serves on the editorial board of several journals and she has authored over 250 publications and numerous reviews and book chapters. Dr. Fernandes obtained her MSc in India, and did a Ph.D. and post-doctoral fellowship in bacterial cell membranes and clinical and public health microbiology. Dr. Fernandes' experience with founding and leading an IPO for a Nasdaq-listed company, and well as her extensive experience with publications in the industry position her well for service on Newco's Board.

Evan Jones. Mr. Jones has served as OpGen's Chief Executive Officer since October 2013 and as Chairman of OpGen's board of directors since September 2010. He served as OpGen's President from October 2013 until April 2015. Since 2007, Mr. Jones has served as managing member of jVen Capital, LLC, a life sciences investment company. Previously, he co-founded Digene Corporation, a publicly traded biotechnology company focused on women's health and molecular diagnostic testing that was sold to Qiagen N.V. (Nasdaq: QGEN) in 2007. He served as chairman of Digene's board of directors from 1995 to 2007, as Digene's chief executive officer from 1990 to 2006, and as Digene's president from 1990 to 1999. Mr. Jones serves on the board of directors of Veracyte, Inc. (Nasdaq: VCYT), a leading genomic diagnostics company, since 2008 and served on the board of directors of Foundation Medicine, Inc. (Nasdaq: FMI), a cancer testing molecular informatics company, from January 2013 to July 2018. Mr. Jones received a B.A. from the University of Colorado and an M.B.A. from The Wharton School at the University of Pennsylvania. We believe that Mr. Jones' qualifications to serve as CEO of the Company and as Chairman of our Board include his extensive experience in the molecular diagnostic testing industry, including as chief executive officer of a public company focused on molecular diagnostic testing, as well as his service as a board member with other public and private companies and Vice Chair of the board at Children's National Medical Center in Washington, D.C.

Newco Executive Officers

The following table sets forth the current executive officers of OpGen who are expected to continue with Newco, and the officers of Curetis N.V. who are expected to be the chief executive officer and chief operating officer of Newco. Newco will make final determinations regarding its executive officers after the closing of the Transaction.

Name	Age	Expected Position with Newco
Oliver Schacht, Ph.D.	49	Chief Executive Officer
Timothy C. Dec	60	Chief Financial Officer and Corporate Secretary
Johannes Bacher	51	Chief Operating Officer
Vadim Sapiro	48	Chief Information Officer

The following information summarizes, for each of Newco's executive officers after completion of the Transaction, his principal occupations and other employment for at least the last five years:

Oliver Schacht, Ph. D. See above under "**Newco Board of Directors**."

Timothy C. Dec. Mr. Dec joined OpGen as its interim Chief Financial Officer in April 2015 and became its Chief Financial Officer in May 2015. Prior to joining OpGen, Mr. Dec served as Senior Vice President and Chief Financial Officer for Clubwidesports, LLC, a start-up sports management software company, from January 2014 to April 2015. From August 2007 to December 2012, Mr. Dec served as Senior Vice President and Chief Financial Officer of Fortress International Group, Inc., a publicly traded company. Mr. Dec has served in chief financial officer or other senior financial executive roles at companies in a number of industries from September 1986 through August 2007, including three publicly traded companies listed on Nasdaq or NYSE American, such as Corvis Corporation, and with private equity-backed companies. Mr. Dec also has public accounting firm experience. Mr. Dec received his B.S. in Accounting from Mount St. Mary's University and an M.B.A. from American University.

Johannes Bacher. Mr. Bacher is expected to be appointed as Chief Operating Officer of Newco after the closing of the Transaction. Mr. Bacher has over 20 years of R&D and managerial experience along with extensive expertise in research & development, clinical trials, international project management, finance, human resources and legal affairs. He is managing the general R&D and Clinical Trial Operations of Curetis. He was responsible for running Curetis' prospective multi-center FDA trial for the Unyvero LRT Application, including the FDA De Novo submission and review process throughout clearance in April 2018 as well as for the subsequent 510(k) submission for Unyvero LRT BAL, which was cleared by the FDA in December 2019. Since co-founding Curetis in 2007, he has continuously served as Managing Director / Director Operations (Curetis AG, since 2008) and Chief Operating Officer (Curetis AG, since 2012; Curetis GmbH and publicly listed Curetis N.V. since 2015). Mr. Bacher has a degree in Electrical Engineering from the University of Stuttgart, Germany, and has previously held positions with Hewlett-Packard, Agilent Technologies and Philips Medical Systems.

Vadim Sapiro. Mr. Sapiro joined OpGen in December 2011 as Chief Information Officer. Mr. Sapiro is responsible for leading the development of OpGen's informatics applications, software, databases and information technology operations. Prior to joining OpGen, Mr. Sapiro was Senior Vice President at SAIC-Frederick, Inc. (now Leidos Biomedical Research, Inc.) from June 2008 to December 2011, overseeing the Information Systems Program for the National Cancer Institute at Frederick (now The Frederick National Laboratory for Cancer Research). From October 2006 to May 2008, Mr. Sapiro served as Vice President for Information Technology of J. Craig Venter Institute, a non-profit research institute. Mr. Sapiro served in other senior information technology roles from July 1999 through October 2006, including another non-profit research institute. Mr. Sapiro holds a B.S. in Mathematics and Computer Science from the University of Maryland.

Independence of the Newco Board of Directors

We believe all of the Newco board members will be independent, as defined by Nasdaq and the SEC rules, except for Mr. Schacht, who will serve as Newco's Chief Executive Officer after the closing of the Transaction, and Evan Jones, the current Chief Executive Officer and Chair of the Board of OpGen. Mr. Schacht and Mr. Jones are not expected to be members of any committees of the Newco board of directors.

Certain Relationships and Related Transactions

Other than as described below there were and are no transactions or series of similar transactions, during the last three fiscal years, to which OpGen was a party or will be a party, in which the amounts involved exceeded or will exceed the lesser of $120,000 or one percent of the average of OpGen's total assets at year end for the past two completed fiscal years. We do not anticipate that there will be any related person transactions between Newco and any of Newco's anticipated directors, executive officers or holders of more than 5% of its capital stock, or any member of the immediate family of the foregoing persons.

Compensation arrangements for Newco's anticipated directors are described elsewhere in this proxy statement/prospectus.

Contractual Relationships

In March 2014, OpGen entered into a supply agreement with Fluidigm Corporation, or Fluidigm, under which Fluidigm supplies the Company with its microfluidic test platform for use in manufacturing the Acuitas MDRO Gene Test. Evan Jones, OpGen's Chief Executive Officer and Chairman of the Board of Directors served as a director of Fluidigm from March 2011 to August 2017. On July 12, 2015, OpGen entered into a letter agreement, or the Fluidigm Agreement, with Fluidigm to expand the companies' existing relationship to include collaborating on the development of test kits and custom analytic instruments for identification, screening and surveillance testing of MDROs. The Fluidigm Agreement also expanded the Supply Agreement between OpGen and Fluidigm, and provides for expansion of the gene targets and organisms to be tested on the Company's existing CLIA lab-based tests, the Acuitas MDRO Gene Test and the Acuitas Resistome Test, using Fluidigm technologies and products. Additionally, Fluidigm has agreed not to develop or directly collaborate with any third party to develop an FDA approved or CE marked diagnostic test for the purpose of detecting resistance genes for identified MDROs if the Company meets certain minimum purchase commitments and other requirements. The initial term of the Fluidigm Agreement is five years. Both parties have the ability to extend the term for an additional five years. Under the expanded Supply Agreement, the term was extended until March 17, 2018, and OpGen has the right to extend the term of the Supply Agreement for up to two additional three-year terms, and has extended the term. OpGen paid $28,787 related to these agreements in the year ended December 31, 2018. OpGen paid $123,067 related to these agreements in the year ended December 31, 2017. OpGen paid $183,713 related to these agreements in the year ended December 31, 2016.

In addition, OpGen has several capital lease arrangements for laboratory equipment manufactured by Fluidigm. There were no payments related to the leased equipment in the year ended December 31, 2018. OpGen paid $91,882 related to the leased equipment in the year ended December 31, 2017. OpGen paid $175,475 related to the leased equipment in the year ended December 31, 2016.

Sales and Purchases of Securities

On May 19, 2016 and June 27, 2016, OpGen offered and sold units in a private offering to members of management and employees and to accredited investors, including jVen Capital, LLC, or jVen Capital, each unit consisting of either (i) one twenty-fifth of a share of common stock and a detachable stock purchase warrant to purchase an additional 0.03 of one share of common stock, or (ii) one share of non-voting convertible preferred stock a detachable stock purchase warrant to purchase an additional 0.03 of one share of common stock, at a price of $1.14 per unit. The total net proceeds to the Company, after deducting offering commissions and expenses was $9.5 million. Pursuant to the private offering the Company issued 269,765 shares of common stock, 2,309,428 shares of Series A non-voting convertible preferred stock and stock purchase warrants to acquire an additional 271,606 shares of common stock. Each share of non-voting convertible preferred stock was convertible at the option of the holder in whole or in part and from time to time into one twenty-fifth of a share of common stock, is entitled to dividends on as "as converted basis" when and if dividends are issued to common stockholders, and participates in liquidation on a *pari passu* basis with common stockholders. Holders of the Series A non-voting convertible preferred stock subsequently converted all 2,309,428 shares of preferred stock into 92,377 shares of common stock. The stock purchase warrants issued as part of the units are exercisable $32.8125 per share beginning 90 days after closing for five years, expiring on May 18, 2021. Evan Jones, OpGen's Chief Executive Officer and Chairman of the Board is a managing member of jVen Capital, LLC and has voting and investment authority over the shares owned by jVen Capital; and Timothy Dec and Vadim Sapiro, executive officers of OpGen, were all investors in these offerings.

On May 31, 2017, OpGen entered into the Note Purchase Agreement with jVen Capital, under which jVen Capital agreed to lend bridge financing in an aggregate principal amount of up to $1,500,000 to OpGen in the form of three $500,000 secured convertible promissory notes. On June 14, 2017, OpGen drew down on the first of three Bridge Financing Notes, with $1 million remaining capacity available. OpGen drew down on the second Bridge Financing Note on July 5, 2017 and the third Bridge Financing Note was never issued. OpGen issued warrants to purchase an aggregate 25,102 shares of common stock to jVen Capital and MGHIF in connection with the Bridge Financing. Evan Jones, OpGen's Chief Executive Officer and Chairman of the Board is a managing member of jVen Capital, LLC and has voting and investment authority over the warrants owned by jVen Capital. The outstanding Bridge Financing Notes were repaid in full upon the closing of the July 2017 Public Offering.

On July 18, 2017, OpGen closed a public offering of 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million, or the July 2017 Public Offering. jVen Capital was one of the investors participating in the offering. Each unit included one twenty-fifth of a share of common stock and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. Each pre-funded unit included one pre-funded warrant to purchase one twenty-fifth of a share of common stock for an exercise price of $0.25 per share, and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. Approximately $1 million of the gross proceeds was used to repay the outstanding Bridge Financing Notes to jVen Capital in July 2017. As of December 31, 2017, all of the pre-funded warrants were exercised.

jVen Capital and three employees of OpGen participated in the July 2017 Public Offering in an aggregate amount of $816,000: (i) jVen Capital participated for $750,000; (ii) Timothy C. Dec, Chief Financial Officer of OpGen participated for $26,000; and (iii) Vadim Sapiro, Chief Information Officer of OpGen, participated $10,000.

Policies for Approval of Related Person Transactions

OpGen has adopted a written policy that transactions with directors, officers and holders of 5% or more of its voting securities and their affiliates, each, a related person, must be approved by OpGen's Audit Committee.

EXECUTIVE COMPENSATION

Historical Executive Compensation of OpGen Executive Officers

The following section describes the compensation paid by OpGen to OpGen executive officers who are expected to serve as executive officers of Newco after the Transaction is completed, Timothy Dec and Vadim Sapiro, as well as Evan Jones, who is expected to serve as a director of Newco.

Summary Compensation Table for 2018 and 2017

This table provides disclosure, for the years ended December 31, 2018 and 2017 for the OpGen executive officers, who are expected to serve as executive officers of Newco after the Transaction is completed, as well as Mr. Jones. Each executive officer's position refers to his current position with OpGen.

Named Executive Officer and Principal Position	Year	Salary ($)	Bonus (2)($)	Stock Awards (1)($)	Option Awards (1)($)	Non-Equity Incentive Plan Compensation (2)($)	All Other Compensation ($)	Total ($)
Evan Jones	2018	$ 351,442	$ —	$ —	$ 42,767	$ 75,000	$ —	$ 469,209
Chief Executive Officer	2017	$ 375,962	$ —	$ —	$ 43,210	$ —	$ —	$ 419,172
Timothy Dec	2018	$ 289,615	$ —	$ —	$ 24,438	$ 65,000	$ —	$ 379,053
Chief Financial Officer	2017	$ 291,102	$ —	$ 10,325	$ 45,580	$ —	$ —	$ 347,007
Vadim Sapiro	2018	$ 289,615	$ —	$ —	$ 24,438	$ 50,000	$ —	$ 364,053
Chief Information Officer	2017	$ 291,102	$ —	$ 10,325	$ 38,559	$ 50,000	$ —	$ 389,986

(1) The "Stock Awards" column reflects the grant date fair value for all restricted stock units awarded under the Amended and Restated 2015 Incentive Plan, or the 2015 Plan, during 2018 and 2017. The "Option Awards" column reflects the grant date fair value for all stock option awards granted under the 2015 Plan during 2018 and 2017, respectively. These amounts are determined in accordance with FASB Accounting Standards Codification 718 (ASC 718), without regard to any estimate of forfeiture for service vesting. Assumptions used in the calculation of the amounts in these columns for 2018 and 2017 are included in a footnote to the Company's condensed consolidated audited financial statements for the year ended December 31, 2018, located in Item 8 of the Company's Annual Report on Form 10-K filed with the SEC on February 27, 2019, or the Annual Report.

(2) On February 19, 2019, the Compensation Committee approved the aggregate accrual for 2018 incentive bonuses for the named executive officers and other employees of the Company. On April 30, 2019, the Compensation Committee recommended, and on May 1, 2019, the Board approved the 2018 incentive bonuses for the named executive officers. The 2018 bonuses were earned under a 2018 Annual Incentive Compensation Program approved by the Compensation Committee in early 2018. The incentive bonuses were earned based on the progress made during 2018 on FDA submissions for the Company's Acuitas AMR Gene Panel in vitro diagnostic tests, progress towards anticipated 2019 commercialization of such tests once cleared by the FDA, advancing on the Company's publication strategy, completion of the CDC contract and finalization of the demonstration project with New York State Department of Health, and advancement of the Company's corporate compliance programs. In order to conserve cash, and to serve as a retention incentive, the payment of the approved 2018 incentive bonuses will occur on October 31, 2020 as long as the named executive officer remains with the Company.

Outstanding Equity Awards at Fiscal Year-End Table—2018

The following table shows the outstanding equity awards held by the OpGen executive officers who are expected to serve as executive officers of Newco, as well as Mr. Jones, as of December 31, 2018.

	OPTION AWARDS					STOCK AWARDS			
Name	Number of Securities Underlying Unexercised Options Exercisable (1)	Number of Securities Underlying Unexercised Options Unexercisable (1)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price ($)	Option Expiration Date	Number of Shares of Stock that have not Vested	Market Value of Shares of Stock that have not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that have not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or other Rights that have not Vested ($) (2)
Evan Jones (3)	3	-	-	55,340.00	9/21/2020	-	-	-	-
	348	-	-	25.00	4/24/2024	-	-	-	-
	400	-	-	305.00	10/23/2024	-	-	-	-
	1,053	479	-	675.00	4/28/2026	-	-	-	-
	70	90	-	515.00	2/23/2027	-	-	-	-
	-	1,050	-	80.40	1/28/2028	-	-	-	-
Timothy Dec (3)	214	14	-	3,000.00	5/4/2025	12	16	-	-
	81	18	-	850.00	11/10/2025	-	-	-	-
	82	37	-	775.00	6/13/2026	-	-	-	-
	59	76	-	515.00	2/23/2027	-	-	-	-
	120	-	-	147.50	8/9/2027	-	-	-	-
	-	600	-	80.40	1/23/2028	-	-	-	-
Vadim Sapiro (4)	-	-	-	3,955.00	3/23/2022	-	-	-	-
	1	-	-	3,955.00	3/23/2022	-	-	-	-
	-	-	-	3,955.00	2/12/2023	-	-	-	-
	-	-	-	3,955.00	2/12/2023	-	-	-	-
	1	-	-	3,955.00	7/25/2023	-	-	-	-
	7	-	-	25.00	4/24/2024	-	-	-	-
	100	-	-	305.00	10/23/2024	-	-	-	-
	50	-	-	3,000.00	5/4/2025	-	-	-	-
	55	25	-	775.00	6/13/2026	-	-	-	-
	48	61	-	515.00	2/23/2027	-	-	-	-
	120	-	-	147.50	8/9/2027	-	-	-	-
	-	600	-	80.40	1/23/2028	-	-	-	-

(1) The standard vesting schedule for all stock option grants is vesting over four years with twenty-five percent (25%) vesting on the first anniversary of the date of grant and six and one-quarter percent (6.25%) vesting on the last day of the next fiscal quarter over three years.

(2) Calculated based on the closing price of the common stock the Nasdaq Capital Market on December 31, 2018 of $26.00 per share.

(3) The stock option awards made to Mr. Jones were awarded on February 15, 2011 (3 shares), April 24, 2014 (348 shares), October 23, 2014 (400 shares) and April 28, 2016 (1,533 shares) and have the vesting schedule set forth in footnote (1). Mr. Jones was granted a stock option award on February 23, 2017 (160), which vests over four years with twenty-five percent (25%) vesting on February 23, 2018 and six and one-quarter percent (6.25%) vesting on the first business day of each quarter thereafter over the next three years. Mr. Jones was granted a stock option award on January 23, 2018 (1,050), which vests over four years with twenty-five percent (25%) vesting on January 23, 2019 and six and one-quarter percent (6.25%) vesting on the quarterly anniversary of the first vesting date thereafter over the next three years.

(4) Mr. Dec was granted stock option awards on May 4, 2015 (228 shares), November 10, 2015 (100 shares), June 13, 2016 (120 shares), February 23, 2017 (136), and August 9, 2017 (120). One-forty-eighth of Mr. Dec's stock option award granted on May 4, 2015 vested on the one month anniversary of the date of grant and thereafter vest over four years with twenty-five percent (25%) vesting on the first yearly anniversary of the date of grant and six and one-quarter percent (6.25%) vesting on the last day of the next fiscal quarter over three years. Mr. Dec's stock option awards granted on November 10, 2015 and June 13, 2016 have the vesting schedule set forth in footnote (1). Mr. Dec's stock option award granted on February 23, 2017 vests over four years with twenty-five percent (25%) vesting on February 23, 2018 and six and one-quarter percent (6.25%) vesting on the first business day of each quarter thereafter over the next three years. Mr. Dec's stock option award granted on August 9, 2017 vested on August 9, 2018. Mr. Dec was granted a stock option award on January 23, 2018 (600), which vests over four years with twenty-five percent (25%) vesting on January 23, 2019 and six and one-quarter percent (6.25%) vesting on the quarterly anniversary of the first vesting date thereafter over the next three years. Mr. Dec was granted restricted stock units on November 10, 2015. Twenty-five percent (25%) of the entire restricted stock units award vests on the first four anniversaries of the date of grant. Mr. Dec was granted restricted stock units on August 9, 2017. The restricted stock units vested in February 2018 upon the successful launch of the Company's Acuitas AMR Gene Panel tests in the research use only, or RUO, market.

(5) The stock option awards granted to Mr. Sapiro on March 23, 2012 (0 shares and 1 share), February 12, 2013 (0 share), July 25, 2013 (1 shares), October 23, 2014 (100 shares) and June 13, 2016 (80 shares) have the vesting schedule set forth in footnote (1). The stock option award granted to Mr. Sapiro on February 12, 2013 for 0 shares vested in full on the first anniversary of the date of grant, February 12, 2014. The stock option award granted to Mr. Sapiro on April 24, 2014 for 7 shares is vesting over four years with twenty-five percent (25%) vesting on December 31, 2014 and six and one-fourth percent (6.25%) vesting quarterly thereafter in equal proportions over the remaining three years. The stock option granted to Mr. Sapiro on May 4, 2015 vested quarterly over the first year following the date of grant. The stock option award granted to Mr. Sapiro on February 23, 2017 for 110 shares vest over four years with twenty-five percent (25%) vesting on February 23, 2018 and six and one-quarter percent (6.25%) vesting on the first business day of each quarter over the next three years. The stock option award granted to Mr. Sapiro on August 9, 2017 for 120 shares vested on August 9, 2018. Mr. Sapiro was granted a stock option award on January 23, 2018 (600), which vests over four years with twenty-five percent (25%) vesting on January 23, 2019 and six and one-quarter percent (6.25%) vesting on the quarterly anniversary of the first vesting date thereafter over the next three years. Mr. Sapiro was granted restricted stock units on August 9, 2017. The restricted stock units vested in February 2018 upon the successful launch of the Company's Acuitas AMR Gene Panel tests in the RUO market.

Retention Plan

On September 21, 2018, the OpGen Board approved a Retention Plan for Executives, or the "Retention Plan." The Company considers the establishment and maintenance of a sound and vital management team to be essential to protecting and enhancing the best interests of the Company and its stockholders. In this connection, the Company recognizes that, as is the case with many publicly held corporations, the possibility of a change in control may arise and that such possibility, and the uncertainty and questions which it may raise among management, may result in the departure or distraction of management personnel to the detriment of the Company and its stockholders. Accordingly, the OpGen Board has determined that appropriate steps should be taken to reinforce and encourage the continued attention and dedication of members of the Company's management to their assigned duties without distraction in circumstances arising from the possibility of a change in control of the Company. The executive officers of the Company, as that term is defined under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder, are the eligible participants in the Retention Plan, or the "Executives." The Executives include the OpGen executive officers who are expected to serve as executive officers of Newco – Timothy Dec and Vadim Sapiro, and Evan Jones, the current Chief Executive Officer of OpGen.

The initial term of the Retention Plan is three (3) years, its term is automatically extended for one (1) year terms thereafter unless the Company provides notice of termination to the Executives at least six (6) months before the termination date; provided, that if a change in control (as defined in the Retention Plan) does occur, the term is then set at two (2) years after the date of the change in control.

The Retention Plan provides for Units to be awarded to the Executives, which can be issued in fractional Units, with each Unit equal to one percent (1%) of the “transaction value” of a change in control transaction. A total of four Units are available for award under the Retention Plan. “Transaction value” means all economic value of a change in control transaction to the Company, including any debt or other obligations assumed by the surviving entity in the transaction, amounts paid to the Company or its stockholders, milestone payments, earn-outs and forgiveness of indebtedness. For purposes of this definition, (i) in the case of the sale, exchange or purchase of the Company's equity securities, the total consideration paid for such securities (including amounts paid to holders of options, warrants and convertible securities), and (ii) in the case of a sale or disposition by the Company of assets, the total consideration paid for such assets, plus the net value of any current assets not sold by the Company.

The Units will vest and be payable only in the event an Executive has a “qualifying termination” during a defined change in control period, or remains employed by the Company or its successor at the termination date of the Retention Plan. A “qualifying termination” is a termination without cause by the Company or a termination for good reason by the Executive in the change in control period that spans from six (6) months before the change in control to the second anniversary after the change in control consummation.

The Retention Plan is binding on any successor to the Company.

Employment Agreements with Executive Officers

On September 24, 2018, the Company amended its Executive Change In Control and Severance Benefits Agreement, each, an “Agreement,” with each of Timothy C. Dec and Vadim Sapiro, and entered into a new employment agreement with Evan Jones.

The Agreement with Mr. Jones is a new agreement that provides that, in the event of a termination without cause by the Company or a termination for good reason by Mr. Jones, he will receive severance equal to six (6) months base salary at the time of termination. In addition, if Mr. Jones’ employment is terminated without cause by the Company or any successor, or by Mr. Jones for good reason at any time within two years after a change of control of the Company, he shall receive the following additional benefits: (1) the severance payment obligation is increased to twelve (12) months; (2) acceleration, vesting and lapse of forfeiture on any outstanding equity awards granted to the Executive, and, if applicable, extended time to exercise vested stock options; and (3) payment by the Company or its successor, for a period of six (6) months, of health benefits for the Executive and/or the Executive’s family at levels substantially equal to those which would have been provided to him or them in accordance with the plans, programs, practices and policies in effect as of the date immediately before the change in control consummation date.

The Agreements with the other Executives amend prior agreements to provide the same terms as described above.

For purposes of the Agreements, the following terms have the following meanings (where applicable):

“cause” means (i) executive’s commission of a felony; (ii) any act or omission of executive constituting dishonesty, fraud, immoral or disreputable conduct that causes material harm to the Company; (iii) executive’s violation of Company policy that causes material harm to the Company; (iv) executive’s material breach of any written agreement between executive and the Company which, if curable, remains uncured after notice; or (v) executive’s breach of fiduciary duty. The termination of executive’s employment as a result of the death or disability is not deemed to be a termination without cause.

“change in control” means:

(i) a transaction or series of transactions (other than an offering of common stock to the general public through a registration statement filed with the SEC) whereby any “person” or related “group” of “persons” (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act (other than the Company, any of its subsidiaries, an employee benefit plan maintained by the Company or any of its subsidiaries or a “person” that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company’s securities outstanding immediately after such acquisition; or

(ii) the consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction: (1) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the Successor) directly or indirectly, at least a majority of the combined voting power of the Successor's outstanding voting securities immediately after the transaction, and (2) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor; provided, however, that no person or group shall be treated for purposes of this definition as beneficially owning 50% or more of the combined voting power of the Successor solely as a result of the voting power held in the Company prior to the consummation of the transaction; or

(iii) the Company's stockholders approve a liquidation or dissolution of the Company.

"good reason" means any of the following, without executive's consent: (i) a material diminution of executive's responsibilities or duties (provided, however, that the acquisition of the Company and subsequent conversion of the Company to a division or unit of the acquiring company will not by itself be deemed to be a diminution of executive's responsibilities or duties); (ii) material reduction in the level of executive's base salary (and any such reduction will be ignored in determining executive's base salary for purposes of calculating the amount of severance pay); (iii) relocation of the office at which executive is principally based to a location that is more than fifty (50) miles from the location at which executive performed his duties immediately prior to the effective date of a change in control; (iv) failure of a successor in a change in control to assume the severance agreement; or (v) the Company's material breach of any written agreement between executive and the Company. Notwithstanding the foregoing, any actions taken by the Company to accommodate a disability of executive or pursuant to the Family and Medical Leave Act shall not be a good reason for purposes of the agreement. Additionally, before executive may terminate employment for a good reason, executive must notify the Company in writing within thirty (30) days after the initial occurrence of the event, condition or conduct giving rise to good reason, the Company must fail to remedy or cure the alleged good reason within the thirty (30) day period after receipt of such notice if capable of being cured within such thirty-day period, and, if the Company does not cure the good reason (or it is incapable of being cured within such thirty-day period), then executive must terminate employment by no later than thirty (30) days after the expiration of the last day of the cure period (or, if the event condition or conduct is not capable of being cured within such thirty-day period, within thirty (30) days after initial notice to the Company of the violation). Transferring executive's employment to a successor is not itself good reason to terminate employment under the agreement, provided, however, that subparagraphs (i) through (v) above shall continue to apply to executive's employment by the successor. This definition is intended to constitute a "substantial risk of forfeiture" as defined under Treasury Regulation 1.409A-1(d).

Prospective Compensation for Newco Executive Officers

We anticipate that the officers of Curetis who will join Newco after the closing of the Transaction will be eligible to participate in Newco's annual incentive bonus plan, and will be eligible to receive long-term equity compensation from Newco under the existing equity compensation plan. In addition, each of the executive officers have stock options from Curetis N.V. that will be assumed by OpGen under the Implementation Agreement. The existing executive officers of OpGen, other than Mr. Jones, will continue to be employed by OpGen under their existing employment agreements, as described above.

DIRECTOR COMPENSATION

Historical Director Compensation for OpGen Directors

Currently, each non-employee OpGen director receives an annual cash retainer of $25,000, payable quarterly, plus additional annual cash compensation for committee chairs ($15,000 for Audit Committee, $10,000 for Compensation Committee and $7,500 for Compliance Committee) and for committee members ($7,000 for Audit Committee, $5,000 for Compensation Committee and $3,500 for Compliance Committee). In addition, each new non-employee director receives an initial equity grant and each non-employee director receives an annual equity grant. On April 30, 2019, the OpGen Compensation Committee recommended, and on May 1, 2019 the OpGen Board approved, an adjusted non-employee director compensation program to include an initial grant of 1,500 restricted stock units and an annual grant to non-employee directors of 750 restricted stock units. All such awards are made under the Company's 2015 Amended and Restated Equity Incentive Plan, as amended, or the 2015 Plan. The annual equity award may be pro-rated in the first year of service depending on when the non-employee director joins the Board or may be deferred until the following year.

Evan Jones, Chairman of the OpGen Board and CEO, is expected to serve as a director of Newco after the Transaction is complete. Mr. Jones does not currently receive additional compensation for service on OpGen's Board.

R. Donald Elsey, an OpGen director who is expected to serve as a director of Newco after the Transaction is complete, was elected to the OpGen Board on February 21, 2019. Mr. Elsey received an initial grant of 1,500 restricted stock units, with a fair market value of $14,370 in May 2019, and has received $24,555 in non-employee director compensation since joining the OpGen Board in February 2019.

We anticipate that, following the closing of the Transaction, the Newco Board of Directors will evaluate the non-employee director compensation, which will be paid to all members of the Newco Board except Mr. Schacht, on a going forward basis.

NO APPRAISAL RIGHTS

Holders of shares of OpGen Common Stock are not entitled to appraisal rights in connection with the Transaction.

REGULATORY APPROVALS

In the United States, OpGen must comply with applicable federal and state securities laws and the rules and regulations of Nasdaq in connection with the issuance of shares of OpGen Common Stock pursuant to the Implementation Agreement and the filing of this proxy statement/prospectus with the SEC. The parties are aware of no additional regulatory approvals required to effect the Transaction.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following is a summary of the material U.S. federal income tax consequences of the Transaction, but does not purport to be a complete analysis of all the potential tax considerations relating thereto and does not address tax consequences in jurisdictions other than the United States. This summary is based upon the provisions of 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 of U.S. federal income tax consequences is for general information only and does not discuss any state, local, foreign or other tax consequences.

The proposed Transaction consists of the issuance of the Consideration by OpGen in exchange for the acquisition by Crystal GmbH, its wholly owned German subsidiary, of all of the capital stock of Curetis GmbH and assumption of certain liabilities of Curetis N.V. by OpGen or Crystal GmbH. A corporation does not recognize gain or loss when it issues stock in exchange for property under Section 1032(a) of the Code. OpGen therefore believes that neither OpGen nor its stockholders will recognize taxable gain or loss on OpGen's issuance of shares in the proposed Transaction.

We have not obtained a tax opinion from legal counsel or tax experts on the Transaction and there is no certainty that the intended federal income tax treatment of the Transaction will be respected by the IRS or any other taxing authority.

DISTRIBUTION OF OPGEN SHARES AND WINDDOWN OF CURETIS N.V.

As contemplated by the Implementation Agreement, Curetis N.V. expects, as soon as practicable after the closing of the Transaction, to distribute all or part of the Consideration Shares to Curetis N.V. shareholders and to wind up its affairs. Curetis N.V. has not yet adopted a formal plan of distribution and dissolution. Curetis N.V. is solely responsible for the distribution of the Consideration Shares to the shareholders of Curetis N.V.

DESCRIPTION OF OPGEN CAPITAL STOCK

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

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 proxy statement/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 paid 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, which plan was submitted on October 3, 2019, which plan included information regarding the October 2019 Offering. The Company believes that it regained compliance with the minimum stockholders' equity standard for continued listing with the closing of the October 2019 Offering. However, there can be no assurance that the Company will be able to maintain compliance with this continuing listing standard.

Common Stock

As of January 21, 2020, there were 5,582,280 shares outstanding, 5,135,609 shares of common stock reserved for the exercise of outstanding stock options, warrants and restricted stock units, and approximately 27 record holders. The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. The Board of Directors are elected to a one year term; the Company does not have a staggered board. Holders of our common stock are entitled to receive ratably any dividends declared by the Board of Directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

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

Preferred Stock

Series A Convertible Preferred Stock

Of the authorized preferred stock, the Company had previously issued 2,309,428 shares of Series A Convertible Preferred Stock. The holder of the Series A Convertible Preferred Stock converted all 2,309,428 shares of Series A Convertible Preferred Stock into shares of common stock. All such converted shares of Series A Convertible Preferred Stock were canceled and will not be reissued. As of November 1, 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, owned in excess of 4.99% immediately prior to the closing of the IPO. In addition, upon at least 61 days' prior notice from the holder to us, the holder may waive such limitation.

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

2016 PIPE Warrants

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

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

Warrants issued in Bridge Financing

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

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

Warrants issued in the July 2017 Public Offering

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

Warrants issued in the February 2018 Public Offering

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

Pre-Funded Warrants issued in the October 2019 Offering

The Company issued pre-funded warrants included in the pre-funded units that were sold in the October 2019 Offering. As of November 1, 2019, all pre-funded warrants were exercised and the common stock was issued to the holders.

Common Warrants in the October 2019 Offering

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

Duration and Exercise Price

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

Cashless Exercise

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

Exercisability

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

Fractional Shares

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

Transferability

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

Trading Market

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

Right as a Stockholder

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

Fundamental Transaction

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

Registration Rights

Investors' Rights Agreement

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

Bridge Financing Registration Rights

In connection with the bridge financing the Company entered into a registration rights agreement with jVen Capital, pursuant to which jVen Capital was 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 under the terms of the bridge financing promissory notes.

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

Our Certificate of Incorporation and Bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our Board of Directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below. The following descriptions are summaries of the material terms of our Certificate of Incorporation, and Bylaws.

Meetings of Stockholders

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

Advance Notice Requirements

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

Amendment to Certificate of Incorporation and Bylaws

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

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 DGCL, 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. In addition, this exclusive forum provision is intended to apply to claims arising under Delaware state law and would not apply to claims brought pursuant to the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent the provision could be construed to apply to such claims, there is uncertainty as to whether a court would enforce the provision in such respect, and our stockholders will not be deemed to have waived compliance with federal securities laws and the rules and regulations thereunder.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the DGCL. 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.

Certain Other Matters

The following provides a description of certain other rights of Company stockholders and provisions of our Certificate of Incorporation in addition to the rights described above in this "Description of OpGen Capital Stock" section. The following is not intended to be a complete discussion and is qualified in its entirety by reference to the DGCL and our Certificate of Incorporation and Bylaws.

Number of Directors. Our Bylaws provide that the board of directors shall consist of no less than three (3) or no more than fifteen (15) members, as fixed from time to time by resolution of the Board of Directors.

Election of Directors. Our Bylaws provide that the election of directors shall be by plurality vote of the shares present and entitled to vote in person or represented by proxy at a duly called meeting of stockholders at which a quorum is present.

Nominations of persons for election to the Board of Directors may be made at a meeting of stockholders (i) by or at the direction of the Board of Directors or (ii) by any stockholder who is a stockholder of record at the time of giving of notice, who is entitled to vote for the election of directors at the meeting and who complies with the notice procedures set forth in our Bylaws as described in the foregoing "Anti-Takeover Effects of Our Certificate of Incorporation, Bylaws and Delaware Law—*Advance Notice Requirements*" section.

Removal of Directors. The DGCL provides that any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors (i) unless the corporation's certificate of incorporation provides, in the case of a corporation whose board is classified, that directors may only be removed by stockholders with cause or (ii) in the case of a corporation having cumulative voting, if less than the entire board is to be removed, no director may be removed without cause if the votes cast against such director's removal would be sufficient to elect such director if then cumulatively voted at an election of the entire board of directors, or, if there be classes of directors, at an election of the class of directors of which such director is a part.

Board Vacancies. Our Bylaws provide that, except as the DGCL may otherwise require, and subject to the rights of the holders of any series of preferred stock with respect to the filling of vacancies or new directorships on the Board of Directors, newly created directorships resulting from death, resignation, disqualification, removal or other cause shall be filled solely by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the class of directors in which the new directorship was created or the vacancy occurred and until such director's successor shall have been elected and qualified. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

Quorum. Our Bylaws provide that for any meeting of stockholders, the presence, in person or by proxy, of the holders of record of a majority of the shares then issued and outstanding and entitled to vote at the meeting constitutes a quorum for the transaction of business; provided, however, that this requirement does not affect any different requirement existing under statute, pursuant to the rights of any authorized class or series of stock, or under our certificate of incorporation, for the vote necessary for the adoption of any measure governed thereby. The stockholders present at a duly called and held meeting at which a quorum is present may continue to do business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum, if any action taken (other than adjournment) is approved by at least a majority of the shares required to constitute a quorum.

Notice of Stockholder Meetings. Written notice of each annual or special meeting of stockholders shall be delivered either personally or by mail to stockholders entitled to vote at such meeting no fewer than ten (10) nor more than sixty (60) days before the date of the meeting. Such notice shall include the time, date and location of the meeting to which such notice relates. The purpose or purposes for which the meeting is called may, in the case of an annual meeting, and shall, in the case of a special meeting, be set forth in the notice. If mailed, notice is given when deposited in the United States mail, postage prepaid, directed to the stockholder at his address as it appears on the stock books of the Company, unless he shall have filed with the Secretary of the Company a written request that notices intended for him be mailed to some other address, in which case such notice shall be mailed to the address designated in such request.

Annual Meetings; Place of Meetings. As provided in our Bylaws, the annual meeting of stockholders shall be held at a date and at such time as the Board of Directors shall determine. At each annual meeting of stockholders, directors shall be elected and any other proper business may be transacted. Each annual or special meeting of stockholders shall be held at such location as may be determined by the Board of Directors or, if no such determination is made, at such place as may be determined by the Chairman of the Board of Directors. If no location is so determined, any annual or special meeting shall be held at the principal executive office of the Company.

Conduct of Meetings. Our Bylaws provide that all annual and special meetings of stockholders shall be conducted in accordance with such rules and procedures as the Board of Directors may determine subject to the requirements of applicable law and, as to matters not governed by such rules and procedures, as the chairman of such meeting shall determine. The Chairman of the Board of Directors shall be the chairman of any annual or special meeting of stockholders. The Secretary, or in the absence of the Secretary, a person designated by the Chairman of the Board of Directors, shall act as secretary of the meeting.

Record Date. For purposes of determining the stockholders entitled to notice of any meeting or to vote or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which shall not be more than sixty (60) days nor fewer than ten (10) days before the date of any such meeting nor more than sixty (60) days before any such other action, and in this event only stockholders at the close of business on the record date are entitled to notice or to vote, as the case may be, notwithstanding any transfer of any shares on the books of the Company after the record date, except as otherwise provided in the DGCL.

Stockholder Action by Written Consent. To the fullest extent permitted by law, whenever any action is required or permitted to be taken at a meeting of stockholders, by law, or by the Certificate of Incorporation, such action may be taken without a meeting, without prior notice and without a vote of stockholders, if a consent in writing, setting forth the action so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.

Indemnification and Advancement of Expenses; Limitation on Personal Liability

Indemnification and Advancement of Expenses. Our Certificate of Incorporation provides that each person who is or was a director or officer of the Company or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, employee benefit plan or other enterprise (including the heirs, executors, administrators or estate of such person), shall be indemnified and advanced expenses by the Company, in accordance with our Bylaws, to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Company to provide broader indemnification rights than said law permitted the Company to provide prior to such amendment), or any other applicable laws as presently or hereinafter in effect. The right to indemnification and advancement of expenses shall not be exclusive of any other right that any person may have or hereafter acquire under any statute, provision of the certificate of incorporation or bylaws of the Company, agreement, vote of stockholders or disinterested directors or otherwise.

Limitation on Personal Liability. Our Certificate of Incorporation provides, to the fullest extent permitted by the DGCL, as the same exists or as may hereafter be, a director of the Company shall not be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL hereafter is amended to further eliminate or limit the liability of directors, then the liability of a director of the Company, in addition to the limitation on personal liability, shall be limited to the fullest extent permitted by the amended DGCL. Any repeal or modification of this limitation on personal liability by the stockholders of the Company shall be prospective only and shall not adversely affect any limitation on the personal liability of a director of the Company existing at the time of such repeal or modification.

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 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 proxy statement/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 paid 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, which plan was submitted on October 3, 2019, which plan included information regarding the October 2019 Offering. The Company believes that it regained compliance with the minimum stockholders' equity standard for continued listing with the closing of the October 2019 Offering. However, there can be no assurance that the Company will be able to maintain compliance with this continuing listing standard.

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.

COMPARISON OF THE RIGHTS OF SHAREHOLDERS OF CURETIS N.V. AND STOCKHOLDERS OF OPGEN

The rights of OpGen stockholders are governed by OpGen's Amended and Restated Certificate of Incorporation, as amended, or the COI, and its Amended and Restated Bylaws, or Bylaws, as well as the Delaware General Corporation Law, or DGCL. The rights of Curetis N.V. shareholders are governed by its articles of association of Curetis N.V., or the Articles, and the laws of the Netherlands.

The following is a summary discussion of the material differences, as of the date of this proxy statement/prospectus, between the current rights of OpGen stockholders and the current rights of Curetis N.V. shareholders. The following description does not purport to be a complete statement of all the differences, or a complete description of the specific provisions referred to in this summary. The identification of specific differences is not intended to indicate that other equally or more significant differences do not exist. OpGen stockholders should read carefully the relevant provisions of the DGCL, the COI and the Bylaws. Curtis N.V. shareholders should read the Articles. OpGen has filed its governing documents referenced in this comparison of stockholder and shareholder rights with the SEC and will send copies to you without charge, upon your request. See "Where You Can Find More Information" beginning on page 209 of this proxy statement/prospectus.

	Rights of OpGen Stockholders	**Rights of Curetis N.V. Shareholders**
Authorized Equity	The authorized capital stock of OpGen 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.	The authorized share capital of Curetis N.V. is divided into 55,000,000 shares, each with a nominal value of €0.01 (referred to in this section as a "Share" or the "Shares", respectively).
Outstanding Capital Stock	Common Stock: 5,582,268 shares issued and outstanding at November 1, 2019. Preferred Stock: None issued and outstanding at November 1, 2019.	The current issued and outstanding share capital of Curetis N.V. consists of 26,282,366 shares at December 11, 2019.
Voting Rights	The COI provides that its Common Stock will exclusively possess all voting power, subject to issuance of any preferred stock issued by the OpGen Board of Directors, or OpGen Board.	Each Curetis N.V. share confers the holder of each Share the right to cast one vote per Share. Curetis N.V. may not exercise any voting rights in respect of Shares held by itself or its subsidiaries.
Quorum and Votes Required	The Bylaws provide that, the presence, in person or by proxy, of the holders of, a majority of the shares then issued and outstanding and entitled to vote at the meeting will constitute a quorum for the transaction of business. The Bylaws additionally provide that a majority of the fixed number of directors will constitute a quorum for the transaction of business, except that when the OpGen Board consists of one director, then the one director will constitute a quorum. The Bylaws provide that the affirmative vote of a majority of the shares present in person or represented by proxy at a duly called meeting of stockholders of OpGen, at which a quorum is present and entitled to vote on the subject matter, will be sufficient to take or authorize action upon any matter which may properly come before the meeting, except that the election of directors will be by plurality vote, unless the vote of a greater or different number thereof is required by statute, by the rights of any authorized class of stock or by the COI.	Other than as specifically required by the Articles or the laws of the Netherlands, all resolutions at any general meeting of the shareholders, or a General Meeting, will be adopted by a majority of Shares voting on such resolution with no quorum requirement. The Articles do provide that certain general meetings of Curetis N.V.'s shareholders require a quorum, including resolutions to appoint a managing director of Curetis N.V., or a Managing Director, other than in accordance with a proposal of the supervisory board of Curetis N.V., or the Supervisory Board, or to suspend or dismiss a Managing Director without a motion by the Supervisory Board, requiring at least one-third of the issued share capital to approve any such vote. All resolutions of the management board of Curetis N.V. Management Board or the Supervisory Board of Curetis N.V. will be adopted by a majority of votes cast at a meeting at which more than half of the Managing Directors or the supervisory directors of Curetis N.V. Supervisory Directors, respectively, are present or represented.

	Rights of OpGen Stockholders	Rights of Curetis N.V. Shareholders
Stockholder or Shareholder Rights Plans	Not applicable	Not applicable
Rights of Preferred Stock	Not applicable	Not applicable
Number of Directors	The COI provides that the number of directors will be established from time to time by the OpGen Board. The Bylaws provide that the number of directors will be fixed from time to time by resolution of the OpGen Board but will not be less than three nor more than 15. The current number of directors is four. Following the completion of the Transaction, the parties expect the number of directors will be seven.	The Articles provide that the Management Board will consist of at least two Managing Directors. The number of Managing Directors is to be determined by the Supervisory Board, after consultation with the Management Board. The Supervisory Board will consist of at least three Supervisory Directors. The number of Supervisory Directors is to be determined by the Supervisory Board.
Election of Directors	The Bylaws provide that the directors will be elected at the annual meeting of the stockholders, except in the case of vacancies on the board, and each director will hold office for the term for which he or she is elected and until his or her successor is elected and qualified. Directors are elected by a plurality vote of the shares present and entitled to vote in person or represented by proxy. There is no staggered Board.	The Articles provide that the Managing Directors are appointed by the shareholders at a General Meeting upon non-binding nomination by the Supervisory Board. Each Managing Director will be appointed for a maximum of four years and can be reappointed for another term of four years. The Supervisory Directors will be appointed by the shareholders at the General Meeting upon a non-binding nomination of the Supervisory Board. Each Supervisory Director will be appointed for a maximum of four years and can be reappointed for another term of four years once. Thereafter, a Supervisory Director can be reappointed for a term of maximum two years, with the possibility to be reappointed for another term of two years.

	Rights of OpGen Stockholders	Rights of Curetis N.V. Shareholders
Director Nominations by Stockholders or Shareholders	The Bylaws provide that nominations by stockholders must be made by timely notice in writing to the Secretary of OpGen. To be timely, a stockholder's notice shall be delivered to or mailed and received at OpGen's principal executive office: (i) in the case of an annual meeting, no fewer than 90 days nor more than 120 days prior to the first anniversary of the date of the written notice for the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is changed by more than 30 days from such anniversary date, notice by the stockholder to be timely must be so received not later than the close of business on the tenth day following the earlier of the day on which notice of the date of the meeting was mailed or public disclosure was made; and (ii) in the case of a special meeting at which directors are to be elected, not later than the close of business on the tenth day following the earlier of the day on which notice of the date of the meeting was mailed or public disclosure was made. Such stockholder's notice must set forth: (i) as to each person whom the stockholder proposes to nominate for election or reelection as a director, all information relating to such person that is required to be disclosed in solicitations of proxies for elections of directors, or is otherwise required, in each case pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected); (ii) as to the stockholder giving the notice, (A) the name and address, as they appear on OpGen's books, of such stockholder and (B) the class and number of shares of OpGen which are owned beneficially and of record by such stockholder of record and by the beneficial owner, if any, on whose behalf the nomination is made; and (iii) as to the beneficial owner, if any, on whose behalf the nomination is made, (A) the name and address of such person and (B) the class and number of shares of OpGen which are beneficially owned by such person. At the request of the OpGen Board, any person nominated by the OpGen Board for election as a director shall furnish to the Secretary of OpGen that information required to be set forth in a stockholder's notice of nomination which pertains to the nominee.	The Articles provide that nominations for Managing Directors and Supervisory Directors will be made on a non-binding basis by the Supervisory Board. Nomination will be included in the notice convening the General Meeting in which the appointment is considered. The General Meeting is not bound by a nomination and may appoint another person than the one that has been nominated, provided that a proposal to appoint such other person is included in the agenda or, failing that, the respective resolution is adopted by unanimous vote in a General Meeting in which the entire issued capital is represented. In addition, shareholders can use their general right to add items to the agenda for a General Meeting to propose the appointment of a Managing Director or Supervisory Director. See *Notice of Meetings of Stockholders or Shareholders and Advance Notice Requirements for Stockholder or Shareholder Proposals (Other than Nominations of Directors)* below for further information in respect of the procedure to add any such items.

	Rights of OpGen Stockholders	Rights of Curetis N.V. Shareholders
Stockholder or Shareholder Action by Written Consent	The Bylaws provide that, to the fullest extent permitted by law, whenever any action is required or permitted to be taken at a meeting of stockholders, by law, by the COI or by the Bylaws, such action may be taken without a meeting, without prior notice and without a vote of stockholders, if a consent in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.	The Articles provide that no shareholder resolutions may be adopted outside of a General Meeting.
Removal of Directors	The COI and Bylaws provide that any director may be removed from office only as provided in the COI, but the COI has no provision related to removal.	The Articles provide that a Managing Director may be suspended or removed by a General Meeting at any time. If the suspension or removal is adopted on the motion of the Supervisory Board, such resolution will be adopted upon a majority of the votes cast. Without the motion of the Supervisory Board, such suspension or removal requires a majority of the votes cast, which majority must constitute at least one-third of the issued share capital of Curetis N.V.
Vacancies on the Board	The Bylaws provide that, subject to the rights of the holders of any series of Preferred Stock with respect to the filling of vacancies or new directorships in the OpGen Board of Directors, newly created directorships resulting from death, resignation, disqualification, removal or other cause shall be filled solely by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the OpGen Board of Directors. Any director elected in this manner shall hold office for the remainder of the full term of the class of directors in which the new directorship was created or the vacancy occurred and until such director's successor shall have been elected and qualified.	In the event that one or more Managing Directors are unable to act or are prevented from acting, the remaining Managing Directors or the only remaining Managing Director will temporarily be in charge of the management of Curetis N.V.. In the event that all Managing Directors or the only Managing Director is unable to act or is prevented from acting, the Supervisory Board will temporarily be in charge of the management of Curetis N.V., in which case the Supervisory Board will be authorized to designate one or more temporary Managing Directors.

	Rights of OpGen Stockholders	Rights of Curetis N.V. Shareholders
Cumulative Voting	The COI provides that no cumulative voting rights exist in the election of directors	The Articles do not provide for cumulative voting rights.
Amendments to Constitutional/Organizational Documents	The COI provides that it may be amended only if the amendment has been approved both by the OpGen Board and by the stockholders of OpGen by the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of the outstanding shares of capital stock of OpGen entitled to vote. The 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.	The General Meeting has the power to amend the Articles. Resolutions of the General Meeting to amend the Articles are adopted by an absolute majority of votes cast upon a proposal of the Management Board, provided that the Management Board requires the approval of the Supervisory Board to make such proposal to the General Meeting.
Special Governance Provisions	Not applicable	Not applicable

	Rights of OpGen Stockholders	Rights of Curetis N.V. Shareholders
Notice of Meeting of Stockholders or Shareholders and Advance Notice for Stockholder or Shareholder Proposals (Other than Nominations of Directors)	The Bylaws provide that written notice of each annual or special meeting of stockholders shall be delivered either personally or by mail to stockholders entitled to vote at such meeting no fewer than 10 nor more than 60 days before the date of the meeting, will include the time, date and location of the meeting to which such Meeting Notice relates and the purpose or purposes for which the meeting is called (which purpose(s) may be excluded in the case of an annual meeting). If mailed, notice is given when deposited in the United States mail, postage prepaid, directed to the stockholder at his address as it shall appear on the stock books of OpGen, unless he shall have filed with the Secretary of OpGen a written request that notices intended for him be mailed to some other address, in which case such notice shall be mailed to the address designated in such request. For business to be properly brought before an annual meeting by a stockholder (other than director nominations), the stockholder must have given timely notice in writing to the Secretary of OpGen. To be timely, a stockholder's notice must be delivered to or mailed and received at the principal executive office of OpGen no fewer than 90 days nor more than 120 days prior to the first anniversary of the date of the meeting notice for the preceding year's annual meeting; provided, however, that in the event that the date of the meeting is changed by more than 30 days from such anniversary date, to be timely, notice by the stockholder must be received no later than the close of business on the tenth day following the earlier of the day on which notice of the date of the meeting was mailed or public disclosure was made. A stockholder's notice to the Secretary must set forth as to each matter the stockholder proposes to bring before the meeting: (i) a brief description of the business desired to be brought before the meeting and the reasons for conducting such business at the meeting; (ii) the name and address, as they appear on OpGen's books, of the stockholder proposing such business, and the name and address of the beneficial owner, if any, on whose behalf the proposal is made; (iii) the class and number of shares of OpGen which are owned beneficially and of record by such stockholder of record and by the beneficial owner, if any, on whose behalf the proposal is made; and (iv) any material interest of such stockholder of record and the beneficial owner, if any, on whose behalf the proposal is made in such business.	General Meetings may be called for any purpose at any time by the Management Board or the Supervisory Board. The annual General Meeting must be held within six months after the financial year. The Articles provide that the shareholders, as well as usufructuaries and pledges to whom the voting rights accrue, shall be given notice of the General Meeting by the Management Board, the Supervisory Board, a Managing Director or a Supervisory Director. The notice of a General Meeting shall be given no later than on the 42nd day prior to the day of the meeting. If the notice period was shorter or if no notice was sent, no valid resolutions may be adopted. Such notice will be given by means of an announcement made by electronic means of communication which is directly and permanently accessible until the General Meeting. Notice of a General Meeting will mention: • the matters to be discussed; • the place and time of the General Meeting; • the procedure for attending the General Meeting by a proxy authorized in writing; • the procedure for attending the General Meeting and the exercise of the voting rights by any means of electronic communication in the event this right can be exercised in such manner. Matters which have not been mentioned in the notice of meeting may be announced in a supplementary notice. No valid resolutions may be adopted on matters which have not been mentioned in the notice of meeting or announced in a supplementary notice with due observance of the notice period. An item of which discussion has been requested in writing by one or more shareholders representing, individually or jointly, at least 3% of Curetis N.V.'s issued capital shall be included in the notice of the General Meeting or announced in a supplementary notice if Curetis N.V. has received the request, including the reasons for the request, or a proposal for a resolution, no later than on the sixtieth day prior to the date of the General Meeting. Dutch corporate law provides that besides the Management Board and the Supervisory Board, one or more shareholders, who jointly represent at least one-tenth of the issued capital may, on their application, be authorized by the Dutch district court judge hearing applications for interim relief to convene a General Meeting. The judge hearing application for interim relief shall disallow the application if it does not appear to him that the applicants have previously requested the management and the supervisory board in writing, stating the exact matters to be considered, to convene a General Meeting and neither the Management Board nor the Supervisory Board, which in this case have equal powers, has taken the necessary steps so that the General Meeting could be held within eight weeks after the request. The district court judge hearing applications for interim relief shall grant the authorization applied for, after having heard or having summoned the public company to appear, if the applicants have shown prima facie that the conditions of the preceding article have been satisfied and that they have a reasonable interest in holding the meeting. Any shareholder may also be authorized by the district court judge hearing applications for interim relief to convene a meeting, if the persons who are authorized fail to hold a General Meeting as prescribed by Dutch corporate law (i.e. the annual General Meeting to be held within six months after the end of the financial year).

	Rights of OpGen Stockholders	Rights of Curetis N.V. Shareholders
Proxies	The Bylaws provide that every person entitled to vote for directors or on any other matter shall have the right to do so either in person or by one or more agents authorized by a written proxy signed by the person and filed with the Secretary of OpGen. A proxy shall be deemed signed if the stockholder's name is placed on the proxy (whether by manual signature, typewriting, telegraphic transmission, or otherwise) by the stockholder or the stockholder's attorney in fact. A validly executed proxy which does not state that it is irrevocable shall continue in full force and effect unless: (i) revoked by the person executing it, before the vote pursuant to that proxy, by a writing delivered to the Corporation stating that the proxy is revoked, or by a subsequent proxy executed by, or as to any meeting by attendance at such meeting and voting in person by, the person executing the proxy; or (ii) written notice of the death or incapacity of the maker of that proxy is received by OpGen before the vote pursuant to that proxy is counted; provided, however, that no proxy shall be valid after the expiration of three (3) years from the date of the proxy, unless otherwise provided in the proxy. A duly executed proxy shall be irrevocable if it states that it is irrevocable and if, and only as long as, it is coupled with an interest sufficient under applicable law to support an irrevocable power. A proxy may be made irrevocable regardless of whether the interest with which it is coupled is an interest in the stock itself or an interest in the Corporation generally.	The Articles provide that each person who is entitled to voting rights will be authorized to attend the General Meeting in person or by a proxy authorized in writing to address the General Meeting and to exercise his, her or its voting rights. The requirement of written form for such authorization will be met if the authorization has been recorded electronically.

	Rights of OpGen Stockholders	Rights of Curetis N.V. Shareholders
Limitation of Personal Liability of Directors and Officers	The COI provides that, to the fullest extent permitted by the DGCL (including Section 102(b)(7) of that law), a director of OpGen shall not be personally liable to OpGen or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL is amended to further eliminate or limit the liability of directors, then the liability of a director of OpGen, in addition to the limitation on personal liability provided in the certificate of incorporation, is be limited to the fullest extent permitted by the amended DGCL. Any repeal or modification of this paragraph by the stockholders of OpGen would be prospective only and would not adversely affect any limitation on the personal liability of a director of OpGen existing at the time of such repeal or modification.	Not applicable
Indemnification of Directors and Officers	The COI provides that each person who is or was a director or officer of OpGen or is or was serving at the request of OpGen as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, employee benefit plan or other enterprise (including the heirs, executors, administrators or estate of such person), is indemnified and advanced expenses by OpGen, in accordance with the Bylaws, to the fullest extent authorized by the DGCL, as the same exists or may be amended (but, in the case of any such amendment, only to the extent that such amendment permits OpGen to provide broader indemnification rights than said law permitted OpGen to provide prior to such amendment), or any other applicable laws. The right to indemnification and advancement of expenses under the COI is not to be exclusive of any other right that any person may have or hereafter acquire under any statute, provision of the COI or Bylaws of OpGen, agreement, vote of stockholders or disinterested directors or otherwise.	The Articles provide that, unless the laws of the Netherlands state otherwise, the following will be reimbursed to the current and former Managing Directors and the current and former Supervisory Directors: • Reasonable costs of conducting a defense against claims, also including claims by Curetis N.V. and its group companies, based on acts or failures to act in the exercise of their duties or any other duties currently or previously performed by them at Curetis N.V.' request; • Any damages or fines payable by such Managing Director or Supervisory Director as a result of any such act or failure to act; • The reasonable costs of appearing in other legal proceedings in which such involved as current or former Managing Directors or Supervisory Directors are involved, with the exception of proceeding primarily aimed at pursuing a claim on their own behalf. Notwithstanding the foregoing, any current or former Managing Director or Supervisory Director is not entitled to reimbursement if and to the extent that: • a Dutch Court, or in the event of arbitration, an arbiter has established in a final and conclusive decision that the act of failure to act of the person concerned may be characterized as willful or grossly negligent, unless the laws of the Netherlands provide otherwise or this would, in the view of the circumstances of the case, be unacceptable according to standards of reasonableness and fairness; or • the costs or financial loss of the person concerned are covered by an insurance and the insurer has paid out the costs or financial loss.

	Rights of OpGen Stockholders	Rights of Curetis N.V. Shareholders
Forum Selection	The COI provides that, unless OpGen consents in writing to the selection of an alternative forum, from and after the time the Common Stock is first a "covered security" pursuant to Section 18(b)(1) of the Securities Act of 1933, as amended, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on behalf of OpGen, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of OpGen to OpGen or its stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, or (iv) any action asserting a claim governed by the internal affairs doctrine.	Not applicable

INTERESTS OF CERTAIN PERSONS IN MATTERS TO BE ACTED UPON

In considering whether to approve the proposals at the Special Meeting, the Company's stockholders should recognize that certain of the Company's directors and executive officers have interests in the Transaction that may differ from, or that are in addition to, their interests as stockholders generally, referred to as the Interested Parties. These interests may cause some of the Interested Parties to view the Transaction differently than you may view them as a disinterested stockholder of the Company, and may influence or may have influenced the Interested Parties in determining to support or approve the Transaction.

As of the Record Date, approximately 39,000 of our issued and outstanding shares of our Common Stock representing less than one percent of the total voting power of stockholders entitled to vote on the Transaction, were held by certain of the Interested Parties.

The executive officers of OpGen have different interests than other stockholders of OpGen in deciding whether to vote in favor of the Transaction. Evan Jones, the current Chief Executive Officer of OpGen, Timothy C. Dec, the current Chief Financial Officer of OpGen, and Vadim Sapiro, the current Chief Information Officer of OpGen are each party to an Executive Change In Control and Severance Benefits Agreement, or a Severance Agreement, with OpGen. See "Executive Compensation – Employment Agreements with Executive Officers" on page 178 of this proxy statement/prospectus for further information. Mr. Jones will no longer be chief executive officer of Newco following the closing of the Transaction, therefore, if the Transaction is a "change in control" of OpGen he will receive an amount equal to 12 months' base salary as severance compensation, reimbursement for health benefits for six months and all of his outstanding equity awards will accelerate. If the Transaction is not a change in control as defined in the Severance Agreement, Mr. Jones will receive six months' base salary as severance. If either of Mr. Dec's or Mr. Sapiro's employment is terminated without cause or for good reason they will receive similar severance payments.

The three executive officers are also participants under the OpGen Retention Plan for Executives. See "Executive Compensation – Retention Plan" on page 179 of this proxy statement/prospectus for further information. Under the Retention Plan, each of Mr. Jones, Mr. Dec and Mr. Sapiro will receive a retention payment equal to 1.0% of the Transaction value (as defined in the Retention Plan) upon the closing of the Transaction if the Transaction meets the definition of a change in control of OpGen as defined in the Retention Plan. As of the date of this proxy statement/prospectus, OpGen estimates that the total value of these retention payments is $424,000. The timing of the payment, if any, depends on if the executive officers remain in their respective positions with OpGen after the closing.

The non-employee directors of OpGen receive annual cash and equity compensation. See "Director Compensation" on page 183 of this proxy statement/prospectus for more information.

Oliver Schacht will be the Chief Executive Officer of Newco after the Transaction closes. He currently holds stock options to acquire 100,000 ordinary shares of Curetis N.V. OpGen will assume the obligations for the Curetis N.V. stock options. None of the other Curetis N.V. Supervisory Board members joining the Newco Board of Directors have any equity holdings in Curetis N.V.

Compensation for the executive officers and non-employee directors of Newco has not been determined as of the date of this proxy statement/prospectus.

Other than as disclosed above, no person who has been a director or executive officer of the Company at any time since the beginning of the Company's most recently completed financial year, or any associate or affiliate of any such director or officer, has any material interest, direct or indirect, by way of beneficial ownership of securities or otherwise, in any matter to be acted upon at the Special Meeting.

SOLICITATION OF PROXIES

This solicitation is made on behalf of the Board of Directors. We are paying for this proxy solicitation. Our officers and other regular employees may solicit proxies by mail, in person or by telephone or telecopy. These officers and other regular employees will not receive additional compensation. The Company may retain a third party proxy solicitor for the Special Meeting and estimates the costs of such proxy solicitor will be approximately $5,000.00. We will reimburse banks, brokers, nominees, custodians and fiduciaries for their reasonable out-of-pocket expenses incurred in sending the proxy materials to beneficial owners of the shares.

LEGAL MATTERS

Ballard Spahr LLP, Philadelphia, Pennsylvania will pass upon the validity of the OpGen Common Stock offered by this proxy statement/prospectus.

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 included herein in reliance upon the report 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 proxy statement/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.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

OpGen Beneficial Ownership as of the Record Date

The following table sets forth the beneficial ownership of OpGen's common stock as of January 24, , 2020, by each OpGen director and executive officer, and by all directors and executive officers as a group. This disclosure will be updated in the final proxy statement/prospectus for the shares outstanding as of the Record Date. Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act. The number of shares of OpGen's common stock outstanding at the close of business on January 24, 2020 was 5,582,280 shares. In computing the number of shares beneficially owned by a person or a group and the percentage ownership of that person or group, shares of OpGen's common stock subject to options and warrants currently exercisable or exercisable within 60 days after January 24, 2020, are deemed outstanding, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. To the knowledge of the directors and executive officers of OpGen, as of January 24, 2020, there are no persons and/or companies who or which beneficially own, directly or indirectly, shares representing more than 5% of the voting rights attached to all outstanding shares of OpGen. Unless otherwise indicated, the address of each beneficial owner listed below is c/o OpGen, Inc., 708 Quince Orchard Road, Suite 205, Gaithersburg, MD 20878.

Name and Address of Beneficial Owner	Number of Shares of common stock	Percentage Beneficially Owned
Directors and Named Executive Officers		
Evan Jones (1)	36,061	*%
R. Donald Elsey (2)	—	*
Tina S. Nova, Ph.D. (3)	190	*
Misti Ushio, Ph.D. (4)	254	*
Timothy C. Dec (5)	1,511	*
Vadim Sapiro (6)	956	*
All current Directors and Executive Officers as a group (6 individuals) (7)	38,972	*%

* Constitutes less than 1%

(1) Consists of (i) 26,211 shares of common stock and currently exercisable warrants to acquire an additional 6,716 shares of common stock beneficially owned by jVen Capital, LLC, (ii) 262 shares of common stock and currently exercisable warrants to acquire an additional 42 shares of common stock owned by Mr. Jones' spouse, and (iii) stock options to purchase 2,830 shares of common stock that are currently vested or that will become vested within 60 days. Mr. Jones is a managing member of jVen Capital, LLC and has voting and investment authority over the shares owned by that entity.

(2) Mr. Elsey was elected to the Board of Directors on February 21, 2019.

(3) Consists of stock options to purchase 190 shares of common stock that are currently vested or that will become vested within 60 days.

(4) Consists of (i) 79 shares of common stock and (ii) stock options to purchase 175 shares of common stock that are currently vested or that will become vested within 60 days.

(5) Consists of (i) 345 shares of common stock, (ii) currently exercisable warrants to acquire an additional 204 shares of common stock, and (iii) stock options to purchase 962 shares of common stock that are currently vested or that will become vested within 60 days.

(6) Consists of (i) 150 shares of common stock, (ii) currently exercisable warrants to acquire an additional 70 shares of common stock, and (iii) stock options to purchase 736 shares of common stock that are currently vested or that will become vested within 60 days.

(7) See the beneficial ownership described in footnotes (2) through (6).

Beneficial Ownership of Curetis N.V. Shares

The following table sets forth the beneficial ownership of Curetis N.V. common shares as of January 24, 2020, by each supervisory board members, management board members, other executive officer, by all such directors and executive officers as a group and each person known to be the beneficial owner of more than 5% of Curetis N.V.'s common shares. Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act. The number of Curetis N.V.'s common shares outstanding at the close of business on January 24, 2020 was 26,282,366 shares. In computing the number of shares beneficially owned by a person or a group and the percentage ownership of that person or group, shares of Curetis N.V.'s common shares subject to options and warrants currently exercisable or exercisable within 60 days after January 24, 2020 are deemed outstanding, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each beneficial owner listed below is c/o Curetis N.V., Max-Eyth-Str. 42, 71088 Holzgerlingen, Germany.

Name and Address of Beneficial Owner	Number of Ordinary Shares	Percentage Beneficially Owned
Supervisory Board Members:		
William Rhodes III	—	—
Mario Crovetto	—	—
Dr. Werner Schäfer	—	—
Prabhavathi Fernandes, Ph.D.	—	—
Dr. Rudy Dekeyser	—	—
Dr. Nils Clausnitzer	—	—
Management Board Members and Executive Officers:		
Oliver Schacht, Ph.D.(1)	100,000	*
Johannes Bacher (1)	100,000	*
Dr. Achim Plum (1)	100,000	*
All Directors and Executive Officers as a group (9 individuals)	300,000	1.1%
5% Stockholders		
LSP Pooling B.V. (NL) (2)	4,322,780	16.4%

* Constitutes less than 1%

(1) Consists of currently exercisable stock options to acquire 100,000 ordinary shares.

(2) As reported on www.afm.nl, filed on April 15, 2019. The address of the shareholder is Johannes Vermeerplein 9, 1071DV Amsterdam, The Netherlands.

HOUSEHOLDING OF PROXY MATERIALS

The SEC has adopted rules that permit companies and intermediaries (e.g., brokers) to satisfy the delivery requirements for Special Meeting materials with respect to two or more stockholders sharing the same address by delivering a single set of Special Meeting materials addressed to those stockholders. This process, which is commonly referred to as "householding," potentially means extra convenience for stockholders and cost savings for companies.

A number of brokers with account holders who are the Company's stockholders will be "householding" our proxy materials. A single set of Special Meeting materials will be delivered to multiple stockholders sharing an address unless contrary instructions have been received from the affected stockholders. Once you have received notice from your broker that they will be "householding" communications to your address, "householding" will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in "householding" and would prefer to receive a separate set of Special Meeting materials, please notify your broker or the Company. Direct your written request to Timothy C. Dec, Corporate Secretary, OpGen, Inc., 708 Quince Orchard Drive, Suite 205, Gaithersburg, Maryland 20878. Stockholders who currently receive multiple copies of these materials at their addresses and would like to request "householding" of their communications should contact their brokers.

WHERE YOU CAN FIND MORE INFORMATION

OpGen files annual, quarterly and current reports, proxy statements and other information with the SEC. OpGen's SEC filings are available to the public on the website maintained by the SEC at http://www.sec.gov. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports are available, free of charge, on or through our website www.opgen.com as soon as practicable after we electronically file such forms, or furnish them to, the SEC.

As of the date of this proxy statement/prospectus, OpGen has filed a registration statement on Form S-4 to register with the SEC the Transaction Shares that OpGen will issue to the Seller in the Transaction. This proxy statement/prospectus is a part of that registration statement and constitutes a prospectus of OpGen, as well as a proxy statement of OpGen for its special meeting.

OpGen has supplied all information contained in this proxy statement/prospectus relating to OpGen. If you would like to request documents from OpGen please send a request in writing or by telephone to the following address:

OpGen, Inc.
708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878
Telephone: 301.869.9683
Attn: Corporate Secretary

INDEX TO FINANCIAL STATEMENTS

OPGEN, INC.

Index to Consolidated Financial Statements for the years ended December 31, 2018 and 2017

Index to Unaudited Condensed Consolidated Financial Statements for the nine months ended September 30, 2019 and 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
OpGen, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of OpGen, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the years then ended and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern.

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred losses from operations since inception and will need additional capital to fund future operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company's auditor since 2014.

Tysons, Virginia
February 27, 2019

OpGen, Inc.
Consolidated Balance Sheets
As of December 31,

	2018	2017
Assets		
Current assets		
Cash and cash equivalents	$ 4,572,487	$ 1,847,171
Accounts receivable, net	373,858	809,540
Inventory, net	543,747	533,425
Prepaid expenses and other current assets	292,918	311,644
Total current assets	**5,783,010**	**3,501,780**
Property and equipment, net	1,221,827	835,537
Goodwill	600,814	600,814
Intangible assets, net	1,085,366	1,353,182
Other noncurrent assets	259,346	328,601
Total assets	**$ 8,950,363**	**$ 6,619,914**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,623,751	$ 1,691,712
Accrued compensation and benefits	1,041,573	746,924
Accrued liabilities	902,019	1,160,714
Deferred revenue	15,824	24,442
Short-term notes payable	398,595	1,010,961
Current maturities of long-term capital lease obligation	399,345	154,839
Total current liabilities	**4,381,107**	**4,789,592**
Deferred rent	162,919	290,719
Note payable	660,340	—
Warrant liability	67	8,453
Long-term capital lease obligation and other noncurrent liabilities	437,189	130,153
Total liabilities	**5,641,622**	**5,218,917**
Commitments (Note 9)		
Stockholders' equity		
Common stock, $0.01 par value; 50,000,000 shares authorized; 8,645,720 and 2,265,320 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	86,457	22,653
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2018 and December 31, 2017, respectively	—	—
Additional paid-in capital	165,313,902	150,114,671
Accumulated other comprehensive loss	(13,093)	(25,900)
Accumulated deficit	(162,078,525)	(148,710,427)
Total stockholders' equity	**3,308,741**	**1,400,997**
Total liabilities and stockholders' equity	**$ 8,950,363**	**$ 6,619,914**

See accompanying notes to consolidated financial statements.

OpGen, Inc.
Consolidated Statements of Operations and Comprehensive Loss
For The Years Ended December 31,

	2018	2017
Revenue		
Product sales	$ 2,395,626	$ 2,771,869
Laboratory services	34,665	41,960
Collaboration revenue	516,016	397,178
Total revenue	**2,946,307**	**3,211,007**
Operating expenses		
Cost of products sold	1,222,919	1,612,838
Cost of services	625,516	520,338
Research and development	5,677,243	6,883,293
General and administrative	7,069,315	6,692,659
Sales and marketing	1,531,556	2,767,670
Total operating expenses	**16,126,549**	**18,476,798**
Operating loss	**(13,180,242)**	**(15,265,791)**
Other income/(expense)		
Interest and other income/(expense)	5,384	(87,255)
Interest expense	(191,195)	(233,505)
Foreign currency transaction (losses)/gains	(10,431)	23,179
Change in fair value of derivative financial instruments	8,386	144,064
Total other expense	**(187,856)**	**(153,517)**
Loss before income taxes	**(13,368,098)**	**(15,419,308)**
Provision for income taxes	—	—
Net loss	**$ (13,368,098)**	**$ (15,419,308)**
Net loss per common share - basic and diluted	**$ (2.22)**	**$ (9.80)**
Weighted average shares outstanding - basic and diluted	6,009,065	1,573,769
Net loss	$ (13,368,098)	$ (15,419,308)
Other comprehensive income/(loss) - foreign currency translation	12,807	(32,076)
Comprehensive loss	**$ (13,355,291)**	**$ (15,451,384)**

See accompanying notes to consolidated financial statements.

OpGen, Inc.
Consolidated Statements of Stockholders' Equity

	Common Stock		Preferred Stock		Additional	Accumulated Other		
	Number of Shares	Amount	Number of Shares	Amount	Paid-in Capital	Comprehensive (Loss) / Income	Accumulated Deficit	Total
Balances at December 31, 2016	**1,012,171**	**$ 10,122**	—	—	**$ 136,442,302**	**$ 6,176**	**$ (133,291,119)**	**$3,167,481**
Stock option exercises	1,167	12	—	—	8,168	—	—	8,180
Public offering of common stock and warrants, net of issuance costs	1,000,000	10,000	—	—	8,813,242	—	—	8,823,242
At the market offering, net of offering costs	227,216	2,272	—	—	3,806,564	—	—	3,808,836
Issuance of RSUs	6,025	60	—	—	(60)	—	—	—
Stock compensation expense	—	—	—	—	911,398	—	—	911,398
Legal settlement in common stock	15,843	158	—	—	109,841	—	—	109,999
Vendor payment in common stock	2,898	29	—	—	23,216	—	—	23,245
Foreign currency translation	—	—	—	—	—	(32,076)	—	(32,076)
Net loss	—	—	—	—	—	—	(15,419,308)	(15,419,308)
Balances at December 31, 2017	**2,265,320**	**22,653**	—	—	**150,114,671**	**(25,900)**	**(148,710,427)**	**1,400,997**
Public offering of common stock and warrants, net of issuance costs	5,912,307	59,123	—	—	13,471,278	—	—	13,530,401
At the market offering, net of offering costs	318,236	3,182	—	—	594,561	—	—	597,743
Issuance of RSUs	5,650	57	—	—	(57)	—	—	—
Stock compensation expense	—	—	—	—	862,281	—	—	862,281
Share cancellation	(31)	—	—	—	—	—	—	—
Interest settlement in common stock	144,238	1,442	—	—	271,168	—	—	272,610
Foreign currency translation	—	—	—	—	—	12,807	—	12,807
Net loss	—	—	—	—	—	—	(13,368,098)	(13,368,098)
Balances at December 31, 2018	**8,645,720**	**$ 86,457**	**—**	$ —	**$ 165,313,902**	**$ (13,093)**	**$ (162,078,525)**	**$3,308,741**

See accompanying notes to consolidated financial statements.

OpGen, Inc.
Consolidated Statements of Cash Flows
Years Ended December 31,

	2018	2017
Cash flows from operating activities		
Net loss	$ (13,368,098)	$ (15,419,308)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	730,884	669,088
Noncash interest expense	133,802	185,294
Share-based compensation	862,281	911,398
Gain on sale of equipment	(5,253)	—
Change in fair value of warrant liabilities	(8,386)	(144,064)
Unamortized discount on bridge loan at repayment	—	85,932
Changes in operating assets and liabilities:		
Accounts receivable	432,814	(260,471)
Inventory	(11,273)	161,027
Other assets	486	(315,688)
Accounts payable	89,493	(563,357)
Accrued compensation and other liabilities	77,871	399,224
Deferred revenue	(8,618)	(12,955)
Net cash used in operating activities	**(11,073,997)**	**(14,303,880)**
Cash flows from investing activities		
Purchases of property and equipment	(147,767)	(276,950)
Proceeds from sale of equipment	10,440	—
Net cash used in investing activities	**(137,327)**	**(276,950)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	597,743	3,808,836
Proceeds from issuance of units, net of selling costs	13,530,401	8,754,882
Proceeds from debt, net of issuance costs	381,253	1,168,222
Proceeds from exercise of stock options	—	76,537
Payments on debt	(371,573)	(1,255,198)
Payments on capital lease obligations	(292,722)	(205,085)
Net cash provided by financing activities	**13,845,102**	**12,348,194**
Effects of exchange rates on cash	12,878	(37,517)
Net increase/(decrease) in cash, cash equivalents and restricted cash	2,646,656	(2,270,153)
Cash, cash equivalents and restricted cash at beginning of year	2,090,551	4,360,704
Cash, cash equivalents and restricted cash at end of year	**$ 4,737,207**	**$ 2,090,551**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 57,393	$ 48,211
Supplemental disclosures of noncash investing and financing activities:		
Shares issued to settle obligations	$ 272,610	$ 133,245
Property and equipment acquired through capital lease	$ 706,778	$ —
Conversion of accounts payable to capital lease	$ 156,775	$ —
Unpaid deferred offering costs	$ —	$ 48,398

See accompanying notes to consolidated financial statements.

Note 1 - Organization

OpGen, Inc. ("OpGen" or the "Company") was incorporated in Delaware in 2001. References in this report to the "Company" include OpGen and its wholly-owned subsidiaries. The Company's headquarters are in Gaithersburg, Maryland, and its principal operations are in Gaithersburg, Maryland. The Company also has operations in Woburn, Massachusetts, Copenhagen, Denmark, and Bogota, Colombia. The Company operates in one business segment.

OpGen, Inc. is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. The Company is 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. Its 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.

The Company'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. The Company is working to deliver products and services, some in development, to a global network of customers and partners.

- The Company's Acuitas molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include its Acuitas antimicrobial resistance, or AMR, Gene Panel (Urine) test in development for patients at risk for complicated urinary tract infection, or cUTI, and its Acuitas AMR Gene Panel (Isolates) test in development for testing bacterial isolates, and its QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of the Acuitas AMR Gene Panel tests is available for sale for research use only, or RUO.
- The Company's Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that 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 is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

The Company's operations are subject to certain risks and uncertainties. The risks include the risk that the Company will not receive 510(k) clearance for its Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software on a timely basis, or at all, rapid technology changes, the need to retain key personnel, the need to protect intellectual property and the need to raise additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop, obtain regulatory approval for and commercialize its proprietary technology as well as raise additional capital.

Note 2 - Going Concern and Management's Plans

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Since inception, the Company has incurred, and continues to incur, significant losses from operations. The Company has funded its operations primarily through external investor financing arrangements and significant actions taken by the Company to reduce costs, including:

- On October 22, 2018, the Company closed a public offering (the "October 2018 Public Offering") of 2,220,000 shares of its common stock at a public offering price of $1.45 per share. The offering raised gross proceeds of approximately $3.2 million and net proceeds of approximately $2.8 million.
- On June 11, 2018, the Company executed an Allonge (the "Allonge") to its Second Amended and Restated Senior Secured Promissory Note, dated June 28, 2017, with a principal amount of $1,000,000 issued to Merck Global Health Innovation Fund, LLC ("MGHIF"). The Allonge provided that accrued and unpaid interest of $285,512 due as of July 14, 2018, the original maturity date, be paid through the issuance of shares of OpGen's common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021. On July 30, 2018, the

Company issued 144,238 shares of common stock to MGHIF in a private placement transaction for $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

- On February 6, 2018, the Company closed a public offering (the "February 2018 Public Offering") of 2,841,152 units at $3.25 per unit, and 851,155 pre-funded units at $3.24 per pre-funded unit, raising gross proceeds of approximately $12 million and net proceeds of approximately $10.7 million. Each unit included one share of common stock and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. As of April 19, 2018, all 851,155 pre-funded warrants issued in the February 2018 Public Offering have been exercised.
- On July 18, 2017, the Company closed a public offering (the "July 2017 Public Offering") of 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million. jVen Capital, LLC ("jVen Capital") was one of the investors participating in the offering. jVen Capital is an affiliate of Evan Jones, the Company's Chairman of the Board and Chief Executive Officer. Each unit included one twenty-fifth of a share of common stock and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. Each pre-funded unit included one pre-funded warrant to purchase one twenty-fifth of a share of common stock for an exercise price of $0.25 per share, and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. Approximately $1 million of the gross proceeds was used to repay the outstanding Bridge Financing Notes to jVen Capital in July 2017.
- In early June 2017, the Company commenced a restructuring of its operations to improve efficiency and reduce its cost structure. Under the restructuring plan the Company is consolidating its operations, including manufacturing, for its FDA-cleared and CE marked QuickFISH and PNA FISH families of products and research and development activities for the Acuitas AMR Gene Panel products and services, in Gaithersburg, Maryland, and reducing the size of its commercial organization while the Company works to complete the development of its Acuitas AMR Gene Panel and Acuitas Lighthouse Knowledgebase products and services in development.
- On May 31, 2017, the Company entered into a Note Purchase Agreement with jVen Capital, under which jVen Capital agreed to provide bridge financing in an aggregate principal amount of up to $1,500,000 to the Company in up to three separate tranches of $500,000 (each, a "Bridge Financing Note" and collectively, the "Bridge Financing Notes"). In connection with the issuance of Bridge Financing Notes, in June and July 2017, the Company issued jVen Capital stock purchase warrants to acquire 5,634 shares with an exercise price of $19.50 per share, and warrants to acquire 6,350 shares with an exercise price of $17.25 per share. The Company drew down on two of three Bridge Financing Notes during June and July 2017, and repaid such outstanding Bridge Financing Notes in full upon the closing of the July 2017 Public Offering.
- On September 13, 2016, the Company entered into the Sales Agreement (the "Sales Agreement") with Cowen and Company LLC ("Cowen") pursuant to which the Company may offer and sell from time to time, up to an aggregate of $25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of $11.5 million. As of December 31, 2018, the Company sold an aggregate of 690,247 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $8.8 million, and gross proceeds of $9.4 million. During the year ended December 31, 2018, the Company has sold 318,236 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $0.6 million, and gross proceeds of $0.6 million. In connection with the October 2018 Public Offering, the Company terminated the at the market offering.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, strategic financings or other transactions, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements and business combination transactions. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. The Company believes that current cash will be sufficient to fund operations into the second quarter of 2019. This has led management to conclude that substantial doubt about the Company's ability to continue as a going concern exists. In the event the Company is unable to successfully raise additional capital during or before the second 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 reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing. 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.

Note 3 - Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements consolidate the operations of all controlled subsidiaries; all intercompany activity is eliminated.

Foreign Currency

The Company has subsidiaries located in Copenhagen, Denmark, and Bogota, Colombia, both of which use currencies other than the U.S. dollar as their functional currency. As a result, all assets and liabilities are translated into U.S. dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the average exchange rates prevailing during the reporting period. Translation adjustments are reported in accumulated other comprehensive (loss)/income, a component of stockholders' equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive (loss)/income at December 31, 2018 and 2017.

Foreign currency transaction gains and losses, excluding gains and losses on intercompany balances where there is no current intent to settle such amounts in the foreseeable future, are included in the determination of net loss. Unless otherwise noted, all references to "$" or "dollar" refer to the United States dollar.

Use of Estimates

In preparing financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, liquidity assumptions, revenue recognition, share-based compensation, allowances for doubtful accounts and inventory obsolescence, and valuation of derivative financial instruments measured at fair value on a recurring basis, deferred tax assets and liabilities and related valuation allowance, depreciation and amortization and estimated useful lives of long-lived assets. Actual results could differ from those estimates.

Fair value of financial instruments

Financial instruments classified as current assets and liabilities (including cash and cash equivalent, receivables, accounts payable, deferred revenue and short-term notes) are carried at cost, which approximates fair value, because of the short-term maturities of those instruments.

For additional fair value disclosures, see Note 12.

Cash and cash equivalents and restricted cash

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. The Company has cash and cash equivalents deposited in financial institutions in which the balances occasionally exceed the federal government agency (FDIC) insured limits of $250,000. The Company has not experienced any losses in such accounts, and management believes it is not exposed to any significant credit risk.

As of December 31, 2018 and 2017, the Company had funds totaling $164,720 and $243,380, respectively, which are required as collateral for letters of credit benefiting its landlords and for credit card processors. These funds are reflected in other noncurrent assets on the accompanying consolidated balance sheets.

Accounts Receivable

The Company's accounts receivable result from revenues earned but not collected from customers. Credit is extended based on an evaluation of a customer's financial condition and, generally, collateral is not required. Accounts receivable are due within 30 to 60 days and are stated at amounts due from customers. The Company evaluates if an allowance is necessary by considering a number of factors, including the length of time accounts receivable are past due, the Company's previous loss history and the customer's current ability to pay its obligation. If amounts become uncollectible, they are charged to operations when that determination is made. The allowance for doubtful accounts was $18,332 and $31,278 as of December 31, 2018 and 2017, respectively.

At December 31, 2018, the Company had accounts receivable from one customer which individually represented 12% of total accounts receivable. At December 31, 2017, the Company had accounts receivable from one customer which individually represented 41% of total accounts receivable. For the year ended December 31, 2018, revenue earned from one customer represented 17% of total revenues. For the year ended December 31, 2017, revenue earned from one customer represented 11% of total revenues.

Inventory

Inventories are valued using the first-in, first-out method and stated at the lower of cost or net realizable value and consist of the following:

	December 31,	
	2018	2017
Raw materials and supplies	$ 368,438	$ 360,134
Work-in process	58,402	51,233
Finished goods	116,907	122,058
Total	$ 543,747	$ 533,425

Inventory includes reagents and components for QuickFISH and PNA FISH kit products, and reagents and supplies used for the Company's laboratory services. Inventory reserves for obsolescence and expirations were $71,270 and $155,507 at December 31, 2018 and 2017, respectively.

Long-lived assets

Property and equipment

Property and equipment is stated at cost and depreciated on a straight-line basis over the estimated useful lives of the related assets. The estimated service lives approximate three to five years. Depreciation expense was $463,068 and $401,272 for the years ended December 31, 2018 and 2017, respectively. Property and equipment consisted of the following at December 31, 2018 and 2017:

	December 31,	
	2018	2017
Laboratory and manufacturing equipment	$ 4,829,323	$ 4,109,367
Office furniture and equipment	700,299	700,299
Computers and network equipment	1,520,713	1,505,651
Leasehold improvements	745,800	729,504
	7,796,135	7,044,821
Less accumulated depreciation	(6,574,308)	(6,209,284)
Property and equipment, net	$ 1,221,827	$ 835,537

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the years ended December 31, 2018 and 2017, the Company determined that its property and equipment was not impaired.

Intangible assets and goodwill

Intangible assets and goodwill as of December 31, 2018 and 2017 were acquired as part of a July 2015 merger transaction in which the Company acquired AdvanDx, Inc. and its subsidiary (the "Merger") and consist of finite-lived intangible assets and goodwill.

Finite-lived intangible assets

Finite-lived intangible assets include trademarks, developed technology and customer relationships, and consisted of the following as of December 31, 2018 and 2017:

		December 31, 2018		December 31, 2017	
	Cost	Accumulated Amortization	Net Balance	Accumulated Amortization	Net Balance
Trademarks and tradenames	$ 461,000	$ (159,783)	$ 301,217	$ (113,679)	$ 347,321
Developed technology	458,000	(226,746)	231,254	(161,322)	296,678
Customer relationships	1,094,000	(541,105)	552,895	(384,817)	709,183
	$ 2,013,000	$ (927,634)	$ 1,085,366	$ (659,818)	$ 1,353,182

Finite-lived intangible assets are amortized over their estimated useful lives. The estimated useful life of trademarks is 10 years, developed technology is 7 years, and customer relationships is 7 years. The Company reviews the useful lives of intangible assets when events or changes in circumstances occur which may potentially impact the estimated useful life of the intangible assets.

Total amortization expense of intangible assets was $267,816 and $267,816 for the years ended December 31, 2018 and 2017, respectively. Expected amortization of intangible assets for each of the next five fiscal years is as follows.

Year Ending December 31,	
2019	$ 267,816
2020	267,816
2021	267,816
2022	165,117
2023	46,104
Thereafter	70,697
Total	$ 1,085,366

Finite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any. During the years ended December 31, 2018 and 2017, the Company determined that its finite-lived intangible assets were not impaired.

In accordance with ASC 360-10, the Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that long-lived assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. During 2018, events and circumstances indicated the Company's intangible assets might be impaired. However, management's estimate of undiscounted cash flows indicated that such carrying amounts were expected to be recovered. Nonetheless, it is reasonably possible that the estimate of undiscounted cash flows may change in the near term, resulting in the need to write down those assets to fair value.

Goodwill

Goodwill represents the excess of the purchase price for AdvanDx, Inc. and subsidiary (collectively, "AdvanDx") over the fair values of the acquired tangible or intangible assets and assumed liabilities. Goodwill is not tax deductible in any relevant jurisdictions.

The Company conducts an impairment test of goodwill on an annual basis as of October 1 of each year, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value. As of December 31, 2018, the Company determined that its goodwill was not impaired.

Deferred rent

Deferred rent is recorded and amortized to the extent the total minimum rental payments allocated to the current period on a straight-line basis exceed or are less than the cash payments required.

Revenue recognition

Subsequent to the Adoption of Accounting Standards Codification Revenue from Contracts with Customers ("ASC 606") on January 1, 2018

The Company derives revenues from (i) the sale of QuickFISH and PNA FISH diagnostic test products and Acuitas AMR Gene Panel (RUO) test products, (ii) providing laboratory services, and (iii) providing collaboration services including funded software arrangements, and license arrangements.

The Company analyzes contracts to determine the appropriate revenue recognition using the following steps: (i) identification of contracts with customers, (ii) identification of distinct performance obligations in the contract, (iii) determination of contract transaction price, (iv) allocation of contract transaction price to the performance obligations and (v) determination of revenue recognition based on timing of satisfaction of the performance obligation.

The Company recognizes revenues upon the satisfaction of its performance obligation (upon transfer of control of promised goods or services to our customers) in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services.

The Company defers incremental costs of obtaining a customer contract and amortizes the deferred costs over the period that the goods and services are transferred to the customer. The Company had no material incremental costs to obtain customer contracts in any period presented.

Deferred revenue results from amounts billed in advance to customers or cash received from customers in advance of services being provided.

For details about the Company's revenue recognition policy prior to the adoption of ASC 606, refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Research and development costs

Research and development costs are expensed as incurred. Research and development costs primarily consist of salaries and related expenses for personnel, other resources, laboratory supplies, fees paid to consultants and outside service partners.

Share-based compensation

Share-based compensation expense is recognized at fair value. The fair value of share-based compensation to employees and directors is estimated, on the date of grant, using the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option. For all time-vesting awards granted, expense is amortized using the straight-line attribution method. The Company accounts for forfeitures as they occur.

Option valuation models, including the Black-Scholes model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award. A discussion of management's methodology for developing each of the assumptions used in the Black-Scholes model is as follows:

Fair value of common stock

For periods prior to the Company's IPO in May 2015, given the lack of an active public market for the common stock, the Company's board of directors determined the fair value of the common stock. In the absence of a public market, and as an emerging company with no significant revenues, the Company believed that it was appropriate to consider a range of factors to determine the fair market value of the common stock at each grant date. The factors included: (1) the achievement of clinical and operational milestones by the Company; (2) the status of strategic relationships with collaborators; (3) the significant risks associated with the Company's stage of development; (4) capital market conditions for life science and medical diagnostic companies, particularly similarly situated, privately held, early stage companies; (5) the Company's available cash, financial condition and results of operations; (6) the most recent sales of the Company's preferred stock; and (7) the preferential rights of the outstanding preferred stock. Since the IPO, the Company uses the quoted market price of its common stock as its fair value.

Expected volatility

Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. Until a significant trading history for its common stock develops, the Company has identified several public entities of similar size, complexity and stage of development; accordingly, historical volatility has been calculated using the volatility of this peer group.

Expected dividend yield

The Company has never declared or paid dividends on its common stock and has no plans to do so in the foreseeable future.

Risk-free interest rate

This is the U.S. Treasury rate for the day of each option grant during the year, having a term that most closely resembles the expected term of the option.

Expected term

This is the period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of 10 years. The Company estimates the expected term of the option to be 6.25 years for options with a standard four-year vesting period, using the simplified method. Over time, management will track actual terms of the options and adjust their estimate accordingly so that estimates will approximate actual behavior for similar options.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the expected future tax consequences attributable to temporary differences between financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred income tax assets to the amount expected to be realized.

Tax benefits are initially recognized in the financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially, and subsequently, measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts.

The Company had federal net operating loss (“NOL”) carryforwards of $178,163,456 and $165,981,195 at December 31, 2018 and 2017, respectively. Despite the NOL carryforwards, which begin to expire in 2022, the Company may have future tax liability due to alternative minimum tax or state tax requirements. Also, use of the NOL carryforwards may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”). To date, the Company has not performed a formal study to determine if any of its remaining NOL and credit attributes might be further limited due to the ownership change rules of Section 382 or Section 383 of the Code. The Company will continue to monitor this matter going forward. There can be no assurance that the NOL carryforwards will ever be fully utilized.

Loss per share

Basic loss per share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options and stock purchase warrants using the treasury stock method, and convertible preferred stock and convertible debt using the if-converted method.

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The number of anti-dilutive shares, consisting of (i) common stock options, (ii) stock purchase warrants, and (iii) restricted stock units representing the right to acquire shares of common stock which have been excluded from the computation of diluted loss per share, was 3.7 million shares and 1.6 million shares as of December 31, 2018 and 2017, respectively.

Adopted accounting pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") and International Accounting Standards Board ("IASB") jointly issued a new revenue recognition standard, Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASC 606") that is designed to improve financial reporting by creating common recognition guidance for U.S. GAAP and International Financial Reporting Standards ("IFRS"). This guidance provides a robust framework for addressing revenue issues, improves the comparability of revenue recognition practices across industries, provides useful information to users of financial statements through improved disclosure requirements and simplifies the presentation of financial statements. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. From March to December 2016, amendments to the new revenue recognition standard were issued to clarify numerous accounting topics, including, but not limited to (i) the implementation guidance on principal versus agent considerations, (ii) the identification of performance obligations, (iii) the licensing implementation guidance, (iv) the objective of the collectability criterion, (v) the application of the variable consideration guidance and modified retrospective transition method, (vi) the way in which impairment testing is performed and (vii) the disclosure requirements for revenue recognized from performance obligations. This guidance permits the use of either a full retrospective method or a modified retrospective approach. The modified retrospective approach is applied only to the most current period presented along with a cumulative-effect adjustment at the date of adoption. This guidance became effective for annual reporting periods beginning after December 15, 2017.

On January 1, 2018, the Company adopted ASC 606, using the modified retrospective method. Results for reporting periods beginning subsequent to December 31, 2017 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting policies prior to adoption. In adopting the guidance, the Company applied the guidance to all contracts and used available practical expedients including assessing contracts with similar terms and conditions on a "portfolio" basis. The adoption of this new guidance did not have a material impact on the Company's condensed consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows: Restricted Cash*, which addresses classification and presentation of changes in restricted cash on the statement of cash flows. The standard requires that restricted cash and restricted cash equivalents be included as components of total cash and cash equivalents as presented on the statement of cash flows. The Company adopted ASU 2016-18 using a retrospective transition method effective January 1, 2018 and applied to the periods presented on the condensed consolidated statements of cash flows. Restricted cash includes cash and cash equivalents that is restricted through legal contracts, regulations or the Company's intention to use the cash for a specific purpose. The Company's restricted cash primarily related to funds held as collateral for letters of credit.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the statements of cash flows:

	December 31, 2018	December 31, 2017	December 31, 2016
Cash and cash equivalents	$ 4,572,487	$ 1,847,171	$ 4,117,324
Restricted cash	164,720	243,380	243,380
Total cash, cash equivalents and restricted cash in the consolidated statements of cash flows	$ 4,737,207	$ 2,090,551	$ 4,360,704

Accounting pronouncements not yet adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASC 842"), which amends the existing accounting standards for leases. The new standard requires lessees to record a right-of-use ("ROU") asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases), whereas under current accounting standards, the Company's lease portfolio consists of operating leases and is not recognized on its consolidated balance sheets. The new standard also requires expanded disclosures regarding leasing arrangements. The new standard is effective for the Company beginning January 1, 2019. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842)*: *Targeted Improvements*, which provides an alternative modified transition method. Under this method, the cumulative-effect adjustment to the opening balance of retained earnings is recognized on the date of adoption with prior periods not restated.

The new standard provides a number of optional practical expedients in transition. The Company expects to elect: (1) the 'package of practical expedients', which permits it not to reassess under the new standard its prior conclusions about lease identification, lease classification, and initial direct costs; (2) the use-of-hindsight; and (3) the practical expedient pertaining to land easements. In addition, the new standard provides practical expedients for an entity's ongoing accounting that the Company anticipates making, such

as the (1) the election for certain classes of underlying asset to not separate non-lease components from lease components and (2) the election for short-term lease recognition exemption for all leases that qualify.

The Company will adopt ASC 842 as of January 1, 2019, using the alternative modified transition method. In preparation of adopting ASC 842, the Company is implementing additional internal controls to enable future preparation of financial information in accordance with ASC 842. The Company has also substantially completed its evaluation of the impact on the Company's lease portfolio. The Company believes the largest impact will be on the consolidated balance sheets for the accounting of facilities-related leases, which represents a majority of its operating leases it has entered into as a lessee. These leases will be recognized under the new standard as ROU assets and operating lease liabilities. The Company will also be required to provide expanded disclosures for its leasing arrangements. As of December 31, 2018, the Company had $2.8 million of undiscounted future minimum operating lease commitments that are not recognized on its consolidated balance sheets as determined under the current standard. For a lessor, the results of operations are not expected to significantly change after adoption of the new standard.

While substantially complete, the Company is still in the process of finalizing its evaluation of the effect of ASC 842 on the Company's consolidated financial statements and disclosures. The Company will finalize its accounting assessment and quantitative impact of the adoption during the first quarter of fiscal year 2019. As the Company completes its evaluation of this new standard, new information may arise that could change the Company's current understanding of the impact to leases. Additionally, the Company will continue to monitor industry activities and any additional guidance provided by regulators, standards setters, or the accounting profession, and adjust the Company's assessment and implementation plans accordingly.

In June 2018, the FASB issued ASU 2018-07: *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, and early adoption is permitted but no earlier than an entity's adoption date of ASC 606. The Company does not expect this new guidance will have a material impact on its financial statements and related disclosures.

The Company has evaluated all other issued and unadopted ASUs and believes the adoption of these standards will not have a material impact on its results of operations, financial position or cash flows.

Note 4 - Revenue from Contracts with Customers

Disaggregated Revenue

The Company provides diagnostic test products, laboratory services to hospitals, clinical laboratories and other healthcare provider customers, and enters into collaboration agreements with government agencies and healthcare providers. The revenues by type of service consist of the following:

	December 31,	
	2018	2017
Product sales	$ 2,395,626	$ 2,771,869
Laboratory services	34,665	41,960
Collaboration revenue	516,016	397,178
Total revenue	$ 2,946,307	$ 3,211,007

Deferred Revenue

Changes in deferred revenue for the period were as follows:

Balance at December 31, 2017	$ 24,442
Revenue recognized in the current period from the amounts in the beginning balance	(14,450)
New deferrals, net of amounts recognized in the current period	5,832
Balance at December 31, 2018	$ 15,824

Contract Assets

The Company had no contract assets as of December 31, 2018, which are generated when contractual billing schedules differ from revenue recognition timing. Contract assets represent a conditional right to consideration for satisfied performance obligations that becomes a billed receivable when the conditions are satisfied.

Unsatisfied Performance Obligations

The Company had no unsatisfied performance obligations related to its contracts with customers at December 31, 2018.

Note 5 - MGHIF Financing

In July 2015, in connection with the Merger, the Company entered into a Purchase Agreement with MGHIF, pursuant to which MGHIF purchased 45,454 shares of common stock of the Company at $110.00 per share for gross proceeds of $5.0 million. Pursuant to the Purchase Agreement, the Company also issued to MGHIF an 8% Senior Secured Promissory Note (the "MGHIF Note") in the principal amount of $1.0 million with a two-year maturity date from the date of issuance. Also in July 2015, the Company entered into a Registration Rights Agreement with MGHIF and certain stockholders, which will require the Company to register for resale by such holders in the future, such shares of Company common stock that cannot be sold under an exemption from such registration. The Company's obligations under the MGHIF Note are secured by a lien on all of the Company's assets.

On June 28, 2017, the MGHIF Note was amended and restated, and the maturity date of the MGHIF Note was extended by one year to July 14, 2018. As consideration for the agreement to extend the maturity date, the Company issued an amended and restated secured promissory note to MGHIF that (1) increased the interest rate to ten percent (10%) per annum and (2) provided for the issuance of common stock warrants to purchase 13,120 shares of its common stock to MGHIF.

On June 11, 2018, the Company executed an Allonge to the MGHIF Note. The Allonge provided that accrued and unpaid interest of $285,512 due as of July 14, 2018, the original maturity date, be paid through the issuance of shares of OpGen's common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021.

On July 30, 2018, the Company issued 144,238 shares of common stock to MGHIF in a private placement transaction for $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

The Allonge to the MGHIF Note was treated as a debt modification and as such the unamortized issuance costs of approximately $7,000 as of June 11, 2018 is deferred and amortized as incremental expense over the term of the MGHIF Note.

Note 6 - Debt

As of December 31, 2018, the Company's outstanding short-term debt consisted of approximately $333,000 due under the MGHIF Note, as well as, the financing arrangements for the Company's insurance with note balances of approximately $65,000 with a final payment scheduled for April 2019. The Company's outstanding long-term debt as of December 31, 2018 consisted of approximately $660,000 due under the MGHIF Note, net of discounts and financing costs (see Note 5 "MGHIF Financing"). As of December 31, 2017, the Company's outstanding short-term debt consisted of the $1.0 million MGHIF Note, net of discounts and financing costs, as well as the financing arrangements for the Company's insurance with note balances of approximately $56,000. The Company did not have any long-term debt as of December 31, 2017. Total principal payments of approximately $333,000 are due annually in 2019, 2020, and 2021.

The Company drew down on two of three Bridge Financing Notes (see discussion in Note 2 "Going Concern and Management's Plans") during June and July of 2017. The outstanding Bridge Financing Notes were repaid in full subsequent to the closing of the July 2017 Public Offering.

The Company accounted for the embedded conversion option granted to jVen Capital in the Bridge Financing Notes as a mark-to-market derivative financial instrument carried at fair value. Changes in fair value of the embedded conversion option were reflected in earnings during the period of change. The embedded conversion option was expensed along with the remaining unamortized discount at the date of the Bridge Financing Notes repayment. The warrants issued to jVen Capital and MGHIF are classified as mark-to-market liabilities under ASC 480 due to certain put features that allow the holder to put the warrant back to the Company for cash equal to the Black-Scholes value of the warrant upon a change of control or fundamental transaction.

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $191,195 and $233,505 for the years ended December 31, 2018 and 2017, respectively.

Note 7 - Stockholders' Equity

As of December 31, 2018, the Company has 50,000,000 shares of authorized common shares and 8,645,720 shares issued and outstanding, and 10,000,000 of authorized preferred shares, of which none were issued or outstanding.

In September 2016, the Company entered into the Sales Agreement with Cowen pursuant to which the Company may offer and sell from time to time, up to an aggregate of $25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of $11.5 million. Pursuant to the Sales Agreement, Cowen may sell the shares of common stock by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including, without limitation, sales made by means of ordinary brokers' transactions on The Nasdaq Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by the Company. The Company pays Cowen compensation equal to 3.0% of the gross proceeds from the sales of common stock pursuant to the terms of the Sales Agreement. As of December 31, 2018, the Company has sold an aggregate of 690,247 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $8.8 million, and gross proceeds of $9.4 million. During the year ended December 31, 2018, the Company sold 318,236 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $0.6 million, and gross proceeds of $0.6 million. In connection with the October 2018 Public Offering, the Company terminated the at the market offering.

In the July 2017 Public Offering, the Company issued 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million. jVen Capital was one of the investors participating in the offering. Each unit included one twenty-fifth of a share of common stock and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. Each pre-funded unit included one pre-funded warrant to purchase one twenty-fifth of a share of common stock for an exercise price of $0.25 per share, and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. At closing, the outstanding Bridge Financing Notes issued to jVen Capital, were repaid in the principal amount of $1 million plus accrued interest of $6,438. All pre-funded warrants issued in the July 2017 Public Offering were exercised during the year ended December 31, 2017.

In connection with the July 2017 Public Offering, the Company issued to its placement agent warrants to purchase 50,000 shares of common stock. The warrants issued to the Placement Agent have an exercise price of $12.50 per share and are exercisable for five years.

In September 2017, the Company issued 15,843 shares of its common stock with an aggregate value of $110,000 to settle a dispute related to pre-Merger AdvanDx activities. In October 2017, the Company issued 2,898 shares of its common stock with an aggregate value of $23,245 to a vendor in exchange for consulting services.

Following receipt of approval from stockholders at a special meeting of stockholders held on January 17, 2018, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to effect a reverse stock split of the issued and outstanding shares of common stock, at a ratio of one share for twenty-five shares, and to reduce the authorized shares of common stock from 200,000,000 to 50,000,000 shares. All share amounts and per share prices in this Annual Report have been adjusted to reflect the reverse stock split.

In the February 2018 Public Offering, the Company issued 2,841,152 units at $3.25 per unit, and 851,155 pre-funded units at $3.24 per pre-funded unit, raising gross proceeds of approximately $12 million and net proceeds of approximately $10.7 million. Each unit included one share of common stock and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. All 851,155 pre-funded warrants issued in the February 2018 Public Offering were exercised during the year ended December 31, 2018.

In connection with the February 2018 Public Offering, the Company issued to its placement agent warrants to purchase 184,615 shares of common stock. The warrants issued to the Placement Agent have an exercise price of $4.0625 per share and are exercisable for five years.

On October 22, 2018, the Company closed the October 2018 Public Offering of 2,220,000 shares of its common stock at a public offering price of $1.45 per share. The offering raised gross proceeds of approximately $3.2 million and net proceeds of approximately $2.8 million.

Stock options

In 2008, the Board adopted, and the stockholders approved, the 2008 Stock Option and Restricted Stock Plan (the "2008 Plan"), pursuant to which the Company's Board of Directors may grant either incentive or non-qualified stock options or shares of restricted stock to directors, key employees, consultants and advisors.

In April 2015, the Board adopted, and the Company's stockholders approved, the 2015 Equity Incentive Plan (the "2015 Plan"); the 2015 Plan became effective upon the execution and delivery of the underwriting agreement for the Company's IPO. Following the effectiveness of the 2015 Plan, no further grants have been made under the 2008 Plan. The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for the grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants.

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 54,200 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date, that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by the Company's Board of Directors. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled, or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. As of December 31, 2018, 50,863 shares remain available for issuance under the 2015 Plan.

For the years ended December 31, 2018 and 2017, the Company recognized stock compensation expense as follows:

	Year Ended December 31,	
	2018	2017
Cost of services	$ 964	$ 13,776
Research and development	241,122	237,103
General and administrative	574,244	603,787
Sales and marketing	45,951	56,732
	$ 862,281	$ 911,398

No income tax benefit for stock-based compensation arrangements was recognized in the consolidated statements of operations due to the Company's net loss position.

As of December 31, 2018, the Company had unrecognized expense related to its stock options of $0.5 million, which will be recognized over a weighted average period of 7.6 years.

A summary of the status of options granted is presented below as of and for the years ended December 31, 2018 and 2017:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2017	119,106	$ 44.00	8.6	$ 663,298
Granted	58,324	$ 17.58		
Exercised	(1,167)	$ 7.01		$ 11,256
Forfeited	(24,538)	$ 36.31		
Expired	(12,330)	$ 83.49		
Outstanding at December 31, 2017	139,395	$ 31.16	8.3	$ 37,339
Granted	95,800	$ 3.84		
Exercised	—	—		
Forfeited	(18,812)	$ 11.98		
Expired	(4,824)	$ 56.12		
Outstanding at December 31, 2018	211,559	$ 20.58	7.6	$ 522
Vested and expected to vest	211,559	$ 20.58	7.6	$ 522
Exercisable at December 31, 2018	10,445	$ 1.25	5.3	$ 522

The total fair value of options vested in the years ended December 31, 2018 and 2017 was $930,921 and $2,086,843, respectively. The fair value of each option grant was estimated at the date of grant using the Black-Scholes option pricing model based on the assumptions below:

	Year Ended December 31,	
	2018	2017
Annual dividend	—	—
Expected life (in years)	5.25 - 6.25	5.25 - 6.25
Risk free interest rate	2.5 - 2.9%	1.8 - 2.3%
Expected volatility	46.0 - 49.6%	44.2 - 53.0%

Restricted stock units

A summary of the status of restricted stock units granted is presented below as of and for the years ended December 31, 2018 and 2017:

	Number of Options	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2017	750	$ 42.50
Granted	11,175	$ 6.93
Vested	(6,025)	$ 8.01
Forfeited	—	—
Unvested at December 31, 2017	5,900	$ 31.16
Granted	—	—
Vested	(5,650)	$ 8.93
Forfeited	—	—
Unvested at December 31, 2018	250	$ 42.50

As of December 31, 2018, there was approximately $9,000 of unrecognized compensation cost related to restricted stock units, which is expected to be recognized over a weighted average period of 0.92 years.

Stock purchase warrants

At December 31, 2018 and 2017, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at December 31, 2018 (1)	Outstanding at December 31, 2017 (1)
March 2008	$ 19,763.50	March 2018	—	2
November 2009	$ 197.75	November 2019	270	270
January 2010	$ 197.75	January 2020	270	270
March 2010	$ 197.75	March 2020	55	55
November 2011	$ 197.75	November 2021	212	212
December 2011	$ 197.75	December 2021	27	27
March 2012	$ 2,747.50	March 2019	165	165
February 2015	$ 165.00	February 2025	9,001	9,001
May 2015	$ 165.00	May 2020	138,310	138,310
May 2016	$ 32.81	May 2021	189,577	189,577
June 2016	$ 32.81	May 2021	82,035	82,035
June 2017	$ 19.50	June 2022	18,754	18,754
July 2017	$ 17.25	July 2022	6,350	6,350
July 2017	$ 12.50	July 2022	50,000	50,000
July 2017	$ 10.625	July 2022	1,000,003	1,000,003
February 2018	$ 4.06	February 2023	184,615	—
February 2018	$ 3.25	February 2023	1,846,153	—
			3,525,797	1,495,031

The warrants listed above were issued in connection with various equity, debt, preferred stock or development contract agreements.

(1) Warrants to purchase fractional shares of common stock resulting from the reverse stock split on January 17, 2018 were rounded up to the next whole share of common stock on a holder by holder basis.

Note 8 - Income Taxes

At December 31, 2018 and 2017, the Company had net deferred tax assets of $52,348,036 and $49,251,408, respectively, primarily consisting of NOL carryforwards, research and experimental ("R&E") credits, and differences between depreciation and amortization recorded for financial statement and tax purposes. The Company's net deferred tax assets at December 31, 2018 and 2017 have been offset by a valuation allowance of $52,348,036 and $49,251,408, respectively. The valuation allowance has been recorded due to the uncertainty of realization of the deferred tax assets. The Company's deferred tax assets and liabilities as of December 31, 2018 and 2017 are as follows:

	December 31, 2018	December 31, 2017
Deferred tax assets:		
NOL carryforward	$ 49,480,731	$ 46,326,407
R&E credit carryforward	2,559,479	2,559,479
Share-based compensation	329,796	345,088
Inventory reserve	19,068	45,338
Depreciation	—	71,756
Interest expense	51,152	—
Accruals and other	284,662	247,093
Total deferred tax assets	52,724,888	49,595,161
Valuation allowance	(52,348,036)	(49,251,408)
Deferred tax liabilities:		
Intangible assets	(256,011)	(343,753)
Depreciation	(120,841)	—
Net	$ —	$ —

The difference between the Company's expected income tax provision (benefit) from applying federal statutory tax rates to the pre-tax loss and actual income tax provision (benefit) relates to the effect of the following:

	2018	2017
Federal income tax benefit at statutory rates	21.0%	34.0%
Permanent adjustment	(1.4)%	—
Provision to return adjustment	(0.2)%	—
State income tax benefit, net of Federal benefit	(6.4)%	6.8%
Tax reform impact	—	(134.5)%
Change in valuation allowance	(13.0)%	93.0%
Change in state tax rates and other	—	0.7%
	0.0%	0.0%

The Company has federal NOL carryforwards of $178,163,456 and $165,981,195 at December 31, 2018 and 2017, respectively. The NOL carryforwards incurred prior to 2018 begin to expire in 2022. Under the Tax Cuts and Jobs Act (the Tax Act), the amount of post 2017 NOLs that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. In addition, the Tax Act generally eliminates the ability to carry back any NOL to prior taxable years, while allowing post 2017 unused NOLs to be carried forward indefinitely. Utilization of the NOL carryforward may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code. There can be no assurance that the NOL carryforward will ever be fully utilized. To date, the Company has not performed a formal study to determine if any of its remaining NOL and credit attributes might be further limited due to the ownership change rules of Section 382 or Section 383 of the Internal Revenue Code of 1986, as amended. The Company will continue to monitor this matter going forward. There can be no assurance that the NOL carryforwards will ever be fully utilized.

In December 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"), most of the provisions of which took effect starting in 2018. The Tax Act made broad and complex changes to the U.S. tax code, including, but not limited to: (i) reducing the U.S. federal corporate tax rate from 35 percent to 21 percent; (ii) eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; (iii) creating a new limitation on deductible interest expense; and (iv) changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017; and (v) changing the U.S. federal taxation of earnings of foreign subsidiaries. The U.S. change in federal taxation for foreign subsidiary earnings included a one-time toll charge on deemed repatriated earnings of foreign subsidiaries as of December 31, 2017. As a result of the accumulated losses in the Company's foreign subsidiary, the Company had no toll tax liability for the tax year ended December 31, 2017. For 2018, the Company considered in its estimated annual effective tax rate additional provisions of Tax Reform including changes to the deduction for interest expense pursuant to IRC Section 163(j) interest limitation.

As a result, the most significant impact on the Company's consolidated financial statements was the reduction of approximately $14.6 million of the deferred tax assets related to net operating losses and other deferred tax assets. Such reduction is offset by a change in the Company's valuation allowance. Additionally, the Company has foreign subsidiaries. At December 31, 2017 and November 2, 2017, the cumulative earnings and profits of these entities were negative. Accordingly, the Company was not liable for the transition tax on foreign earnings enacted under the Tax Act.

Note 9 - Commitments

Operating leases

The Company leases a facility in Gaithersburg, Maryland under an operating lease that expires January 31, 2021, with one additional five-year renewal at the Company's election. The Company also leases a facility in Woburn, Massachusetts under an operating lease that expires January 30, 2022. Additionally, the Company leases office space in Denmark; this lease is currently on a month-to-month basis.

Rent expense under the Company's facility operating leases for the year ended December 31, 2018 and 2017 was $984,639 and $949,244, respectively.

Capital leases

The Company leases lab equipment, office furniture, and computer equipment under various capital leases. The leases expire at various dates through 2021. The leases require monthly principal and interest payments. Following is a schedule by year of the estimated future minimum payments under all operating and capital leases as of December 31, 2018:

Year ending December 31,	Capital Leases	Operating Leases	Total
2019	$ 508,114	$ 1,107,565	$ 1,615,679
2020	408,264	1,125,940	1,534,204
2021	104,579	535,250	639,829
2022	—	40,080	40,080
2023 and thereafter	—	—	—
Total	1,020,957	$ 2,808,835	$ 3,829,792
Less: amount representing interest	(96,251)		
Less: amount representing service costs	(88,172)		
Net present value of future minimum lease payments	836,534		
Current maturities	(399,345)		
Long-term maturities	$ 437,189		

Assets under capital leases were included in the following balance sheet categories as of December 31:

	2018	2017
Laboratory and manufacturing equipment	$ 1,563,346	$ 850,792
Office furniture and equipment	64,790	64,790
Computers and network equipment	24,350	24,350
Less accumulated amortization	(749,480)	(454,471)
Capital lease assets, net	$ 903,006	$ 485,461

Amortization expense associated with equipment under capital leases for the years ended December 31, 2018 and 2017 was $295,009 and $161,606, respectively, and is included within depreciation and amortization expense in the consolidated statements of operations.

Registration and other stockholder rights

In connection with the various investment transactions, the Company entered into registration rights agreements with stockholders, pursuant to which the investors were granted certain demand registration rights and/or piggyback and/or resale registration rights in connection with subsequent registered offerings of the Company's common stock.

Restructuring

In early June 2017, the Company commenced a restructuring of its operations to improve efficiency and reduce its cost structure. The restructuring plans anticipate that the Company will consolidate operations for FDA-cleared and CE marked products and research and development activities for the Acuitas Rapid Test in Gaithersburg, Maryland, and reduce the size of its commercial organization while the Company works to complete the development of its Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase products and services in development.

There were approximately $121,000 of one-time termination benefits that were recognized during the year ended December 31, 2017 related to the restructuring. The Company does not anticipate any further one-time termination benefits related to the restructuring plan. Retention agreements were issued to certain employees in which retention bonuses are earned and paid upon the completion of a designated service period. The service periods ended in December 2017. The Company incurred total retention expense of approximately $68,000 during the year ended December 31, 2017. The future minimum lease payments for the Woburn facility were approximately $1.4 million as of December 31, 2018. A liability for costs that will continue to be incurred under a contract for its remaining term without economic benefit to the entity shall be recognized at the cease-use date. If the contract is an operating lease the fair value of the liability at the cease-use date shall be determined based on the remaining lease rentals, adjusted for the effects of any prepaid or deferred items recognized under the lease, and reduced by estimated sublease rentals that could be reasonably obtained for the property. The Company expects the cease-use date for the Woburn facility to be in the first quarter of 2019. We do not believe there will be significant additional costs related to restructuring outside of what is described herein.

Supply Agreements

In June 2017, the Company entered into an agreement with Life Technologies Corporation, a subsidiary of Thermo Fisher Scientific ("LTC") to supply the Company with Thermo Fisher Scientific's QuantStudio 5 Real-Time PCR Systems ("QuantStudio 5") to be used to run OpGen's Acuitas AMR Gene Panel tests. Under the terms of the agreement the Company must notify LTC of the number of QuantStudio 5s that it commits to purchase in the following quarter. As of December 31, 2018 the Company has acquired fifteen QuantStudio 5s including eleven in the twelve months ended December 31, 2018. As of December 31, 2018 the Company has committed to acquiring an additional three QuantStudio 5s at a total cost of approximately $135,000 in the next three months.

Note 10 - License Agreements, Research Collaborations and Development Agreements

The Company is a party to one license agreement to acquire certain patent rights and technologies related to its FISH product line. Royalties are incurred upon the sale of a product or service which utilizes the licensed technology. Certain of the agreements require the Company to pay minimum royalties or license maintenance fees. The Company recognized net royalty expense of $250,000 and $257,186 for the years ended December 31, 2018 and 2017, respectively. Annual future minimum royalty fees are $250,000 under these agreements.

In September 2017, the Company was awarded a contract from the Centers for Disease Control and Prevention ("CDC") to develop smartphone-based clinical decision support solutions for antimicrobial stewardship, or AMS, and infection control in low- and middle-income countries. The one-year $860,000 award began September 30, 2017 and funds development and evaluation of cloud-based mobile software. The Company worked with subcontractors Ilúm, LLC, an affiliate of Merck, and Universidad El Bosque ("UEB") of Bogota, Colombia under this CDC contract. During the years ended December 31, 2018 and 2017, the Company recognized $503,881 and $357,178 of revenue related to the contract, respectively.

In June 2016, the Company entered into a license agreement with Hitachi, pursuant to which it resolved various matters with respect to previously delivered milestones under the technology development agreement and provided a development license and commercial products license to certain technology. The license agreement contains non-contingent multiple elements (the licenses) that the Company determined did not have stand alone value, and a contingent substantive milestone. The licenses are treated as a single unit of accounting and the Company will recognize the revenue associated with that unit of accounting over the applicable license period. During the years ended December 31, 2018 and 2017, the Company recognized $12,397 and $25,000 of revenue related to the license agreement, respectively.

Note 11 - Related Party Transactions

In October 2016, the Company entered into an agreement with Merck Sharp & Dohme, a wholly-owned subsidiary of Merck Co. & Inc. ("Merck"), an affiliate of MGHIF, a principal stockholder of the Company and a related party to the Company. Under the agreement, Merck provided access to its archive of over 200,000 bacterial pathogens. The Company is initially performing molecular analyses on up to 10,000 pathogens to identify markers of resistance to support rapid decision making using the Acuitas Lighthouse, and to speed development of its rapid diagnostic products. Merck gains access to the high-resolution genotype data for the isolates as well as access to the Acuitas Lighthouse informatics to support internal research and development programs. The Company is required to expend up to $175,000 for the procurement of materials related to the activities contemplated by the agreement. Contract life-to-date, the Company has incurred $171,646 of procurement costs which have been recognized as research and development expense, including $22,603 and $146,177 during the years ended December 31, 2018 and 2017.

In December 2017, we entered into a subcontractor agreement with ILÚM Health Solutions, LLC, an entity created by Merck's Healthcare Services and Solutions division, whereby ILÚM Health Solutions 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 up to three medical sites in Colombia with the aim of improving antibiotic use in resource-limited settings. During the years ended December 31, 2018 and 2017, the Company recognized $329,162 and $210,180 of cost of services expense related to the contract, respectively.

Note 12 - Fair Value Measurements

The Company classifies its financial instruments using a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 - defined as observable inputs such as quoted prices in active markets;
- Level 2 - defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and
- Level 3 - defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions such as expected revenue growth and discount factors applied to cash flow projections.

Financial assets and liabilities measured at fair value on a recurring basis

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the hierarchy.

As part of the Company's bridge financing and amendment to the MGHIF Note, the Company issued stock purchase warrants that the Company considers to be mark-to-market liabilities due to certain put features that allow the holder to put the warrant back to the Company for cash equal to the Black-Scholes value of the warrant upon a change of control or fundamental transaction. The Company determines the fair value of the warrant liabilities using the Black-Scholes option pricing model. Using this model, level 3 unobservable inputs include the estimated volatility of the Company's common stock, estimated terms of the instruments, and estimated risk-free interest rates.

The Company originally accounted for the conversion option embedded in the Bridge Financing Notes as a mark-to-market derivative financial instrument. The Company determined the fair value of the embedded conversion option liability using a probability-weighted expected return method. Using this method, level 3 unobservable inputs include the probability of default, the probability of a qualified financing, the probability of conversion, the estimated volatility of the Company's common stock, estimated terms of the instruments, and estimated risk-free interest rates, among other inputs. The fair value of the conversion option was expensed at the time of repayment of the Bridge Financing Notes.

The following table sets forth a summary of changes in the fair value of level 3 liabilities measured at fair value on a recurring basis for the year ended December 31, 2018:

Description	Balance at December 31, 2017	Change in Fair Value	Balance at December 31, 2018
Warrant liability	$ 8,453	$ (8,386)	$ 67

Financial assets and liabilities carried at fair value on a non-recurring basis

The Company does not have any financial assets and liabilities measured at fair value on a non-recurring basis.

Non-financial assets and liabilities carried at fair value on a recurring basis

The Company does not have any non-financial assets and liabilities measured at fair value on a recurring basis.

Non-financial assets and liabilities carried at fair value on a non-recurring basis

The Company measures its long-lived assets, including property and equipment and intangible assets (including goodwill), at fair value on a non-recurring basis when they are deemed to be impaired. No such fair value impairment was recognized in the year ended December 31, 2018.

OpGen, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2019 (Unaudited)	December 31, 2018 (See Note 3)
Assets		
Current assets		
Cash and cash equivalents	$ 626,420	$ 4,572,487
Accounts receivable, net	377,284	373,858
Inventory, net	468,374	543,747
Prepaid expenses and other current assets	533,411	292,918
Total current assets	**2,005,489**	**5,783,010**
Property and equipment, net	201,762	1,221,827
Finance lease right-of-use assets, net	1,096,472	—
Operating lease right-of-use assets	1,214,482	—
Goodwill	600,814	600,814
Intangible assets, net	884,504	1,085,366
Other noncurrent assets	426,629	259,346
Total assets	**$ 6,430,152**	**$ 8,950,363**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 1,872,762	$ 1,623,751
Accrued compensation and benefits	1,387,498	1,041,573
Accrued liabilities	1,040,562	902,019
Deferred revenue	9,808	15,824
Short-term notes payable	508,292	398,595
Short-term finance lease liabilities	627,620	399,345
Short-term operating lease liabilities	987,833	—
Total current liabilities	**6,434,375**	**4,381,107**
Deferred rent	—	162,919
Note payable	328,843	660,340
Warrant liability	—	67
Long-term finance lease liabilities	411,103	437,189
Long-term operating lease liabilities	812,801	—
Total liabilities	**7,987,122**	**5,641,622**
Commitments (Note 9)		
Stockholders' equity (deficit)		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.01 par value; 50,000,000 shares authorized; 882,268 and 432,286 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively*	8,823	4,323
Additional paid-in capital	170,449,216	165,396,036
Accumulated deficit	(172,007,090)	(162,078,525)
Accumulated other comprehensive loss	(7,919)	(13,093)
Total stockholders' equity (deficit)	**(1,556,970)**	**3,308,741**
Total liabilities and stockholders' equity (deficit)	**$ 6,430,152**	**$ 8,950,363**

*Reflects the 1-for-20 reverse stock split that became effective on August 29, 2019. Refer to Note 8 – Stockholders' equity for further information.

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue				
Product sales	$ 573,035	$ 539,856	$ 1,597,505	$ 1,805,877
Laboratory services	185	12,365	5,435	22,155
Collaboration revenue	75,000	—	1,075,000	359,316
Total revenue	**648,220**	**552,221**	**2,677,940**	**2,187,348**
Operating expenses				
Cost of products sold	262,373	292,984	681,568	939,479
Cost of services	196,184	98,189	592,647	446,144
Research and development	1,139,369	1,286,300	4,069,335	3,821,117
General and administrative	1,560,706	1,743,636	4,901,136	5,365,221
Sales and marketing	376,955	361,310	1,142,755	1,117,380
Transaction costs	538,061	—	538,061	—
Impairment of right-of-use asset	—	—	520,759	—
Total operating expenses	**4,073,648**	**3,782,419**	**12,446,261**	**11,689,341**
Operating loss	**(3,425,428)**	**(3,230,198)**	**(9,768,321)**	**(9,501,993)**
Other (expense) income				
Other income (expense)	1,043	(93)	(8,213)	5,210
Interest expense	(49,099)	(28,074)	(142,672)	(140,453)
Foreign currency transaction gains (losses)	(8,954)	3,025	(9,426)	(6,556)
Change in fair value of derivative financial instruments	—	(85)	67	8,070
Total other expense	**(57,010)**	**(25,227)**	**(160,244)**	**(133,729)**
Loss before income taxes	**(3,482,438)**	**(3,255,425)**	**(9,928,565)**	**(9,635,722)**
Provision for income taxes	—	—	—	—
Net loss	**(3,482,438)**	**(3,255,425)**	**(9,928,565)**	**(9,635,722)**
Net loss available to common stockholders*	**$ (3,482,438)**	**$ (3,255,425)**	**$ (9,928,565)**	**$ (9,635,722)**
Net loss per common share - basic and diluted*	**$ (3.95)**	**$ (10.67)**	**$ (13.32)**	**$ (36.09)**
Weighted average shares outstanding - basic and diluted*	882,280	305,187	745,471	266,997
Net loss	$ (3,482,438)	$ (3,255,425)	$ (9,928,565)	$ (9,635,722)
Other comprehensive gain foreign currency translation adjustment	7,298	1,528	5,174	7,062
Comprehensive loss	**$ (3,475,140)**	**$ (3,253,897)**	**$ (9,923,391)**	**$ (9,628,660)**

* Reflects the 1-for-20 reverse stock split that became effective on August 29, 2019. Refer to Note 8 – Stockholders' equity for further information.

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(unaudited)

	Common Stock*		Preferred Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount				
Balances at December 31, 2017	**113,266**	**$ 1,133**	—	—	**$ 150,136,191**	**$ (25,900)**	**$ (148,710,427)**	**$ 1,400,997**
Public offering of common stock and warrants, net of issuance costs	150,962	1,510	—	—	10,719,890	—	—	10,721,400
Issuance of RSUs	270	3	—	—	(3)	—	—	—
Stock compensation expense	—	—	—	—	238,190	—	—	238,190
Stock cancellation	(2)	—	—	—	—	—	—	—
Foreign currency translation	—	—	—	—	—	(12,579)	—	(12,579)
Net loss	—	—	—	—	—	—	(3,048,084)	(3,048,084)
Balances at March 31, 2018	**264,496**	**$ 2,646**	**—**	**—**	**$ 161,094,268**	**$ (38,479)**	**$ (151,758,511)**	**$ 9,299,924**
Public offering of common stock and warrants, net of issuance costs	33,654	337	—	—	6,394	—	—	6,731
At the market offering, net of offering costs	5,202	52	—	—	192,268	—	—	192,320
Stock compensation expense	—	—	—	—	213,890	—	—	213,890
Foreign currency translation	—	—	—	—	—	18,113	—	18,113
Net loss	—	—	—	—	—	—	(3,332,213)	(3,332,213)
Balances at June 30, 2018	**303,352**	**$ 3,035**	**—**	**—**	**$ 161,506,820**	**$ (20,366)**	**$ (155,090,724)**	**$ 6,398,765**
At the market offering, net of offering costs	10,710	107	—	—	405,316	—	—	405,423
Stock compensation expense	—	—	—	—	206,651	—	—	206,651
Interest settlement in common stock	7,212	72	—	—	272,537	—	—	272,609
Foreign currency translation	—	—	—	—	—	1,528	—	1,528
Net loss	—	—	—	—	—	—	(3,255,425)	(3,255,425)
Balances at September 30, 2018	**321,274**	**$ 3,214**	**—**	**—**	**$ 162,391,324**	**$ (18,838)**	**$ (158,346,149)**	**$ 4,029,551**
Balances at December 31, 2018	**432,286**	**$ 4,323**	—	—	**$ 165,396,036**	**$ (13,093)**	**$ (162,078,525)**	**$ 3,308,741**
Public offering of common stock and warrants, net of issuance costs	450,000	4,500	—	—	4,778,009	—	—	4,782,509
Stock compensation expense	—	—	—	—	98,033	—	—	98,033
Foreign currency translation	—	—	—	—	—	2,826	—	2,826
Net loss	—	—	—	—	—	—	(3,853,116)	(3,853,116)
Balances at March 31, 2019	**882,286**	**$ 8,823**	**—**	**—**	**$ 170,272,078**	**$ (10,267)**	**$ (165,931,641)**	**$ 4,338,993**
Stock compensation expense	—	—	—	—	85,971	—	—	85,971
Foreign currency translation	—	—	—	—	—	(4,950)	—	(4,950)
Net loss	—	—	—	—	—	—	(2,593,011)	(2,593,011)
Balances at June 30, 2019	**882,286**	**$ 8,823**	**—**	**—**	**$ 170,358,049**	**$ (15,217)**	**$ (168,524,652)**	**$ 1,827,003**
Stock compensation expense	—	—	—	—	91,167	—	—	91,167
Share cancellation	(18)	—	—	—	—	—	—	—
Foreign currency translation	—	—	—	—	—	7,298	—	7,298
Net loss	—	—	—	—	—	—	(3,482,438)	(3,482,438)
Balances at September 30, 2019	**882,268**	**$ 8,823**	**—**	**—**	**$ 170,449,216**	**$ (7,919)**	**$ (172,007,090)**	**$ (1,556,970)**

*Reflects the 1-for-20 reverse stock split that became effective on August 29, 2019. Refer to Note 8 – Stockholders' equity for further information.

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Nine Months Ended September 30, 2019	2018
Cash flows from operating activities		
Net loss	$ (9,928,565)	$ (9,635,722)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	687,107	508,162
Noncash interest expense	2,659	108,011
Stock compensation expense	275,171	658,731
Loss (gain) on sale of equipment	9,904	(5,253)
Change in fair value of warrant liability	(67)	(8,070)
Impairment of right-of-use asset	520,759	—
Changes in operating assets and liabilities:		
Accounts receivable	(5,173)	492,444
Inventory	74,449	3,179
Other assets	55,122	(164,346)
Accounts payable	314,559	(493,971)
Accrued compensation and other liabilities	(55,871)	174,560
Deferred revenue	(6,016)	(14,119)
Net cash used in operating activities	**(8,055,962)**	**(8,376,394)**
Cash flows from investing activities		
Purchases of property and equipment	(72,607)	(41,910)
Proceeds from sale of equipment	29,250	10,440
Net cash used in investing activities	**(43,357)**	**(31,470)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	4,782,509	597,743
Proceeds from issuance of units, net of selling costs	—	10,728,132
Proceeds from debt, net of issuance costs	470,519	381,253
Payments on debt	(694,156)	(299,256)
Payments on finance leases	(389,501)	(177,092)
Net cash provided by financing activities	**4,169,371**	**11,230,780**
Effects of exchange rates on cash	4,541	7,419
Net (decrease) increase in cash, cash equivalents and restricted cash	(3,925,407)	2,830,335
Cash, cash equivalents and restricted cash at beginning of period	4,737,207	2,090,551
Cash, cash equivalents and restricted cash at end of period	**$ 811,800**	**$ 4,920,886**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 170,608	$ 32,442
Supplemental disclosures of noncash investing and financing activities:		
Right-of-use assets acquired through finance leases	$ 528,413	$ 585,278
Shares issued to settle obligations	$ —	$ 272,610
Conversion of accounts payable to finance lease	$ 63,600	$ 156,775

See accompanying notes to unaudited condensed consolidated financial statements.

Note 1 – Organization

OpGen, Inc. ("OpGen" or the "Company") was incorporated in Delaware in 2001. References in this report to the "Company" include OpGen and its wholly-owned subsidiaries. The Company's headquarters and its principal operations are in Gaithersburg, Maryland. The Company also has operations in Copenhagen, Denmark, and Bogota, Colombia. The Company operates in one business segment.

OpGen is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. The Company is 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. Its 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.

The Company'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. The Company is working to deliver products and services, some in development, to a global network of customers and partners.

- The Company's Acuitas molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include its Acuitas antimicrobial resistance, or AMR, Gene Panel Urine test in development for patients at risk for complicated urinary tract infection, or cUTI, and its Acuitas AMR Gene Panel test for use with bacterial isolates in development for testing bacterial isolates, and its QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of the Acuitas AMR Gene Panel tests is available for sale for research use only, or RUO and is not for use in diagnostic procedures.
- The Company's Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that 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 is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

The Company's operations are subject to certain risks and uncertainties. The risks include the risk that the Company will not receive 510(k) clearance for its Acuitas AMR Gene Panel test for use with bacterial isolates on a timely basis, or at all, the timing and ultimate success of future 510(k) clearance submissions for additional Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software, rapid technology changes, the need to retain key personnel, the need to protect intellectual property and the need to raise additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop, obtain regulatory approval for and commercialize its proprietary technology as well as raise additional capital.

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" herein.

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 number of shares of OpGen common stock to be issued to Curetis N.V. is fixed, therefore, the percentage ownership of the Company owned by Curetis will not be known until the closing occurs.

On November 12, 2019 the Company filed a Registration Statement on Form S-4 to register the Consideration. The transactions under the Implementation Agreement are subject to approval by the stockholders of the Company and the shareholders and debt holders of Curetis N.V and Curetis GmbH. The Company 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 committed to raise at least $10,000,000 of gross interim equity financing to support the continuing operations of both the Company and the Curetis Group, and to lend funds to the Curetis Group following such offering (See Note 13 – Subsequent Events).

Note 2 – Liquidity and management's plans

The accompanying unaudited condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Since inception, the Company has incurred, and continues to incur, significant losses from operations. The Company has funded its operations primarily through external investor financing transactions, including the following in 2018 and 2019 to date:

- On March 29, 2019, the Company closed a public offering (the "March 2019 Public Offering") of 450,000 shares of its common stock at a public offering price of $12.00 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million.
- On October 22, 2018, the Company closed a public offering (the "October 2018 Public Offering") of 111,000 shares of its common stock at a public offering price of $29.00 per share. The offering raised gross proceeds of approximately $3.2 million and net proceeds of approximately $2.8 million.
- On June 11, 2018, the Company executed an Allonge (the "Allonge") to its Second Amended and Restated Senior Secured Promissory Note, dated June 28, 2017, with a principal amount of $1,000,000 issued to Merck Global Health Innovation Fund, LLC ("MGHIF"). The Allonge provided that accrued and unpaid interest of $285,512 due as of July 14, 2018, the original maturity date, be paid through the issuance of shares of OpGen's common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Promissory Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021. On July 30, 2018, the Company issued 7,212 shares of common stock to MGHIF in a private placement transaction for $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.
- On February 6, 2018, the Company closed a public offering (the "February 2018 Public Offering") of 2,841,152 units at $3.25 per unit, and 851,155 pre-funded units at $3.24 per pre-funded unit, raising gross proceeds of approximately $12 million and net proceeds of approximately $10.7 million. Each unit included one twentieth of a share of common stock and one common warrant to purchase one fortieth of a share of common stock at an exercise price of $65.00 per share. Each pre-funded unit included one pre-funded warrant to purchase one twentieth of a share of common stock for an exercise price of $0.20 per share, and one common warrant to purchase one fortieth of a share of common stock at an exercise price of $65.00 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. The 851,155 pre-funded warrants issued in the February 2018 Public Offering were exercised during the year ended December 31, 2018.
- On September 13, 2016, the Company entered into the Sales Agreement (the "Sales Agreement") with Cowen and Company LLC ("Cowen") pursuant to which the Company could offer and sell from time to time, up to an aggregate of $25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of $11.5 million. During the year ended December 31, 2018, the Company sold 15,912 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $0.6 million, and gross proceeds of $0.6 million. The at the market offering was terminated in connection with the October 2018 Public Offering.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, strategic financings or other transactions, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements and business combination transactions. There can be no assurance that the Company will be able to complete any such transaction on

acceptable terms or otherwise. The Company believes that current cash plus the cash generated from the October 2019 Public Offering (See Note 13 – Subsequent Events) will be sufficient to fund operations into the first quarter of 2020 and to meet the Company's obligations under the Interim Facility. This has led management to conclude that substantial doubt about the Company's ability to continue as a going concern exists. In the event the Company is unable to successfully raise additional capital during or before the end of the first quarter of 2020, 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 reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing. 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.

Note 3 – Summary of significant accounting policies

Basis of presentation and consolidation

The Company has prepared the accompanying unaudited condensed consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") and the standards of accounting measurement set forth in the Interim Reporting Topic of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"). Certain information and note disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted, although the Company believes that the disclosures made are adequate to make the information not misleading. The Company recommends that the unaudited condensed consolidated financial statements be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company's 2018 Annual Report on Form 10-K. In the opinion of management, all adjustments that are necessary for a fair presentation of the Company's financial position for the periods presented have been reflected. All adjustments are of a normal, recurring nature, unless otherwise stated. The interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2018 consolidated balance sheet included herein was derived from the audited consolidated financial statements but does not include all disclosures including notes required by GAAP for complete financial statements.

The accompanying unaudited condensed consolidated financial statements include the accounts of OpGen and its wholly-owned subsidiaries; all intercompany transactions and balances have been eliminated.

Foreign currency

The Company has subsidiaries located in Copenhagen, Denmark, and Bogota, Colombia, both of which use currencies other than the U.S dollar as their functional currency. As a result, all assets and liabilities are translated into U.S. dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the average exchange rates prevailing during the reporting period. Translation adjustments are reported in accumulated other comprehensive loss, a component of stockholders' equity (deficit). Foreign currency translation adjustments are the sole component of accumulated other comprehensive loss at September 30, 2019 and December 31, 2018.

Foreign currency transaction gains and losses, excluding gains and losses on intercompany balances where there is no current intent to settle such amounts in the foreseeable future, are included in the determination of net loss. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar.

Use of estimates

In preparing financial statements in conformity with GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In the accompanying unaudited condensed consolidated financial statements, estimates are used for, but not limited to, liquidity assumptions, revenue recognition, stock-based compensation, allowances for doubtful accounts and inventory obsolescence, discount rates used to discount unpaid lease payments to present values, valuation of derivative financial instruments measured at fair value on a recurring basis, deferred tax assets and liabilities and related valuation allowance, the estimated useful lives of long-lived assets, and the recoverability of long-lived assets. Actual results could differ from those estimates.

Fair value of financial instruments

Financial instruments classified as current assets and liabilities (including cash and cash equivalent, receivables, accounts payable, deferred revenue and short-term notes) are carried at cost, which approximates fair value, because of the short-term maturities of those instruments.

Cash, cash equivalents and restricted cash

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. The Company has cash and cash equivalents deposited in financial institutions in which the balances occasionally exceed the federal government agency ("FDIC") insured limit of $250,000. The Company has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk.

At September 30, 2019, the Company has funds totaling $185,380, which are required as collateral for letters of credit benefiting its landlords and for credit card processors. At December 31, 2018, the Company had funds totaling $164,720, which are required as collateral for letters of credit benefiting its landlords and for credit card processors. These funds are reflected in other noncurrent assets on the accompanying unaudited condensed consolidated balance sheets.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the statements of cash flows:

	September 30, 2019	December 31, 2018	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 626,420	$ 4,572,487	$ 4,735,506	$ 1,847,171
Restricted cash	185,380	164,720	185,380	243,380
Total cash, cash equivalents and restricted cash in the condensed consolidated statement of cash flows	$ 811,800	$ 4,737,207	$ 4,920,886	$ 2,090,551

Accounts receivable

The Company's accounts receivable result from revenues earned but not yet collected from customers. Credit is extended based on an evaluation of a customer's financial condition and, generally, collateral is not required. Accounts receivable are due within 30 to 60 days and are stated at amounts due from customers. The Company evaluates if an allowance is necessary by considering a number of factors, including the length of time accounts receivable are past due, the Company's previous loss history and the customer's current ability to pay its obligation. If amounts become uncollectible, they are charged to operations when that determination is made. The allowance for doubtful accounts was $18,309 and $18,332 as of September 30, 2019 and December 31, 2018, respectively.

One individual customer represented 12% of revenues for the three months ended September 30, 2019. No individual customer represented in excess of 10% of revenues for the three months ended September 30, 2018. One individual customer represented 40% and 16% of revenues for the nine months ended September 30, 2019 and 2018, respectively. At September 30, 2019, one individual customer represented 20% of total accounts receivable. At December 31, 2018, one individual customer represented 12% of total accounts receivable.

Inventory

Inventories are valued using the first-in, first-out method and stated at the lower of cost or net realizable value and consist of the following:

	September 30, 2019	December 31, 2018
Raw materials and supplies	$ 292,271	$ 368,438
Work-in-process	14,676	58,402
Finished goods	161,427	116,907
Total	$ 468,374	$ 543,747

Inventory includes reagents and components for QuickFISH and PNA FISH kit products, and reagents and supplies used for the Company's laboratory services. Inventory reserves for obsolescence and expirations were $129,345 and $71,270 at September 30, 2019 and December 31, 2018, respectively.

Long-lived assets

Property and equipment

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the three and nine months ended September 30, 2019 and 2018, the Company determined that its property and equipment was not impaired.

Leases

The Company determines if an arrangement is a lease at inception. For leases where the Company is the lessee, right-of-use ("ROU") assets represent the Company's right to use the underlying asset for the term of the lease and the lease liabilities represent an obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of the future lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at the commencement date of the underlying lease arrangement to determine the present value of lease payments. The ROU asset also includes any prepaid lease payments and any lease incentives received. The lease term to calculate the ROU asset and related lease liability includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise the option. The Company's lease agreements generally do not contain any material variable lease payments, residual value guarantees or restrictive covenants.

Lease expense for operating leases is recognized on a straight-line basis over the lease term as an operating expense while expense for financing leases is recognized as depreciation expense and interest expense using the accelerated interest method of recognition. The Company has made certain accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12 months or less) and (ii) combines lease and non-lease elements of our operating leases.

ROU assets

ROU assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which the Company can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. In conjunction with adoption of Accounting Standards Update ("ASU") 2016-02, *Leases* (Topic 842) ("ASC 842"), the Company determined that the ROU asset associated with its Woburn, Massachusetts office lease may not be recoverable. As a result, the Company recorded an impairment charge of $520,759 during the nine months ended September 30, 2019.

Intangible assets and goodwill

Intangible assets and goodwill as of September 30, 2019 consist of finite-lived intangible assets and goodwill.

Finite-lived intangible assets

Finite-lived intangible assets include trademarks, developed technology and customer relationships and consisted of the following as of September 30, 2019 and December 31, 2018:

	September 30, 2019			December 31, 2018	
	Cost	Accumulated Amortization	Net Balance	Accumulated Amortization	Net Balance
Trademarks and trade names	$ 461,000	$ (194,361)	$ 266,639	$ (159,783)	$ 301,217
Developed technology	458,000	(275,814)	182,186	(226,746)	231,254
Customer relationships	1,094,000	(658,321)	435,679	(541,105)	552,895
	$ 2,013,000	$ (1,128,496)	$ 884,504	$ (927,634)	$ 1,085,366

Finite-lived intangible assets are amortized over their estimated useful lives. The estimated useful life of trademarks is 10 years, developed technology is 7 years, and customer relationships is 7 years. The Company reviews the useful lives of intangible assets when events or changes in circumstances occur which may potentially impact the estimated useful life of the intangible assets.

Total amortization expense of intangible assets was $66,954 for each of the three months ended September 30, 2019 and 2018. Total amortization expense of intangible assets was $200,862 for each of the nine months ended September 30, 2019 and 2018.

Finite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any. During the three and nine months ended September 30, 2019 and 2018, the Company determined that its finite-lived intangible assets were not impaired.

In accordance with ASC 360-10, *Property, Plant and Equipment*, the Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that long-lived assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. During the fourth quarter of 2018, events and circumstances indicated the Company's intangible assets might be impaired. However, management's estimate of undiscounted cash flows indicated that such carrying amounts were expected to be recovered. Nonetheless, it is reasonably possible that the estimate of undiscounted cash flows may change in the near term resulting in the need to write down those assets to fair value. Management's estimate of cash flows might change if there is an unfavorable development of sales trends.

Goodwill

Goodwill represents the excess of the purchase price paid in a July 2015 merger transaction in which the Company acquired AdvanDx, Inc. and its subsidiary (the "Merger") over the fair values of the acquired tangible or intangible assets and assumed liabilities. Goodwill is not tax deductible in any relevant jurisdictions. The Company's goodwill balance as of September 30, 2019 and December 31, 2018 was $600,814.

The Company conducts an impairment test of goodwill on an annual basis as of October 1 of each year, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value. During the three and nine months ended September 30, 2019 and 2018, the Company determined that its goodwill was not impaired.

Revenue recognition

The Company derives revenues from (i) the sale of QuickFISH and PNA FISH diagnostic test products and Acuitas AMR Gene Panel RUO test products, (ii) providing laboratory services, and (iii) providing collaboration services including funded software arrangements, and license arrangements.

The Company analyzes contracts to determine the appropriate revenue recognition using the following steps: (i) identification of contracts with customers, (ii) identification of distinct performance obligations in the contract, (iii) determination of contract transaction price, (iv) allocation of contract transaction price to the performance obligations and (v) determination of revenue recognition based on timing of satisfaction of the performance obligation.

The Company recognizes revenues upon the satisfaction of its performance obligation (upon transfer of control of promised goods or services to our customers) in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services.

The Company defers incremental costs of obtaining a customer contract and amortizes the deferred costs over the period that the goods and services are transferred to the customer. The Company had no material incremental costs to obtain customer contracts in any period presented.

Deferred revenue results from amounts billed in advance to customers or cash received from customers in advance of services being provided.

Research and development costs

Research and development costs are expensed as incurred. Research and development costs primarily consist of salaries and related expenses for personnel, other resources, laboratory supplies, and fees paid to consultants and outside service partners.

Transaction costs

Transaction costs include expenses associated with legal, accounting, and regulatory services rendered in connection with business combinations. Transaction costs are expensed as incurred in support of the business combination.

Stock-based compensation

Stock-based compensation expense is recognized at fair value. The fair value of stock-based compensation to employees and directors is estimated, on the date of grant, using the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option. For all time-vesting awards granted, expense is amortized using the straight-line attribution method. The Company accounts for forfeitures as they occur.

Option valuation models, including the Black-Scholes model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the expected future tax consequences attributable to temporary differences between financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred income tax assets to the amount expected to be realized.

Tax benefits are initially recognized in the financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially, and subsequently, measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts.

The Company had federal net operating loss (“NOL”) carryforwards of $178.2 million at December 31, 2018. Despite the NOL carryforwards, which begin to expire in 2022, the Company may have future tax liability due to alternative minimum tax or state tax requirements. Also, use of the NOL carryforwards may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”). To date, the Company has not performed a formal study to determine if any of its remaining NOL and credit attributes might be further limited due to the ownership change rules of Section 382 or Section 383 of the Code. The Company will continue to monitor this matter going forward. There can be no assurance that the NOL carryforwards will ever be fully utilized.

Loss per share

Basic loss per share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options and stock purchase warrants using the treasury stock method, and convertible preferred stock and convertible debt using the if-converted method.

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The number of anti-dilutive shares, consisting of (i) common stock options, (ii) stock purchase warrants, and (iii) restricted stock units representing the right to acquire shares of common stock which have been excluded from the computation of diluted loss per share, was 0.2 million shares and 0.2 million shares as of September 30, 2019 and 2018, respectively.

Adopted accounting pronouncements

There have been no developments to the Recent Accounting Pronouncements discussion included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018, including the expected dates of adoption and estimated effects on the Company’s condensed consolidated financial statements, except for the following:

In February 2016, the FASB issued ASC 842, which amends the existing accounting standards for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The Company adopted this guidance effective January 1, 2019 using the modified retrospective transition method and the following practical expedients:

- The Company did not reassess if any expired or existing contracts are or contain leases.
- The Company did not reassess the classification of any expired or existing leases.

Additionally, the Company made ongoing accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12 months or less) and (ii) combines lease and non-lease elements of our operating leases.

Upon adoption of the new guidance on January 1, 2019, the Company recorded an operating lease right of use asset of approximately $2.2 million (net of existing deferred rent) and recognized a lease liability of approximately $2.5 million.

In June 2018, the FASB issued ASU 2018-07: *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, early adoption is permitted but no earlier than an entity's adoption date of ASC 606. The adoption of this new guidance did not have a material impact on the Company's condensed consolidated financial statements.

In August 2018, the SEC issued a final rule that amends certain disclosure requirements that were duplicative, outdated or superseded. In addition, the final rule expanded the financial reporting requirements for changes in stockholders' equity for interim reporting periods. The Company adopted the new guidance on January 1, 2019 with no material impact to the condensed consolidated financial statements.

The Company has evaluated all other issued and unadopted ASUs and believes the adoption of these standards will not have a material impact on its results of operations, financial position or cash flows.

Note 4 – Revenue from contracts with customers

Disaggregated revenue

The Company provides diagnostic test products, laboratory services to hospitals, clinical laboratories and other healthcare provider customers, and enters into collaboration agreements with government agencies and healthcare providers. The revenues by type of service consist of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Product sales	$ 573,035	$ 539,856	$ 1,597,505	$ 1,805,877
Laboratory services	185	12,365	5,435	22,155
Collaboration revenue	75,000	—	1,075,000	359,316
Total revenue	$ 648,220	$ 552,221	$ 2,677,940	$ 2,187,348

Deferred revenue

Changes in deferred revenue for the period were as follows:

Balance at December 31, 2018	$ 15,824
Revenue recognized in the current period from the amounts in the beginning balance	(6,016)
New deferrals, net of amounts recognized in the current period	—
Balance at September 30, 2019	$ 9,808

Contract assets

The Company had no contract assets as of September 30, 2019, which are generated when contractual billing schedules differ from revenue recognition timing. Contract assets represent a conditional right to consideration for satisfied performance obligations that becomes a billed receivable when the conditions are satisfied.

Unsatisfied performance obligations

Remaining contract consideration for which revenue has not been recognized due to unsatisfied performance obligations was $500,000 at September 30, 2019, which the Company expects to recognize over the next six months.

Note 5 – MGHIF financing

In July 2015, the Company entered into a Purchase Agreement with MGHIF, pursuant to which MGHIF purchased 2,273 shares of common stock of the Company at $2,200 per share for gross proceeds of $5.0 million. Pursuant to the Purchase Agreement, the Company also issued to MGHIF an 8% Senior Secured Promissory Note (the "MGHIF Note") in the principal amount of $1.0 million with a two-year maturity date from the date of issuance. The Company's obligations under the MGHIF Note are secured by a lien on all of the Company's assets.

On June 28, 2017, the MGHIF Note was amended and restated, and the maturity date of the MGHIF Note was extended by one year to July 14, 2018. As consideration for the agreement to extend the maturity date, the Company issued an amended and restated secured promissory note to MGHIF that (1) increased the interest rate to ten percent (10%) per annum and (2) provided for the issuance of common stock warrants to purchase 656 shares of its common stock to MGHIF.

On June 11, 2018, the Company executed an Allonge to the MGHIF Note. The Allonge provided that accrued and unpaid interest of $285,512 due as of July 14, 2018, the original maturity date, be paid through the issuance of shares of OpGen's common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021.

On July 30, 2018, the Company issued 7,212 shares of common stock to MGHIF in a private placement transaction for $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

The Allonge to the MGHIF Note was treated as a debt modification and as such the unamortized issuance costs of approximately $7,000 as of June 11, 2018 are deferred and amortized as incremental expense over the term of the MGHIF Note.

Note 6 – Fair value measurements

The Company classifies its financial instruments using a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 - defined as observable inputs such as quoted prices in active markets;
- Level 2 - defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and
- Level 3 - defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions such as expected revenue growth and discount factors applied to cash flow projections.

For the nine months ended September 30, 2019, the Company has not transferred any assets between fair value measurement levels.

Financial assets and liabilities measured at fair value on a recurring basis

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the hierarchy.

As part of the Company's bridge financing and amendment to the MGHIF Note, the Company issued stock purchase warrants that the Company considers to be mark-to-market liabilities due to certain put features that allow the holder to put the warrant back to the Company for cash equal to the Black-Scholes value of the warrant upon a change of control or fundamental transaction. The Company determines the fair value of the warrant liabilities using the Black-Scholes option pricing model. Using this model, level 3

unobservable inputs include the estimated volatility of the Company's common stock, estimated terms of the instruments, and estimated risk-free interest rates.

The following table sets forth a summary of changes in the fair value of level 3 liabilities measured at fair value on a recurring basis for the nine months ended September 30, 2019:

Description	Balance at December 31, 2018	Change in Fair Value	Balance at September 30, 2019
Warrant liability	$ 67	$ (67)	$ —

Financial assets and liabilities carried at fair value on a non-recurring basis

The Company does not have any financial assets and liabilities measured at fair value on a non-recurring basis.

Non-financial assets and liabilities carried at fair value on a recurring basis

The Company does not have any non-financial assets and liabilities measured at fair value on a recurring basis.

Non-financial assets and liabilities carried at fair value on a non-recurring basis

The Company measures its long-lived assets, including property and equipment and intangible assets (including goodwill), at fair value on a non-recurring basis when they are deemed to be impaired. No such fair value impairment was recognized in the three and nine months ended September 30, 2019 and 2018.

Note 7 – Debt

As of September 30, 2019, the Company's outstanding short-term debt consisted of approximately $333,000 due under the MGHIF Note, as well as the financing arrangements for the Company's insurance with note balances of approximately $175,000 with a final payment scheduled for May 2020. The Company's outstanding long-term debt as of September 30, 2019 consisted of approximately $329,000 due under the MGHIF Note (see Note 5 "MGHIF financing"). As of December 31, 2018, the Company's outstanding short-term debt consisted of $333,000 due under the MGHIF Note, net of discounts and financing costs, as well as the financing arrangements for the Company's insurance with note balances of approximately $65,000. The Company's outstanding long-term debt as of December 31, 2018 consisted of approximately $660,000 due under the MGHIF Note, net of discounts and financing costs. Total principal payments of approximately $333,000 are due annually in 2020 and 2021.

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $49,099 and $28,074 for the three months ended September 30, 2019 and 2018, respectively. Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $142,672 and $140,453 for the nine months ended September 30, 2019 and 2018, respectively.

Note 8 – Stockholders' equity (deficit)

As of September 30, 2019, the Company has 50,000,000 authorized shares of common stock and 882,268 shares issued and outstanding, and 10,000,000 authorized shares of preferred stock, of which none were issued or outstanding.

In September 2016, the Company entered into the Sales Agreement with Cowen pursuant to which the Company could offer and sell from time to time, up to an aggregate of $25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of $11.5 million. During the year ended December 31, 2018, the Company sold 15,912 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $0.6 million, and gross proceeds of $0.6 million. In connection with the October 2018 Public Offering, the Company terminated the at the market offering.

In the February 2018 Public Offering, the Company issued 2,841,152 units at $3.25 per unit, and 851,155 pre-funded units at $3.24 per pre-funded unit, raising gross proceeds of approximately $12 million and net proceeds of approximately $10.7 million. Each unit included one twentieth of a share of common stock and one common warrant to purchase one fortieth of a share of common stock at an exercise price of $65.00 per share. Each pre-funded unit included one pre-funded warrant to purchase one twentieth of a share of common stock for an exercise price of $0.20 per share, and one common warrant to purchase one fortieth of a share of common stock at an exercise price of $65.00 per share. The common warrants were exercisable immediately and have a five-year term from the date of issuance. The 851,155 pre-funded warrants issued in the February 2018 Public Offering were exercised during the year ended December 31, 2018.

In connection with the February 2018 Public Offering, the Company issued to its placement agent warrants to purchase 9,231 shares of common stock. The warrants issued to the placement agent have an exercise price of $81.25 per share and are exercisable for five years.

On October 22, 2018, the Company closed the October 2018 Public Offering of 111,000 shares of its common stock at a public offering price of $29.00 per share. The offering raised gross proceeds of approximately $3.2 million and net proceeds of approximately $2.8 million.

On March 29, 2019, the Company closed the March 2019 Public Offering of 450,000 shares of its common stock at a public offering price of $12.00 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million.

Following receipt of approval from stockholders at a special meeting of stockholders held on August 22, 2019, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to affect a reverse stock split of the issued and outstanding shares of common stock, at a ratio of one share for twenty shares. All share amounts and per share prices in this Quarterly Report have been adjusted to reflect the reverse stock split.

Stock options

In 2008, the Company adopted the 2008 Stock Option and Restricted Stock Plan (the "2008 Plan"), pursuant to which the Company's Board of Directors could grant either incentive or non-qualified stock options or shares of restricted stock to directors, key employees, consultants and advisors.

In April 2015, the Company adopted, and the Company's stockholders approved, the 2015 Equity Incentive Plan (the "2015 Plan"); the 2015 Plan became effective upon the execution and delivery of the underwriting agreement for the Company's initial public offering in May 2015. Following the effectiveness of the 2015 Plan, no further grants will be made under the 2008 Plan. The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for the grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants.

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 2,710 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date, that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by the Company's Board of Directors. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. As of September 30, 2019, 3,827 shares remain available for issuance under the 2015 Plan, which includes 17,291 shares automatically added to the 2015 Plan on January 1, 2019.

For the three and nine months ended September 30, 2019 and 2018, the Company recognized stock-based compensation expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cost of services	$ 584	$ (2,807)	$ 1,146	$ 924
Research and development	20,175	56,961	55,635	187,512
General and administrative	65,318	141,974	202,696	434,314
Sales and marketing	5,090	10,523	15,694	35,981
	$ 91,167	$ 206,651	$ 275,171	$ 658,731

No income tax benefit for stock-based compensation arrangements was recognized in the condensed consolidated statements of operations and comprehensive loss due to the Company's net loss position.

The Company did not grant any stock options during the three months ended September 30, 2019. During the three months ended September 30, 2019, 107 options were forfeited and 499 options expired. The Company did not grant any stock options during the

nine months ended September 30, 2019. During the nine months ended September 30, 2019, 143 options were forfeited and 499 options expired. The Company had total stock options to acquire 9,936 shares of common stock outstanding at September 30, 2019.

Restricted stock units

During the nine months ended September 30, 2019, 17,150 restricted stock units were granted, no restricted stock units vested and 500 restricted stock units were forfeited. The Company had 16,663 total restricted stock units outstanding at September 30, 2019.

Stock purchase warrants

At September 30, 2019 and December 31, 2018, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at September 30, 2019 (1)	Outstanding at December 31, 2018 (1)
November 2009	$ 3,955.00	November 2019	17	17
January 2010	$ 3,955.00	January 2020	17	17
March 2010	$ 3,955.00	March 2020	7	7
November 2011	$ 3,955.00	November 2021	15	15
December 2011	$ 3,955.00	December 2021	2	2
March 2012	$ 54,950.00	March 2019	—	8
February 2015	$ 3,300.00	February 2025	451	451
May 2015	$ 3,300.00	May 2020	6,555	6,555
May 2016	$ 656.00	May 2021	9,483	9,483
June 2016	$ 656.00	May 2021	4,102	4,102
June 2017	$ 390.00	June 2022	938	938
July 2017	$ 345.00	July 2022	318	318
July 2017	$ 250.00	July 2022	2,501	2,501
July 2017	$ 212.60	July 2022	50,006	50,006
February 2018	$ 81.20	February 2023	9,232	9,232
February 2018	$ 65.00	February 2023	92,338	92,338
			175,982	175,990

The warrants listed above were issued in connection with various debt, equity or development contract agreements.

(1) Warrants to purchase fractional shares of common stock resulting from the reverse stock split on August 29, 2019 were rounded up to the next whole share of common stock on a holder by holder basis.

Note 9 – Commitments

Registration and other stockholder rights

In connection with the various investment transactions, the Company entered into registration rights agreements with stockholders, pursuant to which the investors were granted certain demand registration rights and/or piggyback and/or resale registration rights in connection with subsequent registered offerings of the Company's common stock.

Supply agreements

In June 2017, the Company entered into an agreement with Life Technologies Corporation ("LTC") to supply the Company with QuantStudio 5 Real-Time PCR Systems ("QuantStudio 5") to be used to run OpGen's Acuitas AMR Gene Panel tests. Under the terms of the agreement, the Company must notify LTC of the number of QuantStudio 5s that it commits to purchase in the following quarter. As of September 30, 2019, the Company has acquired twenty-four QuantStudio 5s including nine in the nine months ended September 30, 2019. As of September 30, 2019, the Company has not committed to acquiring additional QuantStudio 5s in the next three months.

Note 10 – Leases

The following table presents the Company's ROU assets and lease liabilities as of September 30, 2019:

Lease Classification	September 30, 2019
ROU Assets:	
Operating	$ 1,214,482
Financing	1,096,472
Total ROU assets	$ 2,310,954
Liabilities	
Current:	
Operating	$ 987,833
Finance	627,620
Noncurrent:	
Operating	812,801
Finance	411,103
Total lease liabilities	$ 2,839,357

Maturities of lease liabilities as of September 30, 2019 by fiscal year are as follows:

Maturity of Lease Liabilities	Operating	Finance	Total
2019	$ 279,055	$ 180,753	$ 459,808
2020	1,128,294	633,130	1,761,424
2021	536,819	270,043	806,862
2022	40,080	41,961	82,041
2023	—	3,364	3,364
Thereafter	—	280	280
Total lease payments	1,984,248	1,129,531	3,113,779
Less: Interest	(183,614)	(90,808)	(274,422)
Present value of lease liabilities	$ 1,800,634	$ 1,038,723	$ 2,839,357

Statement of operations classification of lease costs are as follows:

		September 30, 2019	
Lease Cost	Classification	Three months ended	Nine months ended
Operating	Operating expenses	$ 216,368	$ 655,963
Finance:			
Amortization	Operating expenses	124,749	329,438
Interest expense	Other expenses	18,704	60,482
Total lease costs		$ 359,821	$ 1,045,883

Other Information	Total
Weighted average remaining lease term (in years)	
Operating leases	1.9
Finance leases	1.8
Weighted average discount rate:	
Operating leases	10.0%
Finance leases	9.2%

Supplemental Cash Flow Information		Total
Cash paid for amounts included in the measurement of lease liabilities		
Cash used in operating activities		
Operating leases	$	655,963
Finance leases	$	60,482
Cash used in financing activities		
Finance leases	$	389,501
ROU assets obtained in exchange for lease obligations:		
Finance leases	$	592,014

Lease Commitments as of December 31, 2018

Minimum lease payments for future years as of December 31, 2018 were as follows:

Year ending December 31,		Total
2019	$	1,615,679
2020		1,534,204
2021		639,829
2022		40,080
2023 and thereafter		—
Total	$	3,829,792

Note 11 – License agreements, research collaborations and development agreements

In 2018, the Company announced a collaboration with the New York State Department of Health ("DOH") and ILÚM Health Solutions, LLC ("ILÚM"), a wholly-owned subsidiary of Merck's Healthcare Services and Solutions division, to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions statewide. The Company is working together 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. As part of the collaboration, the Company will receive $1.6 million over the 15 month demonstration portion of the project. The demonstration project began in early 2019. During the three and nine months ended September 30, 2019, the Company recognized $75,000 and $1.1 million of revenue related to the contract, respectively.

The Company is a party to one license agreement to acquire certain patent rights and technologies related to its FISH product line. Royalties are incurred upon the sale of a product or service which utilizes the licensed technology. The Company recognized net royalty expense of $62,500 for each of the three months ended September 30, 2019 and 2018. The Company recognized net royalty expense of $187,500 for each of the nine months ended September 30, 2019 and 2018. Annual future minimum royalty fees are $250,000 under this agreement.

Note 12 – Related party transactions

In October 2016, the Company entered into an agreement with Merck Sharp & Dohme Corp. ("MSD"), a wholly-owned subsidiary of Merck, and an affiliate of MGHIF, a principal stockholder of the Company and a related party to the Company. Under the agreement, MSD provided access to its archive of over 200,000 bacterial pathogens. The Company is initially performing molecular analyses on up to 10,000 pathogens to identify markers of resistance to support rapid decision making using the Acuitas Lighthouse informatics, and to speed development of its rapid diagnostic products. MSD gains access to the high-resolution genotype data for the isolates as well as access to the Acuitas Lighthouse informatics to support internal research and development programs. The Company is required to expend up to $175,000 for the procurement of materials related to the activities contemplated by the agreement. Contract life-to-date, the Company has incurred $171,646 of procurement costs which have been recognized as research and development expense. The Company did not recognize any research and development expense related to the agreement in the three months ended September 30, 2019 and 2018. The Company recognized research and development expense of $0 and $22,604 related to the agreement in the nine months ended September 30, 2019 and 2018, respectively.

In December 2017, the Company entered into a subcontractor agreement with ILÚM, whereby ILÚM will provide 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 up to three medical sites in Colombia with the aim of improving antibiotic use in resource-limited settings. The Company did not incur any cost of services expense related to the contract in the three months ended September 30, 2019 and 2018. The Company recognized $0 and $198,665 of cost of services expense related to the contract in the nine months ended September 30, 2019 and 2018, respectively.

Note 13 – Subsequent events

On October 28, 2019, the Company closed the October 2019 Public Offering of 2,590,170 units at $2.00 per unit and 2,109,830 pre-funded units at $1.99 per pre-funded unit. The Company also granted the underwriter a 30-day option to purchase up to an additional 705,000 shares of common stock and/or common warrants to purchase up to 705,000 shares of common stock. The offering raised gross proceeds of approximately $9.4 million and net proceeds of approximately $8.3 million.

On October 31, 2019, the Company filed a Form 8-K to report that, following the October 2019 Public Offering, it believed it had regained compliance with the Nasdaq continuing listing requirement for stockholders' equity. Nasdaq confirmed the Company's compliance with all continuing listing requirements in November 2019.

On November 12, 2019, Crystal GmbH, OpGen's subsidiary, as lender, and Curetis GmbH, as borrower, entered into an Interim Facility Agreement, or the Interim Facility. Under the Interim Facility, the lender shall lend to the Borrower, for the benefit of the Curetis Group, committed capital, up to $4 million, between November 18, 2019 and the closing of the transaction contemplated by the Implementation Agreement. Under the Interim Facility, OpGen and Curetis N.V. have confirmed that the October 2019 Public Offering satisfies the closing condition for OpGen to raise at least $10 million, and that the entry into the Interim Facility satisfies an additional closing condition.

On November 12, 2019, the Company filed a Registration Statement on Form S-4 to register the Consideration to be issued under the Implementation Agreement. Such filing was a requirement to closing the transactions contemplated by the Implementation Agreement.

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
T**otal**	**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

Appendix A

IMPLEMENTATION AGREEMENT

Dated September 4, 2019

By and among

OpGen, Inc.

and

Crystal GmbH

and

Curetis N.V.

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IMPLEMENTATION AGREEMENT (this "**Agreement**"), dated as of September 4, 2019, by and among:

(1) **Curetis N.V.**, a public company with limited liability (*naamloze vennootschap*) under the Laws of the Netherlands, with its official seat in Amsterdam, the Netherlands, and its office address at Max-Eyth-Strasse 42, 71088 Holzgerlingen, Germany, registered with the Dutch Trade Register under number 64302679 (the "**Seller**"); and

(2) **Crystal GmbH (a/k/a Platin 1798, GmbH)**, a private limited liability company (*Gesellschaft mit beschränkter Haftung*) organized under the Laws of the Federal Republic of Germany, registered with the commercial register of the local court (*Amtsgericht*) of Frankfurt am Main under HRB 115973 (the "Purchaser"); and

(3) **OpGen, Inc.**, a Delaware corporation, with its office address at 708 Quince Orchard Road, Suite 205, Gaithersburg, MD 20878, USA (the "**Parent**").

RECITALS

(A) WHEREAS, the Seller's shares are admitted to trading on Euronext in Amsterdam, a regulated market of Euronext Amsterdam N.V., as well as Euronext Brussels, and the Parent is listed on NASDAQ Capital Market, a market tier of the NASDAQ;

(B) WHEREAS, Curetis GmbH is a private limited liability company (*Gesellschaft mit beschränkter Haftung*) organized under the laws of the Federal Republic of Germany (the "**Company**"), and a Wholly-Owned Subsidiary of the Seller;

(C) WHEREAS, the Group Companies (as hereafter defined) are principally engaged in the business of providing innovative solutions, through development of proprietary platforms, diagnostic content, applied bioinformatics, lab services, research services and commercial collaborations and agreements, for molecular microbiology diagnostics designed to address the global challenge of detecting severe infectious diseases and identifying antibiotic resistances in hospitalized patients (the "**Business**");

(D) WHEREAS, Parent is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease by developing proprietary molecular diagnostic and 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;

(E) WHEREAS, the Purchaser is a Wholly-Owned Subsidiary of Parent, initially organized for the sole purpose of acquiring the Transferred Shares pursuant to this Agreement;

(F) WHEREAS, the Seller desires to sell to Parent and Purchaser, and Parent and Purchaser desire to purchase from the Seller, the Business, including the Transferred Shares, for the Consideration (as hereafter defined) and on the terms and subject to the conditions hereinafter set forth (the "**Transaction**");

(G) WHEREAS, the Management Board and Supervisory Board (both as hereafter defined) of the Seller have extensively considered the Transaction, the strategy for the combined entities following the Transaction, the Consideration (as hereafter defined) and the consequences for the Seller's stockholders, employees and other stakeholders;

(H) WHEREAS, based on a due and careful consideration of the Transaction, each of the Management Board and Supervisory Board of the Seller have unanimously (i) determined that this Agreement, the Transaction and the other transactions contemplated hereby are expedient and fair to, and in the best interests of, the Seller, the Seller's strategy and the Seller's stockholders, employees and other stakeholders, and (ii) adopted resolutions approving this Agreement, the Transaction, and recommending to the stockholders of the Seller to vote in favor of the Seller Resolutions (as hereafter defined) at the Seller Stockholders' Meeting (as hereafter defined);

(I) WHEREAS, the board of directors of the Parent (the "**Board of Directors**") has unanimously (i) determined that this Agreement, the Transaction and the other transactions contemplated hereby are fair to, advisable and in the best interest of the Parent's stockholders, and (ii) approved this Agreement, the Transaction and the other transactions contemplated hereby, upon the terms and subject to the conditions set forth herein;

(J) WHEREAS, as soon as practicable following the Closing (as hereafter defined), the Seller intends to distribute all or part of the Consideration to the Seller Stockholders to the maximum extent permitted by applicable Laws;

(K) WHEREAS, for United States federal income tax purposes, it is intended that the Transaction contemplated by this Agreement will qualify as a reorganization under the provisions of Section 368(a)(1)(C) of the Code (as hereafter defined), and that this Agreement constitutes a plan of reorganization within the meaning of Section 1.368-2(g) and 1.368-3(a) of the of the United States Treasury Regulations; and

(L) WHEREAS, Parent, Purchaser and the Seller desire to make certain representations, warranties, covenants and agreements in connection with this Agreement.

NOW THEREFORE, in consideration of the mutual covenants and agreements set forth herein, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

ARTICLE I
DEFINITIONS; INTERPRETATION

Section 1.1 Definitions

In addition to terms defined elsewhere in this Agreement, for purposes of this Agreement, the following terms shall have the following meanings (unless otherwise specified):

"**Acceptable Confidentiality Agreement**" means a confidentiality agreement that contains confidentiality and other provisions that are no less favorable in the aggregate to the Target Party than those contained in the Confidentiality Agreement.

"**Acquisition Proposal**" means any inquiry, proposal or offer from any Person (other than a party to this Agreement or any of its Affiliates) relating to any direct or indirect acquisition, in one transaction or a series of transactions, including by way of any merger, consolidation, tender offer, exchange offer, binding share exchange, business combination, sale of substantially all assets, recapitalization, restructuring, investment, liquidation, dissolution or similar transaction, of (i) assets that constitute or represent 25% or more of the total assets or total revenues of the Seller or the Group Companies, on the one hand, or of the Parent or the Purchaser Entities, on the other hand, as the case may be, taken as a whole, or (ii) 25% or more of the Seller Common Stock, on the one hand, or of the Parent Common Stock, on the other hand, as the case may be, then outstanding.

"**Affiliate**" of a Person means any corporation, limited liability company, partnership or other entity that controls, is controlled by, or is under common control with such Person. For purposes of this definition of "Affiliate", "control" means (a) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interests with the power to direct the management and policies of such non-corporate entities.

"**Affiliated Persons**" means (i) any director or officer of the Seller or any Subsidiary, (ii) any Affiliate of the Seller or any Subsidiary or (iii) with respect to the individual referred to in the foregoing clause (i), any member of the immediate family of any of such individual and any Person that, directly or indirectly, is controlled by such immediate family member.

"**AFM**" means the Netherlands Authority for the Financial Markets (*Autoriteit Financiële Markten*).

"**Agreement**" shall have the meaning specified in the Preamble.

"**Balance Sheet Date**" shall have the meaning specified in Section 4.5(c).

"**Benefit Plan**" means any (i) employee benefit plans, as defined in ERISA Section 3(3), (ii) all plans (*Vereinbarungen und Zusagen*), whether of collective or individual nature, and including commitments based on customs and practices (*betriebliche Übung*), regarding company pensions (*betriebliche Altersversorgung*) under which any Person has any obligations vis-à-vis their employees and their dependents to provide company pension benefits, whether directly or via an external funding vehicle (including, without limitation, *Direktversicherung*, *Pensionskasse*, *Pensionsfonds* and *Unterstützungskasse*) and (iii) all other profit-sharing, bonus, stock option, stock purchase, stock bonus, restricted stock, stock appreciation right, phantom stock, vacation pay, holiday pay, paid time off, tuition reimbursement, scholarship, severance, dependent care assistance, excess benefit, fringe benefit, voluntary benefit, deferred compensation, incentive compensation, salary continuation, supplemental retirement, employee loan or loan guarantee program, split dollar, cafeteria plan, and other benefits or compensation arrangements, plans, programs, policies, or agreements.

"**Blue Sky Laws**" shall have the meaning specified in Section 6.5(g).

"**Breach**" means, with respect to any representation, warranty, covenant, obligation or other provision of any agreement, that there has occurred (or a claim has been made that there has occurred) an inaccuracy in or breach of, or a failure to perform or comply with, such representation, warranty, covenant, obligation or other provision, as the case may be; for the avoidance of doubt, the failure of a condition to be satisfied by itself shall not constitute a Breach.

"**Board of Directors**" shall have the meaning specified in the Preamble.

"**Business**" shall have the meaning specified in the Preamble.

"**Business Day**" means any day, other than a Saturday or Sunday, on which commercial banks are not required or authorized to close in New York City (USA), Amsterdam (Netherlands) or Holzgerlingen (Germany).

"**Capital Lease**" means a lease that is required to be capitalized for financial reporting purposes in accordance with GAAP.

"**Cash**" means the aggregated cash, cash equivalents, investments, bank deposits and marketable securities of or held by the Seller and the Group Companies, as the case may be.

"**Change of Board Recommendation**" shall have the meaning specified in Section 6.3(d).

"**Closing**" shall have the meaning specified in Section 3.2.

"**Closing Date**" shall have the meaning specified in Section 3.2.

"**Code**" means the U.S. Internal Revenue Code of 1986, as amended from time to time, and any other successor statute thereto and any regulations issued thereunder.

"**Company**" shall have the meaning specified in the Preamble.

"**Company Common Stock**" means, collectively, the common stock, par value € 1.00 per share, of the Company, and associated rights.

"**Company IP Contracts**" shall have the meaning specified in Section 4.9(c).

"**Company Leases**" shall have the meaning specified in Section 4.8(b).

"**Company Leased Real Property**" shall have the meaning specified in Section 4.8(b).

"**Company Material Contract**" shall have the meaning specified in Section 4.7(b).

"**Company Securities**" shall have the meaning specified in Section 4.4(b).

"**Confidentiality Agreement**" means the confidentiality agreement dated as of November 8, 2018, as amended through the date of this Agreement, by and between the Seller and the Parent.

"**Consideration**" shall have the meaning specified in Section 3.1.

"**Contract**" means any note, bond, mortgage, indenture, contract, agreement, lease, license, permit or other instrument or obligation.

"**Contractual Obligations**" means as to any Person, any provision of any security issued by such Person or of any agreement, undertaking, Contract, indenture, mortgage, deed of trust or other instrument or arrangement to which such Person is a party or by which it or any of such Person's property is bound.

"**Conversion Ratio**" shall have the meaning specified in Section 6.14(a).

"**Convertible Debt Rollover**" shall have the meaning set forth in Section 6.15(b).

"**Damages**" means any and all losses, Liabilities, claims, damages, reasonable expenses (including costs of investigation, defense and related reasonable attorney's fees), awards, assessments, fines, costs, reasonable fees, Taxes, penalties, deficiencies, judgments or other amounts paid or incurred, whether in defense or settlement of any Proceeding or otherwise.

"**DCC**" means the Dutch Civil Code (*Burgerlijk Wetboek*).

"**DGCL**" means Delaware General Corporation Law.

"**Documents**" shall mean all files, documents, instruments, papers, books, reports, records, tapes, microfilms, photographs, letters, budgets, forecasts, ledgers, journals, title policies, customer lists, regulatory filings, Tax Returns and other Tax records, operating data and plans, technical documentation (design specifications, functional requirements, operating instructions, logic manuals, flow charts, etc.), user documentation (installation guides, user manuals, training materials, release notes, working papers, etc.), marketing documentation (sales brochures, flyers, pamphlets, web pages, etc.), and other similar materials, in each case whether or not in electronic form.

"**EIB**" means the European Investment Bank.

"**EIB Guarantee**" means the guarantee provided by Seller to EIB under the EIB Loan Agreement.

"**EIB Loan Agreement**" means the finance contract dated December 12, 2016 and amended and restated by means of an amendment and restatement agreement dated May 20, 2019, each between the Company (as borrower), EIB (as lender) and the Seller, Curetis USA Inc. and Ares Genetics GmbH (as guarantors).

"**Environmental Laws**" means any applicable federal, state, provincial, foreign or local statute, Law, rule, regulation, ordinance, code, binding and enforceable guideline, binding and enforceable written policy or rule of common law now or hereafter in effect and in each case as amended, or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent decree or judgment, to the extent binding on the Company or any of the Subsidiaries, relating to the environment, health and safety, or Hazardous Materials.

"**ERISA**" means the Employee Retirement Income Security Act of 1974, as amended from time to time, and any successor statute thereto, and the regulations issued thereunder.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended from time to time, and any successor statute thereto, and the rules and regulations of the SEC thereunder.

"**Expenses**" shall have the meaning specified in Section 8.3(a);

"**Fairness Opinion**" shall have the meaning specified in Section 4.17.

"**Form S-4 Registration Statement**" shall have the meaning specified in Section 4.20(a).

"**GAAP**" means generally accepted accounting principles in the United States.

"**German Transfer Agreement**" shall have the meaning specific in Section 2.1(d).

"**Governmental Approval**" means approval from a Governmental Authority.

"**Governmental Authority**" means any foreign, federal, state, local, or other governmental or administrative body, instrumentality, department, or agency or any court, tribunal, administrative hearing body, arbitration panel, commission, or other similar dispute-resolving panel or body.

"**Group Companies**" means, collectively, the Company and its Subsidiaries.

"**Group Companies Benefit Plans**" means (i) any "employee benefit plan" (as defined in section 3(3) of ERISA), (ii) all plans (*Vereinbarungen und Zusagen*), whether of collective or individual nature, and including commitments based on customs and practices (*betriebliche Übung*), regarding company pensions (*betriebliche Altersversorgung*) under which the Group Companies have any obligations vis-à-vis the employees and their dependents to provide company pension benefits, whether directly or via an external funding vehicle (including, without limitation, *Direktversicherung*, *Pensionskasse*, *Pensionsfonds* and *Unterstützungskasse*), (iii) any bonus or incentive compensation plan, and (iv) any material agreement providing for employment, change in control benefits, employee retention, individual bonus or incentive compensation, or severance benefits, in each case for the benefit of any current or former employee, officer, director or independent contractor (who is an individual) of the Group Companies, and such individual's beneficiaries and dependents, and as to which a Group Company is a sponsor or direct contracting party thereunder.

"**Group Employee**" means any individual employed or engaged with any of the Group Companies, including all officers.

"**Hazardous Materials**" means (a) substances that are defined or listed in, or otherwise classified pursuant to, any applicable Laws or the regulations thereunder as "hazardous substances," "hazardous materials," "hazardous wastes," "toxic substances," or any other formulation intended to define, list, or classify substances by reason of deleterious properties such as ignitability, corrosivity, reactivity, carcinogenicity, reproductive toxicity, or "EP toxicity," (b) oil, petroleum, or petroleum derived substances, natural gas, natural gas liquids, synthetic gas, drilling fluids, produced waters, and other wastes associated with the exploration, development, or production of crude oil, natural gas, or geothermal resources, (c) any flammable substances or explosives or any radioactive materials, and (d) asbestos in any form or electrical equipment that contains any oil or dielectric fluid containing levels of poly chlorinated biphenyls in excess of 50 parts per million.

"**IFRS**" means the International Financial Reporting Standards issued by the International Accounting Standards Board and the International Financial Reporting Interpretation Committee and their predecessor bodies.

"**Income Tax**'' means any federal, state, local, or non-U.S. income tax measured by or imposed on or with respect to net income, including any interest, penalty, or addition thereto, whether disputed or not.

''**Income Tax Return**'' means any Tax Return, declaration relating to Income Taxes.

"**Indebtedness**" means with respect to any Person, without duplication (a) indebtedness of such Person for borrowed money, (b) any obligations of such Person evidenced by bonds, notes, debentures or other similar instruments, including purchase money obligations or other obligations relating to the deferred purchase price of property (other than trade payables incurred in the ordinary course of business), (c) Liabilities of Persons (other than the Group Companies) secured by a Lien (other than a Permitted Lien) on any asset of the Seller or any of the Subsidiaries, (d) Liabilities under or in respect of letters of credit and bank guarantees (including reimbursement obligations with respect thereto, (e) Liabilities under lease obligations required to be classified and accounted for as Capital Leases and Liabilities under any sale and leaseback transaction, any synthetic lease or tax ownership operating lease transaction or any other transaction that is the functional equivalent of or takes the place of borrowing but that does not constitute a liability on the balance sheet, (f) interest rate and currency obligation swaps, hedges or similar arrangements, and (g) Liabilities in the nature of guarantees of obligations of the type described in the foregoing clauses of any other Person.

"**InsO**" shall have the meaning specified in Section 6.9(c)(i).

"**Intellectual Property**" means all trademarks, service marks, trade names, trade dress, domain names, copyrights, software, Internet web sites, mask works and other semiconductor chip rights, patents, patent applications, trade secrets and all similar proprietary intellectual property rights, including, as applicable, all goodwill associated with any of the foregoing and all registrations and applications to register or renew the registration of any of the foregoing.

"**Interim Borrower**" shall have the meaning specified in Section 6.9(b).

"**Interim Financing**" shall have the meaning specified in Section 6.9(a).

"**Interim Lender**" shall have the meaning specified in Section 6.9(b).

"**Interim Lender Claims**" shall have the meaning specified in Section 6.9(c)(i).

"**Interim Loan Agreement**" shall have the meaning specified in Section 6.9(b).

"**Interim Loan Amount**" shall have the meaning specified in Section 6.9(b).

"**Intervening Event**" shall have the meaning specified in Section 6.3(d).

"**Law(s)**" means any U.S. or non-U.S., federal, state or local statute, law, directive, ordinance, rule, regulation, order, writ, judgment, decree, code, stipulation, determination, award or requirement of a Governmental Authority.

"**Liabilities**" means any liabilities, claims, demands, expenses, commitments or obligations of every kind and description.

"**Lien**" means any lien, charge, mortgage, pledge, easement, encumbrance, security interest, adverse claim or any other title defect or restriction of any kind, including any interest in an asset securing an obligation owed to, or a claim by, any Person other than the owner of the asset, whether such interest is based on the common law, statute, or Contract, whether such interest is recorded or perfected, and whether such interest is contingent upon the occurrence of some future event or events or the existence of some future circumstance or circumstances, including the lien or security interest arising from a mortgage, deed of trust, encumbrance, pledge, hypothecation, assignment, deposit arrangement, security agreement, conditional sale or trust receipt, or from a lease, consignment, or bailment for security purposes and also including reservations, exceptions, encroachments, easements, rights-of-way, covenants, conditions, restrictions, leases, and other title exceptions and encumbrances affecting real property.

"**Losses**" means any and all losses, claims, damages, Liabilities, judgments, expenses and costs, including, without limitation, reasonable attorneys' fees, costs of collection and other fees and expenses, (but not including punitive, exemplary, consequential or indirect damages and liability of any kind.).

"**Management Board**" means the management board of the Seller.

"**Material Adverse Effect**" means any fact, circumstance, change, event, occurrence, development or effect (a "**Change**") that, individually or in the aggregate with all other Changes, has, or could reasonably be expected to have (with or without notice or the passage of time, or both), a material adverse effect on the business, assets, properties, financial condition, or results of operations of the Company and its Subsidiaries, taken as a whole, or Parent and its Subsidiaries, taken as a whole, as the case may be; provided, however, that "Material Adverse Effect" will not be deemed to include:

(a) Any Changes in general United States or global economic conditions, including any Changes affecting financial, credit, foreign exchange or capital market conditions;

(b) Any Changes in economic conditions generally affecting the industry or industries in which such party operates;

(c) Any Changes in political conditions, including any prolonged federal government furlough, shutdown or lack of funding;

(d) Any Changes after the date hereof in applicable Laws, GAAP, IFRS or the interpretation thereof;

(e) Any Changes in geopolitical conditions, acts of terrorism or sabotage, war (whether or not declared), the commencement, continuation or escalation of a war, acts of armed hostility, weather conditions, natural disasters or other force majeure events, including any material worsening of such conditions threatened or existing as of the date hereof;

(f) Any Changes caused by the public announcement or pendency of the Transaction contemplated by this Agreement; and

(g) The effects of any action required to be taken by this Agreement by one of the parties hereto or actions taken (including any adverse Change that results from the other party's unreasonable refusal to permit the applicable party, upon request to the other party, to take any of the actions set forth in Section 6.1) or omitted to be taken by one of such parties with the written consent of the other party hereto;

provided, however, that the effect of any of the Changes described in clause (a) through (e) will not be excluded from the definition of "Material Adverse Effect" to the extent they have a disproportionate impact on the Company or its Subsidiaries as a whole, on the one hand, or the Parent and its Subsidiaries as a whole, on the other hand, as measured relative to companies operating in the industry or industries in which such party operates.

"**Multiemployer Plan**" means any "multiemployer plan" within the meaning of Section 3(37) of ERISA as to which any Group Company or Purchaser Entity, as the case may be, has an obligation to contribute in respect of its current or former employees.

“**NASDAQ**” means the Nasdaq Stock Market.

“**Order**” means any order, writ, judgment, injunction, decree, stipulation, determination or award entered by or with any Governmental Authority.

“**Ordinary Course of Business**” means, with respect to any Person, the conduct of the business of such Person substantially in accordance with such Person’s normal day-to-day customs, practices and procedures.

“**Other Party**” shall have the meaning specified in Section 6.3(g).

“**Outside Date**” shall have the meaning specified in Section 8.1(b).

“**Parent**” shall have the meaning specified in the Preamble.

“**Parent Balance Sheet**” shall have the meaning specified in Section 5.6(c).

“**Parent Common Stock**” means, collectively, the common stock, par value $0.01 per share, of Parent.

"**Parent Equity Award**" means a Parent Stock Option or a Parent Restricted Share, as the case may be.

“**Parent’s Financial Advisor**” means Crosstree Capital Partners, Inc.

“**Parent IP Contracts**” shall have the meaning specified in Section 5.11(c).

“**Parent’s Knowledge**” or a similar phrase, means the actual knowledge of the Chief Executive Officer and Chief Financial Officer of the Parent, having made due inquiries with the Parent personnel listed in Part 2 of **Exhibit A**.

“**Parent Leases**” shall have the meaning specified in Section 5.10(b).

“**Parent Leased Real Property**” shall have the meaning specified in Section 5.10(b).

“**Parent Material Contract**” shall have the meaning specified in Section 5.9(b).

“**Parent Proxy Statement**” means the proxy statement of Parent to be filed as part of the Form S-4 Registration Statement with the SEC, and to be sent to the Parent Stockholders, in connection with the Transaction.

"**Parent Restricted Share**" means any Parent Common Stock subject to vesting, repurchase, or other lapse of restrictions granted under any Parent Stock Plan.

“**Parent SEC Documents**” shall have the meaning specified in Section 5.5(a).

“**Parent Securities**” shall have the meaning specified in Section 5.4(a).

"**Parent Stock Option**" means any option to purchase Parent Common Stock granted under any Parent Stock Plan.

"**Parent Stock Plans**" means the following plans: the 2008 Stock Option and Restricted Stock Plan, as amended (under which no further grants can be made) and the Amended and Restated 2015 Equity Incentive Plan.

“**Parent Stockholder Vote**” means the adoption and approval by the requisite affirmative vote of the Parent’s stockholders of the Transaction pursuant to, and on the terms and conditions set forth, in this Agreement.

“**Parent Stockholders’ Meeting**” shall have the meaning specified in Section 6.7(a).

“**Parent Termination Fee**” shall have the meaning specified in Section 8.3(c).

"**Permits**" means any permit, license, authorization, consent, certificate, approval, permission, waiver, exemption or Order of, registration or filing with, or report or notice to, any Person, including any Governmental Authority.

"**Permitted Liens**" means (i) Liens for Taxes not yet due and payable or that are being contested in good faith and by appropriate proceedings; or (ii) Liens of warehousemen, mechanics and materialmen and other similar Liens incurred in the Ordinary Course of Business.

"**Person**" means any individual, corporation, limited liability company, partnership, association, trust, estate, other entity or organization or group.

"**Proceeding**" means any action, arbitration, audit, hearing, investigation, litigation, suit (whether civil, criminal, administrative, investigative or otherwise) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Authority or arbitrator.

"**Purchaser**" shall have the meaning specified in the Preamble.

"**Purchaser Disclosure Schedules**" shall have the meaning specified in ARTICLE V.

"**Purchaser Entities**" means, collectively, the Parent and its Subsidiaries (other than the Group Companies).

"**Purchaser Entities Benefit Plans**" means (i) any "employee benefit plan" (as defined in section 3(3) of ERISA), (ii) all other profit-sharing plans, (iii) any bonus or incentive compensation plan, (iv) any plan providing for vacation, holiday, paid time off, tuition reimbursement, scholarship, dependent care assistance, excess benefit, fringe benefit or other benefits; and (v) any material agreement providing for employment, change in control benefits, employee retention, individual bonus or incentive compensation, or severance benefits, in each case for the benefit of any current or former employee, officer, director or independent contractor (who is an individual) of Parent or any of its Subsidiaries, and such individual's beneficiaries and dependents, and as to which Parent or any of its Subsidiaries is a sponsor or direct contracting party thereunder.

"**Related to the Business**" means required or necessary for, or exclusively related to or, used in or held for use in connection with, the Business.

"**Release**" means any releasing, disposing, discharging, injecting, spilling, leaking, pumping, dumping, emitting, escaping, emptying, dispersal, leaching, migration or placing into, through or upon the environment, including any land, soil, surface water, ground water or air.

"**Relevant Tax Entity(ies)**" shall have the meaning specified in Section 4.15(a)(i).

"**Representatives**" means, when used with respect to any Person, the directors, officers, employees, consultants, accountants, legal counsel, investment bankers, agents and other representatives of such Person and its Subsidiaries.

"**Requirements of Law**" means as to any Person, provisions of the governing documents or other organizational of such Person, or any Law, treaty, policy, code, rule, regulation, right, privilege, qualification, license or franchise or determination of an arbitrator or a court or other Governmental Authority, in each case applicable or binding upon such Person or any of such Person's property or to which such Person or any of such Person's property is subject or pertaining to any or all of the transactions contemplated or referred to herein.

"**Sarbanes-Oxley Act**" means the Sarbanes-Oxley Act of 2002 and any related rules and regulations promulgated by the SEC

"**SEC**" means the United States Securities and Exchange Commission and any successor thereto.

"**Securities Act**" means the Securities Act of 1933, as amended.

"**Seller**" shall have the meaning specified in the Preamble.

"**Seller Board Recommendation**" shall have the meaning specified in Section 4.2(g).

"**Seller Common Stock**" means the ordinary shares in the share capital of the Seller.

"**Seller Disclosure Schedules**" shall have the meaning specified in ARTICLE IV.

"**Seller Phantom Stock Option Plan**" means the phantom stock option plan of the Seller which terms and conditions are laid down in the "Curetis AG Phantom Stock Option Incentive Plan 2010" dated 3 September 2010, as amended by the supplement to grant agreement(s) dated 18 April 2013 and as supplemented by individual PSOP roll-over agreements entered into on or about 20 October 2015.

"**Seller Resolutions**" shall have the meaning specified in Section 6.6(a).

"**Seller Stock Option**" shall have the meaning specified in Section 6.14(a).

"**Seller Stock Option Plan**" shall have the meaning specified in Section 6.14(a).

"**Seller Stockholder Vote**" means the adoption by the affirmative vote of the general meeting of the Seller Resolutions.

"**Seller Stockholders**" means the holders of Seller Common Stock.

"**Seller Stockholders' Meeting**" shall have the meaning specified in Section 6.6(a).

"**Seller Termination Fee**" shall have the meaning specified in Section 8.3(b).

"**Seller's Financial Advisor**" means H.C. Wainwright & Co., LLC.

"**Seller's Knowledge**" or a similar phrase, means the actual knowledge of the members of the Management Board of the Seller (namely, Oliver Schacht, Johannes Bacher and Achim Plum), having made due inquiries with the personnel listed in Part 1 of **Exhibit A**.

"**Subsidiary**" means, when used with reference to an entity, any other entity of which (a) securities or other ownership interests having ordinary voting power to elect a majority of the Board of Directors or other Persons performing similar functions, or (b) 50% or more of the outstanding securities of which, are owned directly or indirectly by such entity. For the avoidance of doubt, when used in reference to Subsidiaries of the Company, "Subsidiary" shall include Curetis USA Inc., Ares Genetics GmbH, as well as Curetis UK Ltd. and Curetis Schweiz GmbH until completion of their dissolution.

"**Subsidiary Securities**" shall have the meaning specified in Section 4.4(d).

"**Successor Plans**" shall have the meaning specified in Section 6.13(a).

"**Superior Proposal**" means a bona fide Acquisition Proposal (except the references therein to "at least 25%" shall be replaced by "more than 50%") made in writing that is (i) reasonably likely to be completed on a timely basis and (ii) more favorable from a financial point of view to the Target Party than the transactions contemplated by this Agreement, and (b) did not result from a Breach or violation of Section 6.3.

"**Target Board**" shall have the meaning specified in Section 6.3(g).

"**Target Board Recommendation**" shall have the meaning specified in Section 6.3(g).

"**Target Common Stock**" shall have the meaning specified in Section 6.3(g).

"**Target Group**" shall have the meaning specified in Section 6.3(g).

"**Target Party**" shall have the meaning specified in Section 6.3(g).

"**Target Stockholder Vote**" shall have the meaning specified in Section 6.3(g).

"**Tax**" or "**Taxes**" means (x) any federal, state, local, or non-U.S. taxes and similar assessments, duties, reporting obligations, impositions and Liabilities relating to taxes, including income, gross receipts, license, payroll, employment, escheat excise, severance, stamp, occupation, premium, windfall profits, environmental (including taxes under Code §59A), customs duties, capital stock, franchise, profits, withholding, social security (or similar (including health, unemployment, workers' compensation and pension insurance), unemployment, disability, real property, personal property, sales, use, ad valorem, transfer, registration, value added, alternative or add-on minimum, estimated, recapture, public imposts, fees or other taxes of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not, including, but not restricted to, taxes within the meaning of Section 3 German General Fiscal Code (*Abgabenordnung*) (*Steuern und steuerliche Nebenleistungen*), withholding taxes (including construction withholding tax (*Bauabzugsteuer)*, wage tax (*Lohnsteuer*)), social security contributions (*Sozialversicherungsbeiträge*), customs and excise duties (*Zölle*) and liability for taxes owed by third parties (*Haftungsschuld*) including but not restricted to liability in case of fiscal unity (Sec. 73 AO – German Fiscal Code); (y) any liability for the payment of any amounts of the type described in clause (x) as a result of being or ceasing to be a member of an affiliated, consolidated, combined, unitary or similar group, including any arrangement for group or consortium relief or similar arrangement; and (z) any liability for the payment of any amounts of the type described in clauses (x) or (y) as a result of any express or implied obligations to indemnify or otherwise assume or succeed to the Tax liability of any other Person or as a result of any obligation under any Contract or arrangement with any other Person with respect to such amounts and including any liability for taxes of a predecessor or transferor or otherwise by operation of Law.

"**Tax Authority**" means any Governmental Authority having jurisdiction over the assessment, determination, collection, or other imposition of Taxes.

"**Tax Returns**" means any return, declaration, report, claim for refund, estimated return or information return or statement relating to Taxes, including any schedule or attachment thereto, and including any amendment thereof.

"**Transaction**" shall have the meaning specified in the Preamble.

"**Transferred Shares**" shall have the meaning specified in Section 4.4(a).

"**Treasury Regulations**" means the U.S. Treasury Department tax regulations promulgated under the Code, as such regulations may be amended from time to time. References to specific provisions of the Treasury Regulations shall be deemed to include the corresponding provisions of succeeding provisions of the Treasury Regulations.

"**U.S.**" means the United States of America.

"**Wholly-Owned Subsidiary**" means a Subsidiary all of whose capital stock or other equity ownership interests (other than director's qualifying shares, securities or interests, and/or other shares, securities or interests that are required by applicable Laws to be owned or held by other Persons) are owned by the Company or by the Parent (as the case may be) or one or more of their respective Wholly-Owned Subsidiaries.

"**Yorkville**" means YA II PN, Ltd and its Affiliates.

"**Yorkville Agreement**" means the agreement for the issuance of and subscription to notes convertible into shares and share subscription warrants dated October 2, 2018 between the Seller (as issuer) and Yorkville (as investor).

Section 1.2 Rules of interpretation

(a) The descriptive headings herein (including the Table of Contents) are inserted for convenience of reference only and are not intended to be part of or to affect the meaning or interpretation of this Agreement.

(b) References to any U.S. legal term shall, in respect of any jurisdiction other than the U.S., be construed as references to the term or concept that most nearly corresponds to it in that jurisdiction.

(c) The parties to this Agreement have been represented by counsel during the negotiation and execution of this Agreement and waive the application of any Requirements of Law or rule of construction providing that ambiguities in any agreement or other document will be construed against the party drafting such agreement or other document.

(d) The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall". Unless the context otherwise clearly requires (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified in accordance with the terms hereof and thereof; provided that with respect to any agreement, instrument or other document listed in the Seller Disclosure Schedules or Purchaser Disclosure Schedules all such amendments, modifications or supplements must also be listed in the appropriate schedule; (ii) any reference herein to a statute means such statute as amended from time to time and includes any successor legislation thereto and regulations promulgated thereunder; (iii) any reference herein to any Person shall be construed to include such Person's permitted successors and assigns; (iv) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (v) all references to Articles, Sections, Exhibits and Schedules shall be construed to refer to Articles and Sections of, and Exhibits and Schedules to, this Agreement; (vi) "writing", "written" and comparable terms shall be construed to refer to writing, printing, typing and other means (including electronic and computer means) of reproducing information in a visible form; (vii) the terms "day" and "days" mean and refer to calendar day(s) and the terms "year" and "years" mean and refer to calendar year(s); (viii) "$" means U.S. dollars and (ix) "€" means Euro.

(e) Any action required hereunder to be taken within a certain number of days shall, except as may otherwise be expressly provided herein, be taken within that number of calendar days; provided, however, that if the last day for taking such action falls on a Saturday, a Sunday, or a legal holiday, the period during which such action may be taken shall automatically be extended to the next Business Day.

ARTICLE II
PURCHASE AND SALE OF SHARES AND ASSETS; ASSUMPTION OF LIABILITIES

Section 2.1 Purchase and Sale of the Transferred Shares and Transferred Assets

(a) On the terms and subject to the conditions set forth in this Agreement, the Seller hereby sells to the Purchaser the Transferred Shares and the Transferred Assets, and the Purchaser hereby purchases and accepts to acquire such Transferred Shares and Transferred Assets.

(b) On the terms and subject to the conditions set forth in this Agreement, at the Closing, the Seller shall assign (*abtreten*) to Purchaser the Transferred Shares and all of the Seller's right, title and interest in, to and under the Transferred Shares and Purchaser shall accept such assignment in accordance with the German Transfer Agreement.

(c) The Transferred Shares and the Transferred Assets are sold by the Seller free and clear of all Liens except for Permitted Liens and together with all rights attaching to them as at Closing (including, in respect of the Transferred Shares, the right to receive profits not yet distributed or declared on or after the Closing Date).

(d) The assignment of the Transferred Shares will be effected by the share transfer agreement substantially in the form as attached hereto as **Exhibit B** to be executed by Seller and the Purchaser and to be recorded by a German notary on the Closing Date (the "**German Transfer Agreement**").

(e) The assignment of the Transferred Assets will be effected by the assignment and assumption agreement substantially in the form as attached hereto as **Exhibit C** to be executed by Seller and the Purchaser on the Closing Date (the "**Assignment and Assumption Agreement**").

(f) For the purpose of this Section 2.1:

(i) "**Transferred Assets**" means all of the assets of whatever kind and nature (including Cash) of, and Contracts entered into by, the Seller, in each case to the extent solely Related to the Business, including those listed in Section 2.1(f)(i) of the Seller Disclosure Schedules (other than the Transferred Shares and the Excluded Assets); and

(ii) "**Excluded Assets**" shall have the meaning specific in Section 2.1(f)(ii) of the Seller Disclosure Schedules.

Section 2.2 Assumption of Liabilities

(a) On the terms and subject to the conditions set forth in this Agreement, at the Closing, Parent shall cause Purchaser to assume, and Purchaser shall assume, effective as of the Closing, all Liabilities of the Seller to the extent solely Related to the Business, including all Liabilities related to the Transferred Assets and Liabilities listed in Section 2.2(a) of the Seller Disclosure Schedules, but excluding the Retained Liabilities (collectively, the "**Assumed Liabilities**").

(b) Notwithstanding the preceding paragraph, the parties acknowledge and agree that all Liabilities of the Seller not solely Related to the Business, including those Liabilities listed in Section 2.2(a) of the Seller Disclosure Schedules (collectively, the "**Retained Liabilities**") shall be retained and assumed by the Seller, whether before or after the Closing Date.

(c) The assumption of the Assumed Liabilities will be effected by the Assignment and Assumption Agreement to be executed on the Closing Date.

ARTICLE III
CONSIDERATION; CLOSING

Section 3.1 Consideration

In consideration of the sale and transfer of the Transferred Shares and Transferred Assets to the Purchaser and in addition to the assumption of the Assumed Liabilities by the Purchaser, Parent agrees to transfer and deliver to the Seller solely 2,662,564 shares of Parent Common Stock, less the number of shares of Parent Common Stock the issuance of which shall be reserved by the Parent in connection with (i) the assumption of the Seller Stock Option Plan, (ii) any future issuance of shares of Parent Common Stock to recipients of awards under the Seller Phantom Stock Option Plan pursuant to the terms of Section 6.14; and (iii) the Convertible Debt Rollover pursuant to the terms of Section 6.15(b) (together, the "**Consideration**").

Section 3.2 Closing

(a) Subject to the terms and conditions of this Agreement, the closing of the Transaction (the "**Closing**") will take place at 10 a.m., New York City local time, as promptly as practicable, but in no event later than five (5) Business Days after the satisfaction (or, to the extent permitted by Law, waiver by the party entitled to grant such waiver) of the conditions (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the fulfilment or waiver of those conditions) set forth in ARTICLE VII, at the offices of Linklaters LLP, 1345 Avenue of the America, New York, NY 10105 or at such other place, date and time as the Seller and Parent may agree in writing. The date of the Closing is referred to as the "**Closing Date**."

(b) Notwithstanding the preceding paragraph, the parties acknowledge and agree that, in the event that in the reasonable opinion of the Seller, the distribution of all or substantially all of the Consideration to the Seller Stockholders cannot be completed before December 31, 2019, then the Closing shall occur after January 1st, 2020.

(c) At the Closing, Seller shall deliver or cause to be delivered to Parent and Purchaser all the documents set forth in **Part 1** of **Exhibit D**.

(d) At the Closing, Purchaser and Parent shall deliver or cause to be delivered to Seller all the documents set forth in **Part 2** of **Exhibit D**.

Section 3.3 Withholding

(a) All sums payable by Parent or Purchaser pursuant to this Agreement shall be paid free and clear of all deductions or withholdings (including Tax) unless the deduction or withholding is required by any applicable Law. If any amount is required to be deducted or withheld from any amount payable to Seller, Parent or Purchaser shall deduct and withhold such amounts.

(b) Parent and Purchaser shall timely pay any deducted or withheld amounts over to the appropriate Governmental Authority and shall provide Seller with an original or certified copy of a receipt showing such payment. Seller shall provide any forms or certificates the Parent or the Purchaser may reasonably request in order to satisfy deduction or withholding obligations under any applicable Law.

ARTICLE IV
REPRESENTATIONS AND WARRANTIES OF THE SELLER

Except as set forth in the disclosure schedules with respect to this Agreement delivered by the Seller to Parent and Purchaser prior to the execution of this Agreement (the "**Seller Disclosure Schedules**"), the Seller represents and warrants to the Parent and Purchaser as follows:

Section 4.1 Organization and Qualification

(a) Each of the Seller, the Company and each of its Subsidiaries is a duly organized and validly existing corporation or other legal entity in good standing under the Laws of its jurisdiction of formation or organization, with all requisite entity power and authority to own, lease and operate its properties and conduct its business as currently conducted.

(b) Each of the Seller, the Company and each of the Subsidiaries is duly qualified and in good standing as a foreign entity authorized to do business in each of the jurisdictions in which the character of the properties owned, leased or operated by it or the conduct of the business transacted by it makes such qualification necessary, except where the failure to be so qualified and in good standing has not had and is not reasonably likely to have a Material Adverse Effect. The Seller has heretofore provided to Parent true, correct and complete copies of (i) the articles of association (*Satzung*) of the Company as currently in effect as well as a current excerpt from the competent German commercial register concerning the Company. The Company and each of its Subsidiaries are in compliance in all respects with their respective articles of association, bylaws or similar governing documents, true, correct, and complete copies of which as currently in effect have been provided to Parent.

(c) Section 4.1(c) of the Seller Disclosure Schedules sets forth the state of incorporation or organization and the foreign jurisdictions in which each such Group Company is qualified to do business.

Section 4.2 Authority

(a) The Seller has all requisite corporate power and authority to execute and deliver this Agreement and, subject to receipt of the Seller Stockholder Vote and the satisfaction of the conditions set forth in ARTICLE VII, to consummate the transactions contemplated hereby.

(b) The execution and delivery of this Agreement by the Seller and the consummation by the Seller of the transactions contemplated hereby have been duly and validly authorized by the Management Board and Supervisory Board and no other corporate proceedings on the part of the Seller are necessary to authorize this Agreement or to consummate the transactions contemplated hereby, other than the Seller Stockholder Vote.

(c) This Agreement has been duly and validly executed and delivered by the Seller and, assuming due authorization, execution and delivery by Parent and Purchaser, constitutes a legal, valid and binding obligation of the Seller, enforceable against the Seller in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar Requirements of Law of general applicability relating to or affecting creditors' rights and to general equity principles.

(d) The Management Board and Supervisory Board have unanimously (i) determined that this Agreement, the Transaction and the other transactions contemplated hereby are expedient and fair to, and in the best interests of the Seller and the business connected with it, its strategy, its stockholders and other stakeholders, and (ii) adopted resolutions approving this Agreement, the Transaction and the other transactions contemplated hereby, and, subject to Section 6.3, recommending to the stockholders of the Seller the adoption of a resolution approving the sale of substantially all of the Seller's assets pursuant to, and on the terms and conditions set forth in, this Agreement (the "**Seller Board Recommendation**").

Section 4.3 Consents and Approvals; No Violation

(a) Neither the execution and delivery of this Agreement by the Seller nor the consummation of the transactions contemplated hereby will, assuming that the conditions set forth in ARTICLE VII are satisfied, (i) violate or conflict with or result in any Breach of any provision of (A) the articles of association and bylaws of the Seller or (B) the respective certificates of incorporation or bylaws or other similar governing documents of any Group Company, (ii) conflict with or violate in any material respect any Laws binding upon the Seller, the Company or any of its Subsidiaries or (iii) except as set forth in Section 4.3 of the Seller Disclosure Schedules, violate or conflict with, or result in a Breach of any provision of, or require any consent, waiver or approval, or result in a default or result in the loss of a material benefit under, or give rise to any right of termination, cancellation, amendment, modification or acceleration (or an event that, with the giving of notice, the passage of time or otherwise, would constitute a default or give rise to any such right) under any of the terms, conditions or provisions of any Contract to which Seller, the Company or any Group Company is a party or result in the creation of any Lien (other than a Permitted Lien) upon any properties, assets or rights of the Company or any of its Subsidiaries, except as, individually or in the aggregate, would not be reasonably likely to have a Material Adverse Effect.

(b) The execution, delivery and performance of this Agreement by the Seller and the consummation of the transactions contemplated hereby by Seller do not and will not require any material consent, approval, authorization or permit of, action by, or filing with or notification to, any Governmental Authority.

Section 4.4 Capitalization

(a) The share capital stock of the Company consists and as of the Closing will consist of 5,553,689 shares of Company Common Stock (or any such higher number of shares of Company Common Stock as may result from any increase of the share capital of the Company completed in compliance with the terms of this Agreement), all issued and outstanding as of the date of this Agreement and owned by Seller (the "**Transferred Shares**"). All of the Transferred Shares have been duly authorized and validly issued and are fully paid and are free of pre-emptive rights and the Seller is the sole owner of the Transferred Shares and not subject to any restrictions in respect of the sale or assignment of the Transferred Shares.

(b) There are no outstanding (i) securities of the Company convertible into or exchangeable for shares or voting securities or other ownership interests in the Company, (ii) options, warrants, rights or other agreements or commitments to acquire from the Company, or obligations of the Company to issue, any shares, voting securities or other ownership interests in (or securities convertible into or exchangeable for shares stock or voting securities or other ownership interests in) the Company, (iii) obligations of the Company to grant, extend or enter into any subscription, warrant, right, convertible or exchangeable security or other similar agreement or commitment relating to the issuance of any shares, voting securities or other ownership interests in the Company (the items in clauses (i), (ii) and (iii), together with the Transferred Shares, being referred to collectively as "**Company Securities**"). There are no outstanding obligations, commitments or arrangements, contingent or otherwise, of the Company or any of its Subsidiaries to purchase, redeem or otherwise acquire any outstanding Company Securities. There are no voting trusts or other agreements or understandings to which the Company or any of its Subsidiaries is a party with respect to the voting of shares of the Company. During the three (3) year period prior to the date hereof, the Company has not declared or paid any dividend or declared or made any distribution on any of its capital stock or directly or indirectly, redeemed, purchased or otherwise acquired any of its own capital stock other than issuances to the Seller.

(c) Section 4.4(c) of the Seller Disclosure Schedules lists each Subsidiary and sets forth the Company's percentage ownership and, with respect to non-Wholly-Owned Subsidiaries, ownership type in each such Subsidiary. Each of the outstanding shares of capital stock or other securities of or interests in each such Subsidiary is duly authorized, validly issued, fully paid and the Company or one or more of its direct or indirect Wholly-Owned Subsidiaries is the record and beneficial owner of the applicable equity interests of each Subsidiary, free and clear of all Liens other than Permitted Liens.

(d) There are no outstanding (i) securities of the Company or any of its Subsidiaries convertible into or exchangeable for shares of capital stock, voting securities or other ownership interests in any Subsidiary of the Company, (ii) options, warrants, rights or other agreements or commitments to acquire from the Company or any of its Subsidiaries, or obligations of the Company or any of its Subsidiaries to issue, any capital stock, voting securities or other ownership interests in (or securities convertible into or exchangeable for capital stock, voting securities or other ownership interests in) any Subsidiary of the Company, or (iii) obligations of the Company or any of its Subsidiaries to grant, extend or enter into any subscription, warrant, right, convertible or exchangeable security or other similar agreement or commitment relating to the issuance of any capital stock, voting securities or other ownership interests in any Subsidiary of the Company (the items in clauses (i), (ii) and (iii), together with the capital stock of such Subsidiaries, being referred to collectively as "**Subsidiary Securities**"). There are no outstanding obligations of the Company or any of its Subsidiaries to purchase, redeem or otherwise acquire any outstanding Subsidiary Securities. There are no voting trusts or other agreements or understandings to which the Company or any of its Subsidiaries is a party with respect to the voting of capital stock of any Subsidiary of the Company.

(e) Neither the Company nor any of its Subsidiaries owns, directly or indirectly, any capital stock or other equity securities of any entity that is not a Subsidiary of the Company.

Section 4.5 Financial Statements

(a) Seller has provided to Parent the audited consolidated financial statements of the Seller as at and for the periods ended December 31, 2017 and December 31, 2018 (the "**Audited Financial Statements**") and the unaudited consolidated financial statements of the Seller as at and for the period ended June 30, 2019 (collectively, with the Audited Financial Statements, the "**Financial Statements**"). The Financial Statements are set forth in Section 4.5 of the Seller Disclosure Schedules.

(b) The Financial Statements have been prepared in accordance with IFRS applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto). The Financial Statements fairly present, in all material respects, the financial position, results of operations and cash flows of the Group Companies as at their respective dates.

(c) The balance sheet of the Seller as of December 31, 2018 (the "**Balance Sheet Date**") is referred to herein as the "**Seller Balance Sheet**". Except as set forth in Section 4.5(c) of the Seller Disclosure Schedules, the Group Companies have no, and the Assumed Liabilities consist of no, Liabilities of any nature (whether accrued, absolute, contingent or otherwise, whether known or unknown), except Liabilities that (i) are reflected or reserved against in the Seller Balance Sheet (including the notes thereto), (ii) were incurred since the Balance Sheet Date in the Ordinary Course of Business, or (iii) are incurred in connection with the transactions contemplated by this Agreement.

Section 4.6 Absence of Certain Changes

From the Balance Sheet Date to the date hereof, except as set forth in Section 4.6 of the Seller Disclosure Schedules and except resulting from the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby, the Seller and the Group Companies have conducted their business in all material respects only in the Ordinary Course of Business and, without limiting the foregoing, there has not been any:

(a) amendment to the certificate of incorporation, by-laws or other organizational documents of the Group Companies or any outstanding Company Securities or Subsidiary Securities;

(b) declaration, setting aside or payment of any dividend or other distribution with respect to any Company Securities or Subsidiary Securities, or any repurchase or redemption by the Group Companies of any Company Securities or Subsidiary Securities; or

(c) sale, lease, transfer, or assignment of any asset, other than inventory in the Ordinary Course of Business or any distributions of any assets (Cash or otherwise) of the Business;

(d) incurrence of any Liabilities, except current Liabilities incurred in the Ordinary Course of Business and Liabilities under Contracts entered into in the Ordinary Course of Business;

(e) mortgage, pledge or imposition of any Lien on any of its properties or assets (including the Transferred Assets);

(f) issuance, creation, incurrence, or assumption of any Indebtedness (other than between the Seller and its Wholly-Owned Subsidiaries or between Wholly-Owned Subsidiaries of the Seller);

(g) loan to, or entry into any other similar transaction with, any of its directors, officers, or employees;

(h) sale, assignment, or transfer of any Intellectual Property to any Person;

(i) entry into any material transaction or otherwise taking any material action or omission to take any material action, other than in the Ordinary Course of Business, except in connection with the execution and performance of this Agreement and the consummation of the Transaction;

(j) occurrence of any Material Adverse Effect with respect to the Company; or

(k) agreement or commitment to do any of the foregoing.

Section 4.7 Material Contracts

(a) Except as set forth in Section 4.7(a) of the Seller Disclosure Schedules, as of the date hereof, neither the Seller (in respect of Transferred Assets only) nor any Group Company is bound by or a party to any:

(i) Contract relating to Indebtedness that is (1) in excess of $100,000, (2) with or from any officer, director or employee of any Group Company, or (3) entered into other than in the Ordinary Course of Business;

(ii) joint venture, partnership, limited liability company or other similar Contract that is material to the Group Companies, taken as a whole;

(iii) Contract (or series of related Contracts) relating to the acquisition, disposition or lease of any Person, business or material real property or other material assets (whether by merger, sale of stock, sale of assets or otherwise), other than sales of inventory in the Ordinary Course of Business, that would be material to the Group Companies, taken as a whole;

(iv) sales or distribution Contract (or series of related Contracts) involving the supply of goods or services, the aggregate sales value of which (exclusive of VAT) represents more than 25 percent of the turnover of the Group Companies (exclusive of VAT) for the preceding financial year;

(v) Contract (or series of related Contracts) relating to the purchase by the Group Companies of any products or services involving total expenditure in excess of $50,000, other than any Contract executed in the Ordinary Course of Business or Contract that is cancellable by Seller or the Group Companies without penalty on less than 90 days' notice;

(vi) Contract that contains any right of first refusal, non-compete or exclusivity provisions or otherwise that materially limits the type of business or geographic regions in which any Group Company may engage in business;

(vii) Contract primarily for the indemnification by a Group Company of any Person;

(viii) Contract between any of the Seller or the Group Companies, on the one hand, and any of their Affiliates (other than any other Group Company), on the other hand;

(ix) Any Contracts being assigned to Purchaser by the Seller; or

(x) Contract that is material to the operation of the Business and not previously disclosed pursuant to this Section 4.7.

(b) Each Contract set forth in Section 4.7(a) of the Seller Disclosure Schedules (each, a "**Company Material Contract**") is in full force and effect and none of the Seller or the Group Companies or, to the Seller's Knowledge, any other party thereto, is in default or Breach in any material respect under the terms of, and no event has occurred that, with the passage of time or the giving of notice or both, would constitute a Breach by the Seller or the applicable Group Company, or to Seller's Knowledge, any other party thereto under any such Company Material Contract, or would permit modification, acceleration, or termination of any such Company Material Contract or the creation of a Lien on any assets of any Group Company or on the Transferred Assets. None of the Seller or the Group Companies has provided or received from any third party any written notice of any intention to terminate or modify any such Company Material Contract. Seller has made available to Parent a true, correct, and complete copy of each written Company Material Contract together with all amendments, exhibits, attachments, waivers or other changes thereto.

(c) For the avoidance of doubt, this Section 4.7 does not address real estate leases, Intellectual Property licenses, governmental permits, collective bargaining agreements, Group Companies Benefit Plans or insurance matters, which are addressed solely by Section 4.8 (*Real Property*), Section 4.9 (*Intellectual Property*), Section 4.11 (*Compliance with Laws; Permits*), Section 4.13 (*Employees; Labor Matters*), Section 4.14 (*Employee Benefit Plans and Related Matters; ERISA*) and Section 4.16 (*Insurance*), respectively.

Section 4.8 Real Property

(a) Neither Seller nor any Group Company owns any real property as of the date hereof. There are no outstanding options or rights of first refusal to purchase any real property.

(b) Section 4.8(b) of the Seller Disclosure Schedules sets forth all of the real property leased by the Group Companies as of the date hereof (the "**Company Leases**", and together with all interests leased pursuant to the Leases, the "**Company Leased Real Property**"). None of the Group Companies is a sublessor or grantor under any sublease or other instrument granting to another Person any right to the possession, lease, occupancy or enjoyment of the Leased Real Property.

(c) Each Company Lease is in full force and effect and none of the Group Companies or, to the Seller's Knowledge, any other party thereto, is in default or Breach in any material respect under the terms of, and no event has occurred that, with the passage of time or the giving of notice or both, would constitute a Breach by the applicable Group Company, or to Seller's Knowledge, any other party thereto, under any such Company Lease, or would permit modification, acceleration, or termination of any such Company Lease. None of the Group Companies has provided any written notice of any intention to terminate or modify any such Company Lease. Seller has made available to Parent a true, correct, and complete copy of each written Company Lease together with all amendments, exhibits, attachments, waivers or other changes thereto.

(d) For the avoidance of doubt, this Section 4.8 does not address Intellectual Property, compliance with Laws, environmental matters or insurance matters, which are addressed solely by Section 4.9 (*Intellectual Property*), Section 4.12 (*Environmental Matters*) and Section 4.16 (*Insurance*), respectively.

Section 4.9 Intellectual Property

(a) Section 4.9(a) of the Seller Disclosure Schedules sets forth a true, correct, and complete list of all Intellectual Property owned by the Group Companies as of the date hereof that is registered or subject to an application for registration, other than trade secrets, domain names as well as any material unregistered trademarks or trade names. With respect to trade secrets the Group Companies have taken all required measures to protect them in accordance with the applicable laws. No Intellectual Property Related to the Business is registered in the name of or owned by the Seller.

(b) Except as set forth in Section 4.9(a) of the Seller Disclosure Schedule, each patent, design and trademark set forth in Section 4.9(a) of the Seller Disclosure Schedules is registered and recorded in the name of the applicable Group Company, is in full, has been duly applied for and registered in accordance with applicable Law and has not been and is not involved in any opposition, cancellation or interference or similar proceeding. All required filings and fees related to the Intellectual Property set forth on Section 4.9(a) of the Seller Disclosure Schedules have been timely filed with and paid to the relevant Governmental Authority and authorized registrars, and are otherwise in good standing.

(c) Section 4.9(c) of the Seller Disclosure Schedules sets forth a true, correct, and complete list of all material licenses to which the Group Companies is a party that relate to Intellectual Property, other than non-exclusive licenses of generally commercially available "off the shelf" software (collectively, the "**Company IP Contracts**"), including: (i) licenses of Intellectual Property to any of the Group Companies by any other Person; (ii) licenses of Intellectual Property to any other Person by any of the Group Companies; (iii) agreements otherwise granting or restricting the right to use Intellectual Property; and (iv) agreements transferring, assigning or indemnifying any person with respect to Intellectual Property that is required to conduct the Business as currently conducted on the date of this Agreement. Each Company IP Contract is in full force and effect and none of the Group Companies or, to the Seller's Knowledge, any other party thereto, is in default or Breach in any material respect under the terms of, and no event has occurred that, with the passage of time or the giving of notice or both, would constitute a Breach by the applicable Group Company, or to Seller's Knowledge, any other party thereto under any such Company IP Contract, or would permit modification, acceleration, or termination of any such Company IP Contract. None of the Group Companies has provided any written notice of any intention to terminate or modify any such Company IP Contract. Seller has made available to Parent a true, correct, and complete copy of each written Company IP Contract together with all amendments, exhibits, attachments, waivers or other changes thereto.

(d) To the Seller's Knowledge, the Intellectual Property currently owned, licensed or used by the Group Companies or included within the Transferred Assets, and the conduct of the Business as currently and formerly conducted by the Seller and the Group Companies, does not and do not infringe, violate or misappropriate the Intellectual Property, privacy rights, or proprietary rights of any Person. Neither the Seller nor any Group Company has received any communication or notice, and no Proceeding has been instituted, settled or, to the Seller's Knowledge, threatened that alleges any such infringement, violation or misappropriation or otherwise contesting any Group Company's rights in or to such Intellectual Property, and none of such Intellectual Property are subject to any outstanding Order. To the Seller's Knowledge, neither the Seller (in respect of Transferred Assets only) nor any Group Company has any Liability and there is no basis for any Proceeding against the Seller or any such Group Company that could give rise to any Liability arising out of any infringement of the Intellectual Property of any other Person.

(e) The Intellectual Property owned and licensed by the Group Companies and included within the Transferred Assets constitute all of the Intellectual Property used by the Group Companies and the Seller for the conduct of the Business as conducted during the one (1) year prior to the date hereof.

(f) Except as set forth in Section 4.9(f) of the Seller Disclosure Schedule, all Intellectual Property which has been created by employees, officers, consultants and service providers of a Group Company within the scope of their employment or engagement by the Group Company was assigned to the Group Company and, all such employees, officers, consultants and services providers have executed agreements to expressly assign all rights, title and interest in such Intellectual Property to the Group Company. Without limiting the generality of the foregoing, the respective Group Company has entered into binding, written agreements with every current and former employee and officer of the Seller or a Group Company, and every current and former independent contractor or consultant, whereby such employees, officers and independent contractors and consultants (a) assign to the applicable Group Company any ownership interest and right they may have in such Intellectual Property, and (b) acknowledge the respective Group Company's exclusive ownership of all such Intellectual Property and, to the extent permitted by Law, waiving all rights (including right to receive royalties or other payments) in connection therewith. The Seller has provided Parent with true, correct and complete copies of all such agreements. The Seller or a Group Company has satisfied all due and payable compensation claims of every current and former employees, officers and independent contractors and consultants with respect to all Intellectual Property which has been created by such employees, officers, consultants and independent contractors.

(g) The Seller and the Group Companies are in compliance, in all material respects, with all legal requirements applicable to the Intellectual Property owned or licensed by the Group Companies or included within the Transferred Assets.

Section 4.10 Litigation

(a) Except as set forth in Section 4.10(a) of the Seller Disclosure Schedules, there is no Proceeding pending or, to the Seller's Knowledge, threatened against or relating to: (i) the Company or any of its Subsidiaries; (ii) the Seller relating to the Transferred Assets or the Assumed Liabilities; or (iii) relating to the transactions contemplated hereby.

(b) For the avoidance of doubt, this Section 4.10 does not address Intellectual Property or Tax-related litigation, which are addressed solely by Section 4.9 (*Intellectual Property*) and Section 4.15 (*Taxes*), respectively.

Section 4.11 Compliance with Laws; Permits

(a) Except as set forth in Section 4.11(a) of the Seller Disclosure Schedules, the Seller and the Group Companies are in compliance with all applicable Laws, except where the failure to be in compliance would reasonably be expected not to have a Material Adverse Effect. To the Seller's Knowledge, the Seller and the Group Companies are not under investigation with respect to, and have not been given written notice of, any violation of any applicable Law.

(b) Except as set forth in Section 4.11(b) of the Seller Disclosure Schedules, to the Seller's Knowledge, the Group Companies own, hold or possess adequate rights to use all Permits required to conduct the Business as currently conducted other than such Permits the absence of which would reasonably be expected not to have a Material Adverse Effect. To the Seller's Knowledge, there has occurred no material violation of, suspension, reconsideration, imposition of penalties or fines or default (with or without notice or lapse of time or both) under, or event giving rise to any right of termination, amendment or cancellation of, with or without notice or lapse of time or both, any such Permit that is currently in effect, in each case to the extent uncured or otherwise unresolved, other than an expiration of a Permit in the Ordinary Course of Business.

(c) For the avoidance of doubt, this Section 4.11 does not address matters subject to legal proceedings, environmental matters, employee and labor matters, employee benefits matters or Tax matters, which are addressed solely by Section 4.10 (*Litigation*), Section 4.12 (*Environmental Matters*), Section 4.13 (*Employees; Labor Matters*), Section 4.14 (*Employee Benefit Plans and Related Matters; ERISA*) and Section 4.15 (*Taxes*) respectively.

Section 4.12 Environmental Matters

(a) Except as set forth in Section 4.12(a) of the Seller Disclosure Schedules:

(i) since January 1, 2016, each of the Group Companies has, in material respects, been in compliance with all applicable Environmental Laws and has obtained and is, in all material respects, in compliance with all applicable Permits and, to the Seller's Knowledge, no written notice of violation has been received by the Group Companies relating to or arising out of any Environmental Law, other than matters that have been resolved or that are no longer outstanding;

(ii) none of the Group Companies has entered into any agreement with any Governmental Authority which has not been fully completed and pursuant to which it has agreed to remediate any condition resulting from the release of Hazardous Materials; and

(iii) except as set forth in Section 4.12(a)(iii) of the Seller Disclosure Schedules, there is no Proceeding pending or, to the Seller's Knowledge, threatened against or relating to the Company or any of its Subsidiaries relating to Environmental Laws.

(b) Notwithstanding any representations and warranties contained elsewhere in this Agreement, matters arising under Environmental Laws shall be governed exclusively by this Section 4.12.

Section 4.13 Employees; Labor Matters

(a) Except as set forth in Section 4.13(a) of the Seller Disclosure Schedules, none of the Group Companies is a party to or bound by any collective agreements, including collective bargaining agreements (*Tarifverträge*), works council agreements (*Betriebsvereinbarungen*) and other agreements with any employee representative body, nor does any of the Group Companies have any labor representation (*Betrienbsrat*). The Seller has not established and is not required to establish a works council (*ondernemingsraad*) or another body or delegation representing (the interests of) the employees of the Seller or the Group Companies, within the meaning of the Dutch Works Council Act (*Wet op de ondernemingsraden*) or the Dutch European Works Council Act (*Wet op de Europese ondernemingsraden*) that has authority to render advice regarding the Transaction.

(b) Section 4.13(b) of the Seller Disclosure Schedules lays out which, if any, labor unions and other employee representative bodies represent or, to the Seller's Knowledge, purport or attempt to represent any Group Employees. There has not occurred after January 1, 2016, or, to the Seller's Knowledge, been threatened, any material industrial action such as strike or other similar labor activity with an impact on any the Group Companies. There are no material pending or, to the Seller's Knowledge, threatened, grievances or labor disputes, including any Proceeding, with respect to any Group Employee or ex-employees or ex-officers of the Group Companies. To the Seller's Knowledge, none of the Group Companies have engaged in any unfair labor practices that would reasonably be expected, individually or in the aggregate, directly or indirectly, to result in a material liability to the Group Companies. Any and all information or consultation obligations towards the Group Employees or their representatives have been complied with.

(c) To the Seller's Knowledge and to the extent applicable, the Group Companies are in material compliance with all Laws applicable to the Business with respect to the Group Employees and their own policies respecting employment and employment practices, terms and conditions of employment, wages and hours, equal opportunity, civil rights, labor relations, occupational health and safety, collective agreements and arrangements and payroll taxes.

(d) None of Seller or the Group Companies are in receipt of a written complaint, demand letter or charge issued by any government agency that alleges a material violation by the Group Companies of any applicable labor and employment Law, including but not limited to working time, remuneration, classification of contractors as employees, labor relations, occupational health and safety or payroll taxes with respect to the Group Employees. None of the Group Companies have: (i) engaged in any plant closing, work force reduction or other action that has resulted or could reasonably be expected to result in material, outstanding liability under applicable Law with respect to the employees; or (ii) been issued any notice that any such action is to occur in the future with respect to the employees. As of the date hereof, there is no Proceeding pending or, to the Seller's Knowledge, threatened against or relating to any of the Group Companies with respect to the Group Employees and their own policies respecting employment and employment practices, terms and conditions of employment, working time and remuneration, classification of contractors as employees, equal opportunity, civil rights, labor relations, occupational health and safety and payroll taxes with respect to the employees.

(e) The Seller has no employees. Section 4.13(e) of the Seller Disclosure Schedules contains for each Group Company a true, correct, and complete list of all Group Employees, setting forth in respect of each Group Employee, the identification of the employing entity, the position of the Group Employee, the amount of such Group Employee's annual salary, social security contributions and maximum performance bonus, and whether such Group Employee is employed on a full-time basis or not. Further, it contains for each Group Company a true, correct, complete and staff breakdown and FTE of all Group Employees, indicating category of employee. No Group Employee is entitled to any termination right or payment as a result of this Agreement. None of the Group Companies engages individuals other than Group Employees.

(f) There are no pending, or to Seller's Knowledge, threatened, Proceedings involving the Seller or any of the Group Companies under any Laws relating to or arising out of the employment or service of any employee or deemed employee of any Group Company or the Seller, with respect to deemed employees.

Section 4.14 Employee Benefit Plans and Related Matters; ERISA

(a) Section 4.14(a) of the Seller Disclosure Schedules sets forth a complete, separate and correct list of the Group Companies Benefit Plans applicable to all Group Employees, ex-employees, officers and ex-officers of the Group Companies, indicating for each whether of a defined benefit or defined contribution nature and how it is funded. Neither Seller nor any of the Group Companies has or maintains any Multiemployer Plans. With respect to each Group Companies Benefit Plan, Seller has provided or made available to Parent, copies of each of the Group Companies Benefit Plans and their amendments, to the extent applicable: (i) the most recent annual reports and accompanying schedules; (ii) the most recent actuarial reports (Form 5500 Series or equivalent) and accompanying schedules; (iii) the current summary plan description, together with any summary of material modifications relating thereto; (iv) the most recent annual financial report; and (v) the most recent determination letter from the IRS.

(b) With respect to the Group Companies Benefit Plans:

(i) to the Seller's Knowledge, except as would not have a Material Adverse Effect: (A) the Group Companies Benefit Plans have at all times complied in all material respects in accordance with all Laws, regulations and requirements applicable to each of the Group Companies Benefit Plans; (B) to the extent they have been funded externally, all contributions to any external funding vehicle required to be made to any Group Companies Benefit Plan by applicable Laws or by any plan document or other contractual undertaking, and all premiums due or payable with respect to insurance policies funding any Group Companies Benefit Plan, for any period through the date hereof have at all times been made in accordance with the provisions of the relevant Group Company Benefit Plan and those contributions falling due for payment until the Closing Date will have been made at that date; and (C) the total amount of the obligations in respect to employees as of the Balance Sheet Date which are not externally funded has been reported in the actuarial reports provided pursuant to Section 4.14(a);

(ii) there are no pension rights or expectancies, vested or unvested, whether based on individual promise, plan, shop agreement or company practice, which are not externally funded, that have not been reflected in the actuarial reports;

(iii) to the Seller's Knowledge none of the amounts payable by the Group Companies under any of the Group Companies Benefit Plans applicable in the U.S. on account of the transactions contemplated under this Agreement shall fail to be deductible by reason of Section 280G of the Code; and

(iv) none of the Group Companies Benefit Plans applicable in the U.S. provides for post-retirement welfare benefits coverage, except for: (aa) health continuation coverage as required by applicable Law, including section 4980B of the Code or Title I of ERISA; (bb) coverage through the last day of the calendar month in which the retirement date occurs; (cc) the credit balance of any health savings or medical reimbursement accounts; and (dd) rights of beneficiaries to receive the remainder of a participant's benefits upon the participant's death.

(c) There is no Proceeding pending or, to the Seller's Knowledge, threatened against or relating to any of the Group Companies with respect to the Group Companies Benefit Plans, other than routine claims for benefits in the Ordinary Course of Business.

Section 4.15 Taxes

(a) Except as set forth in Section 4.15 of the Seller Disclosure Schedules:

(i) Each of the Group Companies, as well as the Seller's German permanent establishment (the "**Relevant Tax Entities**" or as the case may be "**Relevant Tax Entity**") has timely filed (taking into account any applicable extensions) all income and all other material Tax Returns required to have been filed by it, and all such Tax Returns are accurate and complete in all material respects. All Taxes due and payable by each Relevant Tax Entity have been timely and fully paid.

(ii) To the Seller's Knowledge, there is no audit, examination or other Proceeding involving any Taxes with respect to any of the Relevant Tax Entities that is currently in progress or has been notified in writing.

(iii) There are no Liens for Taxes against any of the Relevant Tax Entities' assets, other than Permitted Liens.

(iv) None of the Relevant Tax Entities have executed or filed with any Tax Authority any agreement extending the period for assessment or collection of any material income Taxes.

(v) The most recent Audited Financial Statements reflect an adequate accrual or reserve for all material Taxes incurred but not yet due and payable by the Group Companies through the date of such Audited Financial Statements, and the unpaid Taxes of the Group Companies for all tax periods commencing after the date of such Audited Financial Statements have been properly accrued on the books and records of the Group Companies.

(vi) No written claim has been made by any Tax Authority in a jurisdiction where the Company or any of its Subsidiaries does not file Tax Returns that the Company or any of its Subsidiaries is or may by subject to taxation by that jurisdiction.

(vii) Each of the Group Companies has timely paid or withheld with respect to their employees (and paid over any amounts withheld to the appropriate Taxing authority to the extent due) all material Taxes required to be paid or withheld.

(viii) There are no Tax indemnity, Tax sharing, Tax allocation or similar agreements in effect as between the Company and any of its Subsidiaries, on the one hand, and any other party, on the other hand, under which the Company could be liable for any material Taxes of any third party (other than commercial business agreements, the principal purpose of which is not the allocation of Taxes).

(b) he Seller and the Relevant Tax Entities have complied, in all material respects, with all Laws applicable to Taxes. There is no Proceeding pending or, to the Seller's Knowledge, threatened against or relating to any of the Relevant Tax Entities with respect to Taxes. All Tax-related documents (including electronically stored data) which are, under the Laws applicable to any Tax Relevant Entity in its jurisdiction of residence, required to be available at the respective Tax Relevant Entity, including but not limited to all transfer pricing and related parties' transaction documentation, are available at the respective Tax Relevant Entity in a manner as required under all applicable Laws.

(c) The representations and warranties set forth in this Section 4.15 constitute the exclusive representations and warranties of Seller with respect to Taxes and Tax matters and no other representation or warranty contained in this Agreement shall be construed to address any Taxes or any Tax matters.

Section 4.16 Insurance

Section 4.16 of the Seller Disclosure Schedules sets forth all material insurance policies maintained by the Group Companies or the Seller with regard to the Business or the Transferred Assets or the Assumed Liabilities. All such policies are in full force and effect; true, correct, and complete copies of which have been provided to Parent. All premiums relating to such policies have been timely paid. Neither the Seller nor any of the Group Companies is in Breach, and neither the Seller nor any of the Group Companies has taken any action or failed to take any action which, with notice or the lapse of time, would constitute such a Breach, or permit termination or modification of, any of such policies. There is no pending claim by the Seller or any of the Group Companies under any of such policies as to which coverage has been denied by the underwriters of such policies.

Section 4.17 Sufficiency of Assets

(a) The Seller holds good and marketable title to, or valid leasehold interests in or valid rights under Contracts to use, free and clear of all Liens (other than Permitted Liens), the Transferred Assets.

(b) The Group Companies hold good and marketable title to, or valid leasehold interests in or valid rights under Contracts to use, free and clear of all Liens (other than Permitted Liens) all tangible property and assets held by any of them.

(c) The assets of the Group Companies and the Transferred Assets are, as of the date hereof, and will be, on the Closing Date: (i) all of the assets used in the conduct of the Business as currently conducted, (ii) sufficient in all material respects for the Company and its Subsidiaries to carry on the Business as currently conducted (except in respect of any Excluded Asset), and (iii) in good repair and in working order, except for ordinary wear and tear.

Section 4.18 Fairness Opinion

Seller has received the written opinion of the Seller's Financial Advisor, dated as of a date reasonably proximate to the date hereof, to the effect that, as of such date, and based upon and subject to the various assumptions, limitations, qualifications and other matters set forth therein, the Consideration to be received by the Company pursuant to this Agreement is fair to the Seller, from a financial point of view (the "**Seller Fairness Opinion**"); it being agreed that neither Parent (nor any of its Affiliates) shall be entitled to rely on the Seller Fairness Opinion.

Section 4.19 Brokers

No agent, broker, investment banker, financial advisor or other firm or Person is or shall be entitled, as a result of any action, agreement or commitment of the Seller or any of its Affiliates, to any broker's, finder's, financial advisor's or other similar fee or commission in connection with any of the transactions contemplated by this Agreement, other than the Seller's Financial Advisor, whose fees and expenses shall be paid by the Seller. The fee provisions of the Seller's agreement with the Seller's Financial Advisor relating to the transactions contemplated by this Agreement have previously been disclosed to the Parent.

Section 4.20 Disclosure Documents

(a) The information supplied by the Seller in writing for inclusion or incorporation by reference in the registration statement of Parent on Form S-4 or any amendment or supplement thereto pursuant to which shares of Parent Common Stock issuable in connection with the Transaction will be registered with the SEC (the "**Form S-4 Registration Statement**") shall not, at the time the Form S-4 Registration Statement is declared effective by the SEC (or, with respect to any post-effective amendment or supplement, at the time such post-effective amendment or supplement becomes effective), contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) The representations and warranties contained in this Section 4.20 will not apply to statements or omissions included or incorporated by reference in the Form S-4 Registration Statement or any amendment or supplement thereto based upon information furnished by Parent or any of its Representatives in writing specifically for use or incorporation by reference therein.

ARTICLE V
REPRESENTATIONS AND WARRANTIES OF PURCHASER

Except as disclosed in the disclosure schedules delivered by Parent and Purchaser to the Seller with respect to this Agreement on the date hereof (the "**Purchaser Disclosure Schedules**"), Parent and Purchaser jointly and severally represent and warrant to the Seller as follows:

Section 5.1 Organization and Qualification; Certificate of Incorporation; Bylaws

(a) Each of Purchaser and Parent is a duly organized and validly existing organization in good standing under the Laws of its jurisdiction of formation, with all requisite entity power and authority to own its properties and conduct its business as currently conducted. Each of Purchaser and Parent is duly qualified and in good standing as a foreign entity authorized to do business in each of the jurisdictions in which the character of the properties owned or held under lease by it or the nature of the business transacted by it makes such qualification necessary, except where the failure to be so qualified has not and would not reasonably be expected to prevent or materially delay the consummation of the transactions contemplated by this Agreement.

(b) True, correct and complete copies of the certificate of incorporation, bylaws or other organizational documents, each as amended to date, of each of Purchaser and Parent have been provided to the Seller. Each such certificate of incorporation, bylaws or other organizational document is in full force and effect. Each of Purchaser and Parent is in compliance in all respects with its respective certificate of incorporation and bylaws (or similar governing documents).

(c) Purchaser was formed by Parent solely for the purpose of effecting the Transaction and has not engaged in any business activities or conducted any operations other than in connection with the Transaction.

Section 5.2 Authority

(a) Each of Purchaser and Parent has all requisite corporate power and authority to execute and deliver this Agreement and, subject to receipt of the Parent Stockholder Vote and the satisfaction of the conditions set forth in ARTICLE VII, to consummate the transactions contemplated hereby.

(b) The execution and delivery of this Agreement by Purchaser and Parent, and the consummation by Purchaser and Parent of the transactions contemplated hereby have been duly and validly authorized by the Board of Directors and no other corporate proceedings on the part of Purchaser or Parent are necessary to authorize this Agreement or to consummate the transactions contemplated hereby, other than the Parent Stockholder Vote.

(c) This Agreement has been duly and validly executed and delivered by each of Purchaser and Parent, and, assuming due authorization, execution and delivery by Seller, constitutes a legal, valid and binding obligation of each of Purchaser and Parent, enforceable against each of Purchaser and Parent in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar Requirements of Law of general applicability relating to or affecting creditors' rights and to general equity principles.

(d) The Board of Directors has unanimously (i) determined that this Agreement, the Transaction and the other transactions contemplated hereby are expedient and fair to, and in the best interests of, the Parent and its stockholders, and (ii) adopted resolutions approving this Agreement, the Transaction and the other transactions contemplated hereby, and, subject to Section 6.3, recommending to the stockholders of Parent the adoption of a resolution approving the purchase of the Transferred Shares and of the Transferred Assets and the assumption of the Assumed Liabilities pursuant to, and on the terms and conditions set forth in, this Agreement (the "**Parent Board Recommendation**").

Section 5.3 Consents and Approvals; No Violation

(a) Neither the execution and delivery of this Agreement by Purchaser or Parent nor the consummation of the transactions contemplated hereby will, assuming that the conditions set forth in ARTICLE VII are satisfied, (i) violate or conflict with or result in any Breach of any provision of the respective organizational documents of Purchaser or Parent, (ii) assuming all consents, approvals and authorizations contemplated in subsection (b) below have been obtained and are effective and all filings described in such clause have been made, conflict with or violate any Requirements of Law binding upon the Purchaser or Parent or any of their respective assets or properties, or (iii) violate or conflict with or result in a Breach of any provision of, or require any consent, waiver or approval, or result in a default or result in the loss of benefit under, or give rise to any right of termination, cancellation, amendment, modification or acceleration (or an event that, with the giving of notice, the passage of time or otherwise, would constitute a default or give rise to any such right) under any of the terms, conditions or provisions of any Contract to which Purchaser or Parent is a party or result in the creation of any Lien (other than a Permitted Lien) upon any properties, assets or rights of the Purchaser Entities, except as, individually or in the aggregate, would not be reasonably likely to have a Material Adverse Effect.

(b) The execution, delivery and performance of this Agreement by Purchaser and Parent and the consummation of the transactions contemplated hereby by Purchaser and Parent do not and will not require any material consent, approval, authorization or permit of, action by, or filing with or notification to, any Governmental Authority, except the filing of the Form S-4 Registration Statement and any other filings required under the Exchange Act with the SEC.

Section 5.4 Capitalization

(a) The authorized capital stock of Parent consists of 882,286 shares of Parent Common Stock, all of which are duly authorized, validly issued, fully paid, and nonassessable. In addition, as of the date hereof, there are (i) outstanding options to purchase an aggregate of 10,425 shares of Parent Common Stock, (ii) outstanding warrants to purchase an aggregate of 175,965 shares of Parent Common Stock, (iii) 16,813 shares of Parent Common Stock reserved for issuance upon the vesting of outstanding restricted stock units, and (vi) no shares of Parent Common Stock held in the treasury of Parent (collectively, the "**Parent Securities**").

(b) Except as set forth in Section 5.4(b) of the Purchaser Disclosure Schedule or otherwise disclosed in the Parent SEC Documents, as of the date hereof, there are no options, stock appreciation rights, warrants, restricted stock units, or other rights, Contracts, arrangements, or commitments of any character relating to the issued or unissued capital stock of Parent or any of its Subsidiaries, or obligating Parent or any of its Subsidiaries to issue, grant, or sell any shares of capital stock of, or other equity interests in, or securities convertible into equity interests in, Parent or any of its Subsidiaries.

(c) Each outstanding share of capital stock of each Subsidiary of Parent (including, for the avoidance of doubt, Purchaser) is duly authorized, validly issued, fully paid, and nonassessable and each such share is owned by Parent or one of its Subsidiaries and is free and clear of all Liens (provided that each outstanding share of capital stock of Purchaser is owned exclusively by Parent). None of the outstanding equity securities or other securities of Parent or any of its Subsidiaries was issued in violation of the Securities Act or any other Requirements of Law.

Section 5.5 Parent SEC Documents

(a) Parent has on a timely basis filed all forms, reports, schedules, statements, financial statements and other documents required to be filed by it with the SEC since January 1, 2016 (together with all information incorporated therein by reference, the "**Parent SEC Documents**"). No Subsidiary of Parent is, or since January 1, 2016 has been, required to file any form, report, registration statement, or other document with the SEC.

(b) Each of the Parent SEC Documents (i) as of the date of the filing of such report, complied in all material respects with the requirements of the Securities Act, the Exchange Act, and the Sarbanes Oxley Act, the rules and regulations thereunder, and (ii) as of its filing date (or, if amended or superseded by a subsequent filing prior to the date hereof, on the date of such filing) did not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. There are no outstanding or unresolved comments in comments letters received from the SEC staff with respect to the Parent SEC Documents. The Parent has not received written notice that any of the Parent SEC Documents are the subject of ongoing SEC review.

Section 5.6 Financial Statements

(a) Each of the financial statements (including, in each case, any notes thereto) contained or incorporated by reference in the Parent SEC Documents complied in all material respects with the rules and regulations of the SEC as of the date of the filing of such reports, was prepared in accordance with GAAP (except in the case of unaudited statements or pro forma statements, as permitted by Form 10-Q or Form 8-K of the SEC) applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto) and fairly presents, or will fairly present, the consolidated financial position of the Parent and its Subsidiaries as of the dates thereof and their consolidated results of operations, changes in stockholders' equity, and cash flow of Parent and its Subsidiaries as of the respective dates of and for the periods referred to in such financial statements, subject, in the case of interim financial statements, to (i) the omission of notes to the extent permitted by Regulation S-X (that, in the case of interim financial statements included in the Parent SEC Documents since Parent's most recent annual report on Form 10-K, would not differ materially from the notes to the financial statements included in such annual report) and (ii) normal, recurring year-end adjustments (the effect of which will not, individually or in the aggregate, be material).

(b) The Parent has heretofore made available to the Seller a complete and correct copy of all amendments or modifications to the Parent SEC Documents (in draft or final form) which are required to be filed with the SEC but have not yet been filed with the SEC.

(c) The audited balance sheet of Parent dated as of the Balance Sheet Date contained in the Parent SEC Documents filed prior to the date hereof is hereinafter referred to as the "**Parent Balance Sheet**". Except as set forth in Section 5.6(c) of the Purchaser Disclosure Schedules, the Purchaser Entities (other than the Purchaser) have no Liabilities of any nature (whether accrued, absolute, contingent or otherwise, whether known or unknown), except Liabilities that (i) are reflected or reserved against in the Parent Balance Sheet (including the notes thereto), (ii) were incurred since the Balance Sheet Date in the Ordinary Course of Business, or (iii) are incurred in connection with the transactions contemplated by this Agreement.

(d) The Purchaser has no Liabilities of any nature (whether accrued, absolute, contingent or otherwise, whether known or unknown), except Liabilities incurred in connection with the Transaction.

Section 5.7 Internal Controls

(a) The Parent maintains internal controls over financial reporting (as defined in Rules 13a-15 and 15d-15 under the Exchange Act) in compliance with the requirements of the Exchange Act. The Parent's internal control over financial reporting is a process designed by the Parent's principal executive officer and principal financial officer, or under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and is effective in performing the functions for which it was established. Since the end of the Parent's most recent audited fiscal year, there has been (i) no significant deficiency or material weakness in the design or operation of the Parent's internal control over financial reporting (whether or not remediated) which is reasonably likely to adversely affect the Parent's ability to record, process, summarize and report financial information, and (ii) no change in the Parent's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Parent's internal control over financial reporting.

(b) The Parent maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act) consisting of controls and other procedures designed to ensure that information the Parent is required to disclose in reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms and that such information is accumulated and communicated to management, including the Parent's chief executive officer and chief financial officer. Each of the principal executive officer and principal financial officer of the Parent have made all certifications required by the Sarbanes-Oxley Act and the NASDAQ, and the statements made in each such certification are complete and correct; the Parent, its Subsidiaries and its directors and officers are each in compliance in all material respects with the applicable provisions of the Sarbanes-Oxley Act.

(c) Except as set forth on Section 5.7(c) of the Purchaser Disclosure Schedules, Parent is, and since January 1, 2016 has been, in compliance with the applicable listing rules and corporate governance rules and regulations of NASDAQ.

Section 5.8 Absence of Certain Changes

From the Balance Sheet Date to the date hereof, except as set forth in Section 5.8 of the Purchaser Disclosure Schedules or disclosed in the Parent SEC Documents, and except resulting from the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby, the Purchaser Entities have conducted their business in all material respects only in the Ordinary Course of Business and, without limiting the foregoing, there has not been any:

(a) amendment to the certificate of incorporation or by-laws of the Purchaser Entities or any outstanding Parent Securities;

(b) declaration, setting aside or payment of any dividend or other distribution with respect to any Parent Securities, or any repurchase or redemption by the Parent or its Subsidiaries of any Parent Securities; or

(c) sale, lease, transfer, or assignment of any asset, other than inventory in the Ordinary Course of Business or any distributions of any assets (Cash or otherwise);

(d) incurrence of any Liabilities, except current Liabilities incurred in the Ordinary Course of Business and Liabilities under Contracts entered into in the Ordinary Course of Business;

(e) mortgage, pledge or imposition of any Lien on any of its properties or assets (including the Transferred Assets);

(f) issuance, creation, incurrence, or assumption of any Indebtedness (other between the Parent and its Wholly-Owned Subsidiaries or between Wholly-Owned Subsidiaries of the Parent);

(g) loan to, or entry into any other similar transaction with, any of its directors, officers, or employees;

(h) sale, assignment, or transfer of any Intellectual Property to any Person;

(i) entry into any material transaction or otherwise taking any material action or omission to take any material action, other than in the Ordinary Course of Business, except in connection with the execution and performance of this Agreement and the consummation of the Transaction;

(j) occurrence of any Material Adverse Effect with respect to the Parent; or

(k) agreement or commitment to do any of the foregoing.

Section 5.9 Material Contracts

(a) Except as set forth in Section 5.9(a) of the Purchaser Disclosure Schedules or disclosed in the Parent SEC Documents, as of the date hereof, no Purchaser Entity is bound by or a party to any:

(i) Contract relating to Indebtedness that is (1) in excess of $100,000, (2) with or from any officer, director or employee of any Purchaser Entity, or (3) entered into other than in the Ordinary Course of Business;

(ii) joint venture, partnership, limited liability company or other similar Contract that is material to the Purchaser Entities, taken as a whole;

(iii) Contract (or series of related Contracts) relating to the acquisition, disposition or lease of any Person, business or material real property or other material assets (whether by merger, sale of stock, sale of assets or otherwise), other than sales of inventory in the Ordinary Course of Business, that would be material to the Purchaser Entities, taken as a whole;

(iv) sales or distribution Contract (or series of related Contracts) involving the supply of goods or services, the aggregate sales value of which (exclusive of VAT) represents more than 25 percent of the turnover of the Purchaser Entities (exclusive of VAT) for the preceding financial year;

(v) Contract (or series of related Contracts) relating to the purchase by the Purchaser Entities of any products or services involving total expenditure in excess of $50,000, other than any Contract executed in the Ordinary Course of Business that is cancellable by any Purchaser Entity without penalty on less than 90 days' notice;

(vi) Contract that contains any right of first refusal, non-compete or exclusivity provisions or otherwise that materially limits the type of business or geographic regions in which the Parent may engage in business;

(vii) Contracts primarily for the indemnification by a Purchaser Entity of any Person;

(viii) Contract between any of the Purchaser Entities, on the one hand, and any of their Affiliates (other than any other Purchaser Entity), on the other hand; or

(ix) Contract that is material to the operation of the business conducted by the Purchaser Entities and not previously disclosed pursuant to this Section 5.9.

(b) Each Contract set forth in Section 5.9(a) of the Purchaser Disclosure Schedules (each, a "**Parent Material Contract**") is in full force and effect and none of the Purchaser Entities or, to the Parent's Knowledge, any other party thereto, is in default or Breach in any material respect under the terms of, and no event has occurred that, with the passage of time or the giving of notice or both, would constitute a Breach by the applicable Purchaser Entity, or to Parent's Knowledge, any other party thereto under any such Parent Material Contract, or would permit modification, acceleration, or termination of any such Parent Material Contract or the creation of a Lien on any assets of any Purchaser Entity. None of the Purchaser Entities has provided or received from any third party any written notice of any intention to terminate or modify, any such Parent Material Contract. Parent has made available to Seller a true, correct, and complete copy of each written Parent Material Contract (including by access to the Parent SEC Documents) together with all amendments, exhibits, attachments, waivers or other changes thereto.

(c) For the avoidance of doubt, this Section 5.9 does not address real estate leases, Intellectual Property licenses, governmental permits, collective bargaining agreements, Purchaser Entities Benefit Plans or insurance policies, which are addressed solely by Section 5.10 (*Real Property*), Section 5.11 (*Intellectual Property*), Section 5.15 (*Compliance with Laws; Permits*), Section 5.16 (*Employees; Labor Matters*), Section 5.16 (*Employee Benefit Plans and Related Matters; ERISA*), and Section 5.18 (*Insurance*), respectively.

Section 5.10 Real Property

(a) None of the Purchaser Entities owns any real property. There are no outstanding options or rights of first refusal to purchase any real property.

(b) Section 5.10(b) of the Purchaser Disclosure Schedules sets forth all of the real property leased by the Purchaser Entities as of the date hereof (the "**Parent Leases**", and together with all interests leased pursuant to the Leases, the "**Parent Leased Real Property**"). None of the Purchaser Entities is a sublessor or grantor under any sublease or other instrument granting to another Person any right to the possession, lease, occupancy or enjoyment of the Parent Leased Real Property.

(c) Each Parent Lease is in full force and effect and none of the Purchaser Entities or, to the Parent's Knowledge, any other party thereto, is in default or Breach in any material respect under the terms of, and no event has occurred that, with the passage of time or the giving of notice or both, would constitute a Breach by the applicable Purchaser Entity, or to Parent's Knowledge, any other party thereto, under any such Parent Lease, or would permit modification, acceleration, or termination of any such Parent Lease. None of the Purchaser Entities has provided any written notice of any intention to terminate or modify any such Parent Lease. Parent has made available to Seller a true, correct, and complete copy of each written Parent Lease together with all amendments, exhibits, attachments, waivers or other changes thereto.

(d) For the avoidance of doubt, this Section 5.10 does not address Intellectual Property, compliance with Laws, environmental matters or insurance matters, which are addressed solely by Section 5.11 (*Intellectual Property*), Section 5.13 (*Compliance with Laws; Permits*), Section 5.14 (*Environmental Matters*) and Section 5.18 (*Insurance*), respectively.

Section 5.11 Intellectual Property

(a) Section 5.11(a) of the Purchaser Disclosure Schedules sets forth a true, correct, and complete list of all Intellectual Property owned by the Purchaser Entities as of the date hereof that is registered or subject to an application for registration, other than trade secrets, as well as any material unregistered trademarks or trade names.

(b) Except as set forth in Section 5.11(b) of the Purchaser Disclosure Schedules, each patent set forth Section 5.11(a) of the Purchaser Disclosure Schedules is registered and recorded in the name of the applicable Purchaser Entity, is in full, has been duly applied for and registered in accordance with applicable Law and has not been and is not involved in any opposition, cancellation or interference or similar proceeding. All required filings and fees related to the Intellectual Property set forth on Section 5.11(a) of the Purchaser Disclosure Schedules have been timely filed with and paid to the relevant Governmental Authority and authorized registrars, and are otherwise in good standing.

(c) Section 5.11(c) of the Purchaser Disclosure Schedules sets forth a true, correct, and complete list of all material licenses to which the Purchaser Entities is a party that relate to Intellectual Property, other than non-exclusive licenses of generally commercially available "off the shelf" software (collectively, the "**Parent IP Contracts**"), including: (i) licenses of Intellectual Property to any of the Purchaser Entities by any other Person; (ii) licenses of Intellectual Property to any other Person by any of the Purchaser Entities; (iii) agreements otherwise granting or restricting the right to use Intellectual Property; and (iv) agreements transferring, assigning or indemnifying any person with respect to Intellectual Property that is required to conduct their business as currently conducted on the date of this Agreement. Each Parent IP Contract is in full force and effect and none of the Purchaser Entities or, to the Parent's Knowledge, any other party thereto, is in default or Breach in any material respect under the terms of, and no event has occurred that, with the passage of time or the giving of notice or both, would constitute a Breach by the applicable Purchaser Entity, or to Parent's Knowledge, any other party thereto under any such Parent IP Contract, or would permit modification, acceleration, or termination of any such Parent IP Contract. None of the Purchaser Entities has provided any written notice of any intention to terminate or modify any such Parent IP Contract. Purchaser has made available to Seller a true, correct, and complete copy of each written Parent IP Contract together with all amendments, exhibits, attachments, waivers or other changes thereto.

(d) To the Parent's Knowledge, the Intellectual Property currently owned, licensed or used by the Purchaser Entities does not and do not infringe, violate or misappropriate the Intellectual Property, privacy rights, or proprietary rights of any Person. None of the Purchaser Entities has received any communication or notice, and no Proceeding has been instituted, settled or, to the Parent's Knowledge, threatened that alleges any such infringement, violation or misappropriation or otherwise contesting any Purchaser Entity's rights in or to such Intellectual Property, and none of such Intellectual Property are subject to any outstanding Order. To the Parent's Knowledge, no Purchaser Entity has any Liability and there is no basis for any Proceeding against any such Purchaser Entity that could give rise to any Liability arising out of any infringement of the Intellectual Property of any other Person.

(e) All Intellectual Property which has been created by employees, officers, consultants and service providers of the Purchaser Entities within the scope of their employment or engagement by the Purchaser Entities was assigned to the Purchaser Entities and, all such employees, officers, consultants and services providers have executed agreements to expressly assign all rights, title and interest in such Intellectual Property to the applicable Purchaser Entity. Without limiting the generality of the foregoing, the Purchaser or the respective Purchaser Entity has entered into binding, written agreements with every current and former employee of the Purchaser Entities, and every current and former independent contractor or consultant, whereby such employees and independent contractors and consultants (a) assign to the applicable Purchaser Entity, as the case may be, any ownership interest and right they may have in such Intellectual Property, and (b) acknowledge Purchaser's or the respective Purchaser Entity's exclusive ownership of all such Intellectual Property and waiving all rights (including right to receive royalties or other payments) in connection therewith. The Purchaser has provided Seller with true, correct and complete copies of all such agreements. The Purchaser Entities are in compliance, in all material respects, with all legal requirements applicable to the Intellectual Property owned or licensed by the Purchaser Entities.

Section 5.12 Litigation

(a) Except as set forth in Section 5.12(a) of the Purchaser Disclosure Schedules, there is no Proceeding pending or, to the Parent's Knowledge, threatened against or relating to the Parent or any of its Subsidiaries or relating to the transactions contemplated hereby.

(b) For the avoidance of doubt, this Section 5.12 does not address Intellectual Property or Tax-related litigation, which are addressed solely by Section 5.11 (*Intellectual Property*) and Section 5.17 (*Taxes*), respectively.

Section 5.13 Compliance with Laws; Permits

(a) Except as set forth in Section 5.13(a) of the Purchaser Disclosure Schedules, the Purchaser Entities are in compliance with all applicable Laws, except where the failure to be in compliance would reasonably be expected not to have a Material Adverse Effect. To the Parent's Knowledge, the Purchaser Entities are not under investigation with respect to and have not been given written notice of, any violation of any applicable Law.

(b) Except as set forth in Section 5.13(b) of the Purchaser Disclosure Schedules, to the Parent's Knowledge, the Purchaser Entities own, hold or possess adequate rights to use all Permits required to conduct their business as currently conducted other than such Permits the absence of which would reasonably be expected not to have a Material Adverse Effect. To the Parent's Knowledge, there has occurred no material violation of, suspension, reconsideration, imposition of penalties or fines or default (with or without notice or lapse of time or both) under, or event giving rise to any right of termination, amendment or cancellation of, with or without notice or lapse of time or both, any such Permit that is currently in effect, in each case to the extent uncured or otherwise unresolved, other than an expiration of a Permit in the Ordinary Course of Business.

(c) For the avoidance of doubt, this Section 5.13 does not address matters subject to legal proceedings, environmental matters, employee and labor matters, employee benefits matters or Tax matters, which are addressed solely by Section 5.12 (*Litigation*), Section 5.14 (*Environmental Matters*), Section 5.15 (*Employees; Labor Matters*), Section 5.16 (*Employee Benefit Plans and Related Matters; ERISA*) and Section 5.17 (*Taxes*), respectively.

Section 5.14 Environmental Matters

(a) Except as set forth in Section 5.14(a) of the Purchaser Disclosure Schedules:

(i) since January 1, 2016, each of the Purchaser Entities has, in material respects, been in compliance with all applicable Environmental Laws and has obtained and is, in all material respects, in compliance with all applicable Permits and, to the Parent's Knowledge, no written notice of violation has been received by the Purchaser Entities relating to or arising out of any Environmental Law, other than matters that have been resolved or that are no longer outstanding;

(ii) none of the Purchaser Entities has entered into any agreement with any Governmental Authority which has not been fully completed and pursuant to which it has agreed to remediate any condition resulting from the release of Hazardous Materials; and

(iii) except as set forth in Section 5.14(a)(iii) of the Purchaser Disclosure Schedules, there is no Proceeding pending or, to the Parent's Knowledge, threatened against or relating to the Purchaser Entities relating to Environmental Laws.

(b) Notwithstanding any representations and warranties contained elsewhere in this Agreement, matters arising under Environmental Laws shall be governed exclusively by this Section 5.14.

Section 5.15 Employees; Labor Matters

(a) None of the Purchaser Entities is a party to or bound by any collective agreements, including collective bargaining agreement.

(b) There is no labor union representing or, to the Parent's Knowledge, purporting or attempting to represent any group of employees of the Purchaser Entities for collective bargaining regarding terms of employment. There has not occurred after January 1, 2016, or, to the Parent's Knowledge, been threatened, any material strike, slowdown, picketing, work stoppage, concerted refusal to work or other similar labor activity with respect to any employees of the Purchaser Entities. There are no material pending or, to the Parent's Knowledge, threatened, grievances or labor disputes, including any Proceeding, with respect to any such employees. To the Parent's Knowledge, none of the Purchaser Entities have engaged in any unfair labor practices that would reasonably be expected, individually or in the aggregate, directly or indirectly, to result in a material liability to the Purchaser Entities.

(c) To the Parent's Knowledge and to the extent applicable, the Purchaser Entities are in material compliance with all Laws applicable to their business with respect to their respective employees and their own policies respecting employment and employment practices, terms and conditions of employment, wages and hours, equal opportunity, civil rights, labor relations, occupational health and safety and payroll taxes with respect to employees.

(d) None of the Purchaser Entities are in receipt of a written complaint, demand letter or charge issued by a foreign, U.S. federal, state, or local agency that alleges a material violation by the Purchaser Entities of any applicable Law respecting employment and employment practices, terms and conditions of employment, wages and hours, equal opportunity, civil rights, labor relations, occupational health and safety or payroll taxes with respect to its employees. None of the Purchaser Entities have: (i) engaged in any plant closing, work force reduction or other action that has resulted or could reasonably be expected to result in material, outstanding liability under applicable Law with respect to the employees; or (ii) been issued any notice that any such action is to occur in the future with respect to the employees. As of the date hereof, there is no Proceeding pending or, to the Parent's Knowledge, threatened against or relating to any of the Purchaser Entities with respect to their respective employees and their own policies respecting employment and employment practices, terms and conditions of employment, wages and hours, equal opportunity, civil rights, labor relations, occupational health and safety and payroll taxes with respect to the employees.

(e) Section 5.15(e) of the Purchaser Disclosure Schedules contains a true, correct, and complete list of all (written or oral) employment agreements, and any ancillary agreements, including but not limited to, confidentiality agreements and non-competition agreements, between any of the Purchaser Entities and any officer, director, employee and/or consultant, as well as any workers of the consultants providing services to any of the Purchaser Entities, and any agreements with consultants/service providers. True and correct copies of all such agreements, including, but not limited to confidentiality agreements and non-competition agreements (whether written or oral), have been delivered to Seller. To the Parent's Knowledge, no employee, consultant, or service provider has violated any term of his or her employment contract or any other contract or agreement with the applicable Purchaser Entity. To the Parent's Knowledge, the employment and/or engagement by any of the Purchaser Entities of any of its employees does not constitute a breach of any of such employees' obligations to third parties, including non-competition or confidentiality obligations.

Section 5.16 Purchaser Entities Benefit Plans and Related Matters; ERISA

(a) Section 5.16(a) of the Purchaser Disclosure Schedules sets forth a complete, separate and accurate list of the Purchaser Entities Benefit Plans applicable to all employees, ex-employees, officers and ex-officers of the Purchaser Entities, indicating for each whether of a defined benefit or defined contribution nature and whether and how it is funded. None of the Purchaser Entities has or maintains any Multiemployer Plans. With respect to each written Purchaser Entities Benefit Plan, Parent has provided or made available to Seller, copies of each of the Purchaser Entities Benefit Plan and their amendments, to the extent applicable: (i) the most recent annual reports to any Governmental Authorities and accompanying schedules, (ii) the current summary plan description, together with any summary of material modifications relating thereto; (iii) the most recent annual financial report; and (iv) the most recent opinion letter or recent determination letter from the IRS.

(b) With respect to the Purchaser Entities Benefit Plans:

(i) except as set forth in Section 5.16(b)(i) of the Purchaser Disclosure Schedules, to the Parent's Knowledge, except as would not have a Material Adverse Effect: (A) the Purchaser Entities Benefit Plans have at all times complied in all material respects with all Laws, regulation and requirements applicable to each of the Purchaser Entities Benefit Plans; and (B) to the extent they have been funded externally, all contributions required to be made to any Purchaser Entities Benefit Plan by applicable Laws or by any plan document or other contractual undertaking, and all premiums due or payable with respect to insurance policies funding any Parent Benefit Plan, for any period through the date hereof have been timely made or paid in full by the final due date thereof in the Ordinary Course of Business consistent with past practice;

(ii) except as set forth in Section 5.16(b)(ii) of the Purchaser Disclosure Schedules, to the Parent's Knowledge none of the amounts payable by the Purchaser Entities under any of the Purchaser Entities Benefit Plans or Parent Stock Plans applicable in the U.S. on account of the transactions contemplated under this Agreement shall fail to be deductible by reason of Section 280G of the Code; and

(iii) none of the Purchaser Entities Benefit Plans applicable in the U.S. provides for post-retirement welfare benefits coverage, except for: (aa) health continuation coverage as required by applicable Law, including section 4980B of the Code or Title I of ERISA; (bb) coverage through the last day of the calendar month in which the retirement date occurs; (cc) the credit balance of any health savings or medical reimbursement accounts; (dd) benefits under any insured short-term or long-term disability policy; and (ee) rights of beneficiaries to receive the remainder of a participant's benefits upon the participant's death.

(c) Except as set forth in Section 5.16(c) of the Purchaser Disclosure Schedules, there is no Proceeding pending or, to the Parent's Knowledge, threatened against or relating to any of the Purchaser Entities with respect to the Purchaser Entities Benefit Plans other than routine claims for benefits in the Ordinary Course of Business.

Section 5.17 Taxes

(a) Except as set forth in Section 5.17(a) of the Purchaser Disclosure Schedules:

(i) Each of the Purchaser Entities has timely filed (taking into account any applicable extensions) all income and all other material Tax Returns required to have been filed by it, and all such Tax Returns are accurate and complete in all material respects. All Taxes shown to be due on such Tax Returns have been paid in full.

(ii) To the Parent's Knowledge, there is no audit, examination or other administrative or court proceeding involving any Taxes with respect to any of the Purchaser Entities that is currently in progress.

(iii) There are no Liens for Taxes against any of the Purchaser Entities' assets, other than Permitted Liens.

(iv) None of the Purchaser Entities have executed or filed with any Tax Authority any agreement extending the period for assessment or collection of any material income Taxes.

(v) Purchaser has not been a United States real property holding corporation (as defined in Section 897(c)(2) of the Code) at any time during the applicable period specified in Section 897(c)(1) of the Code.

(vi) The financial statements of the Parent in its Annual Report on Form 10-K for the year ended December 31, 2018 (the "**Parent Financial Statements**") reflect an adequate accrual or reserve for all material Taxes incurred but not yet due and payable by the Purchaser Entities through the date of such Parent Financial Statements, and the unpaid Taxes of the Group Companies for all tax periods commencing after the date of such Parent Financial Statements have been properly accrued on the books and records of the Purchaser Entities.

(vii) No written claim has been made by any Tax Authority in a jurisdiction where the Parent or any of its Subsidiaries does not file Tax Returns that the Parent or any of its Subsidiaries is or may by subject to taxation by that jurisdiction.

(viii) Each of the Purchaser Entities has timely paid or withheld with respect to their employees (and paid over any amounts withheld to the appropriate Taxing authority to the extent due) all material Taxes required to be paid or withheld.

(ix) There are no Tax indemnity, Tax sharing, Tax allocation or similar agreements in effect as between the Parent and any of its Subsidiaries, on the one hand, and any other party, on the other hand, under which the Parent could be liable for any material Taxes of any third party (other than commercial business agreements, the principal purpose of which is not the allocation of Taxes).

(b) The Purchaser Entities have complied, in all material respects, with all Laws applicable to Taxes. There is no Proceeding pending or, to the Parent's Knowledge, threatened against or relating to any of the Purchaser Entities with respect to Taxes. There are no transfer pricing transactions between the Purchaser Entities.

(c) The representations and warranties set forth in this Section 5.17 constitute the exclusive representations and warranties of Parent and Purchaser with respect to Taxes and Tax matters and no other representation or warranty contained in this Agreement shall be construed to address any Taxes or any Tax matters.

Section 5.18 Insurance

Section 5.18 of the Purchaser Disclosure Schedules sets forth all material insurance policies maintained by the Purchaser Entities. All such policies are in full force and effect; true, correct, and complete copies of which have been provided to Seller. All premiums relating to such policies have been timely paid. None of the Purchaser Entities is in Breach or has taken any action or failed to take any action which, with notice or the lapse of time, would constitute such a Breach, or permit termination or modification of, any of such policies. There is no pending claim by any of the Purchaser Entities under any of such policies as to which coverage has been denied by the underwriters of such policies.

Section 5.19 Brokers

No agent, broker, investment banker, financial advisor or other firm or Person is or shall be entitled, as a result of any action, agreement or commitment of Parent or any of its Affiliates, to any broker's, finder's, financial advisor's or other similar fee or commission in connection with any of the transactions contemplated by this Agreement, other than the Parent's Financial Advisor, whose fees and expenses shall be paid by the Parent. The fee provisions of the Parent's agreement with the Parent's Financial Advisor relating to the transactions contemplated by this Agreement have previously been disclosed to the Seller.

Section 5.20 Parent Common Stock

The shares of Parent Common Stock to be issued in connection with the Transaction (including shares of Parent Common Stock to be issued as Consideration and shares of Parent Common Stock to be reserved for issuance upon exercise of Parent Stock Options and Parent Restricted Shares in each case, to be issued pursuant to Section 6.14), when issued and delivered in accordance with this Agreement, will be duly authorized, validly issued, fully paid and non-assessable and free of all Liens, and upon acceptance by the NASDAQ Capital Market of an application of the listing of additional shares, will have been validly approved for listing (subject to official notice of issuance) on NASDAQ Capital Market.

Section 5.21 Disclosure Documents

(a) The Form S-4 Registration Statement, and any amendments or supplements thereto, when filed, will comply as to form in all material respects with the applicable requirements of the Securities Act. At the time the Form S-4 Registration Statement or any amendment or supplement thereto becomes effective, the Form S-4 Registration Statement, as amended or supplemented, will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) The representations and warranties contained in this Section 5.21 will not apply to statements or omissions included or incorporated by reference in the Form S-4 Registration Statement or any amendment or supplement thereto based upon information furnished by the Seller or any of its Representatives in writing specifically for use or incorporation by reference therein.

Section 5.22 Fairness Opinion

Parent has received the written opinion of the Parent's Financial Advisor, dated as of a date reasonably proximate to the date hereof, to the effect that, as of such date, and based upon and subject to the various assumptions, limitations, qualifications and other matters set forth therein, the Consideration to be received by the Company pursuant to this Agreement is fair to the Parent, from a financial point of view (the "**Parent Fairness Opinion**"); it being agreed that neither Seller, the Company (nor any of their respective Affiliates) shall be entitled to rely on the Parent Fairness Opinion.

ARTICLE VI
COVENANTS

Section 6.1 Conduct of Business Prior to Closing

Except as required or contemplated by this Agreement, required by applicable Requirements of Law or consented to in writing by Parent (in the case of Seller) or Seller (in the case of Purchaser or Parent), in each case which shall not to be unreasonably withheld or delayed, or as set forth in Section 6.1 of the Seller Disclosure Schedules (in the case of Seller) or in Section 6.1 of the Purchaser Disclosure Schedules (in the case of Purchaser and Parent), each of Purchaser, Parent and Seller covenants and agrees that, during the period from the date of this Agreement to the Closing or the date on which this Agreement is terminated pursuant to Section 8.1:

(a) it will conduct and it will cause each of its Subsidiaries to conduct their operations in the Ordinary Course of Business consistent with past practice;

(b) it will use and it will cause each of its Subsidiaries to use commercially reasonable efforts to preserve intact their respective business organizations, to keep available the services of their current officers and employees (other than as a result of employee terminations for cause or terminations of employment at the election of an employee), and to preserve the goodwill of and maintain satisfactory relationships with those Persons having business relationships with them or any of their Subsidiaries, except where the failure to preserve or maintain such relationships would not be material to Group Companies (in the case of Seller) or to the Parent and its Subsidiaries (in case of Parent); and

(c) it will not and it will not permit any of its Subsidiaries to:

(i) adopt or propose any amendments to its certificate of incorporation, bylaws or other similar governing documents, or the respective certificates of incorporation, bylaws or other similar governing documents of any of their Subsidiaries;

(ii) except for equity securities of Parent issued or granted pursuant to a Benefit Plan of the Parent, issue, deliver, sell, pledge, transfer, dispose of or encumber any of its shares of capital stock or other equity or voting interests or of any of its Subsidiaries or any securities convertible into, exchangeable or exercisable for or representing the right to subscribe for, purchase or otherwise receive any such shares or interests or any stock appreciation rights, "phantom" stock rights, performance units, rights to receive shares of capital stock or other rights that are linked to the value of the Company or any Group Company (in case of Seller) or of Parent or any Purchaser Entity (in case of Parent);

(iii) acquire or redeem, directly or indirectly, or amend the terms of, any of its equity securities or any equity interests in any of its Subsidiaries (other than securities of Wholly-Owned Subsidiaries);

(iv) (aa) adjust, split, combine, recapitalize or reclassify its capital stock, or (bb) declare, set aside, make or pay any dividend or distribution (whether in cash, stock or property or any combination thereof) on any shares of its capital stock (other than dividends or other distributions by Wholly-Owned Subsidiaries);

(v) make any material change to any of the accounting methods, principles or practices used by it, except as required by any applicable Requirement of Law or GAAP (in respect of the Parent) or IFRS (in respect of the Company);

(vi) (aa) make or change or rescind any election in respect of Taxes, (bb) adopt or change any accounting method in respect of Taxes, (cc) enter into any agreement (including any closing agreement) with any Tax Authority in respect of Taxes, (dd) settle or compromise any Tax Liability or any claim or assessment in respect of Taxes, (ee) consent to any extension or waiver of the limitation period applicable to any claim or assessment in respect of Taxes, (ff) request any Tax ruling, (gg) enter into any Tax sharing agreement, or (hh) amend any income or other material Tax Return or file any Income Tax Return including any estimated Tax Return or other material Tax Return unless a copy of such Tax Return has been submitted to the other party for review a reasonable period of time prior to filing and such other party has approved such Tax Return, enter into intercompany transactions giving rise to deferred gain or loss of any kind;

(vii) with respect to any officer, employee or director of the Seller, except as required by the terms of any existing agreement between the Company or any of its Subsidiaries (in case of Seller) or between Parent or any of its Subsidiaries (in case of Parent), and such officer, director or employee, or any Benefit Plan as in effect on the date hereof, (aa) increase in compensation (including incentive compensation), benefits or perquisites, except in the Ordinary Course of Business, (bb) grant any increase in severance or termination pay or termination benefits, (cc) enter into any employment, loan, retention, consulting, indemnification, or similar agreement, (dd) enter into any change of control, severance, termination or similar agreement, (ee) amend, waive or otherwise modify in any material respect any of the terms of any employee stock option or stock option plan, or (ff) establish or amend any Benefit Plan or trust agreement or other operative document relating to any Benefit Plan;

(viii) enter into, grant, issue, or make any loan or similar transaction to for from any officer, director or employee;

(ix) enter into any material new line of business outside of its existing business; or enter into any agreement or arrangement that limits or otherwise restricts the Company or any of its Subsidiaries (in case of Seller) or the Parent or any of its Subsidiaries (in case of Parent), or any successor thereto from engaging or competing in any line of business or in any geographic area;

(x) (A) commence any Proceeding, or (B) compromise, settle or agree to settle any Proceeding other than compromises, settlements or agreements that involve the payment of monetary Damages not in excess of $50,000 individually or $100,000 in the aggregate and do not concede any fault on the part of the Company or any of its Subsidiaries (in case of Seller) or on the part of Parent or any of its Subsidiaries (in case of Parent) or impose any material restrictions on any of their respective future activities;

(xi) except for Permitted Liens, sell, pledge, mortgage, dispose of, transfer, lease, license or encumber, or authorize the sale, pledge, disposition, transfer, lease, license or encumbrance of, any property or assets (including the Transferred Assets) valued in excess of $10,000, individually or in the aggregate, other than sales of inventory in the Ordinary Course of Business, or make any distributions of assets (Cash or otherwise);

(xii) maintain inventory other than in the Ordinary Course of Business;

(xiii) incur, modify or assume any Indebtedness (other than with or between Wholly-Owned Subsidiaries);

(xiv) (aa) adopt a plan of complete or partial liquidation or resolutions providing for a complete or partial liquidation, dissolution, restructuring, recapitalization or other reorganization of the Company or any of its Subsidiaries other than any liquidation as contemplated by this Agreement or a liquidation of a Wholly-Owned Subsidiary in connection with which all Liabilities of such Subsidiary are assumed by the Company or any of its Wholly-Owned Subsidiaries (in case of Seller) or by the Parent or any of its Wholly-Owned Subsidiaries (in case of Parent), or (bb) acquire (by merger, amalgamation, consolidation, or acquisition of stock or assets or otherwise) any corporation, partnership or other business organization or division thereof or any material equity interest therein;

(xv) incur any Liabilities, except current Liabilities incurred in the Ordinary Course of Business, and Liabilities under Contracts entered into in the Ordinary Course of Business;

(xvi) authorize or make any new unbudgeted capital expenditures in excess of $50,000 individually or $100,000 in the aggregate or that would constitute an Assumed Liability;

(xvii) amend, modify, extend, renew or terminate, other than in accordance with its terms in effect as of the date hereof, any existing real property lease, or enter into any new lease, sublease, license or other agreement for the use or occupancy of any real property with a term longer than five years or a total rental obligation over the term of such lease, sublease, license or other agreement of $50,000 individually or $100,000 in the aggregate for the same properties, other than leases entered into in the Ordinary Course of Business on terms materially consistent with past practice and current plans previously disclosed to the other party in writing;

(xviii) write up, write down, or write off the book value of any assets material, individually or in the aggregate, to the Parent and its Subsidiaries (in case of Parent) or to the Company and its Subsidiaries (in case of Seller), in each case taken as a whole, other than in the ordinary course of business consistent with past practice or as required by GAAP (in case of Parent) or by IFRS (in case of Seller);

(xix) enter into any material Contract, or modify, amend, terminate or cancel any existing material Contract;

(xx) enter into any transaction or take any other action that would reasonably be expected to prevent or materially delay the completion of the Transaction or result in any of the conditions set forth in ARTICLE VII not being satisfied;

(xxi) fail to timely file any Parent SEC Document required to be filed by the Parent (in case of Parent only) or fail to file any document required to be filed by Seller with the AFM (in case of Seller only);

(xxii) enter into, materially amend or materially modify any Contract with any Affiliates, officers or directors of any Purchaser Entity (in case of Parent) or of any Group Company (in case of Seller);

(xxiii) enter into a collective bargaining agreement;

(xxiv) transfer or license to any Person any Intellectual Property;

(xxv) make of record any statement regarding any Intellectual Property in any judicial or administrative Proceedings, without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed), except to the extent necessary to avoid immediate loss of rights;

(xxvi) submit any document to the United States Patent Office or any foreign patent office without the prior written consent of the other party, except to the extent reasonably necessary to avoid loss of rights; or

(xxvii) authorize, commit or agree to take any of the foregoing actions;

it being provided that, to obtain the consent of one party pursuant to this Section 6.1, the party requesting any such consent shall provide written notice to the other party (e-mail being sufficient) setting forth in reasonable detail the contemplated action. Absent an answer within three (3) Business Days after the date of such notice, the consent sought to be obtained by the requesting party shall be deemed given in respect of the matter detailed in the written notice.

Section 6.2 Control of Operations Pending the Closing

(a) Nothing contained in this Agreement will give Parent or Purchaser, directly or indirectly, the right to control or direct the Group Companies' operations prior to the Closing. Prior to the Closing, the Seller will exercise, consistent with the terms and conditions of this Agreement, complete control and supervision over the operation of the Group Companies.

(b) Nothing contained in this Agreement will give Seller, directly or indirectly, the right to control or direct the Parent's or Purchaser's operations prior to the Closing. Prior to the Closing, the Parent will exercise, consistent with the terms and conditions of this Agreement, complete control and supervision over its operation.

Section 6.3 No Solicitation

(a) From the date of this Agreement until the Closing or, if earlier, the termination of this Agreement pursuant to Section 8.1, the Seller (with respect to the Seller and the Group Companies) and the Parent (with respect to the Parent and the Purchaser Entities) shall not, and shall each cause their respective Subsidiaries and Representatives not to, directly or indirectly: (i) solicit, initiate or knowingly encourage or facilitate (including by way of furnishing information) the submission of any inquiries, proposals or offers that constitute or could reasonably be expected to lead to, any Acquisition Proposal or engage in any discussions or negotiations with respect thereto or otherwise cooperate with or assist or participate in, or facilitate any such inquiries, proposals, discussions or negotiations or provide access to the books, records, properties or employees of the Seller or the Group Companies (in respect of Seller) or the Parent and Purchaser Entities (in respect of Parent) or furnish to any Person any nonpublic or confidential information or data with respect to any Acquisition Proposal or (ii) approve or recommend, or publicly propose to approve or recommend, an Acquisition Proposal or any agreement, arrangement or understanding relating to an Acquisition Proposal (or resolve or authorize or propose to agree to do any of the foregoing), or enter into any merger agreement, letter of intent, confidentiality agreement (other than an Acceptable Confidentiality Agreement solely in accordance with Section 6.3(b) below), agreement in principle, share purchase agreement, asset purchase agreement or share exchange agreement, option agreement or other similar agreement, understanding or arrangement relating to an Acquisition Proposal or enter into any agreement, understanding or arrangement, whether or not in writing or binding on any party, requiring the Seller or the Parent, as applicable, to abandon, terminate or fail to consummate the transactions contemplated hereby or Breach its obligations hereunder or resolve, authorize, propose or agree to do any of the foregoing. The Seller and the Parent shall, and shall cause each of their respective Subsidiaries and Representatives to, immediately cease and terminate any solicitation, knowing encouragement, discussion or negotiation with any Persons conducted by them, their Subsidiaries or any of their Representatives prior to the date of this Agreement with respect to any Acquisition Proposal. The Seller and the Parent shall promptly request that each Person that has heretofore executed a confidentiality agreement in connection with its consideration of any Acquisition Proposal, return or destroy all confidential information heretofore furnished to such Person by or on behalf of the Seller or the Parent (as applicable) or any of their respective Subsidiaries.

(b) Notwithstanding anything to the contrary contained in Section 6.3(a), if at any time following the date of this Agreement and prior to obtaining the Target Stockholder Vote, the Target Party has received an Acquisition Proposal from any Person that the Target Board determines in good faith (after consultation with its outside financial and legal advisors and after taking into account the Person making the Acquisition Proposal and all legal, financial, regulatory and other aspects of such Acquisition Proposal, including the financing terms thereof), that such Acquisition Proposal constitutes or would reasonably be expected to result in a Superior Proposal, then, subject to compliance with this Section 6.3, the Target Party may (i) furnish information (including non-public information) with respect to the Target Group to the Person making such Acquisition Proposal and (ii) participate in discussions or negotiations with the Person making such Acquisition Proposal regarding such Acquisition Proposal; provided that the Person making the Acquisition Proposal must have provided a waiver under any non-disclosure agreement entered into with the Target Party prior to the date hereof to permit the Target Party to make any disclosures to the Other Party required by this Agreement; and provided further that the Target Party (x) will not, and will not allow its Subsidiaries or Representatives to, disclose any material non-public information to such Person without first entering or having entered into an Acceptable Confidentiality Agreement and (y) will simultaneously provide to the Other Party any material non-public information concerning the Target Group provided by the Target Party to such other Person that was not previously made available to the Other Party..

(c) From and after the date of this Agreement, the Target Party shall promptly (but in any event within forty-eight (48) hours) notify the Other Party in writing (e-mail being sufficient) following the receipt by the Target Party or any of its Representatives of any Acquisition Proposal of the type described in Section 6.3(b)(i) above or request by any Person for any information (or access to information) in connection with a possible Acquisition Proposal and shall identify the Person making such Acquisition Proposal or request and set forth the material terms and conditions of any proposals, offers or inquiries and include with such written notice copies of any written proposal, offer, request or other communication. The Target Party shall keep the Other Party reasonably informed on a current basis of the status of any such proposal or request and the status of any discussions or negotiations, including with respect to any material modifications to the terms thereof and promptly (but in no event less than twenty-four hours after receipt) provide to the Other Party copies of all written materials of correspondence sent or provided to the Target Party or any of its Subsidiaries or Representatives that describes any terms or conditions of any Acquisition Proposal. The Target Party shall promptly provide notice to the Other Party of any meeting of the Target Board (or any committee thereof) at which the Target Board (or any such committee) is reasonably expected to consider any of the foregoing, and shall promptly (but in any event within forty-eight (48) hours) notify the Other Party in writing (e-mail being sufficient) that it intends to take any action described in Section 6.3(b)(ii) above. Neither the Target Party nor its Subsidiaries will enter into any confidentiality agreement with any Person subsequent to the date of this Agreement that prohibits the Target Party or any of its Subsidiaries from providing such information to the Other Party.

(d) Notwithstanding anything to the contrary contained in Section 6.3(a), the Target Board may, at any time prior to obtaining the Target Stockholder Vote, withdraw, modify, qualify, or propose publicly to withdraw, modify or qualify in a manner adverse to the Other Party, the Target Board Recommendation (a "**Change of Board Recommendation**") if (i) in each case, the Target Board concludes in good faith, after taking into consideration the advice of its outside legal advisors, that taking such action is required for the Target Board to comply with its fiduciary obligations under applicable Law, and (ii) (A) in the case of a Change of Board Recommendation in respect to an Acquisition Proposal made after the date hereof, the Target Board determines in good faith (after consultation with its outside financial and legal advisors and after taking into account the Person making the Acquisition Proposal and all legal, financial, regulatory and other aspects of such Acquisition Proposal, including the financing terms thereof) that such Acquisition Proposal constitutes a Superior Proposal, or (B) in the case of a Change of Board Recommendation in the absence of an Acquisition Proposal, solely in response to a material event, fact, development, circumstance or occurrence that affects the business, assets or operations of the Target Group that was not known to the Target Party as of the date hereof and occurs after the date hereof and prior to the time that the Target Stockholder Vote is obtained (an "**Intervening Event**").

(e) Further, the Target Board shall not make a Change of Board Recommendation in response to an Acquisition Proposal as determined by Section 6.3(d), unless (i) the Target Party promptly notifies the Other Party, in writing at least five (5) Business Days before taking that action, of its intention to do so, disclosing the current terms and conditions under which such Acquisition Proposal is proposed to be consummated and the identity of the Person making the Acquisition Proposal, and (ii) the Other Party does not make, within five (5) Business Days after its receipt of that written notification, an offer that the Target Board determines, in good faith, after consultation with its outside financial and legal advisors, is at least as favorable to the Target Party as such Acquisition Proposal (it being understood and agreed that any amendment to the financial terms or other material terms of such Acquisition Proposal shall require a new written notification from the Target Party and a new five (5) Business Day period under clause (ii) of this Section 6.3(e)). The Target Board shall not make a Change of Board Recommendation in response to an Intervening Event as permitted by Section 6.3(d), unless (A) the Target Party has provided the Other Party with written information describing such Intervening Event in reasonable detail promptly after becoming aware of it, or becoming aware of or understanding the magnitude or material consequences of it, as applicable, and keeps the Other Party reasonably informed of material developments with respect to such Intervening Event, (B) the Target Party has provided the Other Party at least five (5) Business Days prior written notice advising the Other Party of its intention to make a Change of Board Recommendation with respect to such Intervening Event, attaching a reasonably detailed explanation of the facts underlying the determination by the Target Board that an Intervening Event has occurred and its need to make a Change of Board Recommendation in light of the Intervening Event and (C) the Other Party does not make, within five (5) Target Board Business Days after its receipt of that written notification, an offer that the Target Board determines, in good faith, after consultation with its outside financial and legal advisors, would obviate the need for a Change of Board Recommendation in light of the Intervening Event. During any five (5) Business Day period prior to its effecting a Change of Board Recommendation, the Target Party shall negotiate in good faith with the Other Party regarding any revisions to the terms of the transactions contemplated by this Agreement proposed by the Other Party.

(f) Nothing contained in this Section 6.3 or elsewhere in this Agreement shall prohibit the Target Party from (i) taking and disclosing to its stockholders a position contemplated by Rule 14d-9 or Rule 14e-2(a) promulgated under the Exchange Act or (ii) making any disclosure to the Target Party Stockholders if, in the good faith judgment of the Target Board, taking into consideration the advice of its outside legal advisors, making such disclosure is required for the Target Board to comply with its fiduciary obligations under applicable Law; provided, however, that any such statement or disclosure made that related to an Acquisition Proposal shall be deemed to be a Change of Board Recommendation unless the Target Board reaffirms the Target Board Recommendation in such statement or disclosure.

(g) For the purpose of this Section 6.3, the following terms shall be defined as follows:

(i) "**Target Party**" means, as the case may be, the Seller, in the event of an Acquisition Proposal for the Group Companies or the Seller Common Stock, or the Parent, in the event of an Acquisition Proposal for the Purchaser Entities or the Parent Common Stock;

(ii) "**Other Party**" means the party to this Agreement that is not the Target Party;

(iii) "**Target Group**" means, as the case may be, the Group Companies (if Seller is the Target Party) or the Purchaser Entities (if Parent is the Target Party);

(iv) "**Target Board**" means, as the case may be, the Management Board and Supervisory Board (if Seller is the Target Party) or the Board of Directors (if Parent is the Target Party);

(v) "**Target Common Stock**" means, as the case may be, the Company Common Stock (if Seller is the Target Party) or the Parent Common Stock (if Parent is the Target Party);

(vi) "**Target Stockholder Vote**" means, as the case may be, the Seller Stockholder Vote (if Seller is the Target Party) or the Parent Stockholder Vote (if Parent is the Target Party); and

(vii) "**Target Board Recommendation**" means, as the case may be, the Seller Board Recommendation (if Seller is the Target Party) or the Parent Board Recommendation (if Parent is the Target Party).

Section 6.4 Access to Information

(a) From the date of this Agreement until the Closing or the date this Agreement is terminated pursuant to Section 8.1, the Seller will (i) give Parent and its Representatives reasonable access (during regular business hours upon reasonable notice) to all employees, offices and other facilities and to all books, Contracts, commitments and records (including Tax returns and workpapers) of the Group Companies as Parent may reasonably request, (ii) permit Parent and its Representatives to make such inspections of the Group Companies and their respective properties and assets as Parent may reasonably require, and (iii) cause its officers and those of the Group Companies and use its commercially reasonable efforts to cause its Representatives (including legal and accounting) to furnish Parent and its Representatives with such financial and operating data and other information with respect to the business, properties and personnel of the Group Companies as Parent may from time to time reasonably request other than (x) information concerning Acquisitions Proposals, which shall be governed by Section 6.3, (y) information that may not be disclosed pursuant to a protective order or confidentiality agreement entered into prior to the date of this Agreement and (z) such portions of documents or materials that are subject to an attorney/client or an attorney work product privilege the provision of which, as determined by the Seller's counsel, may eliminate the privilege pertaining to such portion of such documents, only, in the case of this clause (z), after the Seller has endeavored in good faith to enter into arrangements with Parent that would permit the Seller to make such document or information available to Parent without eliminating the privilege (in whole or in part). No investigation by Parent pursuant to this Section 6.4 or otherwise shall affect or be deemed to modify any representation or warranty made by the Seller.

(b) From the date of this Agreement until the Closing or the date this Agreement is terminated pursuant to Section 8.1, the Parent will (i) give Seller and its Representatives reasonable access (during regular business hours upon reasonable notice) to all employees, offices and other facilities and to all books, Contracts, commitments and records (including Tax returns and workpapers) of Parent and its Subsidiaries as Seller may reasonably request, (ii) permit Seller and its Representatives to make such inspections of the Parent and its Subsidiaries and their respective properties and assets as Seller may reasonably require, and (iii) cause its officers and those of its Subsidiaries and use its commercially reasonable efforts to cause its Representatives (including legal and accounting) to furnish Seller and its Representatives with such financial and operating data and other information with respect to the business, properties and personnel of the Parent and its Subsidiaries as Seller may from time to time reasonably request other than (x) information that may not be disclosed pursuant to a protective order or confidentiality agreement entered into prior to the date of this Agreement and (y) such portions of documents or materials that are subject to an attorney/client or an attorney work product privilege the provision of which, as determined by the Parent's counsel, may eliminate the privilege pertaining to such portion of such documents, only, in the case of this clause (y), after the Parent has endeavored in good faith to enter into arrangements with Seller that would permit the Parent to make such document or information available to Seller without eliminating the privilege (in whole or in part). No investigation by Seller pursuant to this Section 6.4 or otherwise shall affect or be deemed to modify any representation or warranty made by the Parent or Purchaser.

(c) The information obtained by Parent pursuant to Section 6.3, Section 6.4(a) and Section 6.4(b) shall be subject to the provisions of the Confidentiality Agreement.

(d) Nothing in this Section 6.4 shall require Parent or Seller to permit any inspection, or to disclose any information, that in the reasonable judgment of Parent or Seller would (i) violate any confidentiality obligations, provided that Parent or Seller shall use its commercially reasonable efforts to obtain the consent of such third party to such inspection or disclosure, or (ii) result in a violation of applicable Requirements of Law, including federal or state securities Laws or any antitrust Laws.

Section 6.5 Registration Statement

(a) As promptly as practicable, and in any event within twenty (20) Business Days after the date of this Agreement if reasonably possible, Parent and Seller shall prepare and Parent shall file the Form S-4 Registration Statement. Parent and Seller shall each furnish all information concerning it and the holders of its capital stock as the other may reasonably request in connection with the preparation of the Form S-4 Registration Statement and any amendment thereto (other than to the extent resulting in a violation of applicable Requirements of Law).

(b) Parent and Seller shall each use commercially reasonable efforts to cause the Form S-4 Registration Statement to comply with the rules and regulations promulgated by the SEC, to respond promptly to any comments of the SEC or its staff, and to have the Form S-4 Registration Statement declared effective under the Securities Act as promptly as practicable after it is filed with the SEC.

(c) The Parent will cause the Parent Proxy Statement to be mailed to its stockholders as promptly as practicable after the Form S-4 Registration Statement is declared effective under the Securities Act. Parent shall use commercially reasonable efforts to cause all documents that it is responsible for filing with the SEC in connection with the Transaction to comply as to form and substance in all material respects with the applicable requirements of the Securities Act and the Exchange Act. Parent shall also promptly file and use commercially reasonable efforts to cause to become effective as promptly as possible, any amendment to the Form S-4 Registration Statement, including the Parent Proxy Statement and, if required, the Parent shall mail to its stockholders any such amendment that becomes necessary after the date the Form S-4 Registration Statement is declared effective.

(d) Parent shall respond promptly to any comments of the SEC or its staff with respect to the Form S-4 Registration Statement. Parent shall promptly notify Seller upon the receipt of any comments from the SEC or its staff or any request from the SEC or their staff for amendments or supplements to the Form S-4 Registration Statement or other information, shall consult with Seller prior to responding to any such comments or requests or filing any amendment or supplement to the Form S-4 Registration Statement, and shall provide Seller with copies of all correspondence and a reasonably detailed summary of all oral communications between it and the SEC and its staff. If Parent or Seller becomes aware of any information that, pursuant to the Securities Act or the Exchange Act, should be disclosed in an amendment or supplement to the S-4 Registration Statement, then the party that discovers such information shall promptly inform the other parties hereto and an appropriate amendment or supplement describing such information shall be filed with the SEC, if required by Law, disseminated to the Parent Stockholders.

(e) Notwithstanding anything to the contrary stated above, prior to filing and mailing the Parent Proxy Statement (or any amendment or supplement thereto), Parent shall provide Seller a reasonable opportunity to review and comment on such Parent Proxy Statement and shall discuss with Seller and include in such Parent Proxy Statement, comments reasonably and promptly proposed by Seller.

(f) Parent will advise Seller, promptly after it receives notice thereof, of the time when the Form S-4 Registration Statement has become effective or any supplement or amendment thereto has been filed, the issuance of any stop order, or any request by the staff of the SEC for amendment of the Form S-4 Registration Statement.

(g) Prior to the Closing, Parent shall use commercially reasonable efforts to qualify the Parent Common Stock under state securities or blue sky laws and the rules and regulation thereunder ("**Blue Sky Laws**") as may be required; provided, however, that Parent shall not be required to (i) qualify to do business as a foreign corporation in any jurisdiction in which it is not now so qualified, (ii) file a general consent to service of process in any jurisdiction or (iii) subject itself to taxation in any jurisdiction in which it is not so subject.

Section 6.6 Seller Stockholder Approval

(a) The Seller shall take all action necessary under all applicable Requirements of Law to call, give notice of, and hold an extraordinary general meeting of the holders of Seller Common Stock (including any adjournments or postponements thereof, the "**Seller Stockholders' Meeting**") for the purpose of obtaining the Seller Stockholder Vote, and the Seller shall not submit any Acquisition Proposal (other than this Agreement) to the vote of the Seller Stockholders or recommend any such Acquisition Proposal for adoption by the Seller Stockholders. Prior to or at the Seller Stockholder's Meeting, the Seller shall provide or make available to Seller Stockholders the Seller Board Recommendation. Without the prior written consent of Parent, (i) the approval of the Transaction pursuant to article 2:107a DCC, (ii) the approval of the dissolution (*ontbinding*) of the Seller in accordance with article 2:19 DCC and the appointment a liquidator (*vereffenaar*) of the Seller in accordance with article 2:19 DCC, (iii) the amendment of the Seller's articles of association to change the Seller's name in accordance with Section 6.19, (iv) the distribution, in whole or in part of the Consideration to the Seller Stockholders, and any (v) such resolutions which are necessary or conducive to the transactions contemplated hereby (hereafter, the "**Seller Resolutions**"), shall be the only matters (other than procedural and technical matters) that the Seller shall propose to be acted on by the Seller Stockholders at the Seller Stockholders' Meeting..

(b) The Seller (in consultation with Parent) shall set a single record date for persons entitled to notice of, and to vote at, the Seller Stockholders' Meeting and shall not change such record date (whether in connection with the Seller Stockholders' Meeting or any adjournment or postponement thereof) without the prior written consent of Parent. The Seller Stockholders' Meeting shall be held on a date selected by the Seller in consultation with Parent as promptly as practicable after the Form S-4 Registration Statement is declared effective under the Securities Act. Once the Seller Stockholders' Meeting has been called and noticed, the Seller shall not postpone or adjourn the Seller Stockholders' Meeting without the consent of Parent (which consent shall not be unreasonably withheld), other than (i) for the absence of a quorum or (ii) to allow reasonable additional time for the filing and mailing of any supplemental or amended disclosure which Seller believes in good faith is necessary under applicable Law and for such supplemental or amended disclosure to be disseminated and reviewed by Seller Stockholders prior to the Seller's Stockholders' Meeting.

(c) The Seller's obligations pursuant to this Section 6.6 shall not be affected by the public announcement or public disclosure of, or the communication to the Seller of, any Acquisition Proposal or inquiry or indication of interest with respect thereto, or by a Change of Board Recommendation (in each case, in the event the Seller is the Target Party). Unless this Agreement is properly terminated in accordance with its terms, the matters to be addressed in the Seller Stockholder Vote shall be submitted to the Seller Stockholders at the Seller Stockholders' Meeting whether or not (x) the Management Board and / or Supervisory Board shall have effected a Change of Board Recommendation or (y) any Acquisition Proposal shall have been publicly proposed or announced or otherwise submitted to the Seller or any of its Representatives.

Section 6.7 Parent Stockholder Approval

(a) The Parent shall take all action necessary under all applicable Requirements of Law to call, give notice of, and hold a meeting of the holders of Parent Common Stock (including any adjournments or postponements thereof, the "**Parent Stockholders' Meeting**") for the purpose of obtaining the Parent Stockholder Vote. Without the prior written consent of Seller, the Parent Stockholder Vote shall be the only matters (other than procedural matters) that the Parent shall propose to be acted on by the Parent stockholders at the Parent Stockholders' Meeting. The Parent Proxy Statement delivered to the stockholders of the Parent in connection with the Parent Stockholders' Meeting shall include the Parent Board Recommendation.

(b) The Parent (in consultation with Seller) shall set a single record date for persons entitled to notice of, and to vote at, the Parent Stockholders' Meeting and shall not change such record date (whether in connection with the Parent Stockholders' Meeting or any adjournment or postponement thereof) without the prior written consent of Seller. The Parent Stockholders' Meeting shall be held on a date selected by the Parent in consultation with Seller as promptly as practicable after the Form S-4 Registration Statement is declared effective under the Securities Act. Once the Parent Stockholders' Meeting has been called and noticed, the Parent shall not postpone or adjourn the Parent Stockholders' Meeting without the consent of Seller (which consent shall not be unreasonably withheld), other than (i) for the absence of a quorum or (ii) to allow reasonable additional time for the filing and mailing of any supplemental or amended disclosure which Parent believes in good faith is necessary under applicable Law and for such supplemental or amended disclosure to be disseminated and reviewed by Parent Stockholders prior to the Parent Stockholders' Meeting.

(c) The Parent's obligations pursuant to this Section 6.7 shall not be affected by the public announcement or public disclosure of, or the communication to the Seller of, any Acquisition Proposal or inquiry or indication of interest with respect thereto, or by a Change of Board Recommendation (in each case, in the event the Parent is the Target Party). Unless this Agreement is properly terminated in accordance with its terms, the matter to be addressed in the Parent Stockholder Vote shall be submitted to the Parent Stockholders at the Parent Stockholders' Meeting whether or not (x) the Board of Directors shall have effected a Change of Board Recommendation or (y) any Acquisition Proposal shall have been publicly proposed or announced or otherwise submitted to the Parent or any of its Representatives.

Section 6.8 Commercially Reasonable Efforts; Consents and Governmental Approvals; Cooperation

(a) Subject to the terms and conditions of this Agreement, each of the parties hereto agrees to use its respective commercially reasonable efforts to take, or cause to be taken, all appropriate action, and to do, or cause to be done, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement. Without limiting the foregoing, each of Seller, Parent and Purchaser agrees to use all commercially reasonable efforts to:

(i) as promptly as practicable, make or obtain (as applicable), from any Governmental Authority or other Person, all notices, filings, consents, waivers, approvals, authorizations, Permits or Orders required to be made or obtained by the Seller, Parent or Purchaser in connection with the authorization, execution and delivery of this Agreement and the consummation of the transactions contemplated hereby;

(ii) prevent the issuance of, or lift or rescind, any judgment, injunction, order, decree or ruling or the taking of any action by any Governmental Authority that could materially adversely affect the ability of the parties hereto to consummate the transactions contemplated by this Agreement;

(iii) not take any action, or knowingly omit to take any action (except, in the case of the Seller, as otherwise permitted by Section 6.3), that would be reasonably likely to result in any of the conditions to the consummation of the Transaction set forth in ARTICLE VII hereof not being satisfied; and

(iv) in the event that any Proceeding relating to the transactions contemplated hereby is commenced, whether before or after the date of this Agreement, cooperate to defend vigorously against it and respond thereto.

(b) Each of Seller and Parent shall keep the other apprised of the status of matters relating to completion of the transactions contemplated hereby, including promptly furnishing the other with copies of notices or other communications received by Seller or Parent, as the case may be, or any of their respective Subsidiaries, from any third party and/or any Governmental Authority whose consent is required, or alleging that the consent of such third party or Governmental Authority is or may be required, with respect to the Transaction and the other transactions contemplated by this Agreement.

Section 6.9 Interim Financing; Interim Loan

(a) Parent shall use commercially reasonable efforts to prepare and file a registration statement on Form S-1 for the registration, sale and issuance of Parent Common Stock with gross proceeds to Parent of at least equal to $10,000,000 (the "**Interim Financing**") as soon as practicable after the date hereof.

(b) As soon as practicable after completion of the Interim Financing, and no later than ten (10) Business Days after such completion, Seller and Parent shall, and shall cause their respective Subsidiaries, to enter into a credit facility agreement (the "**Interim Facility**") pursuant to which Parent or Purchaser (the "**Interim Lender**") shall make available to the Company (the "**Interim Borrower**") (and/or any other Group Company as may be designated in writing by Seller) from time to time, such monies as reasonably determined by the Seller and the Parent to be necessary for the Group Companies to operate the Business and discharge any current Liability Related to the Business as it becomes due, in each case as the Business will be conducted by the Group Companies until Closing.

(c) Seller and Parent undertake to negotiate in good faith and agree the terms of the definitive Interim Facility as soon as possible after the date hereof, provided that the Interim Facility shall remain in place until the Closing Date and provided further that such definitive terms shall comply with the applicable Requirements of Law and in particular comply with the following principles:

(i) In order to avoid an over-indebtedness (*Überschuldung*) of the Interim Borrower in the meaning of section 19 German Insolvency Code ("**InsO**"), the Interim Lender shall agree to subordinate any claim the Interim Lender may have under the Interim Facility (the "**Interim Lender Claims**") in insolvency proceedings over the assets of the Interim Borrower behind all claims of all current and future creditors of the Interim Borrower in the rank of section 39 para. 1 no. 1 to 5 InsO in a way that payments on the Interim Lender Claims outside of insolvency proceedings may only be made (i) from future annual profits, (ii) from a liquidation surplus or (iii) from other free capital (*sonstiges freies Vermögen*) exceeding the liabilities to be stated in the accounts of the Interim Borrower pursuant to commercial Law (*Handelsrecht*); and

(ii) Outside of insolvency proceedings over the assets of the Interim Borrower, this subordination of rank shall capture the Interim Lender Claims only to the extent required in order to avoid an over-indebtedness (*Überschuldung*; section 19 InsO) of the Interim Borrower or any other circumstances which may give reason for an opening of insolvency proceedings over the Interim Borrower's assets, in particular on the basis of section 17 InsO (inability to pay due debts, *Zahlungsunfähigkeit*) or section 18 InsO (impending inability to pay due debts, *drohende Zahlungsunfähigkeit*). For this purpose, the scope of such subordination of rank shall automatically increase and decrease to the extent necessary without any further declarations or actions of any party being required, but in any case, up to the total aggregate amount of the Interim Lender Claims.

Section 6.10 Notification of Certain Matters

Each of Seller and Parent shall give prompt notice to the other of (i) the occurrence or non-occurrence of any fact or event which would be reasonably likely (x) to cause any representation or warranty contained in this Agreement to be untrue or inaccurate in any material respect at any time from the date hereof to the Closing or (y) to cause any covenant, condition or agreement under this Agreement not to be complied with or satisfied and (ii) any failure of Seller, Purchaser or Parent, as the case may be, to comply with or satisfy any covenant, condition or agreement to be complied with or satisfied by it hereunder.

Section 6.11 Further Assurances

Following the Closing, each of Seller, Parent and Purchaser shall, from time to time, execute and deliver such additional instruments, documents, conveyances or assurances and take such other actions as shall be necessary, or otherwise reasonably requested by the other party, to confirm and assure the rights and obligations provided for in this Agreement and render effective the consummation of the transactions contemplated hereby.

Section 6.12 Post-Closing Governance

(a) Unless otherwise agreed by Seller and Parent, the parties shall cause the Board of Directors to consist, as soon as practicable after Closing, of six (6) members. Such Board of Directors shall be chaired by William E. Rhodes III and shall comprise (i) four (4) members (including William E. Rhodes III.) appointed by the Seller and (ii) Evan Jones and R. Donald Elsey of the current Board of Directors, it being provided that such composition shall conform to NASDAQ requirements and that each member of the Board of Directors shall meet all applicable legal and regulatory qualification requirements.

(b) The Seller and the Parent further agree that, as soon as practicable after Closing, (i) Oliver Schacht, Ph.D., shall be appointed as Chief Executive Officer of the Parent and Tim Dec shall be appointed as Chief Financial Officer of the Parent and (ii) other officers and senior management employees of the Parent shall be appointed by the Board of Directors with the recommendation of Oliver Schacht, Ph.D.

Section 6.13 Employee Matters

(a) Parent and Purchaser will cause service rendered by any employee of the Group Companies prior to the Closing to be taken into account for vesting and eligibility purposes (but excluding for benefits accruals purposes with respect to any existing defined benefit plans or any other Benefit Plan, or where such credit would result in a duplication of benefits) under any "employee benefit plan" of Parent or Purchaser ("**Successor Plans**") which is made available to any such Group Companies employee who becomes eligible to participate in a Successor Plan after the Closing subject to the terms of such Successor Plan, to the same extent as such service was or should have been taken into account under the Group Companies Benefit Plan (if any) providing same or similar benefits for those purposes prior to the Closing, except where it would result in a duplication of benefits. For the avoidance of doubt, Successor Plans shall not include any Group Companies Benefit Plan or any Benefit Plan that covers only non-US residents.

(b) Parent will use its reasonable commercial efforts to provide that, in each case, pursuant to the Seller's records which shall be provided by Seller to Parent as soon as possible following Closing: (i) any employee of the Group Companies who becomes eligible to participate in a Successor Plan which is made available after the Closing, subject to the terms of such Successor Plan will not be subject to any waiting period or pre-existing condition limitation under any Successor Plan for any condition for which they would have been entitled to coverage under the Group Companies Benefit Plan providing same or similar benefits in which they participated prior to the Closing, except to the extent of any waiting periods or pre-existing limitation that had not been met as of the Closing; and (ii) Parent will credit any co-payments, deductibles and out-of-pocket expenses incurred by any such Group Companies employee, for the applicable plan year in which the Closing occurs under a Group Companies Benefit Plan providing same or similar benefits, toward any co-payments and deductibles limits and out-of-pocket maximums under any applicable Successor Plan for the applicable plan year in which the Closing occurs.

(c) Parent will use its reasonable commercial efforts after the Closing to provide that: (i) any employee of a Purchaser Entity who becomes eligible to participate in a Successor Plan which was a Group Companies Benefit Plan which is made available after the Closing , subject to the terms of such Successor Plan will not be subject to any waiting period or pre-existing condition limitation under any Successor Plan for any condition for which they would have been entitled to coverage under the Purchaser Entities Benefit Plan providing same or similar benefits in which they participated prior to the Closing, except to the extent of any waiting periods or pre-existing limitation that had not been met as of the Closing; and (ii) Parent will credit any co-payments, deductibles and out-of-pocket expenses incurred by any such Purchaser Entity employee, for the applicable plan year in which the Closing occurs under a Purchaser Entities Benefit Plan providing same or similar benefits, toward any co-payments and deductibles limits and out-of-pocket maximums under any applicable Successor Plan for the applicable plan year in which the Closing occurs.

Section 6.14 Treatment of Stock Options and Other Stock-Based Compensation

(a) As of the Closing Date, Parent shall assume the Curetis Stock Option Plan 2016, as amended on 19 July 2018 (the "**Seller Stock Option Plan**") and each option to acquire shares of Seller Common Stock (each, a "**Seller Stock Option**") that is outstanding under the Seller Stock Option Plan immediately prior to the Closing Date, whether or not then vested or exercisable, shall be, by virtue of the Closing and without any action on the part of the holder thereof, or any other Person, converted into a Parent Stock Option in accordance with this Section 6.14. Each such Parent Stock Option as so assumed and converted shall continue to have, and shall be subject to, the same terms and conditions as applied to the Seller Stock Option immediately prior to the Closing Date. As of the Closing Date, each such Parent Stock Option as so assumed and converted shall be an option to acquire that number of whole shares of Parent Common Stock (rounded down to the nearest whole share) equal to the product of: (i) the number of shares of Seller Common Stock subject to such Seller Stock Option; and (ii) 0.0959 (the "**Conversion Ratio**"), at an exercise price per share of Parent Common Stock (rounded up to the nearest whole cent) equal to the quotient obtained by dividing (A) the exercise price per share of Seller Common Stock of such Seller Stock Option by (B) the Conversion Ratio; *provided, that* the exercise price and the number of shares of Parent Common Stock subject to the Parent Stock Option shall be determined in a manner consistent with the requirements of Section 409A of the Code, and, in the case of Seller Stock Options that are intended to qualify as incentive stock options within the meaning of Section 422 of the Code, consistent with the requirements of Section 424(a) of the Code.

(b) The Seller and Parent undertake to negotiate in good faith and agree, as soon as possible after the date hereof, on the terms of the conversion, assumption by Parent, roll-over or any other appropriate treatment of the outstanding awards under the Seller Phantom Stock Option Plan; provided, that Seller and Parent acknowledge and agree that the maximum number of shares of Parent Common Stock to be issued (or reserved for issuance) in connection with the Transaction by the Parent (i) to the Seller as Consideration, (ii) to holders of options under the Seller Stock Option Plan and awards under the Seller Phantom Stock Option Plan and (iii) to implement the Convertible Debt Rollover as contemplated in Section 6.15(b) may not exceed 2,662,564 shares of Parent Common Stock.

(c) On or prior to the Closing Date, the Seller, the Management Board and Supervisory Board, and the compensation committee thereof, as applicable, shall adopt any resolutions and take any actions (including obtaining any employee consents) that may be necessary to effectuate the provisions of this Section 6.14.

(d) On or prior to the Closing Date, Parent shall reserve for future issuance a number of shares of Parent Common Stock at least equal to the number of shares of Parent Common Stock that will be subject to assumed or granted equity awards to the holders of options under the Seller Stock Option Plan and awards under the Seller Phantom Stock Option Plan (the "**Parent Equity Awards**") as a result of the actions contemplated by this Section 6.14. As soon as practicable after the Closing Date, if and to the extent necessary to cause a sufficient number of shares of Parent Common Stock to be registered and issuable with respect to the Parent Equity Awards, Parent shall prepare and file with the SEC a registration statement on Form S-8 (or any successor or other appropriate form) with respect to the shares of Parent Common Stock subject to the Parent Equity Awards.

Section 6.15 Treatment of Outstanding Indebtedness

(a) The Parent shall use reasonable endeavors to procure by Closing the release of the Seller from any securities, guarantees or indemnities given by or binding upon the Seller in respect of any Liability of the Group Companies (including the EIB Guarantee), by providing to the beneficiary of such securities, guarantees or indemnities an alternative company or bank guarantee or other security arrangement reasonably acceptable to the beneficiary (including to EIB in respect of the EIB Guarantee).

(b) Each of the parties hereto agrees to use its respective commercially reasonable efforts to take, or cause to be taken, all appropriate action, and to do, or cause to be done, all things necessary, proper or advisable to negotiate in good faith and agree with Yorkville the terms of a Contract providing for the assignment and assumption of the Yorkville Agreement by the Seller to the Parent, subject to Closing, and pursuant to which (x) Parent shall be substituted in all rights and Liabilities of the Seller under the Yorkville Agreement, (y) Seller shall be released from all Liabilities towards Yorkville under the Yorkville Agreement and (z) Yorkville shall become entitled to exercise a conversion of the notes originally issued by Seller under the Yorkville Agreement into a certain number of new shares of Parent Common Stock (the "**Convertible Debt Rollover**"), provided that such terms shall replicate to the largest extent possible the terms of the Yorkville Agreement (taking into account, among other things, the calculation of Seller's ownership of Parent Common Stock under this Agreement, and the applicable Requirements of Law) and shall be reasonably acceptable to both Seller and Parent.

Section 6.16 Takeover Statutes

The Seller shall take all reasonable steps to exclude the applicability of, or to assist Parent in any challenge to the validity or applicability to the Transaction or any other transaction contemplated by this Agreement of any "moratorium," "control share acquisition," "business combination," "fair price" or other form of anti-takeover Laws or regulations of any jurisdiction that may purport to be applicable to this Agreement or the transactions contemplated hereby.

Section 6.17 Press Releases

Each of Seller and Parent agrees that no public release or announcement concerning the transactions contemplated hereby shall be issued by any of them without the prior written consent of the other party (which consent shall not be unreasonably withheld or delayed), except as such release or announcement may be required by applicable Law or the rules or regulations of any applicable U.S. or foreign securities exchange or Governmental Authority (including, without limitation, the SEC and the AFM) to which the relevant party is subject or submits, wherever situated, in which case the party required to make the release or announcement shall use all commercially reasonable efforts to allow Seller or Parent, as the case may be, reasonable time to comment on such release or announcement in advance of such issuance, it being understood that the final form and content of any such release or announcement, to the extent so required, shall be at the final discretion of the party required to make such disclosure. Seller and Parent agree that the initial press release to be issued with respect to the Transaction should be in the form agreed by them.

Section 6.18 Tax Matters

(a) The parties intend for the transactions described in this Agreement to qualify as a reorganization within the meaning of Section 368(a)(1)(C) of the Code. The reorganization will consist of (i) the transfer of the Transferred Shares to the Purchaser solely in exchange for the Consideration and the assumption by the Purchaser of the Assumed Liabilities and (ii) the distribution by the Seller on or promptly after the Closing Date of the Consideration to the Seller Stockholders [in liquidation and dissolution of the Seller. The parties to this Agreement hereby adopt this Agreement as a "plan of reorganization" within the meaning of Sections 1.368-2(g) and 1.368-3(a) of the United States Treasury Regulations. The Parent and/or Purchaser and the Seller shall prepare and file with each of their respective Tax Returns all information required by Section 1.368-3 of the United States Treasury Regulations and related provisions of such Treasury Regulations in a manner consistent with treating the transactions contemplated by this Agreement as a reorganization within the meaning of Section 368(a)(1)(C) of the Code.

(b) All transfer, documentary, sales, use, stamp, registration, value added and other such Taxes and fees (including any penalties and interest) incurred in connection with this Agreement (including any real property transfer Tax and any other similar Tax) shall be borne and paid by Purchaser or Parent when due. Parent shall, at its own expense, timely file any Tax Return or other document with respect to such Taxes or fees (and Seller shall cooperate with respect thereto as necessary).

Section 6.19 Change of Name, Liquidation; Transitional Arrangements

(a) The Seller shall use commercially reasonable efforts to change its official name to a name not including the word "Curetis" or any words similar thereto either before the Closing Date (but subject to Closing) or as soon as possible within twenty (20) Business Days after the Closing Date.

(b) The Seller will use commercially reasonable efforts to proceed to wind up its affairs, satisfy all valid claims of creditors and others having claims against the Seller, and distribute any remaining assets to the Seller Stockholders, all in full compliance with applicable Laws, as promptly as practicable after the Closing Date. To the extent that any distribution is subject to withholding or similar taxes, the Seller shall withhold the required amounts from such distributions and remit such amounts to the applicable Tax Authority as required by Law. In no event shall the Seller make any distribution to the Seller Stockholders if, after giving effect to such distribution, in the reasonable judgment of the Supervisory Board and / or Management Board the Seller would be insolvent or unable to pay its debts as they come due, would have remaining liabilities in excess of its remaining assets, or would otherwise be unable to satisfy in full all valid claims against the Seller.

(c) Each of Parent and Purchaser acknowledges and agrees that, from the Closing Date and until such time as the Seller shall have been duly liquidated and dissolved in full compliance with applicable Laws, (i) the Seller shall be entitled to maintain its office address at Max-Eyth Strasse 42, 71088 Holzgerlingen, Germany and retain reasonable access to the resources and infrastructures of the Group Companies for the purpose of completing the operations contemplated in clause (a) and (b) of this Section 6.19, in each case at no cost for the Seller and (ii) any member of the Management Board or Supervisory Board or employee of the Seller who has been appointed at the Board of Directors or has been hired as an officer or employee of Parent and/or Purchaser shall be entitled to dedicate up to 10% of his or her working time to complete the operations contemplated in clause (a) and (b) of this Section 6.19.

Section 6.20 Litigation

(a) Notwithstanding anything to the contrary set forth herein, Seller shall promptly notify Parent if it receives notice of any Proceeding instituted or threatened against the Group Companies or any of its, or their Representatives', directors, officers or Affiliates, including by any Seller Stockholder, before any Governmental Authority, whether relating to this Agreement, the Transaction or the other transactions contemplated hereby or any other matter or claim.

(b) Notwithstanding anything to the contrary set forth herein, Parent shall promptly notify Seller if it receives notice of any Proceeding instituted or threatened against the Purchaser Entities or any of its, or their Representatives', directors, officers or Affiliates, including by any Parent Stockholder, before any Governmental Authority, whether relating to this Agreement, the Transaction or the other transactions contemplated hereby or any other matter or claim.

ARTICLE VII
CONDITIONS TO CONSUMMATION OF THE TRANSACTION

Section 7.1 Conditions to Each Party's Obligation to Effect the Transaction

The respective obligations of the parties hereto to effect the Transaction shall be subject to the satisfaction, or waiver in writing, at or prior to the Closing of the following conditions:

(a) Stockholder Approvals. This Agreement and the transactions contemplated hereby shall have been duly adopted by the Seller Stockholder Vote and by the Parent Stockholder Vote.

(b) No Injunctions or Restraints; Illegality. No order, stay, judgment, injunction or decree issued by any court or Governmental Authority of competent jurisdiction of the federal government of the United States of America or any state thereof making the Transaction illegal or otherwise prohibiting the consummation of the Transaction shall be in effect, and no Governmental Authority shall have instituted any proceeding seeking any such order, stay, judgment, injunction or decree and such proceeding remains unresolved.

(c) Effectiveness of Form S-4 Registration Statement. The Form S-4 Registration Statement shall have been declared effective by the SEC in accordance with the provisions of the Securities Act, no stop order suspending the effectiveness of the Form S-4 Registration Statement shall have been issued by the SEC, and no Proceeding for that purpose shall have been initiated or threatened by the SEC, and all approvals required under Blue Sky Laws relating to the Parent Common Stock issuable to the Seller in payment of the Consideration hereunder will have been received.

(d) Listing. The shares of Parent Common Stock to be issued in payment of the Consideration shall have been approved for listing (subject to official notice of issuance) on NASDAQ Capital Market.

(e) Interim Financing. The Interim Financing shall have been completed.

(f) Convertible Debt Rollover. The documentation implementing the Convertible Debt Rollover (subject to Closing) shall have been agreed and executed by Seller, Parent and the relevant Yorkville entities.

(g) Consents. The Seller shall have received all consents, authorizations, qualifications and orders of all third parties set forth in Section 7.1(g) of the Seller Disclosure Schedules.

Section 7.2 Conditions to Obligations of Parent and Purchaser

The obligations of Parent and Purchaser to effect the Transaction are also subject to the satisfaction, or waiver in writing by Parent, at or prior to the Closing, of the following conditions:

(a) Representations and Warranties. The representations and warranties of the Seller contained in ARTICLE IV shall be true and correct as of the Closing Date as though made as of such date (unless any such representation or warranty expressly relates to an earlier date, in which case such representation or warranty shall be true and correct only as of such earlier date); such representations and warranties shall be deemed to be true and correct unless the respects in which the representations and warranties (without giving effect to any "materiality" or similar limitations or references to Material Adverse Effect set forth therein) are untrue or incorrect, individually or in the aggregate, has prevented or materially delayed, or would reasonably be expected to prevent or materially delay, the consummation of the transactions contemplated by this Agreement.

(b) Performance of Obligations of the Seller. The Seller shall have performed in all material respects the covenants and agreements required to be performed by it under this Agreement at or prior to the Closing.

(c) Officer's Certificate. Parent shall have received a certificate signed on behalf of the Seller by the Chief Executive Officer, the Chief Business Officer, and the Chief Operating Officer certifying as to the matters set forth in Section 7.2(a) and Section 7.2(b).

(d) German Transfer Agreement. The Seller shall have executed and delivered to Purchaser the German Transfer Agreement.

(e) Assignment and Assumption Agreement. The Seller shall have executed and delivered to the Purchaser the Assignment and Assumption Agreement.

(f) Material Adverse Effect of Company. Since the date of this Agreement, there shall not have occurred any Material Adverse Effect with respect to the Company.

(g) Other Documents. The Parent shall have received each other document reasonably requested by Parent for the purpose of permitting or facilitating the consummation of the transactions contemplated by this Agreement.

Section 7.3 Conditions to Obligations of the Seller

The obligation of the Seller to effect the Transaction is also subject to the satisfaction, or waiver in writing by the Seller, at or prior to the Closing of the following conditions:

(a) Representations and Warranties. The representations and warranties of Parent and Purchaser contained in ARTICLE V shall be true and correct as of the Closing Date as though made as of such date (unless any such representation or warranty expressly relates to an earlier date, in which case such representation or warranty shall be true and correct only as of such earlier date); such representations and warranties shall be deemed to be true and correct unless the respects in which the representations and warranties (without giving effect to any "materiality" or similar limitations or references to Material Adverse Effect set forth therein) are untrue or incorrect, individually or in the aggregate, has prevented or materially delayed, or would reasonably be expected to prevent or materially delay, the consummation of the transactions contemplated by this Agreement.

(b) Performance of Obligations of Parent and Purchaser. Parent and Purchaser shall have performed in all material respects the covenants and agreements respectively required to be performed by them under this Agreement at or prior to the Closing.

(c) Officer's Certificate. The Seller shall have received a certificate signed on behalf of Parent by a duly authorized officer certifying as to the matters set forth in Section 7.3(a) and Section 7.3(b).

(d) Interim Facility. The Interim Facility shall have been put in place within five (5) Business Days of completion of the Interim Financing.

(e) Consideration. The Seller shall have received the Consideration in the form of book-entry shares of Parent Common Stock from the transfer agent of the Parent.

(f) German Transfer Agreement. Purchaser shall have executed and delivered to the Seller the German Transfer Agreement.

(g) Assignment and Assumption Agreement. The Purchaser shall have executed and delivered to the Seller the Assignment and Assumption Agreement.

(h) Material Adverse Effect of Company. Since the date of this Agreement, there shall not have occurred any Material Adverse Effect with respect to the Parent.

(i) Other Documents. The Seller shall have received each other document reasonably requested by Seller for the purpose of permitting or facilitating the consummation of the transactions contemplated by this Agreement.

ARTICLE VIII
TERMINATION; AMENDMENT; WAIVER

Section 8.1 Termination

This Agreement may be terminated and the Transaction may be abandoned, at any time prior to the Closing (whether before or after the Seller Stockholders' Meeting or the Parent Stockholders' Meeting), by written notice by the terminating party or parties to the other party or parties specifying the provision or provisions of this Agreement pursuant to which such termination is effected:

(a) by mutual written consent of the Seller and Parent;

(b) by Seller or Parent, if the Interim Financing shall not have been completed on or before October 15, 2019; provided, however, that the right to terminate this Agreement under this Section 8.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement materially contributed to, or resulted in, the failure of the Interim Financing to be completed on or before such date;

(c) by Seller, if the Interim Facility shall not have been put in place within five (5) Business Days of completion of the Interim Financing, provided, however, that the right to terminate this Agreement under this Section 8.1(c) shall not be available to the Seller whose failure to fulfill any obligation under this Agreement materially contributed to, or resulted in, the failure to execute the Interim Facility documentation or otherwise implement the Interim Facility;

(d) by either Seller or Parent, if the Transaction shall not have been consummated on or before January 31, 2020 (the "**Outside Date**"), including as a result of any Governmental Authority of competent jurisdiction having issued an order, decree or ruling, or taken any other action permanently restraining, enjoining or otherwise prohibiting the Transaction (and such order, decree, ruling or other action having become final and non-appealable); provided, however, that the right to terminate this Agreement under this Section 8.1(d) shall not be available to any party whose failure to fulfill any obligation under this Agreement materially contributed to, or resulted in, the failure of the Transaction to be consummated on or before such date;

(e) by either Seller or Parent, if the Seller Stockholders' Meeting shall have been convened, a vote with respect to this Agreement and the Transaction shall have been taken thereat and the Seller Stockholder Vote shall not have been obtained; provided, however, that the right to terminate this Agreement under this Section 8.1(e) shall not be available to any party whose failure to fulfill any obligation under this Agreement materially contributed to, or resulted in, the failure to obtain the Seller Stockholder Vote;

(f) by either Seller or Parent, if the Parent Stockholders' Meeting shall have been convened, a vote with respect to this Agreement and the Transaction shall have been taken thereat and the Parent Stockholder Vote shall not have been obtained; provided, however, that the right to terminate this Agreement under this Section 8.1(f) shall not be available to any party whose failure to fulfill any obligation under this Agreement materially contributed to, or resulted in, the failure to obtain the Parent Stockholder Vote;

(g) by Seller, if there shall have been a Breach of any of the covenants or agreements or any of the representations or warranties set forth in this Agreement on the part of Purchaser or Parent, which Breach, either individually or in the aggregate, would result in, if occurring or continuing at the Closing, the failure of either of the conditions set forth in Section 7.3(a) and Section 7.3(b), as the case may be, and which is not cured within the earlier of (i) the Outside Date and (ii) 30 days following written notice to Parent, or which by its nature or timing cannot be cured within such period; provided that the Seller shall not have the right to terminate this Agreement pursuant to this Section 8.1(g) if the Seller is then in material Breach of any of its representations, warranties, covenants or agreements contained in this Agreement;

(h) by Parent, if there shall have been a Breach of any of the covenants or agreements or any of the representations or warranties set forth in this Agreement on the part of the Seller, which Breach, either individually or in the aggregate, would result in, if occurring or continuing at the Closing, the failure of either of the conditions set forth in Section 7.2(a) and Section 7.2(b), as the case may be and which is not cured within the earlier of (i) the Outside Date and (ii) 30 days following written notice to the Seller, or which by its nature or timing cannot be cured within such period; provided that Parent shall not have the right to terminate this Agreement pursuant to this Section 8.1(h) if either Parent or Purchaser is then in material Breach of any of their representations, warranties, covenants or agreements contained in this Agreement;

(i) by Seller or Parent in order to effect a Change of Board Recommendation and substantially concurrently enter into a definitive agreement providing for a Superior Proposal; provided that (i) Seller (or Parent, as the case may be), has complied with the terms of Section 6.3 and (ii) immediately prior to or substantially concurrently with (as a condition to) the termination of this Agreement, Seller pays to Parent the Seller Termination Fee, or Parent pays to Seller the Parent Termination Fee, as the case may be; or

(j) by Seller or Parent if the Target Board (or a committee thereof) effects a Change of Board Recommendation (or publicly announces any intention to do so).

Section 8.2 Effect of Termination

If this Agreement is terminated prior to the Closing and the Transaction is abandoned pursuant to Section 8.1, this Agreement, except for the applicable provisions of Section 1.1 (*Definitions*), Section 1.2 (*Rules of interpretation*), Section 6.17 (*Press Releases*), Section 8.2 (*Effect of Termination*), Section 8.3 (*Termination Fees; Reimbursement for Expenses*), Section 8.4 (*Limitation on Recovery*), Section 8.5 (*Amendment*) and Section 8.6 (*Extension; Waiver; Remedies*) and ARTICLE IX (*Miscellaneous*), shall forthwith and immediately upon such termination automatically become null and void and have no effect, without any liability on the part of any party hereto (or any of its Representatives); provided, however, that nothing contained in this Section 8.2 shall relieve any party hereto from any liability for any willful Breach of a representation or warranty contained in the Agreement or the Breach of any covenant in this Agreement, in either case arising prior to termination.

Section 8.3 Termination Fees; Reimbursement for Expenses

(a) If this Agreement is terminated pursuant to Section 8.1(e), then Seller shall pay to Parent, within five (5) Business Days of presentation by Parent of reasonably detailed invoices for the same, all Expenses reasonably incurred by Parent provided that the amount paid will not exceed $250,000. If this Agreement is terminated pursuant to Section 8.1(f), then Parent shall pay to Seller, within five (5) Business Days of presentation by Seller of reasonably detailed invoices for the same, all Expenses reasonably incurred by Seller provided that the amount paid will not exceed $250,000. For the purpose of this Section 8.3(a), "**Expenses**" will consist of all out-of-pocket expenses, including all fees and expenses of counsel, accountants, investment bankers, experts and consultants to a party hereto and its Affiliates) incurred by a party in connection with or related to the authorization, preparation, negotiation, execution and performance of this Agreement, the solicitation of the approval of the Transaction by the Seller Stockholders or Parent Stockholders (as the case may be) and all other matters related to the consummation of the Transaction.

(b) Notwithstanding the foregoing, Seller shall pay Parent and/or one of its Subsidiaries, as designated in writing by Parent, an amount in cash equal to $500,000 (the "**Seller Termination Fee**") in the following circumstances:

(i) if Parent terminates this Agreement pursuant to Section 8.1(e) and (x) any Person shall have made, or announced an intention to make, an Acquisition Proposal for the Group Companies or Company Common Stock that becomes public (whether or not conditional and whether or not withdrawn) after the date of this Agreement, and (y) within twelve (12) months of such termination, the Seller enters into a definitive agreement with respect to, or consummates such an Acquisition Proposal;

(ii) if Seller terminates this Agreement pursuant to Section 8.1(i); or

(iii) if Parent terminates this Agreement pursuant to Section 8.1(j).

(c) Notwithstanding the foregoing, Parent shall pay Seller and/or one of its Subsidiaries, as designated in writing by Seller, an amount in cash equal to $500,000 (the "**Parent Termination Fee**") in the following circumstances:

(i) if Seller terminates this Agreement pursuant to Section 8.1(f) and (x) any Person shall have made, or announced an intention to make, an Acquisition Proposal that becomes public (whether or not conditional and whether or not withdrawn) after the date of this Agreement, and (y) within twelve (12) months of such termination the Parent enters into a definitive agreement with respect to, or consummates an Acquisition Proposal;

(ii) if Parent terminates this Agreement pursuant to Section 8.1(i); or

(iii) if Seller terminates this Agreement pursuant to Section 8.1(j).

(d) All payments of the Seller Termination Fee or Parent Termination Fee shall be made as promptly as reasonably practicable (and, in any event within five (5) Business Days) following the date of termination of this Agreement pursuant to Section 8.1, by wire transfer of immediately available funds to an account designated by the recipient. For the avoidance of doubt, in the event that a party is entitled to receive both a reimbursement for Expenses under Section 8.3(a) and the payment of a termination fee under Section 8.3(b) or Section 8.3(c) (as the case may be), then the amount to be paid under Section 8.3(a) shall be deducted from the amount to be paid under Section 8.3(b) or Section 8.3(c) (as the case may be).

(e) Each of the Seller and Parent acknowledges that the agreements contained in this Section 8.3 are an integral part of the transactions contemplated by this Agreement. In the event that the applicable party shall fail to make any payment pursuant to this ARTICLE VIII when due, the party which fails to make such payment when due shall reimburse the party to whom such payment is due for all reasonable costs and expenses actually incurred by the party to whom payment is due (including reasonable fees and expenses of counsel) in connection with the collection under and enforcement of this Section 8.3, together with interest on the unpaid amount at the prime rate set forth in *The Wall Street Journal* in effect on the date such payment was required to be made.

Section 8.4 Limitation on Recovery

If this Agreement is properly terminated pursuant to Section 8.1(i) or Section 8.1(j) then: (i) the sole and exclusive remedy of the Other Party against the Target Party and its former, current and future direct or indirect equity holders, controlling Persons, stockholders, directors, officers, employees, agents, Affiliates, members, managers, general or limited partners or assignees for Damages shall be to receive the Seller Termination Fee or Parent Termination Fee, as the case may be and as provided by Section 8.3; and (ii) no former, current and future direct or indirect equity holders, controlling Persons, stockholders, directors, officers, employees, agents, Affiliates, members, managers, general or limited partners or assignees of the Target Party shall have any further Liability or obligation relating to or arising out of this Agreement or the transactions contemplated by this Agreement.

Section 8.5 Amendment

To the extent permitted by applicable Law, this Agreement may be amended by the parties, at any time before or after adoption of this Agreement by the Seller Stockholder Vote or Parent Stockholder Vote but, after any such Seller Stockholder Vote or Parent Stockholder Vote, no amendment shall be made that requires the approval of the stockholders of the Seller or Parent without the approval of such stockholders under applicable Law. This Agreement may not be amended, changed, supplemented or otherwise modified except by an instrument in writing signed on behalf of all of the parties.

Section 8.6 Extension; Waiver; Remedies

(a) Each party hereto, by action taken or authorized by their respective boards of directors or equivalent governing body, as applicable, may to the extent legally allowed, (i) extend the time for the performance of any of the obligations or other acts of any other party hereto, (ii) waive any inaccuracies in the representations and warranties contained herein made or to be made by any other party hereto or in any document delivered pursuant hereto by any other party hereto, or (iii) waive compliance by any other party hereto with any of the agreements or conditions contained herein. Any such extension or waiver shall not be deemed an amendment to this Agreement. Any agreement on the part of any party to any such extension or waiver shall be valid only if set forth in an instrument in writing signed on behalf of such party.

(b) The failure of any party hereto to exercise any rights, power or remedy provided under this Agreement, or to insist upon compliance by any other party hereto with its obligations hereunder, and any custom or practice of the parties at variance with the terms hereof, shall not constitute a waiver by such party of its right to exercise any such or other right, power or remedy or to demand such compliance.

ARTICLE IX
MISCELLANEOUS

Section 9.1 Non-survival of Representations and Warranties

None of the representations and warranties in this Agreement shall survive the Closing. This Section 9.1 shall not limit any covenant or agreement of the parties that by its terms contemplates performance after the Closing.

Section 9.2 Expenses

(a) Whether or not the Transaction is consummated, except as otherwise specifically provided in Section 8.3, all costs and expenses incurred in connection with this Agreement and the transactions contemplated by this Agreement shall be paid by the party incurring such costs and expenses.

(b) Notwithstanding the foregoing, all costs and expenses incurred by Seller and Parent in connection with the preparation, review, filing, printing, and mailing of the Form S-1 Registration Statement and Form S-4 Registration Statement (including, for the avoidance of doubt in connection with the preparation of financial statements and audits required in connection therewith) shall be borne in equal proportion by Seller and Parent.

Section 9.3 Entire Agreement; Assignment; No Additional Representations

(a) This Agreement, together with the Seller Disclosure Schedules, the Purchaser Disclosure Schedules, the Exhibits hereto, the Confidentiality Agreement and the other documents to be delivered pursuant to this Agreement, constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all other prior agreements and understandings, both written and oral, between the parties with respect to subject matter hereof and thereof. The Agreement and any rights or obligations hereunder shall not be assigned or transferred by any party directly or indirectly by operation of Law, contract or otherwise without the prior written consent of the other parties such consent not to be unreasonably delayed or withheld.

(b) Except for the representations and warranties contained in ARTICLE V or the Purchaser Disclosure Schedules, Seller acknowledges and agrees that none of Parent or Purchaser or any other Person on behalf of Parent or Purchaser has made any representation or warranty, express or implied, as to Parent, the Purchaser Entities or the accuracy or completeness of any information regarding the Parent or the Purchaser Entities furnished or made available to Seller and its Representatives. Neither Purchaser nor any other Person will have or be subject to any Liability or indemnification obligation to the Seller or any other Person resulting from the distribution to the Seller, or the Seller's use of, any such information.

(c) Except for the representations and warranties contained in ARTICLE IV or the Seller Disclosure Schedules, Parent and Purchaser acknowledge and agree that none of the Seller or the Group Companies, or any other Person has made any representation or warranty, expressed or implied, as to the Seller, the Group Companies or the accuracy or completeness of any information regarding the Seller or the Group Companies furnished or made available to Parent, Purchaser and their Representatives. Neither Seller, the Group Companies nor any other Person will have or be subject to any Liability or indemnification obligation to the Purchaser or any other Person resulting from the distribution to the Purchaser or Parent, or the Purchaser's or Parent's use of, any such information.

Section 9.4 Validity; Specific Performance

(a) Whenever possible, each provision or portion of any provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable Requirements of Law; but if any provision or portion of any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable Law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or portion of any provision in such jurisdiction, and this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision or portion of any provision had never been contained herein.

(b) Except as set forth in Section 8.4, the parties hereto agree that irreparable Damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise Breached and that such Damages would not be fully compensable by an award of money Damages. It is accordingly agreed that, except as set forth in Section 8.4, the parties hereto shall be entitled to an injunction or injunctions to prevent Breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement without posting a bond or other undertaking, this being in addition to any other remedy to which they are entitled at Law or in equity.

Section 9.5 Notices

All notices, requests, claims, demands and other communications hereunder shall be given (and shall be deemed to have been duly received if given) by hand delivery in writing or if by internationally recognized courier service two Business Days following sending by overnight delivery, or, upon delivery by facsimile transmission (with receipt confirmed) during the hours of 9:00 A.M. and 5:00 P.M. in the recipient's time zone as follows:

if to Parent or Purchaser:

OpGen, Inc.
708 Quince Orchard Road
Suite 205
Gaithersburg, MD 20878
USA
Attn: Evan Jones, Chairman and Chief Executive Officer

Phone:
Facsimile:
E-mail:

with copies to:

Ballard Spahr LLP

1375 Market Street, 51st floor
Philadelphia, PA 19103-7599
USA
Attn: Mary J. Mullany

Phone:
Facsimile:
E-mail:

if to the Seller:

Curetis N.V.
Max-Eyth Strasse 42
71088 Holzgerlingen
Germany
Attn: CEO, CBO and COO

Phone:
Facsimile:
E-mail:

with copies to:

Linklaters LLP

1345 Avenue of the Americas, 21st floor
New York, NY 10105
Attn: Scott I. Sonnenblick

Phone:
Facsimile:
E-mail:

or to such other address as the Person to whom notice is given may have previously furnished to the others in writing in the manner set forth above.

Section 9.6 Governing Law; Jurisdiction; Venue

This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware (without giving effect to conflict of law principles thereof). Each of the parties hereto (i) consents to submit itself to the exclusive personal jurisdiction of the state and federal courts sitting in the County of New Castle, State of Delaware, in the event any dispute arises out of this Agreement or any transaction contemplated by this Agreement, (ii) agrees that it will not attempt to deny or defeat such personal jurisdiction by motion or other request for leave from any such court, (iii) agrees that it will not bring any action relating to this Agreement or any transaction contemplated by this Agreement in any court other than any such court and (iv) waives any right to trial by jury with respect to any action related to or arising out of this Agreement or any transaction contemplated by this Agreement. The parties irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby or thereby in any such court, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

Section 9.7 Parties in Interest

This Agreement shall be binding upon and inure solely to the benefit of each party hereto, and nothing in this Agreement, express or implied is intended to confer upon any other Person any rights or remedies of any nature whatsoever under or by reason of this Agreement. Furthermore, nothing in this Agreement shall constitute an amendment to, or be construed as amending, modifying or terminating, any benefit plan, program, arrangement or agreement (including, without limitation, any Benefit Plan or Successor Plan) or to affect Parent's or the Seller's or any of their Subsidiaries' ability to amend, modify or terminate any employee benefit plan, program or arrangement, sponsored, maintained or contributed to by Parent, Seller or any of their respective Subsidiaries. Without limiting the foregoing, no provision of this Agreement shall create any third-party beneficiary or other rights in any employee or former employee or any beneficiary or dependent thereof, in respect of continued employment (or resumed employment) with Parent or any of its Subsidiaries, or with respect to the compensation, benefits or other terms and conditions of employment with Parent or Seller or any of their respective Subsidiaries.

Section 9.8 No Personal Liability

This Agreement shall not create or be deemed to create any personal liability or obligation on the part of any direct or indirect stockholder of the Seller, the Purchaser, Parent or any of their respective Representatives.

Section 9.9 Disclosure Schedules

The inclusion of any information in the Seller Disclosure Schedules or Purchaser Disclosure Schedules shall not be deemed to be an admission or acknowledgment, in and of itself, that such information is required by the terms hereof to be disclosed, is material, has resulted in or would result in a Material Adverse Effect or is outside the Ordinary Course of Business.

Section 9.10 Counterparts

This Agreement may be executed in two or more counterparts (including by facsimile or by an electronic scan delivered by electronic mail), each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same agreement and shall become effective when counterparts have been signed by each of the parties hereto delivered to the other parties, it being understood that all parties need not sign the same counterpart.

[*The remainder of this page is intentionally blank.*]

IN WITNESS WHEREOF, each of the parties has caused this Agreement to be executed on its behalf by its officers thereunto duly authorized, all at or on the day and year first above written.

OPGEN, INC.

By:	/s/ Evan Jones
Name:	Evan Jones
Title:	Chairman and Chief Executive Officer

IN WITNESS WHEREOF, each of the parties has caused this Agreement to be executed on its behalf by its officers thereunto duly authorized, all at or on the day and year first above written.

CRYSTAL GMBH

By:	/s/ Evan Jones
Name:	Evan Jones
Title:	Managing Director

By:	/s/ Timothy C. Dec
Name:	Timothy C. Dec
Title:	Managing Director

IN WITNESS WHEREOF, each of the parties has caused this Agreement to be executed on its behalf by its officers thereunto duly authorized, all at or on the day and year first above written.

CURETIS N.V.

By:	/s/ Oliver Schacht
Name:	Oliver Schacht
Title:	Chief Executive Officer

By:	/s/ Johannes Bacher
Name:	Johannes Bacher
Title:	Chief Operating Officer

By:	/s/ Achim Plum
Name:	Achim Plum
Title:	Chief Business Officer

Exhibit	Description
A	Knowledge
B	German Transfer Agreement
C	Form of Assignment and Assumption Agreement
D	Closing Deliverables

Schedules

Seller Disclosure Schedule

Purchaser Disclosure Schedule

The Exhibits and Schedules to the Implementation Agreement are not being filed in accordance with applicable SEC rules. Such Exhibits and Schedules are not material to understanding the Implementation Agreement. The information will be disclosed supplementally to the SEC upon request.

Crosstree Capital New York, LLC
420 Lexington Avenue
Suite 2440
New York, New York 10170

September 3, 2019

Board of Directors
Opgen, Inc.
708 Quince Orchard Road Suite 205
Gaithersburg, MD 20878

Members of the Board of Directors:

We understand under the terms of the implementation agreement, OpGen, Inc. (the Company) proposes to acquire 100% of the shares of Curetis GmbH from Curetis N.V., thereby acquiring all of Curetis GmbH's assets and liabilities, including the Curetis name (the "Transaction"). Curetis GmbH owns substantially all of the assets, liabilities and contractual obligations of the Curetis Group, including its subsidiaries Curetis USA Inc. and Ares Genetics GmbH. Upon Closing (as defined in the draft Implemenation Agreement), Curetis GmbH will be a wholly-owned subsidiary of OpGen.

At the closing of the transaction (the "Closing"), Curetis N.V. will be entitled to receive 2,662,564 new shares of common stock of OpGen (less the number of shares to be reserved for issuance to current holders of options, phantom stock and convertible debt securities issued by Curetis N.V.), reflecting a valuation of the combined business of roughly $24 million.

As of September 3, 2019, these 2,662,564 new shares would represent approximately 72.5% of the outstanding equity of OpGen (on a fully diluted basis), and current equity holders of OpGen (including option holders and warrant holders) would hold approximately 27.5% of the equity of OpGen (on a fully diluted basis) (the "Consideration"). The respective equity holdings upon Closing will be subject to any dilutive issuance of securities by OpGen between the date hereof and the date of Closing.

Crosstree Capital New York LLC ("Crosstree"), has been engaged by the Opgen Board of Directors pursuant to an engagement letter dated August 27, 2018 (the "Engagement Letter") to render a fairness opinion to the Board of Directors of the Company in connection with the Transaction. We will receive a fee for our services pursuant to the Engagement Letter, which will be payable upon delivery of this opinion, and we also will be reimbursed for expenses incurred. The Company has agreed to indemnify Crosstree against liabilities arising out of or in connection with the services rendered and to be rendered by Crosstree under such Engagement Letter.

You have asked for our opinion as investment bankers as to whether the Consideration to be paid pursuant to the Implementation Agreement is fair, from a financial point of view, to the stockholders.

In conducting our analysis and arriving at the opinion expressed herein, we have, among other things, {i) reviewed the draft Implementation Agreement, which, for purposes of this opinion we have assumed, with your permission to be identical in all material respects to the document to be executed; (ii) reviewed certain financial and other information about the Company that was publicly available; (iii) reviewed information furnished to us by the Company's management, including certain internal financial analyses, budgets, reports and other information; (iv) held discussions with various members of senior management of the Company concerning historical and current operations, financial conditions and prospects, including recent financial performance; (v) reviewed the recent share trading price history of the Company; (vi) reviewed the valuation of the Company implied by the Consideration; (vii) reviewed the valuations of publicly traded companies that we deemed comparable in certain respects to the Company; (viii) reviewed the financial terms of selected acquisition transactions involving companies in lines of business that we deemed comparable in certain respects to the business of the Company; (ix) reviewed the premiums paid in selected acquisition transactions; (x) prepared a discounted cash flow analysis of the Company on a stand alone basis. In addition, we have conducted such other quantitative reviews, analyses and inquiries relating to the Company as we considered appropriate in rendering this opinion; (xi) assessed the general economic, market and financial conditions; (xii) taken into consideration our experience in other similar transactions and securities valuations; and (xiii) performed such other analyses and considered such other factors as we have deemed appropriate.

In our review and analysis and in rendering this opinion, we have assumed and relied upon, but have not assumed any responsibility to independently investigate or verify, the accuracy, completeness and fair presentation of all financial and other information that was provided to us by the Company or that was publicly available to us (including, without limitation, the information described above), or that was otherwise reviewed by us. This opinion is expressly conditioned upon such information (whether written or oral) being complete, accurate and fair in all respects material to our analysis. We have further relied upon the assurance of management of the Company that they are unaware of any facts that would make the information provided to us incomplete or misleading in any respect. Our analyses were based, among other things, on the financial projections of the Company (the "Financial Projections") furnished to us by senior management of the Company. With respect to the Financial Projections, we note that projecting future results of any company is inherently subject to uncertainty. We express no opinion as to the Financial Projections or the assumptions on which they are based. In addition, in rendering this opinion, we have assumed that the Financial Projections have been reasonably prepared by management and reflect management's best currently available estimates and good faith judgment of the future competitive, operating and regulatory environment and related financial performance of the Company, that the Financial Projections and the assumptions derived therefrom provide a reasonable basis for our opinion. Although the Financial Projections did not form the principal basis for our opinion, but rather constituted one of many items that we employed, changes to the Financial Projections could affect the opinion rendered herein. In arriving at our opinion, we made qualitative judgments as to the significance and relevance of each analysis and factor.

Our opinion speaks only as of the date hereof and we expressly disclaim any undertaking or obligation to advise any person of any change in any fact or matter affecting our opinion of which we become aware after the date hereof.

We have made no independent investigation of any legal or accounting matters affecting the Company, and we have assumed the correctness in all respects material to our analysis of all legal and accounting advice given to the Company and its Board of Directors, including, without limitation, advice as to the legal, accounting and tax consequences of the terms of, and transactions contemplated by, the Implementation Agreement to the Company and its stockholders. In addition, in preparing this opinion, we have not taken into account any tax consequences of the Transaction to either the Company or to any holder of Common Stock.

In rendering this opinion we have also assumed that: (i) in all respects material to our analysis, that the representations and warranties of each party contained in the Implementation Agreement are true and correct, that each party will perform all of the covenants and agreements required to be performed by it under the Implementation Agreement and that all conditions to the consummation of the Transaction will be satisfied without waiver thereof which would affect the amount or timing of receipt of the Consideration; (ii) there is not now, and there will not as a result of the consummation of the transactions contemplated by the Implementation Agreement be, any default, or event of default, under any indenture, credit agreement or other material agreement or instrument to which the Company or any of its subsidiaries or affiliates is a party; and (iii) all material assets and liabilities (contingent or otherwise, known or unknown) of the Company were as set forth in the consolidated financial statements provided to us by the Company as of the respective dates of such financial statements.

Crosstree has acted as financial advisor to the Board in connection with the Transaction and will receive a fee for our services, a portion of which becomes payable upon the completion of the Transaction. In addition, the Company has agreed to indemnify Crosstree for certain liabilities arising out of our engagement.

It is understood that our opinion is solely for the use and benefit of the Board of Directors of the Company in its consideration of the Transaction, and our opinion does not address the relative merits of the transactions contemplated by the Implementation Agreement as compared to any alternative transactions that might be available to the Company, nor does it address the underlying business decision by the Company to engage in the Transaction or the terms of the Implementation Agreement or the documents referred to therein. Our opinion does not constitute a recommendation as to how any holder of shares of capital stock of the Company should vote or act on any matter relevant to the Implementation Agreement. Other than as specifically set forth herein, we are not expressing any opinion with respect to the terms and provisions of the Implementation Agreement or the enforceability of any such terms or provisions. Our opinion may not be used or referred to by the Company, or quoted or disclosed to any person in any matter, without our prior written consent. Notwithstanding the foregoing, if required by law, our opinion may be included in the Company's information statement or similar disclosure document with respect to the Transaction; provided that it is reproduced in full, and that any summary of, or other description of, the opinion in such information statement or other disclosure document, or other reference to Crosstree or its opinion, will be acceptable to Crosstree and its counsel in their sole discretion.

Based upon and subject to the foregoing, we are of the opinion as investment bankers that, as of the date hereof, the Consideration to be paid pursuant to the Implementation Agreement is fair, from a financial point of view, to the stockholders.

/s/ Crosstree Capital New York, LLC
Crosstree Capital New York, LLC

2,662,564 Shares of Common Stock

PROXY STATEMENT/PROSPECTUS

January 24, 2020

PROXY

OPGEN, INC.
708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878

SPECIAL MEETING OF STOCKHOLDERS – MARCH 10, 2020
PROXY SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS

The undersigned stockholder of OpGen, Inc. hereby constitutes and appoints Evan Jones and Timothy C. Dec as attorneys and proxies, with full power of substitution, to appear, attend and vote all of the shares of common stock and/or standing in the name of the undersigned at a Special Meeting of Stockholders to be held at the offices of Ballard Spahr LLP located at 1909 K Street, NW, 12th Floor, Washington, DC 20006 on March 10, 2020, beginning at 10:00 a.m., local time, and at any adjournment or adjournments thereof, upon the following:

Proposal One: To approve the business combination transaction pursuant to an Implementation Agreement dated September 4, 2019, by and among OpGen, Inc., Curetis N.V., a public company with limited liability under the Laws of the Netherlands, and Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and wholly owned subsidiary of OpGen, Inc.

For / / Against / / Abstain / /

Proposal Two: To approve the issuance or reservation for issuance of 2,662,564 shares of the Common Stock to be issued or reserved for issuance in connection with the transaction contemplated by the Implementation Agreement in accordance with the Implementation Agreement and as required by and in accordance with the applicable rules of The Nasdaq Capital Market.

For / / Against / / Abstain / /

Proposal Three: To approve a proposal to adjourn the Special Meeting to a later date or dates, if necessary, to permit further solicitation and vote of proxies if, based upon the tabulated vote at the time of the Special Meeting, OpGen, Inc. is not authorized to consummate the transactions contemplated by Proposals No. One and Two.

For / / Against / / Abstain / /

The undersigned hereby revokes any proxies as to said shares heretofore given by the undersigned and ratifies and confirms all that said proxy lawfully may do by virtue hereof.

THE SHARES REPRESENTED HEREBY WILL BE VOTED AS SPECIFIED HEREON WITH RESPECT TO THE ABOVE PROPOSALS, BUT IF NO SPECIFICATION IS MADE THEY WILL BE VOTED FOR THE PROPOSALS LISTED ABOVE. THE ABOVE-NAMED ATTORNEYS AND PROXIES SHALL HAVE THE DISCRETION TO VOTE YOUR SHARES AS TO ANY ADDITIONAL MATTER PROPERLY PRESENTED AT THE SPECIAL MEETING.

Please mark, date and sign exactly as your name appears hereon, including designation as executor, trustee, etc., if applicable, and return the proxy in the enclosed postage-paid envelope as promptly as possible. It is important to return this proxy properly signed in order to exercise your right to vote if you do not attend the meeting and vote in person. A corporation must sign in its name by the president or other authorized officer. All co-owners and each joint owner must sign.

Date: _____

_____
Signature(s)

_____
Address if different from that on envelope:

_____
Street Address

_____
City, State and Zip Code

Please check if you intend to be present at the Special Meeting: ____