2019

Annual Report

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

FORM 10-K

(Mark one)

☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

Commission file number 001-37367

OPGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**06-1614015**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
708 Quince Orchard Road, Suite 205 Gaithersburg, Maryland	**20878**
(Address of principal executive offices)	**(Zip Code)**

(240) 813-1260
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock	OPGN	Nasdaq Capital Market
Common Warrants	OPGNW	Nasdaq Capital Market

The aggregate market value of the voting common stock held by non-affiliates of the registrant as of June 30, 2019, was $6,934,767 (based upon the last reported sale price of $7.86 per share on June 28, 2019, on The Nasdaq Capital Market.

As of March 20, 2020, 11,930,236 shares of common stock of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

OPGEN, INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2019

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K for the year ended December 31, 2019 (the "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In this Annual Report, we refer to OpGen, Inc. as the "Company," "OpGen," "we," "our" or "us." All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect" or the negative version of these words and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A "Risk Factors." In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances included herein may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to complete the business combination of OpGen and Curetis;
- our liquidity and working capital requirements, including our cash requirements over the next 12 months;
- our ability to maintain compliance with the ongoing listing requirements for the Nasdaq Capital Market;
- our ability to integrate the OpGen and Curetis business if all approvals are obtained;
- receipt of regulatory clearance of our submitted 510(k) pre-market submission for our Acuitas AMR Gene Panel test for use with bacterial isolates;
- the impact of the coronavirus pandemic on our business and operations;
- the completion of our development efforts for the Acuitas AMR Gene Panel Urine test and Acuitas Lighthouse Software, and the timing of regulatory submissions;
- our ability to sustain or grow our customer base for our current research use only and rapid pathogen ID testing products;
- regulations and changes in laws or regulations applicable to our business, including regulation by the FDA;
- anticipated trends and challenges in our business and the competition that we face;
- the execution of our business plan and our growth strategy;
- our expectations regarding the size of and growth in potential markets;
- our opportunity to successfully enter into new collaborative or strategic agreements;
- 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. Any forward-looking statement made by us in this Annual Report speaks only as of the date on which it is made. We disclaim any duty to update any of these forward-looking statements after the date of this Annual Report to confirm these statements to actual results or revised expectations.

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to the risk factors described in Part I, Item 1A of this Annual Report. 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 Annual Report 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.

NOTE REGARDING TRADEMARKS

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®. All other trademarks, servicemarks or trade names referred to in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report 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.

PART I

Item 1. Business

Please refer to the Glossary at the end of this Business section for definitions or descriptions of scientific, diagnostic, healthcare, regulatory, and OpGen-specific terms used in this Annual Report.

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, 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. The issuance of the January 2020 AI letter effectively placed the Acuitas AMR Gene Panel (Isolates) 510(k) submission on hold until OpGen provided a formal response to the questions posed or a 180-day hold period ends, after which the Acuitas AMR Gene Panel (Isolates) 510(k) submission may be considered withdrawn and a second submission required. OpGen is continuing to work interactively with the FDA to finalize its formal response to the January 2020 AI letter to provide the required responses as well as answering additional questions that arose through this second interactive response review process. OpGen is continuing to work with the FDA to address additional questions that have arisen during the interactive review process. The FDA shared with OpGen a working plan to complete the FDA's review of the Acuitas AMR Gene Panel (Isolates) 510(k) submission. However, we anticipate delays to the planned timeline as a result of the ongoing coronavirus pandemic. Consequently, the anticipated timeline for the remainder of the second interactive response review, and ultimately the clearance of the Acuitas AMR Gene Panel (Isolates) diagnostic test is currently unknown, although we anticipate that the extensive review process is nearing completion.

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 I 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 of 2019 and is expected to last until the end of March 2020. We believe a successful demonstration project will lead to a statewide program. Under the demonstration project, OpGen worked 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 received approximately $1.6 million for the 15-month demonstration portion of the project, of which approximately $1.3 million was earned in 2019.

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.

Implementation Agreement with Curetis N.V.

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

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 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. 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) 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 Annual Report, the number of shares representing the Consideration would equal approximately 32.3% of the outstanding shares of OpGen common stock. The number of shares of OpGen common stock to be issued to Curetis N.V. is fixed, therefore, the percentage ownership of the Company as of the date of closing will be different.

The Company filed a Registration Statement on Form S-4 to register the Consideration, which was declared effective by the SEC on January 23, 2020. The transactions under the Implementation Agreement are subject to approval by the stockholders of the Company and MGHIF, and the shareholders and debt holders of Curetis N.V and Curetis GmbH. The Company delivered a proxy statement to its stockholders and called for a special meeting of its stockholders on March 10, 2020 to approve the transactions contemplated by the Implementation Agreement. Because a quorum was not represented at the special meeting, the stockholders present voted to adjourn the meeting in order to allow additional time for stockholders to vote on the proposals presented. Accordingly, the special meeting was adjourned to March 30, 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 Public Offering. The Company used the proceeds from the October 2019 Public Offering for the following purposes: to (1) pursue completion of the business combination transaction with Curetis; (2) provide short-term funding to Curetis under the Interim Facility to fund the Curetis Group's current operations; and (3) support research and development and regulatory activities for the Company's anticipated FDA 510(k) submissions for the Acuitas AMR Gene Panel test and the Acuitas Lighthouse Software.

On November 12, 2019, Crystal GmbH, OpGen's subsidiary, as lender, and Curetis GmbH, as borrower, entered into the Interim Facility Agreement, or the Original Interim Facility. Under the Original Interim Facility, the lender agreed to 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 with Curetis. The purpose of the loans is to provide capital to fund the operations of Curetis, including the discharge of current liabilities when due. On March 18, 2020, the lender, and borrower. entered into an Amended and Restated Interim Facility Agreement, or the Interim Facility, which amended and restated the Original Interim Facility and increased the available borrowings by the borrower to $5 million. 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 are 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. As of the year ended December 31, 2019, Curetis GmbH had borrowed approximately $2.5 million and OpGen had recognized approximately $23,000 of interest income under the Interim Facility.

On February 11, 2020, the Company entered into an At the Market Common Stock Sales Agreement, or the ATM Agreement, with H.C. Wainwright & Co., LLC, or Wainwright, pursuant to which the Company may offer and sell from time to time in an "at the market offering," at its option, up to an aggregate of $15.7 million of shares of the Company's common stock through Wainwright, as sales agent, or the 2020 ATM Offering. Pursuant to the ATM Agreement, Wainwright may sell the shares 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. Wainwright will use commercially reasonable efforts to sell the shares from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay Wainwright a commission equal to three percent (3.0%) of the gross sales proceeds of any shares sold through Wainwright in the 2020 ATM Offering, and has provided Wainwright with customary indemnification and contribution rights. The Company currently intends to use the net proceeds of the 2020 ATM Offering for the following purposes: prior to the closing of the transactions contemplated by the Implementation Agreement to (1) complete the business combination with Curetis; (2) provide short-term funding to Curetis under the Interim Facility, to fund the Curetis Group's operations, including the Unyvero LRT BAL regulatory clearance-related activities, Unyvero platform R&D activities, Ares Genetics-related R&D and business development activities with potential collaborators and distributors; and (3) fund research and development and regulatory activities in support of the Company's anticipated FDA 510(k) submissions for the Acuitas AMR Gene Panel test and the Acuitas Lighthouse Software; and, if any proceeds remain following the closing of the transactions under the Implementation Agreement, to: (4) commercialize Newco's products, with a focus on the Unyvero platform and diagnostic tests, and the Acuitas AMR Gene Panel tests; (5) support further development and commercialization of the Ares Genetics database and Acuitas Lighthouse Software; (6) fund directed efforts to the customers and collaborators of each company to introduce the products and services of Newco; (7) invest in

manufacturing and operations infrastructure to support sales of products; and (8) the balance, if any, for general corporate purposes. If the transactions under the Implementation Agreement do not close, to the extent any proceeds remain, the Company plans to use any remaining proceeds to support OpGen's operations as far as possible into 2020.

OpGen's Products and Products in Development

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.

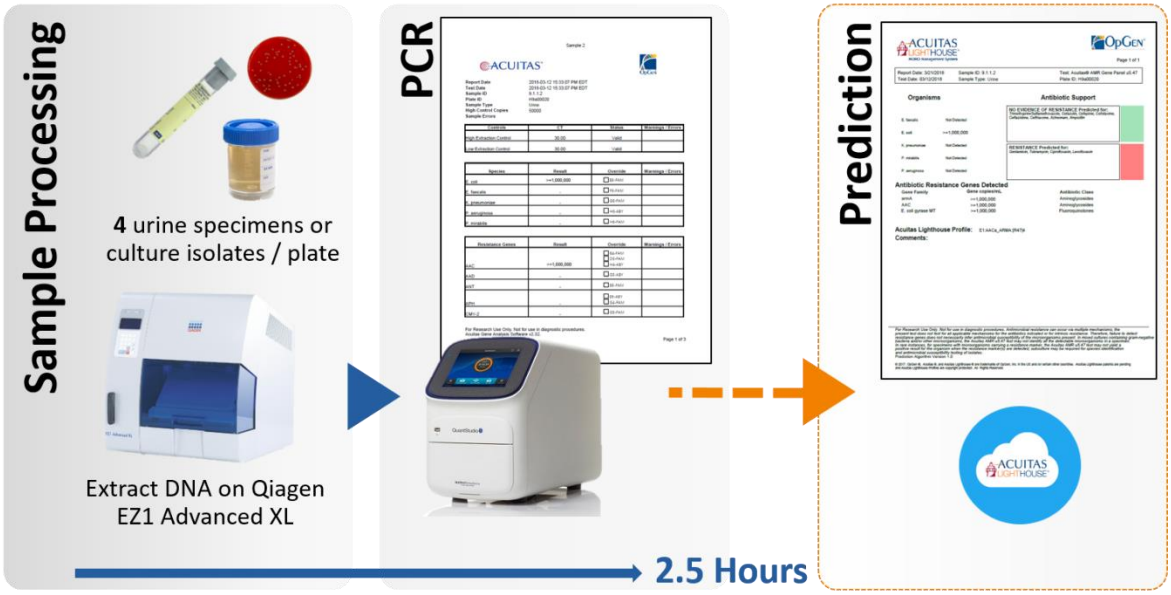
The Acuitas AMR Gene Panel is a development-stage, qualitative and semi-quantitative nucleic acid-based *in vitro* diagnostic test that is designed for simultaneous detection and identification of multiple bacterial nucleic acids and select genetic determinants of antimicrobial resistance in urine specimens 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. In the pilot phase of the Initiative, the test is contributing to the research mission by genotyping carbapenem resistant isolates from up to 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 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 is continuing to work interactively with the FDA to provide responses necessary to address questions related to the submission as well as additional questions that may arise through this second interactive response review process.

The Acuitas Lighthouse Software (RUO) manages and evaluates data that identify the most common microbial causes of cUTI and key genetic determinants of antibiotic drug resistance, based on the amplification data of gene targets extracted from urine specimens. Through analysis of this data, the Acuitas Lighthouse Software can identify five bacterial species and predict resistance to up to fourteen different antibiotics from across nine antibiotic classes including: Aminoglycosides, Carbapenems, Cephalosporins, Fluoroquinolones, Polymyxins, Penicillins, Sulfonamides, Trimethoprim and Vancomycin. The Acuitas Lighthouse Software consists of the Acuitas Lighthouse Portal, a web application; the Acuitas Lighthouse Prediction Engine, data analysis software; and draws from the Lighthouse Knowledgebase, a relational database management system; and minor supporting software components. The Acuitas Lighthouse Software (RUO) was selected by The New York State Department of Health Wadsworth Center for the genomic microbiology component of The New York State Infectious Disease Digital Health Initiative. All components of the Acuitas Lighthouse Software are hosted in a cloud-based web application that is protected by security measures. The input to Acuitas Lighthouse Software is a data file generated by processing the results from the Acuitas AMR Gene Panel (Urine) test through the Acuitas AMR Gene Panel (Urine) Gene Analysis Software. This input file indicates which gene targets were detected by the assay and is loaded into the Acuitas Lighthouse Software via an interface of the Acuitas Lighthouse Portal, accessed by the user through a web browser. The Acuitas AMR Gene Panel (Urine) Gene Analysis Software results are retained by the Acuitas Lighthouse Knowledgebase and are sent to the Acuitas Lighthouse Prediction Engine for analysis. The Acuitas Lighthouse Prediction Engine contains software implementations of data models that were derived using a training panel of thousands of bacterial isolates with detailed genotypic and phenotypic characterizations, all stored

within the Acuitas Lighthouse Knowledgebase. These models, each specific to one microbial species and antibiotic drug pairing, are used to make predictions of antibiotic resistance by analyzing the loaded input data. The results from the Acuitas Lighthouse Prediction Engine indicate whether there is evidence of resistance detected through the presence of specific genes, and if there is known intrinsic resistance to certain drugs. These final results are reported to the user via a Prediction Report and the Resistance Dashboard interface in the Acuitas Lighthouse Portal; both displays present the Acuitas Lighthouse Prediction Engine output in combination with selected input data and metadata, as well as the semi-quantitative counts of gene copies / mL for urine specimens. Our development of the Acuitas Lighthouse Software and the Acuitas AMR Gene Panel (Urine) test, thus far, has resulted from a comprehensive, multi-year effort, which remains ongoing, to help address urgent clinical needs for improved rapid antibiotic decision-making capabilities.

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



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.

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.

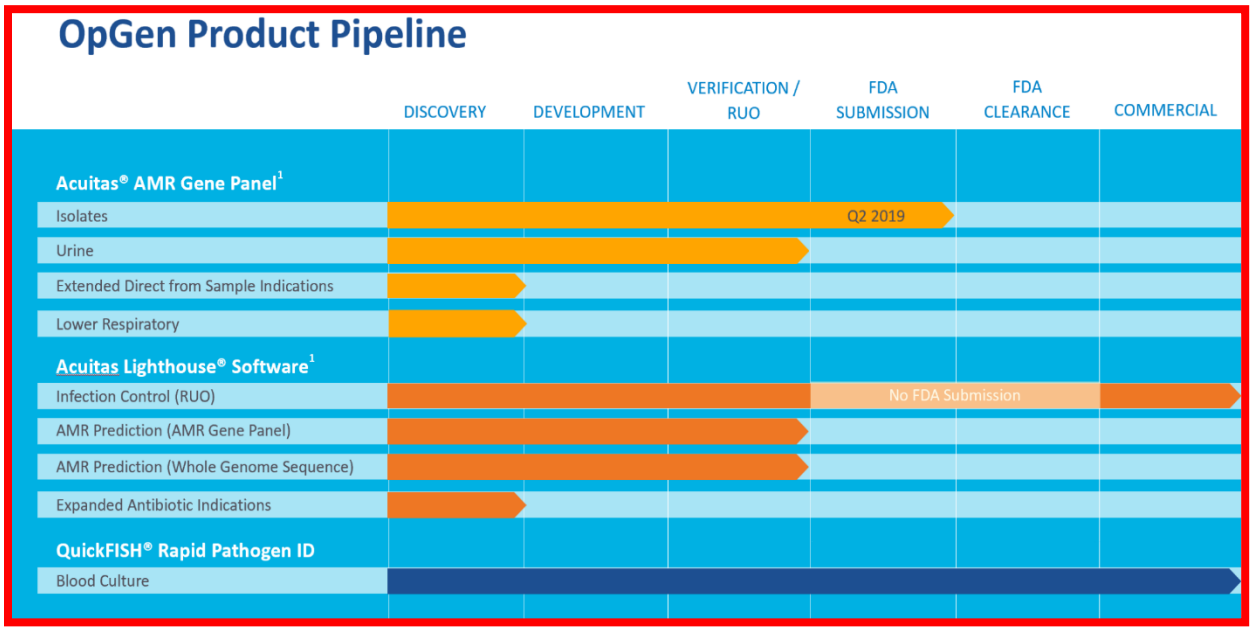
The lack of currently available treatment options and scarcity of new treatment options in development are compounding the emerging Superbug problem. It has been close to 30 years since a new class of antibiotics was developed and successfully introduced. As a result, we believe that rapid, accurate 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 the first quarter of 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, however we discontinued these efforts and began the process to dissolve the subsidiary in 2019. After completing the business combination with Curetis, 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 and commercializing the Curetis 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 2019, 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 Post Market 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, PNA FISH 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 PNA FISH and 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, 2019, we had total ownership rights to 29 U.S. patents and applications, including eight pending U.S. non-provisional patent applications, and 21 issued U.S. patents. More specifically, as of December 31, 2019, related to our FISH products, we had ownership rights to 12 U.S. patents and patent applications, including one pending U.S. non-provisional patent applications, and 11 issued U.S. patents. These issued patents begin to expire in November 2024 and will be fully expired by October 2033. As of December 31, 2019, related to our Acuitas products, we had ownership rights to four U.S. patents and patent applications, including three pending U.S. non-provisional patent applications, and one issued U.S. patent. As of December 31, 2019, related to our other products, we had ownership rights to 13 issued U.S. patents. These issued patents begin to expire in June 2026 and will be fully expired by January 2037. A majority of our issued and exclusively licensed FISH patents from Dako Denmark A/S expired over the last six years. The remaining nine exclusively licensed U.S. FISH patents expire between 2020 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.

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. 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 I, Class II or Class III. Devices deemed to pose lower risk are placed into either Class I or Class II.

Class I 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 I device, like us, to gain clearance for marketing through the 510(k) process. Many Class I devices, however, are exempt from 510(k) clearance because the level of risk is low.

Class II devices are considered higher risk devices than Class I devices. Class II 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 II 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 II devices are exempt from filing a 510(k) but in some instances, Class II devices may be required to file a Premarket Approval, or PMA, application, for example, when changes in their technology or intended use present novel risks that warrant separate review as a Class III medical device.

Class III devices are deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices for which no substantially equivalent previously cleared device exists and require a PMA before commercialization.

All medical device manufacturers must register their establishments and list their devices with the FDA. Establishment registration requires 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; by statute, the FDA has 90 days to review the pre-market notification. 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 low to moderate risk 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. FDAMA also permits 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. The De Novo classification process is generally more costly and time consuming than the 510(k) process.

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 I and Class II 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 the test uses a noninvasive sampling

method, does not introduce energy into the subject, and is not used in a diagnostic procedure without confirmation of the diagnosis by another established medically diagnostic procedure or product. 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 products classified as devices, such as ours, and 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 design 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 cannot assure you 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.

Glossary

The following scientific, healthcare, regulatory and OpGen-specific terms are used throughout this Annual Report:

"Acuitas AMR Gene Panel (Urine)" is a qualitative and semi-quantitative nucleic acid-based in vitro diagnostic test that is capable of 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.

"Acuitas Lighthouse" is our informatics platform, developed internally to provide real-time information on the MDRO status for patients and hospitals. We combine our molecular test information and microbiology test results from our customized CLIA-based tests to create Acuitas Lighthouse profiles for hospitals, health systems and communities, which we call our Acuitas Lighthouse informatics, and we are developing Acuitas Lighthouse Software for use with our Acuitas AMR Gene Panel in development. Acuitas Lighthouse profiling facilitates MDRO tracking and results can be aggregated with hospital data to provide customized reports including alerts, prevalence, trend analysis and transmission information.

"antibiotic stewardship" has been defined by the CDC to mean hospital-based programs dedicated to improving use of antibiotic therapy with the goal of optimizing the treatment of infections and reducing the adverse events associated with antibiotic use.

"CDC" means the U.S. Centers for Disease Control and Prevention.

"CMS" means the Centers for Medicare and Medicaid Services.

"CRE" means carbapenem-resistant Enterobacteriaceae, an MDRO.

"DNA sequencing" is the process of determining the precise order of nucleotides within a DNA molecule.

"epidemiologically linked" means situations where it is shown that one person is the source of an infection that spreads through contact to one or more other persons.

"ESBL" means extended spectrum beta lactamase bacteria.

"FDA" means the U.S. Food and Drug Administration.

"HAIs" means healthcare-associated infections. Such infections could arise first in the hospital or other healthcare setting, or could result from a patient, colonized with an organism, developing an active infection once admitted to the hospital or other healthcare setting.

"HIPAA" means the Federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act. HIPAA and HITECH Act are Federal laws mandating security and privacy of protected personal health information of patients.

"informatics" refers to methods, algorithms and processes for the collection, classification, storage and analysis of biochemical and biological data and information using computers, especially as applied in molecular genetics and genomics. Our focus is on acquiring such data and information related to MDROs to assist in diagnosis and screening of patients and antibiotic stewardship initiatives by acute care hospitals. When we use the term "advanced informatics," we mean informatics combined with higher levels of complexity, sophistication and subject matter expertise related to MDROs, diagnostics, antibiotic stewardship, and the development of associated analysis tools, or the novel application of existing informatics in future products or services. In this Annual Report, we also sometimes use the phrase "informatics products and services," often interchangeably with "informatics platform," to describe the Company's focus on the use of informatics and advanced informatics in its current and future product and service offerings.

"informatics platform" means a combination of software tools and analytical processes that streamline the production and analysis of informatics data. When we use the term informatics platform, we are primarily referring to Acuitas Lighthouse.

"IVD" means in vitro diagnostic.

"KPC" means Klebsiella pneumoniae Carbapenemase, an MDRO.

"MDRO" means a multidrug-resistant organism.

"PCR" means polymerase chain reaction.

"PNA" means peptide nucleic acid.

"QSR" means Quality System Regulation.

"SEC" means the U.S. Securities and Exchange Commission.

"Securities Act" means the Securities Act of 1933, as amended.

"UTI" means urinary tract infection.

Employees

As of December 31, 2019, we had 40 employees worldwide, with 39 employed in the United States and 1 employed in Denmark. There are 38 full-time employees. The 39 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.

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.

Available Information

The Company maintains a website at www.opgen.com. Our Code of Business Conduct and Ethics is available on our website. We are not incorporating our website into this Annual Report. 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, filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available free of charge on our website as soon as practicable after electronic filing of such material with, or furnishing it to, the SEC. This information may be read at the SEC website at http://www.sec.gov.

Item 1A. Risk Factors

The following are significant factors known to us that could materially harm our business, financial condition or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this Annual Report. The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, also may adversely affect our business, financial condition and operating results. If any of these risks actually occur, our business, financial condition, and operating results could suffer significantly.

Risks Related to Our Business

We have a history of losses, and we expect to incur losses for the next several years. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2019 and 2018 contains explanatory language that substantial doubt exists about our ability to continue as a going concern.

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the years ended December 31, 2019 and 2018, we had net losses of $12.4 million and $13.4 million, respectively. From our inception through December 31, 2019, we had an accumulated deficit of $174.5 million. The reports of our independent registered public accounting firm on our financial statements for the years ended December 31, 2019 and 2018 each contain explanatory language that substantial doubt exists about our ability to continue as a going concern. We completed a number of financings in 2019 and 2018, including the October 2019 Public Offering, March 2019 Public Offering, October 2018 Public Offering, February 2018 Public Offering, 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 $27.2 million. We began raising capital under the 2020 ATM Offering in February 2020. We cannot assure you that we can continue to raise the capital necessary to fund our business.

We need to raise equity capital to support our business and that of Curetis under the Interim Facility. If we cannot do so successfully, we will not be able to continue as a going concern.

We need to raise equity capital to support our business and that of Curetis under the Interim Facility. If we cannot do so successfully, we will not be able to continue as a going concern. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, the ATM Offering, 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.

We believe that current cash on hand will be sufficient to fund operations into the third quarter of 2020. In the event we are unable to successfully raise additional capital during or before the third quarter of 2020, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to immediately 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. If such sufficient financing is not received timely, we would then need to pursue a plan to license or sell assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

In July 2015, in connection with our acquisition of our subsidiary, AdvanDx, MGHIF made investments in the Company, including the $1 million MGHIF Note, secured by a security interest in substantially all of our assets, including our intellectual property assets. The debt is due to be paid in six semi-annual payments of $166,667 which began on January 2, 2019 and will end 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.

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

The proposed combination with Curetis is subject to the approval of our stockholders and MGHIF, and we cannot provide any assurance that stockholder approval will be obtained. The shareholders and debt holders of Curetis N.V. and Curetis GmbH have approved the transaction. We did not have a quorum for our special meeting of stockholders and have had to postpone the meeting until March 30, 2020. If the proposed transaction is not approved by our stockholders, we may become liable to reimburse Curetis N.V. for its expenses up to a maximum amount of $250,000. In case of termination of the Implementation Agreement in accordance with its terms, Curetis 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.

We have agreed to use a significant portion of the capital raised in the October 2019 Public Offering and in the 2020 ATM Offering to support the operations of Curetis in the period prior to the closing. This reduces the proceeds invested in OpGen's operations, which could have a negative impact on us if the proposed transaction is not consummated, or if the approval process takes longer than anticipated.

Pursuant to the Implementation Agreement, on November 12, 2019, we entered into the Interim Facility pursuant to which we have agreed to lend to Curetis GmbH up to $4 million of the proceeds of the October 2019 Public Offering and the 2020 ATM Offering to fund and support the operations, and satisfy the current obligations, of Curetis in the period prior to closing. On March 18, 2020, we entered into an Amended and Restated Interim Facility, which increased the available borrowings by Curetis GmbH to $5 million. 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.

If the transaction contemplated by the Implementation Agreement does not close, we anticipate that it will be difficult for Curetis to repay us under the Interim Facility, if at all. Any unanticipated loans under the Interim Facility, or failure to be repaid under the Interim Facility would have a material adverse effect on our financial condition.

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

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

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

If the combination with Curetis closes, we will assume the indebtedness of Curetis N.V. and Curetis. As of December 31, 2019, Curetis N.V. owed indebtedness of $1.4 million to lenders under the Curetis Convertible Notes and owed indebtedness of $20.3 million of principal (plus interest of $2.6 million) under a loan provided by the EIB. In addition, OpGen has secured indebtedness to MGHIF under the MGHIF Note. Pursuant to the Implementation Agreement, OpGen will be required to assume 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 have incurred significant transaction costs as a result of the proposed business combination transaction with Curetis, which could have a material adverse effect on our financial condition.

We have incurred 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 have been 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 the combined company.

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

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

Management and the board of directors of OpGen will change upon the consummation of the 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. Most of the current members of the management board of Curetis N.V. have experience serving on the boards of companies listed on Euronext and German prime standard companies, but not on U.S. publicly-listed companies and this could impact the transition of Newco.

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

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

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

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

- the difficulty of integrating the acquired companies, and their concepts and operations;
- the difficulty in combining our financial operations and reporting;
- the potential disruption of the ongoing businesses and distraction of our management;
- changes in our business focus and/or management;
- risks related to international operations;

- the potential impairment of relationships with employees and partners as a result of any integration of new management personnel; and
- the potential inability to manage an increased number of locations and employees.

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

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

We 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 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.

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

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

Even if we achieve significant revenues, we may not become profitable, and even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain consistently profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business or continue to pursue our growth strategy. We believe that current cash on hand will be sufficient to fund operations into the third quarter of 2020. In the event we are unable to successfully raise additional capital during or before the third quarter of 2020, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing. We have no committed sources of capital and may find it difficult to raise money on terms favorable to us or at all. The failure to obtain sufficient capital to support our operations would have an adverse effect on our business, financial condition and results of operations.

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

The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In May 2019, we filed a 510(k) submission with the FDA seeking clearance of our Acuitas AMR Gene Panel (Isolates) diagnostic test. In July 2019, we received correspondence from the FDA requesting additional information related to this filing. 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. If we cannot successfully address the questions posed by the FDA, our receipt of clearance for this product will be delayed. In addition, the time and expense needed to respond to the FDA's request for additional information may divert time and attention from our other regulatory submissions in process, which may adversely affect our strategy and ability to commercialize our diagnostic tests and bioinformatics products and services.

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

As of December 31, 2019, we had approximately $188.3 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 with Curetis is completed, we estimate that then current OpGen stockholders will own approximately 82%, and Curetis N.V. will own approximately 18% of the outstanding shares of OpGen. 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.

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

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

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

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

The current customers we are targeting for our Acuitas AMR Gene Panel and Acuitas Lighthouse Software 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. We need to provide a compelling case for the savings, patient safety and recovery, reduced length of stay and reduced costs that come from adopting our MDRO diagnosis and antibiotic stewardship products and services. If we are not able to successfully increase our customer base, 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.

In addition, if our business combination transaction with Curetis does not close, we will likely need to re-assess our strategy and targeting of customers in international markets. We have and, in the event the transaction with Curetis does not close, expect to continue to incur substantial costs in order to obtain customers in foreign markets. Accordingly, in the event the transaction does not close, we may not be able to continue target such customers in international markets.

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

It is not possible to predict the future of the emerging COVID-19 global pandemic or the development of potential tests or treatments. No assurance can be given that OpGen's or, following the closing of the proposed business combination, Curetis' products will aid in the testing or the treatment of this virus.

Curetis, the other party to the proposed business combination with OpGen, has commenced offering products for the testing for SARS-CoV-2, the causal pathogen of COVID-19. OpGen and Curetis may offer other products for testing or treatment of coronavirus. There can be no assurance that the Curetis test or any such future tests will be broadly adopted for use. OpGen and Curetis are among many companies that are trying to develop tests for coronavirus, most of whom have far greater resources than us. If one of these companies develops an effective test, our development of such tests may not significantly increase our revenues and results of operations.

The coronavirus pandemic could adversely impact our business, financial condition and results of operations.

The novel coronavirus pandemic has impacted the global economy and may impact our operations here in the United States, including the potential interruption of our clinical trial activities and our supply chain, and may impact Curetis' operations. As a result of the outbreak, we and certain of our suppliers may be affected and could experience closures and labor shortages, which could disrupt activities. We could therefore face difficulty sourcing key components necessary to produce our product candidates, which may negatively affect our clinical development activities. Even if we are able to find alternate sources for some of these components, they may cost more, which could affect our results of operations and financial position. In addition, the coronavirus outbreak could delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. In addition, healthcare providers are focused almost exclusively on dealing with the coronavirus pandemic, and may be unable to continue to participate in our activities.

At this point in time, there is significant uncertainty relating to the potential effect of the novel coronavirus on our business. As coronavirus becomes more widespread each day manufacturing closures and travel restrictions may remain or worsen, all of which would have a negative impact on our ability to operate our business, financial condition and results of operations.

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

We are developing an under three hour antibiotic resistance diagnostic product that we believe 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 such 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 approximately 47 antibiotic resistance genes to help guide clinician antibiotic therapy decisions when test results are evaluated using the Acuitas Lighthouse Software. 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, expensive and we are not assured that we will have sufficient funds to successfully complete such efforts. 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 research use only 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. We need to comply with the applicable laws and regulations regarding such other uses. Failure to comply with such laws and regulations may have a significant impact on the Company.

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

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

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

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

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

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

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- we may not achieve any milestones, or receive any milestone payments, under our collaborations, including milestones and/or payments that we expect to achieve or receive;
- the clinical trials, if any, conducted as part of these collaborations may not be successful;
- a collaborator might elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors, such as an acquisition, that diverts resources or creates competing priorities;
- we may not have access to, or may be restricted from disclosing, certain information regarding product or services candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product or services candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product or services candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product or services, which may cause collaborators to cease to devote resources to the commercialization of our product or services candidates;
- a collaborator with marketing and distribution rights to one or more of our product or services candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product or services candidates, may cause delays or termination of the research, development or commercialization of such product or services candidates, may lead to additional responsibilities for us with respect to such product or services candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to a collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product or services candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

We rely on several sole suppliers and manufacturers, including Thermo Fisher Scientific and QIAGEN, for supplying certain reagents, raw materials, supplies and substances which we use to manufacture our products. An interruption in our operations could occur if we encounter delays or difficulties in securing these items or manufacturing our products, and if we cannot, then obtain an acceptable substitute. Any such interruption or damage to third party suppliers or manufacturers for any reason, such as fire or other events beyond

our control, including as a result of natural disasters, terrorist attacks, or the occurrence of a contagious disease or illness, such as the novel coronavirus, could significantly affect our business, financial condition, results of operations and reputation.

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

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

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

We also face competition from commercial laboratories, such as Bio-Reference Laboratories, Inc., Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, Pathnostics, and EuroFins, which 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 or where our intellectual property rights are not recognized.

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

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

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

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

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

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

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

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

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

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

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

In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the U.S. 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.

Data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

The collection, use, storage, transfer, and other processing of personal data, including personal health data, regarding individuals in the European Economic Area is governed, as of May 2018, by the General Data Protection Regulation, or GDPR. The GDPR imposes several requirements on companies that process personal data, including requirements relating to the processing of health and other sensitive data, the consent of the individuals to whom the personal data relates, the information provided to the individuals regarding data processing activities, the notification of data processing obligations to the competent national data protection authorities and certain measures to be taken when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data out of the European Economic Area, including to the U.S. Failure to comply with the requirements of the GDPR, and the related national data protection laws of the European Union Member States, may result in fines and other administrative penalties. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms

ensuring compliance with the new data protection rules, including as implemented by individual countries. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any future European activities.

California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General will commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA, and clinical trial regulations, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of the CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

We cannot provide assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks may prove too great for us to reasonably bear and may adversely affect our ability to achieve profitability or maintain profitably in the future.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Securities and 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.

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 at all. In addition, following the August 2019 reverse stock split, 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.

We must maintain compliance with the Nasdaq Capital Market ongoing listing requirements, including the minimum bid price of our common stock and our stockholders' equity. If we fail to maintain such compliance, our common stock could be delisted from the Nasdaq Capital Market. If our common stock is not listed on a national securities exchange, trading in our common stock will be more limited, and would discourage investors from investing in our securities.

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.

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 December 31, 2019, 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;
- 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.

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 December 31, 2019, we had outstanding warrants to acquire 5,111,107 shares of our common stock, and stock options to purchase 9,654 shares of our common stock. The expiration of the term of such options and warrants range from January 2020 to February 2025. A significant number of such warrants are out of the money, but the holders have the right to effect a cashless exercise of such warrants. If a significant number of such warrants and stock options are exercised by the holders, the percentage of our common stock owned by our existing stockholders will be diluted.

We issued warrants to purchase an aggregate of 1,255 shares of common stock to jVen Capital and MGHIF in connection with the bridge financing transactions. These warrants must be revalued each reporting period. Such assessments involve the use of estimates that could later be found to differ materially from actual results, which could have an adverse effect on our financial condition.

In June and July 2017, we issued warrants to purchase an aggregate 1,255 shares of common stock to jVen Capital and MGHIF in connection with the bridge financing transactions. Each of these warrants has a put feature that allow the holder to put the warrants back to the Company for cash equal to the Black-Scholes value upon a change of control or fundamental transaction. The warrants are each recorded as a liability on our financial statements, and we are required to revalue each of the warrants each financial quarter. Such revaluations necessarily involve the use of estimates, assumptions, probabilities and application of complex accounting principles. Actual value at the time the warrants are exercised could vary significantly from the value assigned to such liabilities on a quarterly basis. We cannot assure you that the revaluation of the warrants will equal the value in the future and know that the actual value could be significantly different, which could have a material adverse effect on our financial condition. In addition, as these warrants will be valued based upon the Black-Scholes value, which assesses a value to the warrants even if the exercise price is below the current fair market value of the underlying security, warrant holders could get a disproportionate amount of the consideration upon a change of control or fundamental transaction under certain circumstances.

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 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.

Risks Related to Regulation of Our Business

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

We have submitted one 510(k) submission with the FDA for our Acuitas AMR Gene Panel (Isolates) test and have plans to make additional De Novo and 510(k) submissions for our Acuitas AMR Gene Panel test and for our Acuitas Lighthouse Software. Such process is complex, time consuming and expensive. For any filed 510(k) or De Novo submissions, 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.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses.

We are currently offering for sale our FDA-cleared QuickFISH and PNA FISH products, and our Acuitas AMR Gene Panel (Urine) test as an RUO test to CROs, pharmaceutical companies, hospitals and other healthcare facilities. We believe that our promotional activities for these products falls within the scope of the FDA's enforcement discretion and applicable premarket exemptions. However, the FDA could disagree and require us to stop promoting our Acuitas AMR Gene Panel (Urine) test as an RUO test, or our FDA-cleared products for unapproved or "off-label" uses unless and until we obtain FDA clearance or approval for those uses. We could be subject to regulatory or enforcement actions for any violations, including, but not limited to, the issuance of an untitled letter, a Form 483 letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products would be impaired.

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

We do not have significant experience in complying with the rules and regulations of the FDA and foreign regulatory authorities. The rapid diagnostic products 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, we and our suppliers are required to comply with FDA's QSR regulations for the manufacture, labeling, distribution and promotion of the QuickFISH and PNA FISH products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval, and with ISO regulations. 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.

We and our suppliers are also subject to periodic inspections by the FDA to determine compliance with the FDA's requirements, including primarily the QSR and medical device reporting regulations. The results of these inspections can include inspectional observations on FDA's Form 483, untitled letters, warning letters, or other forms of enforcement. Since 2009, the FDA has significantly increased its oversight of companies subject to its regulations, by hiring new investigators and stepping up inspections of manufacturing facilities. The FDA has recently also significantly increased the number of warning letters issued to companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our FDA-cleared products are ineffective or pose an unreasonable health risk, the FDA could take a number of regulatory actions, including but not limited to, preventing us from manufacturing any or all of our devices or performing laboratory testing on human specimens, which could materially adversely affect our business.

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

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from

the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

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

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

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

Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of regulated products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture.

Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. 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. 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 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.

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

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

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

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

- required compliance with existing and changing foreign health care and other regulatory requirements and laws, such as those relating to patient privacy;

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

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

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

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

Risks Related to Compliance with Healthcare and Regulations

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

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

The 2010 Health Care Reform Legislation includes the Open Payments Act (formerly referred to as the Physician Payments Sunshine Act), which, in conjunction with its implementing regulations, requires manufacturers of certain drugs, biologics, and devices that are reimbursed by Medicare, Medicaid and the Children's Health Insurance Program to report annually certain payments or "transfers of value" provided to physicians and teaching hospitals and to report annually ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. Recent amendments to the Open Payments Act expand the categories of health care providers for which reporting is required. The failure to report appropriate data accurately, timely, and

completely could subject us to significant financial penalties. Other countries and several states currently have similar laws and more may enact similar legislation.

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

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

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

- the federal Anti-Kickback Statute, which constrains certain marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent;
- federal physician self-referral laws, such as the Stark Law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral; 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.

If we or our operations, are found to be in violation of any of these laws and regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. We will monitor changes in government enforcement as we grow and expand our business. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and hurt our reputation. If we were excluded from participation in U.S. federal healthcare programs, we would not be able to receive, or to sell our tests to other parties who receive reimbursement from Medicare, Medicaid and other federal programs, and that could have a material adverse effect on our business.

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. 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. The Company also leases 12,770 square feet of space at its facility in Woburn, Massachusetts under an operating lease that expires in January 2022, and provides the Company with options to extend the lease beyond the current expiration date. Additionally, the Company leases 2,967 square feet of office space in Denmark; this lease is currently on a month-to-month basis. Rent expenses under the Company's facility operating leases for the years ended December 31, 2019 and 2018 were $862,143 and $949,244, respectively.

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.

Item 3. 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.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

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

As of December 31, 2019, there were approximately 27 stockholders of record of our common stock, which does not include stockholders that beneficially own shares held in a "nominee" or in "street" name.

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 7. 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 included elsewhere in this Annual Report. 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" included under Part I, Item 1A of this Annual Report.

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 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. The issuance of the January 2020 AI letter effectively placed the Acuitas AMR Gene Panel (Isolates) 510(k) submission on hold until OpGen provided a formal response to the questions posed or a 180-day hold period ends, after which the Acuitas AMR Gene Panel (Isolates) 510(k) submission may be considered withdrawn and a second submission required. OpGen is continuing to work interactively with the FDA to finalize its formal response to the January 2020 AI letter to provide the required responses as well as answering additional questions that arose through this second interactive response review process. OpGen is continuing to work with the FDA to address additional questions that have arisen during the interactive review process. The FDA shared with OpGen a working plan to complete the FDA's review of

the Acuitas AMR Gene Panel (Isolates) 510(k) submission. However, we anticipate delays to the planned timeline as a result of the ongoing coronavirus pandemic. Consequently, the anticipated timeline for the remainder of the second interactive response review, and ultimately the clearance of the Acuitas AMR Gene Panel (Isolates) diagnostic test is currently unknown, although we anticipate that the extensive review process is nearing completion.

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.

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 effect 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 Annual Report have been adjusted to reflect the reverse stock split.

2019 Financing Transactions

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. The following financing transactions took place during 2019:

- 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, raising gross proceeds of approximately $9.4 million and net proceeds of approximately $8.3 million. Each unit included one share of common stock and one common warrant to purchase one share of common stock at an exercise price of $2.00 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 one share of common stock at an exercise price of $2.00 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. As of December 31, 2019, all 2,109,830 pre-funded warrants issued in the October 2019 Public Offering have been exercised.
- 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.

Results of Operations for the Years Ended December 31, 2019 and 2018

Revenues

	Years Ended December 31,	
	2019	**2018**
Revenue		
Product sales	$ 2,168,179	$ 2,395,626
Laboratory services	5,435	34,665
Collaboration revenue	1,325,000	516,016
Total revenue	$ 3,498,614	$ 2,946,307

Our total revenue for the year ended December 31, 2019 increased 19%, to $3.5 million from $2.9 million, when compared to the same period in 2018. This increase is primarily attributable to:

- Product Sales: the decrease in revenue of 9% in 2019 as compared to 2018 is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products (QuickFISH and PNA FISH);
- Laboratory Services: the decrease in revenue of 84% in 2019 as compared to 2018 is a result of decreases in sales of our Acuitas test products; and
- Collaboration Revenue: the increase in collaboration revenue of 157% in 2019 as compared to 2018 is primarily the result of increased Acuitas revenue associated with our NYSDOH contract.

Operating expenses

	Years Ended December 31,	
	2019	2018
Cost of products sold	$ 911,565	$ 1,222,919
Cost of services	720,156	625,516
Research and development	5,121,168	5,677,243
General and administrative	6,252,442	7,069,315
Sales and marketing	1,464,721	1,531,556
Transaction costs	779,048	—
Impairment of right-of-use asset	520,759	—
Total operating expenses	$ 15,769,859	$ 16,126,549

The Company's total operating expenses for the year ended December 31, 2019 decreased 2%, to $15.8 million from $16.1 million, when compared to the same period in 2018. This decrease is primarily attributable to:

- Costs of products sold: expenses for the year ended December 31, 2019 decreased approximately 25% 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;
- Costs of services: expenses for the year ended December 31, 2019 increased approximately 15% when compared to the same period in 2018. The change in costs of services is primarily attributable to increased costs of services associated with our NYSDOH contract;
- Research and development: expenses for the year ended December 31, 2019 decreased approximately 10% when compared to the same period in 2018, primarily due to a decrease in expenses related to our 510(k) submission for the Acuitas AMR Gene Panel for use with bacterial isolates;
- General and administrative: expenses for the year ended December 31, 2019 decreased approximately 12% when compared to the same period in 2018, primarily due to decreased payroll and outside service costs; and
- Sales and marketing: expenses for the year ended December 31, 2019 decreased approximately 4% when compared to the same period in 2018, primarily due to reduced marketing related costs.

Other income (expense)

	Years Ended December 31,	
	2019	2018
Interest expense	$ (187,549)	$ (191,195)
Foreign currency transaction gains/(losses)	2,410	(10,431)
Change in fair value of derivative financial instruments	67	8,386
Interest and other income	9,859	5,384
Total other expense	$ (175,213)	$ (187,856)

Other expense for the year ended December 31, 2019 decreased to a net expense of $175,213 from a net expense of $187,856 in the same period of 2018. The decrease was primarily a result of a decrease in foreign currency losses and interest income recognized in 2019.

Liquidity and capital resources

At December 31, 2019, the Company had cash and cash equivalents of $2.7 million, compared to $4.6 million at December 31, 2018. The Company has funded its operations primarily through external investor financing arrangements and has raised significant funds in 2019 and 2018, including:

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 offering raised gross proceeds of approximately $9.4 million and net proceeds of approximately $8.3 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.

On October 22, 2018, the Company closed its October 2018 Public Offering of 110,000 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 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, will 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 its 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.

During the year ended December 31, 2018, the Company sold 15,912 shares of its common stock under its 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.

Sources and uses of cash

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

	Years Ended December 31,	
	2019	**2018**
Net cash used in operating activities	$ (11,505,439)	$ (11,073,997)
Net cash used in investing activities	(2,502,576)	(137,327)
Net cash provided by financing activities	12,168,146	13,845,102

Net cash used in operating activities

Net cash used in operating activities in 2019 consists primarily of our net loss of $12.4 million, reduced by certain non-cash items, including depreciation and amortization expense of $0.9 million, share-based compensation of $0.4 million, partially offset by the net change in operating assets and liabilities of $0.9 million. Net cash used in operating activities for 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 expense of $0.9 million, and 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 2019 consisted primarily of funds provided to Curetis GmbH as part of the interim facility. Net cash used in investing activities in 2018 consisted 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 2019 of $12.2 million consisted primarily of net proceeds from the October 2019 Public Offering and March 2019 Public Offering. 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 at the market offering.

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, which have been prepared in accordance with GAAP. The preparation of financial statements in conformity with 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, stock-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, estimated useful lives of long-lived assets, and the recoverability 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. 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

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.

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 December 31 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

On January 1, 2018, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASC 606"), using the modified retrospective method. 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 consolidated financial statements. Prior period amounts have not been adjusted in connection with the adoption of this standard.

On January 1, 2018, the Company adopted ASU 2016-18, *Statement of Cash Flows: Restricted Cash*, using a retrospective transition method 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 amended 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 previous accounting standards, the Company's lease portfolio consisting of operating leases were not recognized on its consolidated balance sheets. The new standard required expanded disclosures regarding leasing arrangements. The new standard was effective for the Company beginning January 1, 2019.

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.

Prior to the adoption of ASC 842, deferred rent was recorded and amortized to the extent the total minimum rental payments allocated to the period on a straight-line basis exceeded or were less than the cash payments required.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires an entity to measure and recognize expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded through net income instead of directly reducing the amortized cost of the investment under the current other-than-temporary impairment model. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company does not expect the adoption of this standard to have a significant impact on its 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 December 31, 2019 and 2018, 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, 2019; (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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, the Company is not required to provide the information required by this Item.

Item 8. Financial Statements

The Company's consolidated financial statements and the report of our independent registered public accounting firm are included in this Annual Report as indicated in Part IV, Item 15.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company's management evaluated, with the participation of the Company's principal executive and principal financial officers, the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2019. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding disclosure. Based on their evaluation, management has concluded that the Company's disclosure controls and procedures were effective as of December 31, 2019.

Changes in Internal Control over Financial Reporting

As of December 31, 2019, there have been no changes in the Company's internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal controls over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). The Company's internal control system was designed to provide reasonable assurance regarding the preparation and fair presentation of published financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of management, including the Company's Chief Executive Officer and Chief Financial Officer, the Company assessed the effectiveness of internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in its statement "Internal Control-Integrated Framework (2013)."

Based on this assessment, management has concluded that, as of December 31, 2019, internal control over financial reporting is effective based on these criteria.

This Annual Report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to the rules of the SEC that permit the Company to provide only management's report in this Annual Report.

Item 9B. Other Information

As previously reported, Crystal GmbH, OpGen's subsidiary, as lender, and Curetis GmbH, as borrower, entered into an Interim Facility Agreement, or the Original Interim Facility, on November 12, 2019. Under the Original Interim Facility, the lender agreed to 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. The purpose of the loans are to provide capital to fund the operations of Curetis, including the discharge of current liabilities when due.

On March 18, 2020, the lender and borrower entered into an Amended and Restated Interim Facility Agreement, or the Interim Facility, which amended and restated the Original Interim Facility and increased the available borrowings by the borrower to $5 million. Other than the increase to the available borrowings, the material terms of the Original Interim Facility remain in place under the Interim Facility. 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. 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 Exhibit 10.19 to this Form 10-K and is incorporated by reference herein. You are encouraged to read the Interim Facility for a complete understanding of its terms.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The Board of Directors of the Company (the "Board") are elected at the annual meeting of stockholders, and serve for a term of one year and until his or her successor is elected and qualified. Executive officers of the Company are elected by the Board, and serve for a term of one year and until their successors have been elected and qualified or until their earlier resignation or removal by the Board. There are no family relationships among any of the directors and executive officers of the Company. None of the executive officers or directors has been involved in any legal proceedings of the type requiring disclosure by the Company during the past ten years. There are no arrangements or understandings between any director or executive officer and the Company pursuant to which he or she was selected as a director.

The following table sets forth the names and ages of all directors continuing in office, director nominees and executive officers of the Company and their respective positions with the Company as of December 31, 2019:

Name	Age	Position
Directors		
Evan Jones	63	Chief Executive Officer, Director and Chairman of the Board
R. Donald Elsey	66	Director
Tina S. Nova, Ph.D.	66	Director
Misti Ushio, Ph.D.	48	Director
Other Executive Officers		
Timothy C. Dec	61	Chief Financial Officer and Corporate Secretary
Vadim Sapiro	48	Chief Information Officer

Board of Directors

The following information summarizes, for each of our 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 director:

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.

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.

Tina S. Nova, Ph.D. Dr. Nova has been a director of OpGen since April 2017. Dr. Nova is a life science industry veteran with extensive experience building and leading novel genomics- based businesses. She currently serves as president and chief executive officer of Decipher Biosciences, Inc., a molecular diagnostics company, a position she had held since August 2018. From September 2015 to July 2018, she served as president and chief executive officer of Molecular Stethoscope, Inc. Prior thereto, she served as senior vice president and general manager of Illumina's oncology business unit from July 2014 to August 2015. From March 2000 to

April 2014, Dr. Nova was a co-founder and director, president and chief executive officer of Genoptix Medical Laboratory, which was purchased by Novartis Pharmaceuticals Corporation for nearly $500 million in 2011. She has also held senior executive positions with Nanogen, Inc., Ligand Pharmaceuticals, Inc. and Hybritech, Inc. Dr. Nova currently serves on the board of directors for Arena Pharmaceuticals, Veracyte, Inc. and is vice chairman of the board of directors of Rady's Pediatric Genomics & Systems Medicine Institute. She holds a B.S. degree in Biological Sciences from the University of California, Irvine, and a Ph.D. in Biochemistry from the University of California, Riverside. Dr. Nova's qualifications and skills include her experience building and leading a number of companies in the health care and life science industry and her board experience on other public reporting companies.

Misti Ushio, Ph.D. Dr. Ushio has been a director of OpGen since March 2012. Dr. Ushio is the co-founding chief executive officer and a director of TARA Biosystems, a position she has held since February 2016. Prior thereto, she was Chief Strategy Officer and a Managing Director at Harris & Harris Group, Inc. from May 2007 to February 2016. Prior to joining Harris & Harris, Dr. Ushio worked at Merck & Co. (NYSE: MRK) for over ten years in bioprocess research & development, and was a Technology Licensing Officer at Columbia University. Dr. Ushio currently serves or has served on the boards of Accelerator-NYC, AgBiome, Enumeral Biomedical, Lodo Therapeutics, Petra Pharma, Senova Systems and SynGlyco. Dr. Ushio holds a B.S. in Chemical Engineering from Johns Hopkins University, an M.S. in Chemical Engineering from Lehigh University, and a Ph.D. in Biochemical Engineering from University College London.

Executive Officers

The following information summarizes, for each of our officers, his principal occupations and other employment for at least the last five years:

Evan Jones. See above under "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.

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.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's officers and directors and persons who own more than 10% of the Company's outstanding common stock to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and any other equity securities of the Company. Directors, officers, and greater than 10% stockholders are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file. Based solely on a review of the Company's records and written representations by the persons required to file such reports, all filing requirements of Section 16(a) were satisfied with respect to the 2019 fiscal year.

Code of Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is posted on the Corporate Governance section of our website, which is located at www.opgen.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer, we will disclose the nature of such amendment or waiver on our website or in a Current Report on Form 8-K.

Communications with the Board of Directors

Stockholders who want to communicate with members of the Board, including the independent directors, individually or as a group, should address their communications to the Board, the Board members or the Board committee, as the case may be, and send them to c/o Chair of the Audit Committee, OpGen, Inc., 708 Quince Orchard Road, Suite 205, Gaithersburg, MD 20878. The Chair of the Audit Committee will forward all such communications directly to such Board members. Any such communications may be made on an anonymous and confidential basis.

There have been no changes to the procedures by which interested parties may communicate with the Board.

Audit Committee Financial Expert

During 2019, Mr. Elsey, Dr. Nova and Dr. Ushio served on the Audit Committee, which was chaired by Mr. Elsey. The Board of Directors has determined that each member of the Audit Committee is "independent" and "financially literate" for Audit Committee purposes as such terms are defined in the rules of the SEC and the applicable rules of The NASDAQ Stock Market. During 2019, Mr. Elsey was the designated "audit committee financial expert" as defined in the rules of the SEC.

Item 11. Executive Compensation

Summary Compensation Table

This table provides disclosure, for the years ended December 31, 2019 and 2018 for the named executive officers, who are (1) any individual serving in the office of Chief Executive Officer during any part of 2019 and (2) the Company's two most highly compensated officers, other than the Chief Executive Officer, who were serving in such capacity on December 31, 2019.

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	2019	$ 425,000	$ -	$ 23,426	$ -	$ -	$ -	$448,426
Chief Executive Officer	2018	$ 351,442	$ -	$ -	$ 42,767	$ 75,000	$ -	$469,209
Timothy Dec	2019	$ 300,000	$ -	$ 15,470	$ -	$ -	$ -	$315,470
Chief Financial Officer	2018	$ 289,615	$ -	$ -	$ 24,438	$ 65,000	$ -	$379,053
Vadim Sapiro	2019	$ 300,000	$ -	$ 11,050	$ -	$ -	$ -	$311,050
Chief Information Officer	2018	$ 289,615	$ -	$ -	$ 24,438	$ 50,000	$ -	$364,053

(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 (the "Plan") during 2019 and 2018. The "Option Awards" column reflects the grant date fair value for all stock option awards granted under the 2015 Plan during 2019 and 2018, 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 2019 and 2018 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 this 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.

Employment Agreements with Our Named Executive Officers

On September 21, 2018, the Board approved a Retention Plan for Executives (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 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 (the "Executives"). The Executives include the named executive officers – Evan Jones, Timothy Dec and Vadim Sapiro.

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.

On September 24, 2018, the Company entered into an Executive Change In Control and Severance Benefits Agreement with Evan Jones and amended its Executive Change In Control and Severance Benefits Agreement (each, an "Agreement"), with each of Timothy C. Dec and Vadim Sapiro.

The Agreement with Mr. Jones was 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).

Outstanding Equity Awards at Fiscal Year-End Table—2019

The following table shows the outstanding equity awards held by the named executive officers as of December 31, 2019.

	OPTION AWARDS					STOCK AWARDS			
Name	(1) Number of Securities Underlying Unexercised Options Exercisable	(1) Number of Securities Underlying Unexercised Options Unexercisable	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	2,650	2,995.00	-	-
	348	-	-	25.00	4/24/2024	-	-	-	-
	400	-	-	305.00	10/23/2024	-	-	-	-
	1,437	96	-	675.00	4/28/2026	-	-	-	-
	110	50	-	515.00	2/23/2027	-	-	-	-
	459	591	-	80.40	1/28/2028	-	-	-	-
Timothy Dec (4)	228	-	-	3,000.00	5/4/2025	1,750	1,977.50	-	-
	100	-	-	850.00	11/10/2025	-	-	-	-
	112	8	-	775.00	6/13/2026	-	-	-	-
	93	43	-	515.00	2/23/2027	-	-	-	-
	120	-	-	147.50	8/9/2027	-	-	-	-
	263	337	-	80.40	1/23/2028	-	-	-	-
Vadim Sapiro (5)	1	-	-	3,955.00	3/23/2022	1,250	1,413	-	-
	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	-	-	-	-
	75	5	-	775.00	6/13/2026	-	-	-	-
	75	35	-	515.00	2/23/2027	-	-	-	-
	120	-	-	147.50	8/9/2027	-	-	-	-
	263	337	-	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, 2019 of $1.13 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. Mr. Jones was granted restricted stock units on May 1, 2019 (2,650). Thirty-three and one third percent (33.3%) of the entire restricted stock units award vests on the first three anniversaries of the date of grant.

(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 May 1, 2019 (1,750). Thirty-three and one third percent (33.3%) of the entire restricted stock units award vests on the first three anniversaries of the date of grant

(5) The stock option awards granted to Mr. Sapiro on March 23, 2012 (1 share), July 25, 2013 (1 share), 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 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 for 50 shares 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 May 1, 2019 (1,250). Thirty-three and one third percent (33.3%) of the entire restricted stock units award vests on the first three anniversaries of the date of grant

Director Compensation

Since May 2015, each non-employee 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 director receives an initial stock option grant to purchase 60 shares of common stock and each non-employee director receives an annual stock option grants to purchase 25 shares of common stock. All such awards are made under the 2015 Plan. The annual stock option awards may be pro-rated in the first year of service depending on when the non-employee director joins the Board. This compensation program was reviewed by the Compensation Committee in February 2017, and the determination was made to continue to the program without change.

Evan Jones, Chairman of the Board and CEO, does not receive additional compensation for service on our Board. See "**Summary Compensation Table**" for his 2019 compensation.

Compensation for the non-employee directors for the year ended December 31, 2019 was:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
R. Donald Elsey (2)	$ 34,555	14,370	-	48,925
Timothy J.R. Harris (3)	$ 16,750	-	-	16,750
Tina S. Nova (2)	$ 39,500	5,475	-	44,975
Misti Ushio (2)	$ 42,000	5,475	-	47,475

(1) The "Option Awards" column reflects the grant date fair value for all stock option and restricted stock awards granted under the 2015 Plan during 2019. 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 are included in a footnote to the Company's consolidated audited financial statements for the year ended December 31, 2019 in Item 8 of this Annual Report.

(2) As of December 31, 2019, the non-employee directors held the following vested stock options: Nova 190; and Ushio 175.

(3) Effective June 30, 2019, Timothy Harris resigned from the Board of OpGen due to other commitments.

2008 Plan

Our 2008 Stock Option and Restricted Stock Plan, as amended, or 2008 Plan, was approved by our Board and stockholders in April 2008; subsequent increases in the number of shares available for awards under the 2008 Plan were approved by our Board and stockholders in January 2009, February 2011, March 2012, December 2012, April 2014 and October 2014. A total of 57,911 shares of our common stock are reserved for issuance under the 2008 Plan.

The 2008 Plan provided for the grant of stock options and restricted stock awards. The Compensation Committee determined the time or times at which a stock option will vest or become exercisable and the terms on which such option will remain exercisable. The Compensation Committee determined the conditions and restrictions and purchase price, if any, for grants or sales or restricted stock to plan participants. The Compensation Committee may also at any time accelerate the vesting or exercisability of an award.

Under the 2008 Plan, in the event of any dissolution or liquidation of the Company, the sale of all or substantially all of the Company's assets, or the merger or consolidation of the Company where the Company is not the surviving entity or which results in the acquisition of all or substantially all of the Company's then outstanding common stock, the Compensation Committee may: (a) provide for the assumption or substitution of some or all of the outstanding awards; (b) provide for a cash-out payment; or (c) in the case there is no assumption, substitution or cash-out, provide that all awards not exercised or awards providing for the future delivery of common stock will terminate upon the closing of the transaction.

Following our 2015 Equity Incentive Plan, or 2015 Plan, becoming effective, no further grants have been or will be made under our 2008 Plan.

2015 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 grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants. The 2015 Plan was amended by the Compensation Committee in February 2017 to revise the provisions with respect to net settlement of awards in response to change in regulations, and to establish standard periods for exercise of vested stock options following termination of service events.

Administration. The Compensation Committee administers the 2015 Plan, including the determination of the recipient of an award, the number of shares or amount of cash subject to each award, whether an option is to be classified as an incentive stock option or non-qualified stock option, and the terms and conditions of each award, including the exercise and purchase prices and the vesting and duration of the award. Our Board may appoint one or more separate committees of our Board, each consisting of one or more members of our Board, to administer our 2015 Plan with respect to employees who are not subject to Section 16 of the Exchange Act. Subject to applicable law, our Board may also authorize one or more officers to designate employees, other than employees who are subject to Section 16 of the Exchange Act, to receive awards under our 2015 Plan and/or determine the number of such awards to be received by such employees subject to limits specified by our Board.

Authorized shares. Under our 2015 Plan, the aggregate number of shares of our 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 the number of shares subject to vesting restrictions under the 2008 Plan on 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 are 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 (i) 4% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year, and (ii) another lesser amount determined by our Board. As of January 1, 2020, 229,075 shares remain available for future awards under the 2015 Plan.

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. No more than 160,000 shares may be delivered upon the exercise of incentive stock options granted under the 2015 Plan.

Types of awards

Stock options. A stock option is the right to purchase a certain number of shares of stock, at a certain exercise price, in the future. Under our 2015 Plan, incentive stock options and non-qualified options must be granted with an exercise price of at least 100% of the fair market value of our common stock on the date of grant. Incentive stock options granted to any holder of more than 10% of our voting shares must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. The stock option

agreement specifies the date when all or any installment of the option is to become exercisable. Payment of the exercise price may be made in cash or, if provided for in the stock option agreement evidencing the award, (1) by surrendering, or attesting to the ownership of, shares which have already been owned by the optionee, (2) by delivery of an irrevocable direction to a securities broker to sell shares and to deliver all or part of the sale proceeds to us in payment of the aggregate exercise price, (3) by a "net exercise" arrangement, or (4) by any other form that is consistent with applicable laws, regulations and rules.

Restricted stock. Restricted stock is a share award that may be subject to vesting conditioned upon continued service, the achievement of performance objectives or the satisfaction of any other condition as specified in a restricted stock agreement. Participants who are granted restricted stock awards generally have all of the rights of a stockholder with respect to such stock, other than the right to transfer such stock prior to vesting.

Restricted stock units. Restricted stock units give recipients the right to acquire a specified number of shares of stock at a future date upon the satisfaction of certain conditions, including any vesting arrangement, established by our Compensation Committee and as set forth in a restricted stock unit agreement. Unlike restricted stock, the stock underlying restricted stock units will not be issued until the restricted stock units have vested and are settled, and recipients of restricted stock units generally will have no voting or dividend rights prior to the time the vesting conditions are satisfied and the award is settled.

Dividend equivalents. At our Compensation Committee's discretion, performance-based restricted stock or restricted stock unit awards may provide for the right to dividend equivalents. Subject to the terms of the 2015 Plan, our Compensation Committee will determine the terms and conditions of any stock unit award, which will be set forth in a stock unit agreement to be entered into between us and each recipient.

Stock appreciation rights. Stock appreciation rights typically will provide for payments to the recipient based upon increases in the price of our common stock over the exercise price of the stock appreciation right. The exercise price of a stock appreciation right will be determined by our Compensation Committee, which shall not be less than the fair market value of our common stock on the date of grant. Our Compensation Committee may elect to pay stock appreciation rights in cash or in common stock or in a combination of cash and common stock.

Performance-based awards. Awards under our 2015 Plan may be made subject to the attainment of performance goals.

Other plan features

No Transfer. Unless the agreement evidencing an award expressly provides otherwise, no award granted under the 2015 Plan may be transferred in any manner (prior to the vesting and lapse of any and all restrictions applicable to shares issued under such award), other than by will or the laws of descent and distribution, provided, however, that an incentive stock option may be transferred or assigned only to the extent consistent with Section 422 of the Code.

Adjustments. In the event of a recapitalization, stock split or similar capital transaction, our Compensation Committee will make appropriate and equitable adjustments to the number of shares reserved for issuance under the 2015 Plan, the limitations regarding the total number of shares underlying awards given to an individual participant in any calendar year, the number of shares that can be issued as incentive stock options, the number of shares subject to outstanding awards and the exercise price under each outstanding option or stock appreciation right.

Change in Control. If we are involved in a merger or other reorganization, outstanding awards will be subject to the agreement of merger or reorganization. Such agreement will provide for (1) the continuation of the outstanding awards by us if we are the surviving corporation, (2) the assumption or substitution of the outstanding awards by the surviving corporation or its parent or subsidiary, (3) immediate vesting, exercisability and settlement of the outstanding awards followed by their cancellation, or (4) settlement of the intrinsic value of the outstanding awards (whether or not vested or exercisable) in cash, cash equivalents, or equity (including cash or equity subject to deferred vesting and delivery consistent with the vesting restrictions applicable to such award or the underlying shares) followed by cancellation of such awards.

Termination or Amendment. Our Board may amend or terminate the 2015 Plan at any time, subject to stockholder approval where required by applicable law. Any amendment or termination may not materially impair the rights of holders of outstanding awards without their consent. No incentive stock option may be granted after the tenth anniversary of the date the 2015 Plan was adopted by our Board.

Effective Date. The 2015 Plan was initially adopted by our Board and subsequently approved by our stockholders in April 2015. The 2015 Plan became effective on May 4, 2015. Awards may be granted under the 2015 Plan until April 1, 2025.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The number of shares of the Company's common stock outstanding at the close of business on December 31, 2019 was 5,582,280 shares. The following table sets forth the beneficial ownership of the Company's common stock as of December 31, 2019 by each Company director and executive officer, by all directors and executive officers as a group, and by each person who owned of record, or was known to own beneficially, more than 5% of the outstanding shares of our common stock. Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act. 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 our common stock subject to options and warrants currently exercisable or exercisable within 60 days after December 31, 2019 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 the Company, as of December 31, 2019, 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 the Company. 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)	36,051	*%
R. Donald Elsey (2)	-	*
Tina S. Nova, Ph.D.(3)	190	*
Misti Ushio, Ph.D. (4)	254	*
Timothy C. Dec (5)	1,500	*
Vadim Sapiro (6)	949	*
All current Directors and Executive Officers as a group 6 individuals) (7)	38,493	*%

* 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 2,820 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) 343 shares of common stock, (ii) currently exercisable warrants to acquire an additional 204 shares of common stock, and (iii) stock options to purchase 953 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 729 shares of common stock that are currently vested or that will become vested within 60 days.

(7) See the beneficial ownership described in footnotes (1) through (6).

Employee Incentive Plans

The following table shows, as of December 31, 2019, the Company's equity compensation plans under which the Company's equity securities are authorized for issuance:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights(1)	Weighted average exercise price of outstanding options, warrants and rights(2)	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders	5,135,733	$ 12.73	5,784
Equity compensation plans not approved by security holders	—	—	—
Total	5,135,733	$ 12.73	5,784

(1) Includes 14,975 outstanding restricted stock units for which there is no exercise price.

(2) Includes the weighted-average exercise price of stock options and warrants only.

Item 13. Certain Relationships and Related Person Transactions, and Director Independence

Certain Relationships and Related Person 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 $0 and $22,603 during the years ended December 31, 2019 and 2018.

In December 2017, the Company 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, 2019 and 2018, the Company recognized $0 and $329,162 of cost of services expense related to the contract, respectively.

Compensation arrangements for our directors and named executive officers are described in Item 11 "Executive Compensation" of this Annual Report.

Policies for Approval of Related Person Transactions

We have adopted a written policy that transactions with directors, officers and holders of 5% or more of our voting securities and their affiliates, each, a related person, must be approved by our Audit Committee.

Independence of the Board of Directors Members

During 2019, the Board members were R. Donald Elsey, Timothy Harris, Evan Jones, Tina Nova, David Rubin and Misti Ushio. The Company defines "independent" as that term is defined in Rule 5605(a)(2) of the NASDAQ listing standards. For 2019, Mr. Elsey and Drs. Harris, Nova, Rubin and Ushio qualified as independent and none of them has any material relationship with the Company that might interfere with his or her exercise of independent judgment.

Item 14. Principal Accounting Fees and Services

Audit Fees

CohnReznick LLP has served as the independent registered public accounting firm of the Company since 2014. The following table presents the aggregate fees billed to the Company by CohnReznick for its audits of the Company's consolidated annual financial statements and other services for the years ended December 31, 2019 and 2018.

	2019	2018
Audit Fees (1)	$ 403,540	$ 373,096
Audit Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total Fees	$ 403,540	$ 373,096

(1) Audit Fees consist of fees billed for professional services performed by CohnReznick for the audit of our consolidated annual financial statements for the years ended December 31, 2019 and 2018, the review of our quarterly financial statements on Form 10-Q, filing of Registration Statements on Forms S-1, S-3, S-4 and S-8, and associated Consent Letters and related services that are normally provided in connection with statutory and regulatory filings or engagements.

Policy on Audit Committee Pre-Approval

Our Audit Committee has a policy in place that requires its review and pre-approval of all audit and permissible non-audit services provided by our independent registered public accounting firm. The services requiring pre-approval by the audit committee may include audit services, audit-related services, tax services and other services. All such audit and permissible non-audit services were pre-approved in accordance with this policy during the fiscal year ended December 31, 2019. The Audit Committee considers whether the provision of each non-audit service is compatible with maintaining the independence of our independent registered public accounting firm. The responsibility to pre-approve audit and non-audit services may be delegated by the Audit Committee to one or more members of the Audit Committee; provided that any decisions made by such member or members must be presented to the full Audit Committee at its next scheduled meeting.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements.

The consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the years then ended, the related notes to the consolidated financial statements and the report of CohnReznick LLP, independent registered public accounting firm, are filed herewith following the signature page.

(a)(2) Financial Statement Schedules.

Not applicable.

(a)(3) Exhibits: See below

(b) Exhibits

EXHIBIT INDEX

Exhibit Number	Description
2.1	Implementation Agreement, dated as of September 4, 2019, by and among Curetis N.V., Crystal GmbH, and OpGen (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on September 4, 2019)
3.1.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of Current Report on Form 8-K, File No. 001-37367, filed on May 13, 2015)
3.1.2	Certificate of Correction to Amended and Restated Certificate of Incorporation of the Registrant, dated June 6, 2016 (incorporated by reference to Exhibit 3.1 of Current Report on Form 8-K, filed on June 6, 2016)
3.1.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant dated and filed with the Delaware Secretary of State on January 17, 2018 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on January 17, 2018)
3.1.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of OpGen, Inc., filed with the Secretary of the State of Delaware on August 28, 2019 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on August 28, 2019)
3.4	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Form S-1, File No. 333-202478, filed on March 3, 2015)
4.1 *	Form of Common Stock Certificate of the Registrant
4.2	Form of 2015 Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.6 of Form S-1/A, File No. 333-202478, filed on March 20, 2015)
4.3	Form of Underwriters' Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.2 of Current Report on Form 8-K, File No. 001-37367, filed on May 13, 2015)
4.4	Form of Warrant to Purchase Common Stock (issued to jVen Capital, LLC and Merck Global Health Innovation Fund) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K Amendment No. 2, filed on July 10, 2017)
4.5	Form of Offered Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.8 of Form S-1/A, File No. 333-202478, filed on April 23, 2015)
4.6	Form of 2016 Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.1 of Current Report on Form 8-K, filed on May 17, 2016)
4.7	Form of Common Stock Purchase Warrant for July 2017 Public Offering (incorporated by reference to Exhibit 4.4 to the Registrants Form S-1, Amendment No. 2, File No. 333-218392, filed on July 11, 2017)
4.8	Form of Placement Agent Warrant for July 2017 Public Offering (incorporated by reference to Exhibit 4.5 to the Registrants Form S-1, File No. 333-218392, filed on July 11, 2017)

Exhibit Number	Description
4.9	Form of Common Stock Purchase Warrant for February 2018 Public Offering (incorporated by reference to Exhibit 4.3 to the Registrants Form S-1/A, File No. 333-222140, filed on January 31, 2018)
4.10	Form of Placement Agent Warrant for February 2018 Public Offering (incorporated by reference to Exhibit 4.5 to the Registrants Form S-1/A, File No. 333-222140, filed on January 31, 2018)
4.11	Form of Underwriter's Warrant for October 2019 Public Offering (incorporated by reference to Exhibit 4.10 to the Registrants Form S-1/A, File No. 333-233775, filed on October 11, 2019)
4.12	Form of Common Stock Purchase Warrant for October 2019 Public Offering (incorporated by reference to Exhibit 4.11 to the Registrants Form S-1/A, File No. 333-233775, filed on October 11, 2019)
4.13*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
10.1	Lease Agreement, dated as of June 30, 2008, between the Registrant and ARE-708 Quince Orchard, LLC (the "Landlord") (incorporated by reference to Exhibit 10.1 of Form S-1/A, file No. 333-202478, filed March 3, 2015)
10.1.1	First Amendment to Lease, dated as of April 4, 2011, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1.1 of Form S-1, File No. 333-202478, filed March 3, 2015)
10.1.2	Second Amendment to Lease Agreement, dated as of August 15, 2012, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1.2 of Form S-1, File No. 333-202478, filed March 3, 2015)
10.1.3	Third Amendment to Lease, dated as of December 30, 2013, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1.3 of Form S-1, File No. 333-202478, filed March 3, 2015)
10.1.4	Fourth Amendment to Lease Agreement, dated as of March 21, 2014, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.4 of Form S-1, File No. 333-202478, filed March 3, 2015)
10.1.5	Fifth Amendment to Lease Agreement, dated as of March 20, 2015, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1.5 of Form S-1, Amendment No. 1, File No. 333-202478, filed on March 20, 2015)
10.1.6	Sixth Amendment to Lease Agreement (and Amendment to Reimbursement Agreement), dated as of April 30, 2015, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1.6 of Form S-1, Amendment No. 8, File No. 333-202478, filed on May 1, 2015)
10.1.7	Seventh Amendment to Lease Agreement, dated as of June 30, 2015, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1 of Current Report on Form 8-K, filed on July 7, 2015)
10.1.8	Eighth Amendment to Lease Agreement, dated September 8, 2015, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.6 of Quarterly Report on Form 10-Q, filed on November 13, 2015)

Exhibit Number	Description
10.2	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.2 of Form S-1, File No. 333-202478, filed on March 3, 2015)
10.3	2015 Equity Incentive Plan, as amended and restated on March 29, 2018 (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 29, 2018)
10.4 !	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.16 to the Registrant's Form S-1, Amendment No. 2, File No. 333-202478, filed on April 6, 2015)
10.5	Warrant Agreement, dated as of May 8, 2015, between the Registrant and Philadelphia Stock Transfer, Inc., as warrant agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 13, 2015)
10.6.1 !	Form of Stock Option Agreement under the 2015 Equity Incentive Plan for employees and consultants (incorporated by reference to Exhibit 10.9.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 24, 2017)
10.6.2 !	Form of Stock Option Agreement under the 2015 Equity Incentive Plan for non-employee directors (initial grant) (incorporated by reference to Exhibit 10.9.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 24, 2017)
10.6.3 !	Form of Stock Option Agreement under the 2015 Equity Incentive Plan for non-employee directors (annual grant) (incorporated by reference to Exhibit 10.9.3 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 24, 2017)
10.7 !	Form of Restricted Stock Unit Award Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed March 24, 2017)
10.8	Common Stock and Note Purchase Agreement, dated as of July 14, 2015, between the Registrant and Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 16, 2015)
10.9	Senior Secured Promissory Note, dated as of July 14, 2015, between the Registrant and Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on July 16, 2015)
10.9.1	Second Amended & Restated Senior Secured Promissory Note, dated June 28, 2017, by and between the Registrant and Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, Amendment No. 1, filed on June 28, 2017)
10.9.2	Allonge, dated June 11, 2018, to the Second Amended and Restated Senior Secured Promissory Note, dated June 28, 2017, with a principal amount of $1,000,000 issued by OpGen, Inc. to Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on June 11, 2018)
10.10 !	Stock Option Award Agreement, dated April 28, 2016, by and between the Registrant and Evan Jones (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed on August 11, 2016)
10.11 !	Executive Change In Control and Severance Benefits Agreement, dated September 24, 2018 between OpGen, Inc. and Evan Jones (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on September 25, 2018)
10.12 !	Executive Change In Control and Severance Benefits Agreement, dated September 24, 2018 between OpGen, Inc. and Timothy C. Dec (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed on September 25, 2018)
10.13 !	Executive Change In Control and Severance Benefits Agreement, dated September 24, 2018 between OpGen, Inc. and Vadim Sapiro (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed on September 25, 2018).
10.14 !	OpGen, Inc. Retention Plan for Executives (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 25, 2018)
10.15	Underwriting Agreement, dated October 23, 2019, by and between OpGen, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K, filed on October 28, 2018)

Exhibit Number	Description
10.16	Interim Facility Agreement, dated as of November 11, 2019, by and between Curetis GmbH, as Borrower, and Crystal GmbH, a wholly owned subsidiary of the Registrant, as Lender (incorporated by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-4, File No. 333-234657, filed on November 12, 2019)
10.17	At the Market Offering Agreement, by and between OpGen, Inc. and H.C. Wainwright & Co., LLC dated February 11, 2020 (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K, filed on February 12, 2020)
10.18	Assignment of the Agreement for the Issuance of and Subscription to Notes Convertible into Shares, dated February 24, 2020, among OpGen, Inc., YA II PN, LTD, and Curetis N.V. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 28, 2020)
10.19*	Amended and Restated Interim Facility Agreement, dated as of March 18, 2020, by and among Curetis GmbH, as Borrower, Crystal GmbH, a wholly owned subsidiary of the Registrant, as Lender and Curetis N.V.
21.1 *	Subsidiaries of the Registrant
23.1 *	Consent of CohnReznick LLP
31.1 *	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2 *	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)
32.1 *	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101 *	Interactive data files pursuant to Rule 405 of Regulation S-T; (i) the Balance Sheets, (ii) the Statements of Operations and Comprehensive Loss, (iii) the Statements of Stockholders' Equity, (iv) Statements of Cash Flows and (v) the Notes to the Financial Statements

* Filed herewith
! Denotes management compensation plan or contract

(c) Not applicable.

Item 16. Form 10-K Summary

The Company has chosen not to include a summary of this Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

OPGEN, INC.

By: /s/ Evan Jones
Evan Jones
Chief Executive Officer

Date: March 23, 2020

By: /s/ Timothy C. Dec
Timothy C. Dec
Chief Financial Officer

Date: March 23, 2020

POWER OF ATTORNEY

We, the undersigned officers and directors of OpGen, Inc., hereby severally constitute and appoint Evan Jones and Timothy C. Dec, our true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution in her or him for her or him and in her or his name, place and stead, and in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as she or he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or her or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Evan Jones Evan Jones	Chief Executive Officer and Director (principal executive officer)	March 23, 2020
/s/ Timothy C. Dec Timothy C. Dec	Chief Financial Officer (principal financial officer and principal accounting officer)	March 23, 2020
/s/ R. Donald Elsey R. Donald Elsey	Director	March 23, 2020
/s/ Tina S. Nova Tina Nova	Director	March 23, 2020
/s/ Misti Ushio Misti Ushio	Director	March 23, 2020

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OPGEN, INC.

Index to Consolidated Financial Statements

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, 2019 and 2018, 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, 2019 and 2018, 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
March 23, 2020

OpGen, Inc.
Consolidated Balance Sheets
As of December 31,

	2019	2018
Assets		
Current assets		
Cash and cash equivalents	$ 2,708,223	$ 4,572,487
Accounts receivable, net	567,811	373,858
Inventory, net	473,030	543,747
Note receivable	2,521,479	—
Prepaid expenses and other current assets	396,760	292,918
Total current assets	**6,667,303**	**5,783,010**
Property and equipment, net	130,759	1,221,827
Finance lease right-of-use assets, net	958,590	—
Operating lease right-of-use assets	1,043,537	—
Goodwill	600,814	600,814
Intangible assets, net	817,550	1,085,366
Other noncurrent assets	203,271	259,346
Total assets	**$ 10,421,824**	**$ 8,950,363**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,056,035	$ 1,623,751
Accrued compensation and benefits	855,994	1,041,573
Accrued liabilities	1,046,661	902,019
Deferred revenue	9,808	15,824
Short-term notes payable	373,599	398,595
Short-term finance lease liabilities	579,030	399,345
Short-term operating lease liabilities	1,017,414	—
Total current liabilities	**4,938,541**	**4,381,107**
Deferred rent	—	162,919
Note payable	329,456	660,340
Warrant liability	—	67
Long-term finance lease liabilities	313,263	437,189
Long-term operating lease liabilities	547,225	—
Total liabilities	**6,128,485**	**5,641,622**
Commitments (Note 9)		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.01 par value; 50,000,000 shares authorized; 5,582,280 and 432,286 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	55,823	4,323
Additional paid-in capital	178,779,814	165,396,036
Accumulated deficit	(174,524,983)	(162,078,525)
Accumulated other comprehensive loss	(17,315)	(13,093)
Total stockholders' equity	**4,293,339**	**3,308,741**
Total liabilities and stockholders' equity	**$ 10,421,824**	**$ 8,950,363**

See accompanying notes to consolidated financial statements.

OpGen, Inc.
Consolidated Statements of Operations and Comprehensive Loss
For The Years Ended December 31,

	2019	2018
Revenue		
Product sales	$ 2,168,179	$ 2,395,626
Laboratory services	5,435	34,665
Collaboration revenue	1,325,000	516,016
Total revenue	**3,498,614**	**2,946,307**
Operating expenses		
Cost of products sold	911,565	1,222,919
Cost of services	720,156	625,516
Research and development	5,121,168	5,677,243
General and administrative	6,252,442	7,069,315
Sales and marketing	1,464,721	1,531,556
Transaction costs	779,048	—
Impairment of right-of-use asset	520,759	—
Total operating expenses	**15,769,859**	**16,126,549**
Operating loss	**(12,271,245)**	**(13,180,242)**
Other (expense) income		
Interest and other income, net	9,859	5,384
Interest expense	(187,549)	(191,195)
Foreign currency transaction gains/(losses)	2,410	(10,431)
Change in fair value of derivative financial instruments	67	8,386
Total other expense	**(175,213)**	**(187,856)**
Loss before income taxes	**(12,446,458)**	**(13,368,098)**
Provision for income taxes	—	—
Net loss	**$ (12,446,458)**	**$ (13,368,098)**
Net loss per common share - basic and diluted	**$ (7.70)**	**$ (44.49)**
Weighted average shares outstanding - basic and diluted	1,616,939	300,453
Net loss	$ (12,446,458)	$ (13,368,098)
Other comprehensive (loss)/income - foreign currency translation	(4,222)	12,807
Comprehensive loss	**$ (12,450,680)**	**$ (13,355,291)**

See accompanying notes to consolidated financial statements.

OpGen, Inc.
Consolidated Statements of Stockholders' Equity

	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	295,615	2,956	—	—	13,527,447	—	—	13,530,403
At the market offering, net of offering costs	15,912	159	—	—	597,583	—	—	597,742
Issuance of RSUs	283	3	—	—	(3)	—	—	—
Stock compensation expense	—	—	—	—	862,281	—	—	862,281
Stock cancellation	(2)	—	—	—	—	—	—	—
Interest settlement in common stock	7,212	72	—	—	272,537	—	—	272,609
Foreign currency translation	—	—	—	—	—	12,807	—	12,807
Net loss	—	—	—	—	—	—	(13,368,098)	(13,368,098)
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	5,150,000	51,500	—	—	13,010,908	—	—	13,062,408
Issuance of RSUs	12	—	—	—	—	—	—	—
Stock compensation expense	—	—	—	—	372,870	—	—	372,870
Stock cancellation	(18)	—	—	—	—	—	—	—
Foreign currency translation	—	—	—	—	—	(4,222)	—	(4,222)
Net loss	—	—	—	—	—	—	(12,446,458)	(12,446,458)
Balances at December 31, 2019	**5,582,280**	**$ 55,823**	**—**	**—**	**$178,779,814**	**$ (17,315)**	**$(174,524,983)**	**$ 4,293,339**

See accompanying notes to consolidated financial statements.

OpGen, Inc.
Consolidated Statements of Cash Flows
Years Ended December 31,

	2019	2018
Cash flows from operating activities		
Net loss	$ (12,446,458)	$ (13,368,098)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	921,379	730,884
Noncash interest expense	13,158	133,802
Noncash interest income	(21,479)	—
Stock compensation expense	372,870	862,281
Loss (gain) on sale of equipment	9,904	(5,253)
Change in fair value of warrant liability	(67)	(8,386)
Impairment of right-of-use asset	520,759	—
Changes in operating assets and liabilities:		
Accounts receivable	(195,019)	432,814
Inventory	70,286	(11,273)
Other assets	577,193	486
Accounts payable	(503,516)	89,493
Accrued compensation and other liabilities	(818,433)	77,871
Deferred revenue	(6,016)	(8,618)
Net cash used in operating activities	**(11,505,439)**	**(11,073,997)**
Cash flows from investing activities		
Note receivable	(2,500,000)	—
Purchases of property and equipment	(31,826)	(147,767)
Proceeds from sale of equipment	29,250	10,440
Net cash used in investing activities	**(2,502,576)**	**(137,327)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	4,782,509	3,400,013
Proceeds from issuance of units and exercises of pre-funded warrants, net of selling costs	8,279,899	10,728,131
Proceeds from debt, net of issuance costs	470,519	381,253
Payments on debt	(828,850)	(371,573)
Payments on finance lease obligations	(535,931)	(292,722)
Net cash provided by financing activities	**12,168,146**	**13,845,102**
Effects of exchange rates on cash	(3,735)	12,878
Net (decrease) increase in cash, cash equivalents and restricted cash	(1,843,604)	2,646,656
Cash, cash equivalents and restricted cash at beginning of year	4,737,207	2,090,551
Cash, cash equivalents and restricted cash at end of year	**$ 2,893,603**	**$ 4,737,207**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 187,359	$ 57,393
Supplemental disclosures of noncash investing and financing activities:		
Shares issued to settle obligations	$ —	$ 272,610
Right-of-use assets acquired through finance leases	$ 528,413	$ 706,778
Conversion of accounts payable to finance lease	$ 63,600	$ 156,775

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 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.

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. Additionally, following receipt of approval from stockholders at a special meeting of stockholders held on August 22, 2019, the Company filed an additional 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 shares. All share amounts and per share prices in this Annual Report have been adjusted to reflect the reverse stock splits.

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.

Pursuant to the Implementation Agreement, OpGen has 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 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 and (b) 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.

The Company filed a Registration Statement on Form S-4 to register the Consideration which was declared effective by the U.S. Securities and Exchange Commission on January 23, 2020. The transactions under the Implementation Agreement are subject to approval by the stockholders of the Company and MGHIF, and the shareholders and debt holders of Curetis N.V and Curetis GmbH. The Company delivered a proxy statement to its stockholders and held a special meeting of its stockholders on March 10, 2020 to approve the transactions contemplated by the Implementation Agreement. Because a quorum was not represented at the special meeting, the stockholders present voted to adjourn the special meeting in order to allow additional time for stockholders to vote on the proposal. Accordingly, the special meeting was adjourned to March 30, 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 $10,000,000 of gross interim equity financing to support the continuing operations of both the Company and Curetis, and to lend funds to Curetis following such offering (See Note 13 – Interim Facility). The October 2019 Public Offering was such interim equity financing.

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 28, 2019, the Company closed a public offering (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, raising gross proceeds of approximately $9.4 million and net proceeds of approximately $8.3 million. Each unit included one share of common stock and one common warrant to purchase one share of common stock at an exercise price of $2.00 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 one share of common stock at an exercise price of $2.00 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. As of December 31, 2019, all 2,109,830 pre-funded warrants issued in the October 2019 Public Offering have been exercised.
- 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 110,000 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 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. As of April 19, 2018, all pre-funded warrants issued in the February 2018 Public Offering have been exercised.

- 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. 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.

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. 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 third quarter of 2020. 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 third 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

The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The consolidated financial statements consolidate the operations of all controlled subsidiaries; all intercompany activity is eliminated.

Reclassification

Certain prior period amounts in the consolidated statements of cash flows have been reclassified to conform to the current period presentation. $3.4 million was reclassified from "Proceeds from issuance of units and exercises of pre-funded warrants, net of selling costs" to "Proceeds from issuance of common stock, net of issuance costs" There is no change to consolidated operating loss, net loss or cash flows as a result of this change in classification.

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, 2019 and 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 United States 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 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.

For additional fair value disclosures, see Note 14.

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, 2019 and 2018, the Company had funds totaling $185,380 and $164,720, 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 $20,753 and $18,332 as of December 31, 2019 and 2018, respectively.

At December 31, 2019, the Company had accounts receivable from one customer which individually represented 44% of total accounts receivable. At December 31, 2018, the Company had accounts receivable from one customer which individually represented 12% of total accounts receivable. For the year ended December 31, 2019, revenue earned from one customer represented 38% of total revenues. For the year ended December 31, 2018, revenue earned from one customer represented 17% 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,	
	2019	2018
Raw materials and supplies	$ 315,542	$ 368,438
Work-in process	35,080	58,402
Finished goods	122,408	116,907
Total	$ 473,030	$ 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 $92,454 and $71,270 at December 31, 2019 and 2018, 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 $186,244 and $463,068 for the years ended December 31, 2019 and 2018, respectively. Property and equipment consisted of the following at December 31, 2019 and 2018:

	December 31, 2019	2018
Laboratory and manufacturing equipment	$ 3,310,290	$ 4,829,323
Office furniture and equipment	631,774	700,299
Computers and network equipment	1,469,534	1,520,713
Leasehold improvements	745,800	745,800
	6,157,398	7,796,135
Less accumulated depreciation	(6,026,639)	(6,574,308)
Property and equipment, net	$ 130,759	$ 1,221,827

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, 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 lease may not be recoverable. As a result, the Company recorded an impairment charge of $520,759 during the year ended December 31, 2019.

Intangible assets and goodwill

Intangible assets and goodwill as of December 31, 2019 and 2018 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, 2019 and 2018:

	December 31, 2019			December 31, 2018	
	Cost	Accumulated Amortization	Net Balance	Accumulated Amortization	Net Balance
Trademarks and tradenames	$ 461,000	$ (205,887)	$ 255,113	$ (159,783)	$ 301,217
Developed technology	458,000	(292,170)	165,830	(226,746)	231,254
Customer relationships	1,094,000	(697,393)	396,607	(541,105)	552,895
	$ 2,013,000	$(1,195,450)	$ 817,550	$ (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 $267,816 for each of the years ended December 31, 2019 and 2018. Expected amortization of intangible assets for each of the next five fiscal years is as follows.

Year Ending December 31,	
2020	$ 267,816
2021	267,816
2022	165,117
2023	46,104
2024	46,104
2025	24,593
Total	$ 817,550

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, 2019 and 2018, 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 2019, 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 December 31 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, 2019, 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, fees paid to consultants and outside service partners.

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. 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 $188,282,298 and $178,163,456 at December 31, 2019 and 2018, 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 5.1 million shares and 0.2 million shares as of December 31, 2019 and 2018, respectively.

Adopted accounting pronouncements

On January 1, 2018, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASC 606"), using the modified retrospective method. 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 guidance did not have a material impact on the Company's consolidated financial statements. Prior period amounts have not been adjusted in connection with the adoption of this standard.

On January 1, 2018, the Company adopted ASU 2016-18, *Statement of Cash Flows: Restricted Cash*, using a retrospective transition method 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 consolidated statements of cash flows:

	December 31, 2019	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 2,708,223	$ 4,572,487	$ 1,847,171
Restricted cash	185,380	164,720	243,380
Total cash, cash equivalents and restricted cash in the consolidated statements of cash flows	$ 2,893,603	$ 4,737,207	$ 2,090,551

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASC 842"), which amended 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 previous accounting standards, the Company's lease portfolio consisting of operating leases were not recognized on its consolidated balance sheets. The new standard required expanded disclosures regarding leasing arrangements. The new standard was effective for the Company beginning January 1, 2019.

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.

Prior to the adoption of ASC 842, deferred rent was recorded and amortized to the extent the total minimum rental payments allocated to the period on a straight-line basis exceeded or were less than the cash payments required.

Recently issued accounting standards

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires an entity to measure and recognize expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded through net income instead of directly reducing the amortized cost of the investment under the current other-than-temporary impairment model. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company does not expect the adoption of this standard to have a significant impact on its 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:

	Years Ended December 31, 2019	2018
Product sales	$ 2,168,179	$ 2,395,626
Laboratory services	5,435	34,665
Collaboration revenue	1,325,000	516,016
Total revenue	$ 3,498,614	$ 2,946,307

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 December 31, 2019	$	9,808

Contract Assets

The Company had no contract assets as of December 31, 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

The Company had no unsatisfied performance obligations related to its contracts with customers at December 31, 2019.

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 is deferred and amortized as incremental expense over the term of the MGHIF Note.

Note 6 - Debt

As of December 31, 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 $40,000 with a final payment scheduled for May 2020. The Company's outstanding long-term debt as of December 31, 2019 consisted of approximately $329,000 due under the MGHIF Note, net of discounts and financing costs (see Note 5 "MGHIF Financing"). 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. 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 $187,549 and $191,195 for the years ended December 31, 2019 and 2018, respectively.

Note 7 - Stockholders' Equity

As of December 31, 2019, the Company has 50,000,000 shares of authorized common shares and 5,582,280 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 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.

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. Additionally, following receipt of approval from stockholders at a special meeting of stockholders held on August 22, 2019, the Company filed an additional 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 shares. All share amounts and per share prices in this Annual Report have been adjusted to reflect the reverse stock splits.

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 110,000 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.

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 offering raised gross proceeds of approximately $9.4 million and net proceeds of approximately $8.3 million. As of December 31, 2019, the 2,109,830 pre-funded warrants issued in the October 2019 Public Offering have been exercised.

In connection with the October 2019 Public Offering, the Company issued to its placement agent warrants to purchase 235,000 shares of common stock. The warrants issued to the placement agent have an exercise price of $2.60 per share and are exercisable for five years.

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) 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 December 31, 2019, 5,784 shares remain available for issuance under the 2015 Plan.

For the years ended December 31, 2019 and 2018, the Company recognized stock compensation expense as follows:

	Years Ended December 31,	
	2019	2018
Cost of services	$ 2,781	$ 964
Research and development	74,841	241,122
General and administrative	269,292	574,244
Sales and marketing	25,956	45,951
	$ 372,870	$ 862,281

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, 2019, the Company had unrecognized expense related to its stock options of $0.2 million, which will be recognized over a weighted average period of 1.3 years.

A summary of the status of options granted is presented below as of and for the years ended December 31, 2019 and 2018:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2018	6,970	$ 623.20	8.3	$ 37,339
Granted	4,790	$ 76.80		
Exercised	—	$ —		
Forfeited	(941)	$ 239.60		
Expired	(241)	$ 1,122.40		
Outstanding at December 31, 2018	10,578	$ 411.60	7.6	$ 522
Granted	—	$ —		
Exercised	—	$ —		
Forfeited	(302)	$ 222.17		
Expired	(622)	$ 269.87		
Outstanding at December 31, 2019	9,654	$ 418.10	8.0	$ —
Vested and expected to vest	9,654	$ 418.10	8.0	$ —
Exercisable at December 31, 2019	—	$ —	—	$ —

The total fair value of options vested in the years ended December 31, 2019 and 2018 was $375,789 and $930,921, 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:

	Years Ended December 31,	
	2019	2018
Annual dividend	—	—
Expected life (in years)	—	5.25 - 6.25
Risk free interest rate	—	2.5 - 2.9%
Expected volatility	—	46.0 - 49.6%

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, 2019 and 2018:

	Number of Options	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2018	295	$ 623.20
Granted	—	—
Vested	(283)	$ 178.60
Forfeited	—	—
Unvested at December 31, 2018	12	$ 623.20
Granted	17,150	$ 8.77
Vested	(12)	$ 623.20
Forfeited	(2,175)	$ 8.80
Unvested at December 31, 2019	14,975	$ 8.76

As of December 31, 2019, there was approximately $96,000 of unrecognized compensation cost related to restricted stock units, which is expected to be recognized over a weighted average period of 2.3 years.

Stock purchase warrants

At December 31, 2019 and 2018, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at December 31, 2019 (1)	Outstanding at December 31, 2018 (1)
November 2009	$ 3,955.00	November 2019	—	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	6,697	6,697
May 2016	$ 656.20	May 2021	9,483	9,483
June 2016	$ 656.20	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	$ 81.25	February 2023	9,232	9,232
February 2018	$ 65.00	February 2023	92,338	92,338
October 2019	$ 2.00	October 2024	4,700,000	—
October 2019	$ 2.60	October 2024	235,000	—
			5,111,107	176,132

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 August 22, 2019 were rounded up to the next whole share of common stock on a holder by holder basis.

Note 8 - Income Taxes

At December 31, 2019 and 2018, the Company had net deferred tax assets of $54,359,488 and $52,348,036, 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, 2019 and 2018 have been offset by a valuation allowance of $54,359,488 and $52,348,036, 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, 2019 and 2018 are as follows:

	December 31, 2019	2018
Deferred tax assets:		
NOL carryforward	$ 51,247,762	$ 49,480,731
R&E credit carryforward	2,559,479	2,559,479
Share-based compensation	325,571	329,796
Inventory reserve	23,213	19,068
Depreciation	1,754	—
Interest expense	95,077	51,152
Accruals and other	286,692	284,662
Total deferred tax assets	54,539,548	52,724,888
Valuation allowance	(54,359,488)	(52,348,036)
Deferred tax liabilities:		
Intangible assets	(180,060)	(256,011)
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:

	2019	2018
Federal income tax benefit at statutory rates	21.0%	21.0%
Permanent adjustment	(1.9)%	(1.4)%
Provision to return adjustment	0.4%	(0.2)%
State income tax benefit, net of Federal benefit	4.4%	(6.4)%
Tax reform impact	—	—
Change in valuation allowance	(23.9)%	(13.0)%
Change in state tax rates and other	—	—
	0.0%	0.0%

The Company has federal NOL carryforwards of $188,282,298 and $178,163,456 at December 31, 2019 and 2018, 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

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, 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, 2019, the Company has acquired twenty-four QuantStudio 5s including nine during the year ended December 31, 2019. As of December 31, 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 December 31, 2019:

Lease Classification	December 31, 2019
ROU Assets:	
Operating	$ 1,043,537
Financing	958,590
Total ROU assets	$ 2,002,127
Liabilities	
Current:	
Operating	$ 1,017,414
Finance	579,030
Noncurrent:	
Operating	547,225
Finance	313,263
Total lease liabilities	$ 2,456,932

Maturities of lease liabilities as of December 31, 2019 by year are as follows:

Maturity of Lease Liabilities	Operating	Finance	Total
2020	$ 1,128,294	$ 633,130	$ 1,761,424
2021	536,819	281,914	818,733
2022	40,080	45,374	85,454
2023	—	3,364	3,364
2024	—	280	280
Total lease payments	1,705,193	964,062	2,669,255
Less: imputed interest	(140,554)	(71,769)	(212,323)
Present value of lease liabilities	$ 1,564,639	$ 892,293	$ 2,456,932

Consolidated statement of operations classifications of lease costs are as follows:

Lease Cost	Classification	Year ended December 31, 2019
Operating	Operating expenses	$ 869,968
Finance:		
Amortization	Operating expenses	467,319
Interest expense	Other expenses	75,018
Total lease costs		$ 1,412,305

Other Information	Total
Weighted average remaining lease term (in years)	
Operating leases	1.7
Finance leases	1.6
Weighted average discount rate:	
Operating leases	10.0%
Finance leases	9.3%

Supplemental Cash Flow Information	Total
Cash paid for amounts included in the measurement of lease liabilities	
Cash used in operating activities	
Operating leases	$ 869,968
Finance leases	$ 75,018
Cash used in financing activities	
Finance leases	$ 535,931
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 year ended December 31, 2019, the Company recognized $1.3 million of revenue related to the contract.

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 for each of the years ending December 31, 2019 and 2018. Annual future minimum royalty fees are $250,000 under these agreements.

Note 12 - 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 $0 and $22,603 during the years ended December 31, 2019 and 2018.

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, 2019 and 2018, the Company recognized $0 and $329,162 of cost of services expense related to the contract, respectively.

Note 13 – Interim Facility

On September 4, 2019, OpGen entered into the Implementation Agreement. Under the Implementation Agreement, OpGen has agreed to purchase, through Crystal GmbH, all of the outstanding shares and acquire all of the related business assets of Curetis GmbH to create a combined business within OpGen.

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 Curetis, committed capital, up to $4 million, between November 18, 2019 and the closing of the transaction. The purpose of the loans is to provide capital to fund the operations of Curetis, 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. As of the year ended December 31, 2019, Curetis GmbH had borrowed approximately $2.5 million and OpGen had recognized approximately $23,000 of interest income under the Interim Facility.

Note 14 - 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, 2019:

Description	Balance at December 31, 2018	Change in Fair Value	Balance at December 31, 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 year ended December 31, 2019.

Note 15 – Subsequent Events

On February 11, 2020, the Company entered into an At the Market Common Stock Sales Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which the Company may offer and sell from time to time in an "at the market offering," at its option, up to an aggregate of $15.7 million of shares of the Company's common stock through Wainwright, as sales agent, (the "2020 ATM Offering"). Pursuant to the ATM Agreement, Wainwright may sell the shares 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. Wainwright will use commercially reasonable efforts to sell the shares from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay Wainwright a commission equal to three percent (3.0%) of the gross sales proceeds of any shares sold through Wainwright in the 2020 ATM Offering, and has provided Wainwright with customary indemnification and contribution rights. As of March 20, 2020, the Company has sold an aggregate of 2,383,528 shares of its common stock under ATM Agreement resulting in aggregate net proceeds to the Company of approximately $4.4 million, and gross proceeds of $4.5 million.

Subsequent to December 31, 2019, the Company issued 4,071,000 shares of common stock pursuant to the exercise of outstanding warrants sold in the October 2019 Public Offering for gross proceeds of approximately $8.1 million. As of March 20, 2019, 629,000 common warrants related to the October 2019 Public Offering remain outstanding.

On March 18, 2020, the Company's subsidiary, Crystal GmbH, as lender, and Curetis GmbH, as borrower and Curetis N.V. entered into an Amended and Restated Interim Facility Agreement, pursuant to which the parties amended and restated the Interim Facility Agreement and increased the available borrowing by the borrower to $5 million. Subsequent to December 31, 2019, the lender had provided an additional $2.2 million of borrowings to Curetis under the Interim Facility.

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic, which continues to spread throughout the United States and around the world. As of March 23, 2020, the Company is aware of changes in its business as a result of COVID-19 but uncertain of the impact of those changes on its financial position, results of operations or cash flows. Management believes any disruption, when and if experienced, could be temporary; however, there is uncertainty around when any disruption might occur, the duration and hence the potential impact. As a result, we are unable to estimate the potential impact on our business as of the date of this filing.

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OpGen, Inc. Board of Directors
as of August 1, 2020

Oliver Schacht, Ph.D., *Chief Executive Officer and Director*

William E. Rhodes, III, *Chairman of the Board (2)*

Mario Crovetto*(1)(2)*

R. Donald Elsey, *Chief Financial Officer, Lyra Therapeutics, Inc. (1)(3)*

Prabhavathi Fernandes, Ph.D. *(1)(2)(3)*

Evan Jones *(3)*

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(1) Member of Audit Committee
(2) Member of Compensation Committee
(3) Member of Compliance Committee

OpGen, Inc. Executive Officers
as of August 1, 2020

Oliver Schacht, Ph.D., *Chief Executive Officer and Director*

Timothy C. Dec, *Chief Financial Officer and Corporate Secretary*

Johannes Bacher, *Chief Operating Officer*

Stock and Investor Information

Corporate Offices:
708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878
301.869.9683

Common Stock:
Common Stock is listed on the Nasdaq Capital Market under the symbol "OPGN"

Independent Auditors:
CohnReznick LLP
8000 Towers Crescent Dr
Suite1000
Tysons, VA 22182

Transfer Agent:
Philadelphia Stock Transfer, Inc.
2320 Haverford Road
Suite 230
Ardmore, PA 19003

At the written request of each record owner or beneficial owner of our securities we will provide, without charge, a copy of the OpGen, Inc. Annual Report on Form 10-K for the year ended December 31, 2019, or any exhibit thereto not included herein. Requests should be sent to the Corporate Secretary at the address above.

Except for the historical matters contained herein, statements made in this report are forward looking and are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. Investors are cautioned that forward looking statements involve risks and uncertainties that may affect our business and prospects, including economic, competitive, governmental, technological, and other factors discussed in this report and in our filings with the Securities and Exchange Commission, including without limitation, the Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 24, 2020.

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