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, 2018

☐ **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(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.01 per share	**The Nasdaq Capital Market**
Warrants, exercisable for one share of common stock	**The Nasdaq Capital Market**

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 ☒

The aggregate market value of the voting common stock held by non-affiliates of the registrant as of June 30, 2018, was $9,971,095 (based upon the last reported sale price of $1.78 per share on June 29, 2018, on The Nasdaq Capital Market.

As of February 26, 2019, 8,645,720 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, 2018

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K for the year ended December 31, 2018 (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:

- the completion of our development efforts for the Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software, and the timing of commercialization;
- our ability to sustain or grow our customer base for our current products;
- 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;
- 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 agreements;
- regulations and changes in laws or regulations applicable to our business, including regulation by the FDA;
- 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 multidrug-resistant microorganisms, or MDROs. Our proprietary DNA tests and informatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize care decisions for patients with acute infections.

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 Acuitas molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include our Acuitas antimicrobial resistance, or AMR, Gene Panel (Urine) test in development for patients at risk for complicated urinary tract infections, or cUTI, our Acuitas AMR Gene Panel (Isolates) test in development for testing bacterial isolates, and our 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 available for sale for research use only, or RUO.
- Our 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 our 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.

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 September 2018, we announced a collaboration with the New York State Department of Health, or 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 portion of the collaboration is the completion of a development project, expected to last one year, that we believe will lead to a statewide program. Under the demonstration project, OpGen will work with DOH's Wadsworth Center and ILÚM to develop an infectious disease digital health and precision medicine platform that connects healthcare institutions to DOH and uses genomic microbiology for statewide surveillance and control of antimicrobial resistance. The DOH, ILÚM and OpGen will work collaboratively to build a sustainable, flexible infectious diseases reporting, tracking and surveillance tool for antimicrobial resistance that can be applied across New York State.

In October 2018, we entered into a supply agreement with QIAGEN N.V. to advance our rapid diagnostics for antimicrobial resistance. Under the agreement, we 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 our Acuitas AMR Gene Panel products. Under the terms of

the agreement, we 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, both RUO and, when 510(k) clearance is obtained, as diagnostic products.

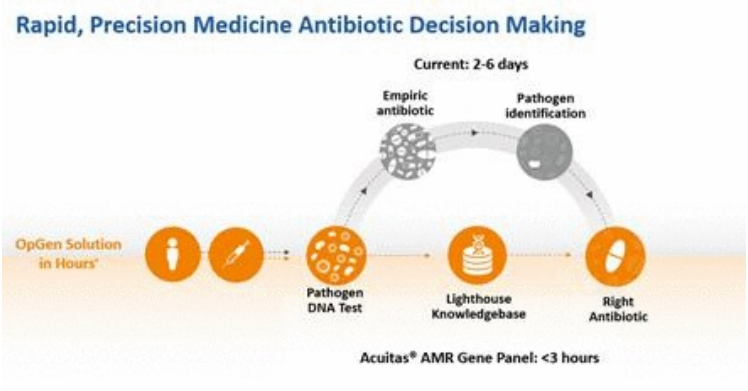
In June 2017, we entered into a global supply agreement to provide customer access to Thermo Fisher Scientific's products to support the commercialization of our Acuitas Rapid Test and Acuitas Lighthouse Software products in development to combat MDROs. We are working to expand all of these established relationships and to enter into additional collaborative arrangements in the future.

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.

We are developing high resolution Acuitas AMR Gene Panel tests designed to determine pathogen levels in clinical specimens and the key drug resistance gene profiles of Gram-negative organisms. Our Acuitas AMR Gene Panel (RUO) tests are available for sale for research use only. Following completion of our research and development efforts and receipt of appropriate regulatory clearances, we anticipate our Acuitas AMR Gene Panel tests will be used in the clinical setting to provide pathogen and antibiotic resistance gene information to aid in decision-making for patients at risk for cUTI, lower respiratory tract infections, blood stream infections, and for testing of bacterial isolates.

Lead Rapid Diagnostics and Acuitas Lighthouse Software

Our Acuitas products in development are: the Acuitas AMR Gene Panel (Isolates) for testing of bacterial isolates from multiple human sample types, the Acuitas AMR Gene Panel (Urine) for direct testing of urine samples for patients at risk for cUTI and to identify potential antibiotic resistance markers, and our Acuitas Lighthouse Software to aid in the management of test results and to predict antibiotic resistance to six classes of front-line antibiotics. Our lead product in development is the Acuitas AMR Gene Panel (Urine) for patients at risk for cUTI. The AMR Gene Panel (Urine) is a direct test that will be able to be performed in under three hours to identify five pathogens associated with urinary tract infections, or UTIs, and their levels, and 47 genes associated with antibiotic resistance. We anticipate that the Acuitas Lighthouse Software will be used to provide additional interpretation of test results including probability of resistance for fourteen antibiotics commonly used to treat cUTI. Approximately 10,000 bacterial isolates from the Merck SMART surveillance network and other sources have been tested and added to the Acuitas Lighthouse Knowledgebase to support development and use of the Acuitas Lighthouse Software antibiotic resistance prediction decision-making algorithms. In September 2018 we completed specimen accrual and testing of urine specimens for the clinical verification study for the Acuitas AMR Gene Panel (Urine) rapid diagnostic 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, confirmed the targeted performance of the new test to identify patients with UTIs and subsequently to predict antibiotic resistance to six classes of front line antibiotics. These data and additional data from our ongoing research support the potential for the Acuitas Lighthouse Software to provide actionable antibiotic resistance prediction information directly from clinical specimens in under three hours. The figure below describes the workflow and anticipated results from our new testing approach.



Current Diagnostic Tests and Informatics

Our 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.

We currently offer our Acuitas AMR Gene Panel (RUO) tests to contract research organizations, or CROs, pharmaceutical companies, hospitals and other healthcare providers for research use only.

We offer our Acuitas Lighthouse Software to health care facilities and public health facilities for infection control and surveillance purposes.

Our Strategy

We are using our current product and service offerings, and will use our products in development to build and commercialize a comprehensive precision medicine solution for combatting infectious disease with a focus on developing diagnostic tests for rapid pathogen identification and genetic profiling, antibiotic resistance analysis and advanced informatics to store and analyze MDRO and other infectious disease data for hospitals, out-patient settings and other healthcare providers.

The two core components of our strategy are development and commercialization of rapid diagnostic tests and leveraging our Acuitas Lighthouse information services into new markets and channels.

- **Rapid diagnostics** – We are developing OpGen-branded Acuitas AMR Gene Panel tests for use on the Thermo Fisher Scientific Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System. The first of these new tests will be for antibiotic resistance testing of bacterial isolates. The second indication for the Acuitas AMR Gene Panel is for management of patients with cUTI. We anticipate developing tests for additional clinical indications such as lower respiratory tract infections and for new antibiotic decision- making applications. The second rapid diagnostics growth driver is anticipated to be through strategic partner relationships where we will work to expand channel access for our proprietary DNA tests through development and subsequent use of these tests, utilizing the Acuitas Lighthouse Software on established rapid in vitro diagnostic testing platforms.
- **Acuitas Lighthouse informatics and services** – We are pursuing commercial opportunities to provide our Acuitas Lighthouse informatics and companion genomic testing to pharmaceutical companies, CROs, health systems, third party in vitro diagnostic companies, and government agencies. Through our participation in the New York State Infectious Disease Digital Health Initiative we anticipate deploying our Acuitas Lighthouse Software throughout the State to help identify and track patients with Superbug infections. Our focus in the health system segment is on helping guide antibiotic decision-making and supporting patient safety initiatives. We are actively pursuing government funding for development and deployment of our Acuitas Lighthouse informatics in the United States and internationally.

In support of our strategy we are working to:

- complete development, clinical evaluations, obtain necessary regulatory approvals, and successfully commercialize our Acuitas AMR Gene Panel (Urine) for cUTIs with a goal of achieving three-hour antibiotic resistance analysis from the time of specimen collection;
- commercialize our Acuitas AMR Gene Panel tests for RUO, which started in January 2018;
- make a FDA 510(k) submission for the Acuitas AMR Gene Panel (Isolates) test in the first quarter of 2019 to support commercial launch;
- successfully complete the demonstration project of the New York State Digital Health Initiative to support Statewide deployment in subsequent years;
- obtain third party funding to expand our Acuitas AMR Gene Panel test development and access to additional third party rapid testing platforms;
- expand our business collaborations with Merck and other pharmaceutical companies;
- capitalize on opportunities to deploy our Acuitas Lighthouse informatics and genomic testing for pharmaceutical/CRO services;
- grow our Acuitas Lighthouse data warehouse offerings for resistance and susceptibility data in hospital, hospital system, or broader community applications through continued development of the Acuitas Lighthouse Knowledgebase;
- seek government funding to advance programs focused on identification and treatment of MDROs; and

- continue development of our Acuitas Lighthouse Software and work to install Acuitas Lighthouse Software to customer sites in the United States and globally.

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.

Recent Events

Business Initiatives

In October 2018, we entered into a supply agreement with QIAGEN N.V. to advance our rapid diagnostics for antimicrobial resistance. Under the agreement, we 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 our Acuitas AMR Gene Panel products. Under the terms of the agreement, we 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, both RUO and, when 510(k) clearance is 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, we 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 portion of the collaboration is the completion of a development project, expected to last one year, that we believe will lead to a statewide program. Under the demonstration project, OpGen will work with DOH's Wadsworth Center and ILÚM to develop an infectious disease digital health and precision medicine platform that connects healthcare institutions to DOH and uses genomic microbiology for statewide surveillance and control of antimicrobial resistance. The DOH, ILÚM and OpGen will work collaboratively to build a sustainable, flexible infectious diseases reporting, tracking and surveillance tool for antimicrobial resistance that can be applied across New York State. The goal of this 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 for rapid detection of multidrug-resistant bacterial pathogens along with its Acuitas Lighthouse Software for high resolution pathogen tracking. OpGen will receive a $1.5 million contract for the 12-month demonstration portion of the project, with the potential for full implementation during the next four years, should certain milestones be achieved by all parties involved.

In June 2017, the Company entered into a global supply agreement to use Thermo Fisher Scientific's technology to support the commercialization of its rapid molecular products. Under the terms of the agreement, OpGen will commercialize the AMR Gene Panel tests for Pathogen ID and resistance genes on Thermo Fisher's new mid-throughput real-time PCR system. In January 2018, the Company entered into a second global 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® Probes for quick, multiplexed gene detection.

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

three sites from the project intend to continue using the Acumen software tool, and we are in discussions with ILÚM to establish a distribution relationship for Colombia and the region.

Corporate Events

Following receipt of approval from stockholders at a special meeting of stockholders held on January 17, 2018, we filed an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split of the issued and outstanding shares of our common stock, at a ratio of one share for twenty-five shares, and to reduce the authorized shares of our common stock from 200,000,000 to 50,000,000 shares. All share amounts and per share prices in this Annual Report have been adjusted to reflect the reverse stock split.

On June 20, 2017, we received a notice from the Listing Qualifications Staff of the Nasdaq Stock Market LLC, or Nasdaq, notifying us that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer met the requirement to maintain a minimum closing bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had a period of 180 calendar days to regain compliance with the rule. On December 21, 2017, the Company received written notification, or the December Notice, from the Listing Qualifications Staff of Nasdaq, or the Staff, indicating that, based upon (i) the Company's continued non-compliance with the minimum bid price rule and (ii) the Company's inability to meet The Nasdaq Capital Market initial listing requirements, specifically maintaining a minimum of stockholders' equity, the Staff had determined that the Company was not eligible for an additional 180 day extension to meet the minimum bid price rule. On February 5, 2018, subsequent to completion of our reverse stock split, we received written notification from the Listing Qualifications Staff of Nasdaq that the minimum bid price deficiency of the Company's stock had been cured, and the Company would continue to be listed and trade on The Nasdaq Stock Market. In addition, the Company was informed that it was in compliance with all applicable listing standards of The Nasdaq Capital Market as of that date.

Financings

On October 22, 2018, we closed a public offering, or the October 2018 Public Offering of 2,220,000 shares of 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 $2.8 million.

On June 11, 2018, the Company executed an Allonge to its Second Amended and Restated Senior Secured Promissory Note, dated June 28, 2017, with a principal amount of $1,000,000 issued to MGHIF. The Allonge provided that accrued and unpaid interest of $285,512 due as of July 14, 2018, the original maturity date, would be paid through the issuance of shares of OpGen's common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021. On July 30, 2018, the Company issued 144,238 shares of common stock to MGHIF in a private placement transaction for $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

On February 6, 2018, the Company closed a public offering, or the February 2018 Public Offering, of 2,841,152 units at $3.25 per unit, and 851,155 pre-funded units at $3.24 per pre-funded unit, raising gross proceeds of approximately $12 million and net proceeds of approximately $10.7 million. Each unit included one share of common stock and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance.

On May 31, 2017, the Company entered into a Note Purchase Agreement with jVen Capital, under which jVen Capital agreed to provide bridge financing in an aggregate principal amount of up to $1,500,000 to the Company in up to three separate tranches of Bridge Financing Notes. The interest rate on each Bridge Financing Note was ten percent (10%) per annum (subject to increase upon an event of default). In connection with the Bridge Financing Notes, the Company issued jVen Capital stock purchase warrants to acquire 5,634 shares with an exercise price of $19.50 per share, and stock purchase warrants to acquire 6,350 shares at an exercise price of $17.25 per share. On June 14, 2017, the Company drew down on the first of three Bridge Financing Notes, with $1 million remaining capacity available. The Company drew down on the second Bridge Financing Note on July 5, 2017 and the third Bridge Financing Note was never issued. The outstanding Bridge Financing Notes were repaid in full upon the closing of the July 2017 Public Offering.

As a condition to the receipt of the bridge financing, the Company issued the Second Amended & Restated Senior Secured Promissory Note, or the MGHIF Note, to MGHIF, which extended the maturity date of the promissory note from July 14, 2017 to July 14, 2018. In return for MGHIF's consent to such extension, the Company increased the interest rate of the MGHIF Note to 10% per annum and

issued warrants to purchase shares of common stock to MGHIF equal to 20% of the principal balance of the MGHIF Note, plus interest accrued thereon, as of June 28, 2017.

On July 18, 2017, the Company closed a public offering, or the July 2017 Public Offering, of 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million, or the July 2017 Public Offering. jVen Capital was one of the investors participating in the offering. Each unit included one twenty-fifth of a share of common stock and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. Each pre-funded unit included one pre-funded warrant to purchase one twenty-fifth of a share of common stock for an exercise price of $0.25 per share, and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. Approximately $1 million of the gross proceeds was used to repay the outstanding Bridge Financing Notes to jVen Capital in July 2017. As of December 31, 2017, all of the pre-funded warrants have been exercised.

In September 2016, the Company entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company LLC, or Cowen, pursuant to which the Company may offer and sell from time to time, up to an aggregate of $25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of $11.5 million. As of December 31, 2018, the Company sold an aggregate of 690,247 shares of its common stock under this at the market offering, resulting in aggregate net proceeds to the Company of approximately $8.8 million, and gross proceeds of $9.4 million. During the year ended December 31, 2018, the Company sold 318,236 shares of its common stock under this at the market offering, resulting in aggregate net proceeds to the Company of approximately $0.6 million, and gross proceeds of $0.6 million. In connection with the October 2018 Public Offering, the Company terminated the at the market offering.

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.

Products

Acuitas AMR Gene Panel and Acuitas Lighthouse Software

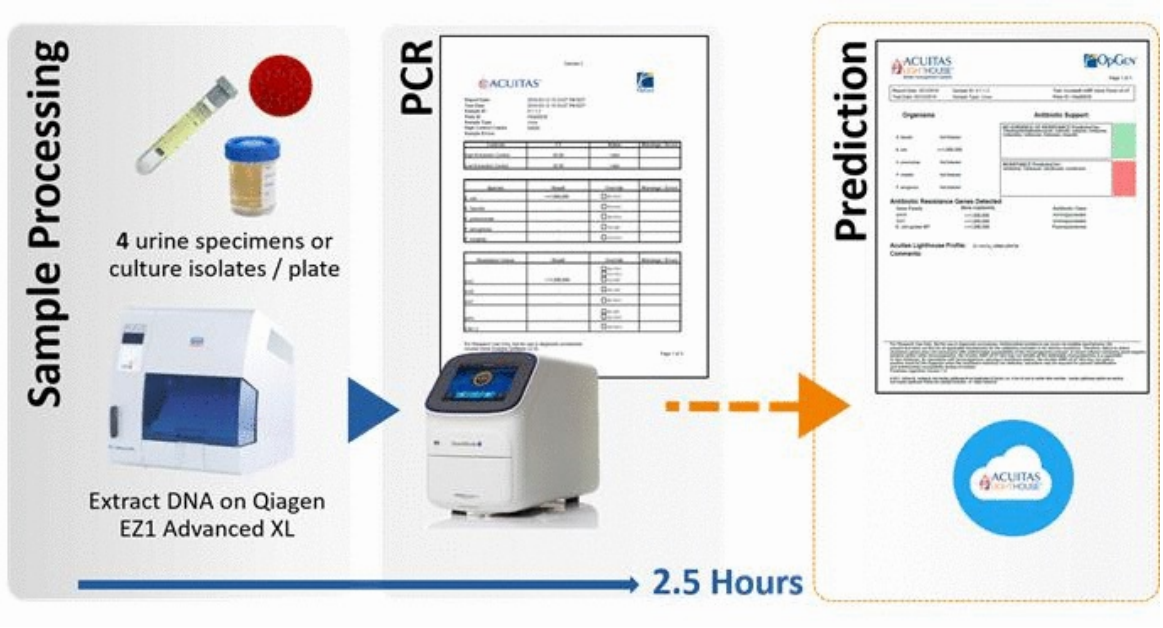
The Acuitas AMR Gene Panel is a qualitative and semi-quantitative nucleic acid-based in vitro diagnostic test that is capable of simultaneous detection and identification of multiple bacterial nucleic acids and select genetic determinants of antimicrobial resistance in urine specimens or bacterial colonies isolated from urine and other body sites. The Acuitas AMR Gene Panel (Urine) is intended as an aid in the diagnosis of specific agents of UTIs 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 47 gene targets which span 600 subtypes and convey resistance to 9 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*). While the test is currently designed to detect only five bacterial species, this test will detect resistance genes in other organisms if present without providing species identification. Test results are provided in under three hours, compared with traditional microbiology methods, which can take two to three days.

We are also developing the Acuitas AMR Gene Panel (Isolates) test for testing bacterial isolates. The RUO test is being used in the New York State Infectious Disease Digital Health Initiative for testing of bacterial isolates. The test is genotyping carbapenem resistant isolates from three health systems in the New York City Metro Area. Results are subsequently analyzed by the Acuitas Lighthouse Software to support a series of infection control tracking capabilities that are of interest to the Department of Public Health and healthcare providers. Following the anticipated FDA clearance of the Acuitas AMR Gene Panel (Isolates) test, we expect use of the test to expand to include use of the test information to support antibiotic decision making in acute care patient management of patients with MDRO infections.

The Acuitas Lighthouse Software 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 was selected by the New York State Department of Health Wadsworth Laboratories for the genomic microbiology component of the New York State Infectious Disease Digital Health Initiative. All components of the Acuitas Lighthouse Software are securely hosted in a cloud-hosted, web-based application. 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 (1) 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. Development of the Acuitas Lighthouse Software and the Acuitas AMR Gene Panel (Urine) was the result of a comprehensive, multi-year development effort 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:

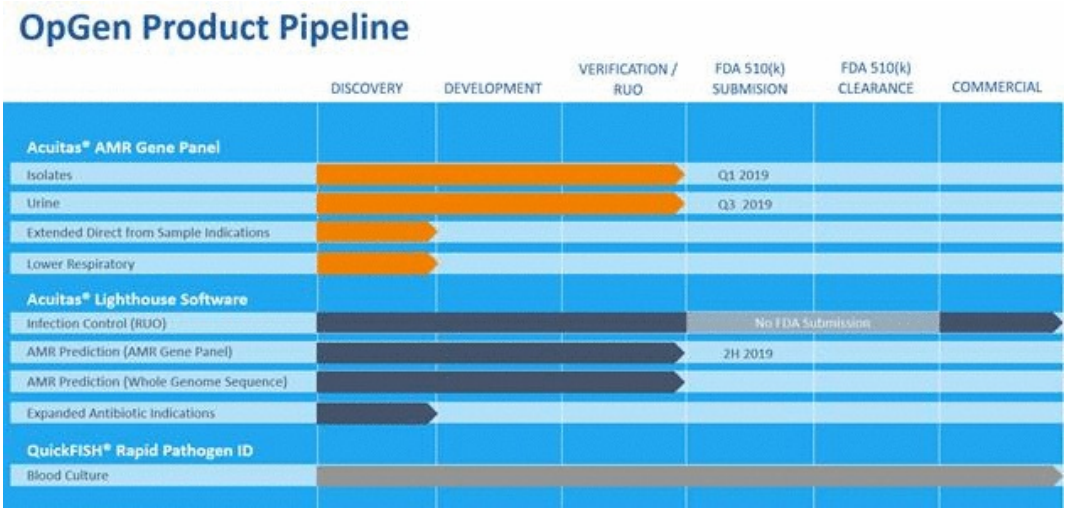
QuickFISH	PNA FISH
Staphylococcus	Staphylococcus
Enterococcus	Enterococcus
Gram-negative bacteria	Gram-negative bacteria
Candida	Candida

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.

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

During 2018, we finalized the regulatory approach for commercializing the initial Acuitas AMR Gene Panel tests and the Acuitas Lighthouse Software. We anticipate completing clinical trials and filing three separate 510(k) submissions during 2019 as described below. 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

- 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, 5-8 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.

In February 2019, we announced the completion of the clinical trials needed to support the 510(k) submission for the Acuitas AMR Gene Panel (Isolates). The clinical trials tested more than 1,000 clinical isolates at four participating clinical sites: The Johns Hopkins University School of Medicine; Wadsworth Center, New York State Department of Health; University Hospitals Cleveland Medical Center; and IHMA, Inc. We have completed key analytical validation testing activities including reproducibility studies and DNA sequencing of over 1,000 isolates to support the planned 510(k) submission.

Commercial Sales

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

We are generating data to support the commercialization of our Acuitas AMR Gene Panel (Urine) and Acuitas Lighthouse Software products through a structured clinical verification program including academic medical centers and clinical collaborators. In November 2018 we announced that we have completed specimen accrual and testing of urine specimens for the clinical verification study with the Acuitas AMR Gene Panel (Urine) test and Acuitas Lighthouse Software. The three participating clinical sites were Beth Israel Deaconess Medical Center, Geisinger Health System, and Intermountain Healthcare. The results of the study, which tested 670 remnant urine specimens from patients at increased risk for cUTI, will be summarized and discussed in a peer-reviewed manuscript anticipated to be published in 2019.

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 80 customers in the US 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, Curetis and Nanosphere. We believe our focus on identifying antibiotic-resistant genes, rather than primarily organisms, the genes and associated diseases included in our gene tests, and our Acuitas Lighthouse informatics offerings distinguish us from such competitors.

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

Competitors may develop their own versions of our product offerings in countries where we do not have patents or where our intellectual property rights are not recognized.

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

Manufacturing

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

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

Seasonality of Business

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

Quality Assurance

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

Raw Materials and Suppliers

We procure PCR amplification reagents and the QuantStudio 5 Real-Time PCR System from Thermo Fisher Scientific. DNA purification reagents and the EZ1 DNA Purification System are procured from QIAGEN, NV. We purchase the PNA probes, glass slides and specialty consumables for our QuickFISH products from third party manufacturers who have long lead times and who manufacture several of these products for us on a sole source basis. We also purchase our collection kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors. While we have developed alternative sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective or whether alternative sources will be available

when we need them. If these suppliers can no longer provide us with the materials we need to manufacture our Acuitas AMR Gene Panel products or our QuickFISH products, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, our business would be negatively affected.

Payments and Reimbursement

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

Intellectual Property

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

As of December 31, 2018, we had total ownership rights to 23 patents, including seven pending United States non-provisional patent applications, and 16 issued United States patents. More specifically, as of December 31, 2018, related to our FISH products, we had ownership rights to 11 patents, including three pending United States non-provisional patent applications, and eight issued United States patents. These issued patents began to expire in November 2024 and will be fully expired by March 2032. As of December 31, 2018, related to our Acuitas products, we had ownership rights to three pending United States non-provisional patent applications and no issued United States patents. As of December 31, 2018, related to our other products, we had ownership rights to nine patents, including one pending United States non-provisional patent application, and eight issued United States patents related to our other products. These issued patents began to expire in June 2026 and will be fully expired by May 2032. A majority of our issued and exclusively licensed FISH patents expired over the last six years. The remaining 23 exclusively licensed United States FISH patents expire between 2019 and 2024.

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 Labele d for Research Use Only or Investigational Use Only – Guidance for Industry and Food and Drug Administration Staff." This guidance sets forth the requirements to utilize such designations, labeling requirements and acceptable distribution practices, among other requirements.

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

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

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

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

FDA's Premarket Clearance and Approval Requirements

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

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

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

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

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

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

510(k) Clearance Pathway

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

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

De Novo Classification Request

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

Premarket Approval Pathway

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

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

Clinical Trials

Clinical trials are almost always required to support a PMA application and are usually required to support non-exempt Class 1 and Class 2 510(k) premarket submissions. Clinical trials may also be required to support certain marketing claims. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an investigational device exemption, or IDE application with the FDA and obtain IDE approval prior to conducting the human clinical trials. The IDE application must be supported by appropriate data, such as analytical, animal and laboratory testing results, manufacturing

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

21st Century Cures Act

The 21st Century Cures Act contains several sections specific to antimicrobial innovation and antibiotic stewardship, and other provisions related to medical device innovations. The Company believes that implementation of the 21st Century Cures Act may have a positive impact on the Company's businesses through facilitating innovation and/or reducing the regulatory burden imposed on medical device manufacturers, especially those involved in antimicrobial susceptibility testing. The Company cannot predict how and when these initiatives under the Act will be implemented at the federal or state level in which we may do business, or the effect any future regulation will have on us.

Pervasive and Continuing FDA Regulation

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

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our cleared devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

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

Failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, which might include any of the following sanctions: (1) untitled letters, Form 483 observations, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products; (7)

operating restrictions; (8) withdrawing 510(k) clearances or PMA approvals that have already been granted; (9) refusal to grant export approval for our products; or (10) criminal prosecution.

After a medical device is placed on the market, numerous regulatory requirements apply. These include: all of the relevant elements of the QSR, labeling regulations, restrictions on promotion and advertising, the medical device reporting (which requires the manufacturer to report to the FDA if its device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), the Reports of Corrections and Removals regulations (which requires manufacturers to report certain recalls and field actions to the FDA), and other post-market requirements.

Health Insurance Portability and Accountability Act

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

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

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

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

Federal and State Physician Self-referral Prohibitions

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

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

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

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

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

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

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

Federal and State Anti-Kickback Laws

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

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

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

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

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

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

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

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

Other Federal and State Fraud and Abuse Laws

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

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

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

International Regulation

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

Environmental Matters

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

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, 2018, we had 50 employees worldwide, with 48 employed in the United States, 1 employed in Denmark and 1 employed in Colombia. There are 44 full-time employees. The 48 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 Woburn, Massachusetts, 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, 2018 and 2017 contains explanatory language that substantial doubt exists about our ability to continue as a going concern.

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the years ended December 31, 2018 and 2017, we had net losses of $13.4 million and $15.4 million, respectively. From our inception through December 31, 2018, we had an accumulated deficit of $162.1 million. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2018 and 2017 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. We completed a number of financings in 2018 and 2017, including the October 2018 Public Offering, February 2018 Public Offering, the July 2017 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 $26.7 million.

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

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

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

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

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

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

We believe that current cash on hand will be sufficient to fund operations into the second quarter of 2019. In the event we are unable to successfully raise additional capital during or before the second quarter of 2019, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to 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 beginning on January 2, 2019 and ending on July 1, 2021. Such secured creditor rights could negatively impact our ability to raise money in the future. If we default on payments under the MGHIF Note, MGHIF has the rights of a secured creditor. If those rights are exercised, it could have a material adverse effect on our financial condition.

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

The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other 510(k)-cleared products. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use.

We anticipate making three FDA submissions in 2019 for our Acuitas AMR Gene Panel products and Acuitas Lighthouse software. If we are not able to achieve clearance of such products and services on a timely basis, or at all, we will not be able to pursue our business strategy on the anticipated timeline and our business, results of operations and financial condition will be materially adversely impacted.

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

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

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

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

The current customers we are targeting for our Acuitas AMR Gene Panel 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.

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

We are developing new 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 new products and services, our business will be materially, adversely affected.

We are developing a new 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 new diagnostic products is difficult and we cannot assure you that we will be successful in such product development efforts, or, if successful, that we will receive the necessary regulatory clearances to commercialize such products. We have identified 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. We currently estimate that such antibiotic resistance diagnostic tests will be commercially available in late 2019. Any significant delays or failures in this process could have a material adverse effect on our business and financial condition.

We offer these products in development to the 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 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.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists and laboratory and field personnel could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team. The efforts of each of these persons will be critical to us as we continue to develop our products and services and as we attempt to transition to a company with broader product offerings. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Our research and development programs depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses. We also face competition from universities, public and private research institutions and other organizations in recruiting and retaining highly qualified scientific personnel.

In addition, our success depends on our ability to attract and retain personnel with extensive experience in infection control in inpatient settings. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our current and future products and service offerings. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our discovery, development, verification and commercialization programs.

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

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

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

We manufacture our Acuitas, QuickFISH and PNA FISH products in our facility in Gaithersburg Maryland. We do not have redundant facilities. Our facility and the equipment we use manufacture our products would be costly to replace and could require substantial lead time to repair or replace, if damaged or destroyed. The facility may be harmed or rendered inoperable by natural or man-made disasters, including flooding and power outages, which may render it difficult or impossible for us manufacture our

products for some period of time. The inability to manufacture our products may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

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

If demand for these products 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, QIAGEN, and Fluidigm Corporation, 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 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, Nanosphere, and Curetis.

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.

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.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred net losses since inception and do not expect to become profitable in 2019 or for several years thereafter. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. We may be unable to use these net operating loss carryforwards, or NOLs, and certain tax credit carryforwards to offset income before such unused NOLs tax credit carryforwards expire. Under Section 382 of the Internal Revenue Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change NOLs and other pre- change tax attributes to offset its post-change income may be limited. The AdvanDx Merger resulted in an ownership change for AdvanDx and, accordingly, AdvanDx's net operating loss carryforwards and certain other tax attributes in U.S. taxing jurisdictions are subject to limitations on their use after the AdvanDx Merger. OpGen's net operating loss carryforwards may also be subject to limitation as a result of prior shifts in equity ownership and/or the AdvanDx Merger. Additional ownership changes in the future could result in additional limitations on the use of our net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. We have not performed an analysis on previous ownership changes. It is possible that we have experienced an ownership change, or that we will experience an ownership change in the future. We had U.S. federal NOL carryforwards of $178.2 million and research and development tax credits of $2.6 million as of December 31, 2018, that may already be or could be limited if we experience an ownership change. In addition, the Tax Cuts and Jobs Act limits the amount of losses incurred for tax years beginning after December 31, 2017 that can be used on a yearly basis. The limit is equal to 80 % of taxable income for a given year. However, losses incurred after December 31, 2017 may be carried forward indefinitely.

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 January 2018 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, 2018, the market price of our common stock fluctuated from a high of $136.00 per share to a low of $0.76 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, 2018, we had outstanding warrants to acquire 3,525,797 shares of our common stock, and stock options to purchase 211,559 shares of our common stock. The expiration of the term of such options and warrants range from March 2019 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 25,102 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 25,102 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 May 2020, although if our revenue exceeds $1.07 billion in any fiscal year before that time, we would cease to be an emerging growth company as of the end of that fiscal year. In addition, if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our second fiscal quarter of any fiscal year before May 2020, we would cease to be an emerging growth company as of December 31 of that year. As an emerging growth company, we take advantage of exemptions from various reporting requirements applicable to certain other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced financial statement and financial-related disclosures, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirement of holding a nonbinding advisory vote on executive compensation and obtaining stockholder approval of any golden parachute payments not previously approved by our stockholders. We cannot predict whether investors will find our common stock less attractive if we choose to rely on any of these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure we may make, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks Related to Regulation of Our Business

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our Acuitas AMR Gene Panel tests 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 are currently in the process of completing three 510(k) submissions with the FDA for our Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software. Such process is complex, time consuming and expensive. The FDA may not clear or approve these products for the indications that are necessary or desirable for successful commercialization. Failure to receive, or a significant delay in receiving, a required clearance or approval for our products would have a material adverse effect on our ability to expand our business.

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

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

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

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

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

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

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

Risks Related to Compliance with Healthcare 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 new health care insurance exchanges and by modifying the methodology for reimbursing medical services, drugs and devices. The U.S. Congress is seeking to replace the 2010 Health Care Reform Legislation. At this time the Company is not certain as to the impact of federal health care legislation on its business.

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

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

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

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

- the federal Anti-Kickback Statute, which constrains certain marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent;

- federal physician self-referral laws, such as the Stark Law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral; 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 office 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, 2018 and 2017 were $984,639 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, 2018, there were approximately 33 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

On July 30, 2018, the Company issued 144,238 shares of common stock to MGHIF in a private placement transaction for satisfaction of $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note. A Form D was filed on August 3, 2018. The private placement was made in accordance with Rule 506 promulgated under the Securities Act.

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 a merger with AdvanDx ("the Merger"). 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, AdvanDx are collectively referred to hereinafter as the "Company." The Company's headquarters and its principal operations are in Gaithersburg, Maryland. The Company also has operations in Woburn, Massachusetts, Copenhagen, Denmark, and Bogota, Colombia. The Company operates in one business segment.

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

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

- The 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 complicated urinary tract infections, or cUTIs, and its Acuitas AMR Gene Panel (Isolates) test in development for testing bacterial isolates, and its QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of the Acuitas AMR Gene Panel tests is available for sale for research use only, or RUO.
- The Company's Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that combine clinical lab test results with patient and hospital information to provide analytics and actionable insights to help manage MDROs in the hospital and patient care environment. Components of the informatics systems include the Acuitas Lighthouse Knowledgebase and the Acuitas Lighthouse Software. The Acuitas Lighthouse Knowledgebase is a relational database management system and a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens. The Acuitas Lighthouse Software system includes the Acuitas Lighthouse Portal, a suite of web applications and dashboards, the Acuitas Lighthouse Prediction Engine, which is a data analysis software, and other supporting software components. The Acuitas Lighthouse Software can be customized and made specific to a healthcare facility or collaborator, such as a pharmaceutical company.

The Company's operations are subject to certain risks and uncertainties. The risks include the risk that the Company will not receive 510(k) clearance for its Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software on a timely basis, or at all, rapid technology changes, the need to retain key personnel, the need to protect intellectual property and the need to raise additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop, obtain regulatory approval for and commercialize its proprietary technology as well as raise additional capital.

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 our common stock from 200,000,000 to 50,000,000 shares. All share amounts and per share prices in this Annual Report have been adjusted to reflect the reverse stock split.

2018 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 2018:

- On October 22, 2018, the Company closed its October 2018 Public Offering of 2,220,000 shares of its common stock at a public offering price of $1.45 per share. The offering raised gross proceeds of approximately $3.2 million and net proceeds of approximately $2.8 million.
- On June 11, 2018, the Company executed an Allonge 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, be paid through the issuance of shares of OpGen's common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021. On July 30, 2018, the Company issued 144,238 shares of common stock to MGHIF in a private placement transaction for $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.
- On February 6, 2018, the Company closed 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 share of common stock and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. As of December 31, 2018, all 851,155 pre-funded warrants issued in the February 2018 Public Offering have been exercised.
- During the year ended December 31, 2018, the Company sold 318,236 shares of its common stock under its ongoing at the market offering resulting in aggregate net proceeds to the Company of approximately $0.6 million, and gross proceeds of $0.6 million. The at the market offering was launched in September 2016. In connection with the October 2018 Public Offering, the Company terminated the at the market offering.

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

Revenues

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

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

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

Operating expenses

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

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

- Costs of products sold: expenses for the year ended December 31, 2018 decreased approximately 24% when compared to the same period in 2017. The change in costs of products sold is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products;
- Costs of services: expenses for the year ended December 31, 2018 increased approximately 20% when compared to the same period in 2017. The change in costs of services is primarily attributable to increased costs of services associated with our CDC contract;
- Research and development: expenses for the year ended December 31, 2018 decreased approximately 18% when compared to the same period in 2017, primarily due to a decrease in costs related to the automated rapid pathogen identification project that was suspended in 2017, offset by increased costs related to clinical studies;
- General and administrative: expenses for the year ended December 31, 2018 increased approximately 6% when compared to the same period in 2017, primarily due to increased payroll and consultant costs; and
- Sales and marketing: expenses for the year ended December 31, 2018 decreased approximately 45% when compared to the same period in 2017, primarily due to the reductions in the size of our commercial organization in 2017.

Other income (expense)

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

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

Liquidity and capital resources

At December 31, 2018, the Company had cash and cash equivalents of $4.6 million, compared to $1.8 million at December 31, 2017. The Company has funded its operations primarily through external investor financing arrangements and has raised significant funds in 2018 and 2017, including:

On October 22, 2018, the Company closed its October 2018 Public Offering of 2,220,000 shares of its common stock at a public offering price of $1.45 per share. The offering raised gross proceeds of approximately $3.2 million and net proceeds of approximately $2.8 million.

On June 11, 2018, the Company executed an Allonge 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 144,238 shares of common stock to MGHIF in a private placement transaction for $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

On February 6, 2018, the Company closed 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 share of common stock and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance.

During the year ended December 31, 2018, the Company sold 318,236 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. During the year ended December 31, 2017, the Company sold 227,216 shares of its common stock under its at the market offering resulting in aggregate net proceeds to the Company of approximately $3.8 million, and gross proceeds of $4.0 million. In connection with the October 2018 Public Offering, the Company terminated the at the market offering.

On July 18, 2017, the Company closed its July 2017 Public Offering of 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million. jVen Capital, an affiliate of Evan Jones, the Company's Chairman of the Board and Chief Executive Officer, and three employees of the Company participated in the July 2017 Public Offering. Each unit included one share of common stock and one common warrant to purchase one share of common stock at an exercise price of $0.425 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 $0.425 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. Approximately $1 million of the gross proceeds was used to repay the outstanding Bridge Financing Notes to jVen Capital in July 2017.

On May 31, 2017, the Company entered into a Note Purchase Agreement with jVen Capital, under which jVen Capital agreed to provide bridge financing in an aggregate principal amount of up to $1,500,000 to the Company in up to three separate tranches of Bridge Financing Notes. The interest rate on each Bridge Financing Note was ten percent (10%) per annum (subject to increase upon an event of default). In connection with the Bridge Financing Notes, the Company issued jVen Capital stock purchase warrants to acquire 5,634 shares with an exercise price of $19.50 per share, and stock purchase warrants to acquire 6,350 shares at an exercise price of $17.25 per share. On June 14, 2017, the Company drew down on the first of three Bridge Financing Notes, with $1 million remaining capacity available. The Company drew down on the second Bridge Financing Note on July 5, 2017 and the third Bridge Financing Note was never issued. The outstanding Bridge Financing Notes were repaid in full upon the closing of the July 2017 Public Offering.

On June 6, 2017, as amended on June 28, 2017, the Company issued the amended and restated MGHIF Note to MGHIF, which extended the maturity date of the MGHIF Note from July 14, 2017 to July 14, 2018. In return for MGHIF's consent to such extension, the Company increased the interest rate of the MGHIF Note to 10% per annum and issued warrants to purchase shares of common stock to MGHIF equal to 20% of the principal balance of the MGHIF Note, plus interest accrued thereon, as of June 28, 2017.

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

There were approximately $121,000 of one-time termination benefits that were recognized during the year ended December 31, 2017 related to the restructuring. The Company incurred total retention expense of approximately $68,000 during the year ended December 31, 2017. The future minimum lease payments for the Woburn facility were approximately $1.4 million as of December 31, 2018. A liability for costs that will continue to be incurred under a contract for its remaining term without economic benefit to the entity shall be recognized at the cease-use date. If the contract is an operating lease, the fair value of the liability at the cease-use date shall be determined based on the remaining lease rentals, adjusted for the effects of any prepaid or deferred items recognized under the lease, and reduced by estimated sublease rentals that could be reasonably obtained for the property. The Company expects the cease use date for the Woburn facility to be in the next three months. We have not estimated the contract termination costs associated with this lease given that we have not yet reached the cease use date. We do not believe there will be significant additional costs related to restructuring outside of what is described herein.

Sources and uses of cash

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

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

Net cash used in operating activities

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

Net cash used in investing activities

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

Net cash provided by financing activities

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

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 U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our audited consolidated financial statements, estimates are used for, but not limited to, liquidity assumptions, revenue recognition, share-based compensation, allowances for doubtful accounts and inventory obsolescence, and valuation of derivative financial instruments measured at fair value on a recurring basis, deferred tax assets and liabilities and related valuation allowance, depreciation and amortization and estimated useful lives of long-lived assets. Actual results could differ from those estimates.

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

Revenue Recognition

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

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

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

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

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

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

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

Impairment of Long-Lived Assets

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

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

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

Share-Based Compensation

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

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

materially affect the grant-date fair value of an award. These assumptions include the fair value of the underlying and the expected life of the award.

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

Recent accounting pronouncements

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

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

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

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

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

The Company will adopt ASC 842 as of January 1, 2019, using the alternative modified transition method. In preparation of adopting ASC 842, the Company is implementing additional internal controls to enable future preparation of financial information in accordance with ASC 842. The Company has also substantially completed its evaluation of the impact on the Company's lease portfolio. The Company believes the largest impact will be on the consolidated balance sheets for the accounting of facilities-related leases, which represents a majority of its operating leases it has entered into as a lessee. These leases will be recognized under the new standard as ROU assets and operating lease liabilities. The Company will also be required to provide expanded disclosures for its leasing arrangements. As of December 31, 2018, the Company had $2.8 million of undiscounted future minimum operating lease commitments that are not recognized on its consolidated balance sheets as determined under the current standard. For a lessee, the results of operations are not expected to significantly change after adoption of the new standard.

While substantially complete, the Company is still in the process of finalizing its evaluation of the effect of ASC 842 on the Company's consolidated financial statements and disclosures. The Company will finalize its accounting assessment and quantitative impact of the adoption during the first quarter of fiscal year 2019. As the Company completes its evaluation of this new standard, new information may arise that could change the Company's current understanding of the impact to leases. Additionally, the Company will continue to monitor industry activities and any additional guidance provided by regulators, standards setters, or the accounting profession, and adjust the Company's assessment and implementation plans accordingly.

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

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

Off-Balance Sheet Arrangements

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

JOBS Act

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

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," the Company intends to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. The Company will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which it has total annual gross revenues of $1.07 billion or more; (ii) December 31, 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, 2018. 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, 2018.

Changes in Internal Control over Financial Reporting

As of December 31, 2018, 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, 2018. 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, 2018, 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

None.

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. On July 14, 2015, the Company entered into a Common Stock and Note Purchase Agreement (the "Purchase Agreement") with MGHIF. Pursuant to the Purchase Agreement, the Board was expanded and MGHIF had the right, subject to the consent of the Company, to fill the new vacancy on the Board. Additionally, for as long as MGHIF holds at least five percent (5%) of the outstanding common stock of the Company, the Board is required to nominate MGHIF's designee, or any replacement, for election by the stockholders at each annual or special meeting of the stockholders at which directors are elected. Although MGHIF currently holds approximately 5.7% of the outstanding common stock, MGHIF nominated, and the Board consented to, David M. Rubin Ph.D. serving as its designee on the Board. Otherwise, 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, 2018:

Name	Age	Position
Directors		
Evan Jones	62	Chief Executive Officer, Director and Chairman of the Board
Timothy J.R. Harris, Ph.D., D.Sc	68	Director
Tina S. Nova, Ph.D.	65	Director
David M. Rubin, Ph.D.	53	Director
Misti Ushio, Ph.D.	47	Director
Other Executive Officers		
Timothy C. Dec	60	Chief Financial Officer and Corporate Secretary
Vadim Sapiro	47	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 our Chief Executive Officer since October 2013 and as Chairman of our Board since September 2010. He served as our 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.

Timothy J.R. Harris, Ph.D., D.Sc. Dr. Harris has been a director of OpGen since April 2015. Dr. Harris is a science and business leader with nearly 40 years of experience guiding and leading laboratory work and scientists in a range of molecular research areas. He is a molecular biologist, biochemist and geneticist by training and is currently EVP R&D at Bioverativ Inc., a Sanofi Company and a Venture Partner at SV Health Investors, a position he has held since March 2016. He was the SVP for Precision Medicine at Biogen from March 2015 until February 2016, and prior to that SVP of Translational Medicine at Biogen Idec from June 2011 to February 2016. He was the Chief Technology Officer and Director of the Advanced Technology Program at SAIC-Frederick, Inc. in Maryland from January 2007 to June 2011, which operates the National Cancer Institute's leading center for cancer and AIDS research (now Frederick National Laboratory operated by Leidos Inc.). He has served as President and Chief Executive Officer of

Novasite Pharmaceuticals, and he founded SGX Pharmaceuticals in 1999 (formerly Structural Genomix), where he built the company to more than 130 employees, raised $85M in capital, and generated more than $20M in revenue during six years as CEO before it was sold to Eli Lilly. Before founding SGX, Dr. Harris was Senior Vice President, Research and Development at Sequana/Axys. He began his scientific career working on animal viruses such as foot & mouth disease and was one of the first molecular biologists (1981) at Celltech (now UCB Pharma) in the United Kingdom. He subsequently spent nearly five years at Glaxo Group Research as Director of Biotechnology from 1989 to 1993. Dr. Harris received a Ph.D. and M.S. in General Virology and a B.Sc. in Biochemistry from the University of Birmingham in England and has an honorary doctorate (D.Sc.) from the University of Birmingham, UK awarded in July 2010. He is currently a visiting Professor at Columbia University.

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 Genome Dx, 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 for the newly formed Rady Pediatric Genomics and Systems Medicine Institute, which is part of Rady Children's Hospital-San Diego. 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.

David M. Rubin, Ph.D. Dr. Rubin has been a director of OpGen since July 2015. Dr. Rubin is currently a managing director at MGHIF, where he is responsible for identifying investment opportunities in emerging health care solutions and services, with a particular emphasis on solutions for precision medicine. Prior to joining MGHIF, Dr. Rubin led Merck & Co.'s portfolio management efforts in Oncology. Dr. Rubin joined Merck in 2007 from Cognia Corporation, where he was the president and chief executive officer. Previously, Dr. Rubin was at The Wilkerson Group/IBM Global Services. Dr. Rubin previously served on the board of VirtualScopics, Inc. (Nasdaq: VSCP) from 2012 through 2014 and several other GHI portfolio companies. Dr. Rubin currently serves on the boards of directors of Electrocore, LLC and Navigating Cancer, Inc. Dr. Rubin was a National Institute of Health and American Cancer Society post-doctoral fellow at Harvard Medical School. Dr. Rubin also received training in post-graduate business at Harvard University. Dr. Rubin holds a Ph.D. from Temple University in Molecular Biology and a B.A. from SUNY Binghamton in Biology.

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 our interim Chief Financial Officer in April 2015 and became our 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 the Company's informatics applications, software, databases and information technology operations. Prior to joining OpGen, Mr. Sapiro was Senior Vice President at SAIC-Frederick (now Leidos Biomedical Research Inc.) from June 2008 to December 2011, overseeing the Information Systems Program for the National Cancer Institute at SAIC-Frederick. From January 2007 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 December 2006, including another non-profit research institute. Mr. Sapiro holds a B.S. in Mathematics and Computer Science from the University of Maryland.

Newly Elected Director

On February 21, 2019, the Board of Directors of the Company elected R. Donald Elsey as a member of its Board of Directors. The Board also confirmed that Mr. Elsey is an independent director under applicable standards, including Nasdaq corporate governance standards. His term as a director began on February 21, 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 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. Because of his financial and management background and experience, the Board also appointed Mr. Elsey to serve as the chair of the Board's Audit Committee. He also qualifies as a financial expert.

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 2018 fiscal year except that Mr. Dec did not file a Form 4 in November 2018 to report the vesting of a tranche of restricted stock units.

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 2018, Mr. D'Andrea and Dr. Rubin and Dr. Ushio served on the Audit Committee, which was chaired by Mr. D'Andrea. 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 2018, Mr. D'Andrea was the designated "audit committee financial expert" as defined in the rules of the SEC . Mr. D'Andrea resigned from the Board in November 2017 and Dr. Nova was appointed to the Audit Committee in his place. In February 2019, Mr. Elsey was elected to the Board of Directors and Audit Committee, and was appointed as Chair of the Audit Committee. At that time, Dr. Nova left the Audit Committee.

Item 11. Executive Compensation

Summary Compensation Table

This table provides disclosure, for the years ended December 31, 2018 and 2017 for the named executive officers, who are (1) any individual serving in the office of Chief Executive Officer during any part of 2017 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, 2018.

Named Executive Officer and Principal Position	Year	Salary ($)	Bonus (2)($)	Stock Awards (1)($)	Option Awards (1)($)	Non-Equity Incentive Plan Compensation (2)($)	All Other Compensation ($)	Total ($)
Evan Jones	2018	$ 351,442	$ -	$ -	$ 42,767	$ -	$ -	$ 394,209
Chief Executive Officer	2017	$ 375,962	$ -	$ -	$ 43,210	$ -	$ -	$ 419,172
Timothy Dec	2018	$ 289,615	$ -	$ -	$ 24,438	$ -	$ -	$ 314,053
Chief Financial Officer	2017	$ 291,102	$ -	$ 10,325	$ 45,580	$ -	$ -	$ 347,007
Vadim Sapiro	2018	$ 289,615	$ -	$ -	$ 24,438	$ -	$ -	$ 314,053
Chief Information Officer	2017	$ 291,102	$ -	$ 10,325	$ 38,559	$ 50,000	$ -	$ 389,986

(1) The "Stock Awards" column reflects the grant date fair value for all restricted stock units awarded under the Amended and Restated 2015 Incentive Plan (the "Plan") during 2018 and 2017. The "Option Awards" column reflects the grant date fair value for all stock option awards granted under the 2015 Plan during 2018 and 2017, respectively. These amounts are determined in accordance with FASB Accounting Standards Codification 718 (ASC 718), without regard to any estimate of forfeiture for service vesting. Assumptions used in the calculation of the amounts in these columns for 2018 and 2017 are included in a footnote to the Company's condensed consolidated audited financial statements for the year ended December 31, 2018, located in Item 8 of this Annual Report.

(2) On February 19, 2019, the Compensation Committee approved the aggregate accrual for 2018 bonuses for the named executive officers and other employees of the Company. The Company will file a Form 8-K to report the 2018 bonuses for the named executive officers once they are determined and approved.

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 is a new agreement that provides that, in the event of a termination without cause by the Company or a termination for good reason by Mr. Jones, he will receive severance equal to six (6) months base salary at the time of termination. In addition, if Mr. Jones' employment is terminated without cause by the Company or any successor, or by Mr. Jones for good reason at any time within two years after a change of control of the Company, he shall receive the following additional benefits: (1) the severance payment obligation is increased to twelve (12) months; (2) acceleration, vesting and lapse of forfeiture on any outstanding equity awards granted to the Executive, and, if applicable, extended time to exercise vested stock options; and (3) payment by the Company or its successor, for a period of six (6) months, of health benefits for the Executive and/or the Executive's family at levels substantially equal to those which would have been provided to him or them in accordance with the plans, programs, practices and policies in effect as of the date immediately before the change in control consummation date.

The Agreements with the other Executives amend prior agreements to provide the same terms as described above.

For purposes of the Agreements, the following terms have the following meanings (where applicable):

"cause" means (i) executive's commission of a felony; (ii) any act or omission of executive constituting dishonesty, fraud, immoral or disreputable conduct that causes material harm to the Company; (iii) executive's violation of Company policy that causes material harm to the Company; (iv) executive's material breach of any written agreement between executive and the Company which, if curable, remains uncured after notice; or (v) executive's breach of fiduciary duty. The termination of executive's employment as a result of the death or disability is not deemed to be a termination without cause.

"change in control" means:

(i) a transaction or series of transactions (other than an offering of common stock to the general public through a registration statement filed with the SEC) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act (other than the Company, any of its subsidiaries, an employee benefit plan maintained by the Company or any of its subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; or

(ii) the consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction: (1) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the Successor) directly or indirectly, at least a majority of the combined voting power of the Successor's outstanding voting securities immediately after the transaction, and (2) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor; provided, however, that no person or group shall be treated for purposes of this definition as beneficially owning 50% or more of the combined voting power of the Successor solely as a result of the voting power held in the Company prior to the consummation of the transaction; or

(iii) the Company's stockholders approve a liquidation or dissolution of the Company.

"good reason" means any of the following, without executive's consent: (i) a material diminution of executive's responsibilities or duties (provided, however, that the acquisition of the Company and subsequent conversion of the Company to a division or unit of the

acquiring company will not by itself be deemed to be a diminution of executive's responsibilities or duties); (ii) material reduction in the level of executive's base salary (and any such reduction will be ignored in determining executive's base salary for purposes of calculating the amount of severance pay); (iii) relocation of the office at which executive is principally based to a location that is more than fifty (50) miles from the location at which executive performed his duties immediately prior to the effective date of a change in control; (iv) failure of a successor in a change in control to assume the severance agreement; or (v) the Company's material breach of any written agreement between executive and the Company. Notwithstanding the foregoing, any actions taken by the Company to accommodate a disability of executive or pursuant to the Family and Medical Leave Act shall not be a good reason for purposes of the agreement. Additionally, before executive may terminate employment for a good reason, executive must notify the Company in writing within thirty (30) days after the initial occurrence of the event, condition or conduct giving rise to good reason, the Company must fail to remedy or cure the alleged good reason within the thirty (30) day period after receipt of such notice if capable of being cured within such thirty-day period, and, if the Company does not cure the good reason (or it is incapable of being cured within such thirty-day period), then executive must terminate employment by no later than thirty (30) days after the expiration of the last day of the cure period (or, if the event condition or conduct is not capable of being cured within such thirty-day period, within thirty (30) days after initial notice to the Company of the violation). Transferring executive's employment to a successor is not itself good reason to terminate employment under the agreement, provided, however, that subparagraphs (i) through (v) above shall continue to apply to executive's employment by the successor. This definition is intended to constitute a "substantial risk of forfeiture" as defined under Treasury Regulation 1.409A-1(d).

Outstanding Equity Awards at Fiscal Year-End Table—2018

The following table shows the outstanding equity awards held by the named executive officers as of December 31, 2018.

	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)	73	-	-	2,767.00	9/21/2020	-	-	-	-
	6,969	-	-	1.25	4/24/2024	-	-	-	-
	8,000	-	-	15.25	10/23/2024	-	-	-	-
	21,079	9,581	-	33.75	4/28/2026	-	-	-	-
	1,400	1,800	-	25.75	2/23/2027	-	-	-	-
	-	21,000	-	4.02	1/28/2028	-	-	-	-
Timothy Dec (4)	4,286	286	-	150.00	5/4/2025	250	325		
	1,625	375	-	42.50	11/10/2025	-	-	-	-
	1,650	750	-	38.75	6/13/2026	-	-	-	-
	1,190	1,530	-	25.75	2/23/2027	-	-	-	-
	2,400	-	-	7.375	8/9/2027	-	-	-	-
	-	12,000	-	4.02	1/23/2028	-	-	-	-
Vadim Sapiro (5)	2	-	-	197.75	3/23/2022	-	-		
	36	-	-	197.75	3/23/2022	-	-	-	-
	10	-	-	197.75	2/12/2023	-	-	-	-
	5	-	-	197.75	2/12/2023	-	-	-	-
	25	-	-	197.75	7/25/2023	-	-	-	-
	143	-	-	1.25	4/24/2024	-	-	-	-
	2,000	-	-	15.25	10/23/2024	-	-	-	-
	1,000	-	-	150.00	5/4/2025	-	-	-	-
	1,100	500	-	38.750	6/13/2026	-	-	-	-
	962	1,238	-	25.75	2/23/2027	-	-	-	-
	2,400	-	-	7.375	8/9/2027	-	-	-	-
	-	12,000	-	4.02	1/23/2028	-	-	-	-

(1) The standard vesting schedule for all stock option grants is vesting over four years with twenty-five percent (25%) vesting on the first anniversary of the date of grant and six and one-quarter percent (6.25%) vesting on the last day of the next fiscal quarter over three years.

(2) Calculated based on the closing price of the common stock the Nasdaq Capital Market on December 31, 2018 of $1.30 per share.

(3) The stock option awards made to Mr. Jones were awarded on February 15, 2011 (73 shares), April 24, 2014 (6,969 shares), October 23, 2014 (8,000 shares) and April 28, 2016 (30,660 shares) and have the vesting schedule set forth in footnote (1). Mr. Jones was granted a stock option award on February 23, 2017 (3,200), 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 (21,000), which vests over four years with twenty-five percent (25%) vesting on January 23, 2019 and six and one-quarter percent (6.25%) vesting on the quarterly anniversary of the first vesting date thereafter over the next three years.

(4) Mr. Dec was granted stock option awards on May 4, 2015 (4,572 shares), November 10, 2015 (2,000 shares), June 13, 2016 (2,400 shares), February 23, 2017 (2,720), and August 9, 2017 (2,400). 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 (12,000), which vests over four years with twenty-five percent (25%) vesting on January 23, 2019 and six and one-quarter percent (6.25%) vesting on the quarterly anniversary of the first vesting date thereafter over the next three years. Mr. Dec was granted restricted stock units on November 10, 2015. Twenty-five percent (25%) of the entire restricted stock units award vests on the first four anniversaries of the date of grant. Mr. Dec was granted restricted stock units on August 9, 2017. The restricted stock units vested in February 2018 upon the successful launch of the Company's Acuitas AMR Gene Panel tests in the RUO market.

(5) The stock option awards granted to Mr. Sapiro on March 23, 2012 (2 shares and 36 shares), February 12, 2013 (10 shares), July 25, 2013 (25 shares), October 23, 2014 (2,000 shares) and June 13, 2016 (1,600 shares) have the vesting schedule set forth in footnote (1). The stock option award granted to Mr. Sapiro on February 12, 2013 for 5 shares vested in full on the first anniversary of the date of grant, February 12, 2014. The stock option award granted to Mr. Sapiro on April 24, 2014 for 143 shares is vesting over four years with twenty-five percent (25%) vesting on December 31, 2014 and six and one-fourth percent (6.25%) vesting quarterly thereafter in equal proportions over the remaining three years. The stock option granted to Mr. Sapiro on May 4, 2015 vested quarterly over the first year following the date of grant. The stock option award granted to Mr. Sapiro on February 23, 2017 for 2,200 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 2,400 shares vested on August 9, 2018. Mr. Sapiro was granted a stock option award on January 23, 2018 (12,000), which vests over four years with twenty-five percent (25%) vesting on January 23, 2019 and six and one-quarter percent (6.25%) vesting on the quarterly anniversary of the first vesting date thereafter over the next three years. Mr. Sapiro was granted restricted stock units on August 9, 2017. The restricted stock units vested in February 2018 upon the successful launch of the Company's Acuitas AMR Gene Panel tests in the RUO market.

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 1,200 shares of common stock and each non- employee director receives an annual stock option grants to purchase 500 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 2018 compensation. As managing director of MGHIF, Dr. Rubin is precluded from receiving compensation for serving as a director of OpGen, Inc. Compensation for the non-employee directors for the year ended December 31, 2018 was:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Harry J. D'Andrea (2)	$ 40,000	2,568	-	42,658
Timothy J.R. Harris (2)	$ 33,500	2,568	-	36,068
Tina S. Nova (2)	$ 32,500	2,568	-	35,068
David M. Rubin (3)	$ -	-	-	-
Misti Ushio (2)	$ 42,000	2,568	-	44,568

(1) The "Option Awards" column reflects the grant date fair value for all stock option awards granted under the 2015 Plan during 2018. 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, 2018 in Item 8 of this Annual Report.

(2) As of December 31, 2018, the non-employee directors held the following vested stock options: D'Andrea 4,700; Harris 4,481; Nova 2,775; and Ushio 2,875.

(3) As managing director of MGHIF, Dr. Rubin is precluded from receiving compensation for serving as a director of OpGen, Inc.

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, 2018, 123,023 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, 2018 was 8,645,720 shares. The following table sets forth the beneficial ownership of the Company's common stock as of December 31, 2018 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, 2018 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, 2018, 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, other than as set forth below. 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
5% Stockholders		
Merck Global Health Innovation Fund, LLC (1) One Merck Drive 2W116 Whitehouse Station, NJ 08889	491,927	5.60%
Directors and Named Executive Officers		
Evan Jones (2)	410,506	4.65%
Harry D'Andrea (3)	6,271	*
R. Donald Elsey (4)	-	-
Timothy J.R. Harris, Ph.D., D.Sc. (5)	9,624	*
Tina S. Nova, Ph.D.(6)	2,775	*
David M. Rubin, Ph.D. (7)	-	-
Misti Ushio, Ph.D. (8)	4,446	*
Timothy C. Dec (9)	25,050	*
Vadim Sapiro (10)	15,218	*
All current Directors and Executive Officers as a group (9 individuals) (11)	473,890	5.34%

* Constitutes less than 1%

(1) Consists of (i) 360,774 shares of common stock, and (ii) currently exercisable warrants to acquire an additional 131,153 shares of common stock.

(2) Consists of (i) 227,138 shares of common stock and currently exercisable warrants to acquire an additional 134,317 shares of common stock beneficially owned by jVen Capital, LLC, (ii) 5,246 shares of common stock and currently exercisable warrants to acquire an additional 834 shares of common stock owned by Mr. Jones' spouse, and (iii) stock options to purchase 42,971 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.

(3) Consists of (i) 1,571 shares of common stock and (ii) stock options to purchase 4,700 shares of common stock that are currently vested.

(4) Mr. Elsey was elected to the Board of Directors on February 21, 2019.

(5) Consists of (i) 3,576 shares of common stock, (ii) currently exercisable warrants to acquire an additional 1,567 shares of common stock, and (iii) stock options to purchase 4,481 shares of common stock that are currently vested or that will become vested within 60 days.

(6) Consists of stock options to purchase 2,775 shares of common stock that are currently vested or that will become vested within 60 days.

(7) Dr. Rubin is the managing director of Merck Global Health Innovation Fund, LLC ("MGHIF"), but does not have nor share voting power over the shares of our common stock owned by MGHIF.

(8) Consists of (i) 1,571 shares of common stock and (ii) stock options to purchase 2,875 shares of common stock that are currently vested or that will become vested within 60 days.

(9) Consists of (i) 6,658 shares of common stock, (ii) currently exercisable warrants to acquire an additional 4,071 shares of common stock, and (iii) stock options to purchase 14,321 shares of common stock that are currently vested or that will become vested within 60 days.

(10) Consists of (i) 3,004 shares of common stock, (ii) currently exercisable warrants to acquire an additional 1,393 shares of common stock, and (iii) stock options to purchase 10,821 shares of common stock that are currently vested or that will become vested within 60 days.

(11) See the beneficial ownership described in footnotes (2) through (10).

Employee Incentive Plans

The following table shows, as of December 31, 2018, 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	211,809	$ 20,58	50,863
Equity compensation plans not approved by security holders	—	—	—
Total	211,809	$ 20.58	50,863

(1) Includes 250 outstanding restricted stock units for which there is no exercise price.

(2) Includes the weighted-average exercise price of stock options 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 $22,603 and $146,177 during the years ended December 31, 2018 and 2017.

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, 2018 and 2017, the Company recognized $329,162 and $210,180 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 2018, the Board members were Harry D’Andrea, 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 2018, Mr. D’Andrea 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 2013. 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, 2018 and 2017.

	2018	2017
Audit Fees (1)	$ 383,681	$ 411,681
Audit Related Fees		
Tax Fees	-	-
All Other Fees	-	-
Total Fees	$ 383,681	$ 411,681

(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, 2018 and 2017, the review of our quarterly financial statements on Form 10-Q, filing of Registration Statements on Forms S-1, S-3 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, 2018. 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.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements.

The consolidated balance sheets of the Company as of December 31, 2018 and 2017, 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
1.1	Underwriting Agreement, dated October 18, 2018, by and between OpGen, Inc. and Aegis Capital Corp. (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K, filed on October 18, 2018)
3.1	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)
3.2	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)
3.3	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)
3.4	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 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)
4.3	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)
4.4	Form of Pre-Funded Common Stock Purchase Warrant for February 2018 Public Offering (incorporated by reference to Exhibit 4.4 to the Registrants Form S-1/A, File No. 333-222140, filed on January 31, 2018)
4.5	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)
4.6	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)
4.7	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)
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)

Exhibit Number	Description
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)
10.2	Lease Extension #6, dated October 14, 2016, by and between the Registrant and Cummings Properties, LLC (related to AdvanDx facility) (incorporated by reference to Exhibit 10.2 of Quarterly Report on Form 10-Q, filed November 14, 2016)
10.3	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)
10.4	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)
10.5 !	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)
10.6	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)
10.7.1 !	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)
10.7.2 !	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)
10.7.3 !	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)
10.8 !	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)
10.9	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)
10.10	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)
10.10.1	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)

Exhibit Number	Description
10.10.2	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)
10.11	Third Amended and Restated Investors' Rights Agreement, dated as of December 18, 2013, among the Registrant and, certain investors (registration rights provisions) (incorporated by reference to Exhibit 4.2 to the Registrant's Form S-1, File No. 333-202478, filed on March 3, 2015)
10.12	Registration Rights Agreement, dated as of July 14, 2015, among the Registrant, Merck Global Health Innovation Fund, LLC, SLS Invest AB and LD Pensions (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed on July 16, 2015)
10.13	Letter Agreement, dated July 12, 2015, between the Registrant and Fluidigm Corporation (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 14, 2015)
10.14	Securities Purchase Agreement, dated as of May 12, 2016, by and between the Registrant the Purchasers party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 17, 2016)
10.15	Amended and Restated Securities Purchase Agreement, dated as of May 18, 2016, by and between the Registrant and the Purchasers party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 20, 2016)
10.16 !	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)
10.17	Common Stock Sales Agreement, dated September 13, 2016, by and between the Registrant and Cowen and Company, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 14, 2016)
10.18	Amended & Restated Note Purchase Agreement, dated as of July 10, 2017, by and between the Registrant and jVen Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, Amendment No. 2, filed on July 10, 2017)
10.19	Form of Secured Convertible Promissory Note #1 to be issued to jVen Capital, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K/A, filed on July 10, 2017)
10.20	Form of Secured Promissory Note #2 and #3 to be issued to jVen Capital, LLC (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K/A, filed on July 10, 2017)
10.21	Amended and Restated Registration Rights Agreement, dated as of June 6, 2017, by and between the Registrant and the Investors party thereto (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed on June 6, 2017)
10.22±	Supply Agreement, dated as of June 15, 2017, by and between the Registrant and Life Technologies Corporation (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on June 19, 2017)
10.23	Securities Purchase Agreement, dated as of July 12, 2017, among the Registrant and the purchasers signatory thereto, (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 14, 2017)
10.24	Engagement Letter with H.C Wainwright & Co., dated as of June 12, 2017 (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-1, Amendment No. 2, File No. 333-218392, filed on July 11, 2017)
10.25 !	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)
10.26 !	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)
10.27 !	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).
10.28	Form of Securities Purchase Agreement between the Registrant and the purchasers signatory thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 2, 2018)

Exhibit Number	Description
10.29	Engagement Letter, dated as of December 18, 2017, between the Registrant and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-1, Amendment No. 1, File No. 333-222140, filed on January 31, 2018)
10.30 !	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)
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, (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
± Confidential treatment has been requested for certain portions of this agreement pursuant to an application for confidential treatment filed with the Securities and Exchange Commission on June 19, 2017. Such provisions have been filed separately with the Commission.

(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: February 27, 2019

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

Date: February 27, 2019

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)	February 27, 2019
/s/ Timothy C. Dec Timothy C. Dec	Chief Financial Officer (principal financial officer and principal accounting officer)	February 27, 2019
R. Donald Elsey	Director	
/s/ Timothy J.R. Harris Timothy J.R. Harris	Director	February 27, 2019
/s/ Tina S. Nova Tina Nova	Director	February 27, 2019
/s/ David M. Rubin David M. Rubin	Director	February 27, 2019
/s/ Misti Ushio Misti Ushio	Director	February 27, 2019

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, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the years then ended and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern.

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred losses from operations since inception and will need additional capital to fund future operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company's auditor since 2014.

Tysons, Virginia
February 27, 2019

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

	2018	2017
Assets		
Current assets		
Cash and cash equivalents	$ 4,572,487	$ 1,847,171
Accounts receivable, net	373,858	809,540
Inventory, net	543,747	533,425
Prepaid expenses and other current assets	292,918	311,644
Total current assets	**5,783,010**	**3,501,780**
Property and equipment, net	1,221,827	835,537
Goodwill	600,814	600,814
Intangible assets, net	1,085,366	1,353,182
Other noncurrent assets	259,346	328,601
Total assets	**$ 8,950,363**	**$ 6,619,914**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,623,751	$ 1,691,712
Accrued compensation and benefits	1,041,573	746,924
Accrued liabilities	902,019	1,160,714
Deferred revenue	15,824	24,442
Short-term notes payable	398,595	1,010,961
Current maturities of long-term capital lease obligation	399,345	154,839
Total current liabilities	**4,381,107**	**4,789,592**
Deferred rent	162,919	290,719
Note payable	660,340	—
Warrant liability	67	8,453
Long-term capital lease obligation and other noncurrent liabilities	437,189	130,153
Total liabilities	**5,641,622**	**5,218,917**
Commitments (Note 9)		
Stockholders' equity		
Common stock, $0.01 par value; 50,000,000 shares authorized; 8,645,720 and 2,265,320 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	86,457	22,653
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2018 and December 31, 2017, respectively	—	—
Additional paid-in capital	165,313,902	150,114,671
Accumulated other comprehensive loss	(13,093)	(25,900)
Accumulated deficit	(162,078,525)	(148,710,427)
Total stockholders' equity	**3,308,741**	**1,400,997**
Total liabilities and stockholders' equity	**$ 8,950,363**	**$ 6,619,914**

See accompanying notes to consolidated financial statements.

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

	2018	2017
Revenue		
Product sales	$ 2,395,626	$ 2,771,869
Laboratory services	34,665	41,960
Collaboration revenue	516,016	397,178
Total revenue	**2,946,307**	**3,211,007**
Operating expenses		
Cost of products sold	1,222,919	1,612,838
Cost of services	625,516	520,338
Research and development	5,677,243	6,883,293
General and administrative	7,069,315	6,692,659
Sales and marketing	1,531,556	2,767,670
Total operating expenses	**16,126,549**	**18,476,798**
Operating loss	**(13,180,242)**	**(15,265,791)**
Other income/(expense)		
Interest and other income/(expense)	5,384	(87,255)
Interest expense	(191,195)	(233,505)
Foreign currency transaction (losses)/gains	(10,431)	23,179
Change in fair value of derivative financial instruments	8,386	144,064
Total other expense	**(187,856)**	**(153,517)**
Loss before income taxes	**(13,368,098)**	**(15,419,308)**
Provision for income taxes	—	—
Net loss	**$ (13,368,098)**	**$ (15,419,308)**
Net loss per common share - basic and diluted	**$ (2.22)**	**$ (9.80)**
Weighted average shares outstanding - basic and diluted	6,009,065	1,573,769
Net loss	$ (13,368,098)	$ (15,419,308)
Other comprehensive income/(loss) - foreign currency translation	12,807	(32,076)
Comprehensive loss	**$ (13,355,291)**	**$ (15,451,384)**

See accompanying notes to consolidated financial statements.

OpGen, Inc.
Consolidated Statements of Stockholders' Equity

	Common Stock		Preferred Stock		Additional	Accumulated Other		
	Number of Shares	Amount	Number of Shares	Amount	Paid-in Capital	Comprehensive (Loss) / Income	Accumulated Deficit	Total
Balances at December 31, 2016	**1,012,171**	**$ 10,122**	—	—	**$136,442,302**	**$ 6,176**	**$(133,291,119)**	**$ 3,167,481**
Stock option exercises	1,167	12	—	—	8,168	—	—	8,180
Public offering of common stock and warrants, net of issuance costs	1,000,000	10,000	—	—	8,813,242	—	—	8,823,242
At the market offering, net of offering costs	227,216	2,272	—	—	3,806,564	—	—	3,808,836
Issuance of RSUs	6,025	60	—	—	(60)	—	—	—
Stock compensation expense	—	—	—	—	911,398	—	—	911,398
Legal settlement in common stock	15,843	158	—	—	109,841	—	—	109,999
Vendor payment in common stock	2,898	29	—	—	23,216	—	—	23,245
Foreign currency translation	—	—	—	—	—	(32,076)	—	(32,076)
Net loss	—	—	—	—	—	—	(15,419,308)	(15,419,308)
Balances at December 31, 2017	**2,265,320**	**22,653**	—	—	**150,114,671**	**(25,900)**	**(148,710,427)**	**1,400,997**
Public offering of common stock and warrants, net of issuance costs	5,912,307	59,123	—	—	13,471,278	—	—	13,530,401
At the market offering, net of offering costs	318,236	3,182	—	—	594,561	—	—	597,743
Issuance of RSUs	5,650	57	—	—	(57)	—	—	—
Stock compensation expense	—	—	—	—	862,281	—	—	862,281
Share cancellation	(31)	—	—	—	—	—	—	—
Interest settlement in common stock	144,238	1,442	—	—	271,168	—	—	272,610
Foreign currency translation	—	—	—	—	—	12,807	—	12,807
Net loss	—	—	—	—	—	—	(13,368,098)	(13,368,098)
Balances at December 31, 2018	**8,645,720**	**$ 86,457**	**—**	$ —	**$165,313,902**	**$ (13,093)**	**$(162,078,525)**	**$ 3,308,741**

See accompanying notes to consolidated financial statements.

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

	2018	2017
Cash flows from operating activities		
Net loss	$ (13,368,098)	$ (15,419,308)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	730,884	669,088
Noncash interest expense	133,802	185,294
Share-based compensation	862,281	911,398
Gain on sale of equipment	(5,253)	—
Change in fair value of warrant liabilities	(8,386)	(144,064)
Unamortized discount on bridge loan at repayment	—	85,932
Changes in operating assets and liabilities:		
Accounts receivable	432,814	(260,471)
Inventory	(11,273)	161,027
Other assets	486	(315,688)
Accounts payable	89,493	(563,357)
Accrued compensation and other liabilities	77,871	399,224
Deferred revenue	(8,618)	(12,955)
Net cash used in operating activities	**(11,073,997)**	**(14,303,880)**
Cash flows from investing activities		
Purchases of property and equipment	(147,767)	(276,950)
Proceeds from sale of equipment	10,440	—
Net cash used in investing activities	**(137,327)**	**(276,950)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	597,743	3,808,836
Proceeds from issuance of units, net of selling costs	13,530,401	8,754,882
Proceeds from debt, net of issuance costs	381,253	1,168,222
Proceeds from exercise of stock options	—	76,537
Payments on debt	(371,573)	(1,255,198)
Payments on capital lease obligations	(292,722)	(205,085)
Net cash provided by financing activities	**13,845,102**	**12,348,194**
Effects of exchange rates on cash	12,878	(37,517)
Net increase/(decrease) in cash, cash equivalents and restricted cash	2,646,656	(2,270,153)
Cash, cash equivalents and restricted cash at beginning of year	2,090,551	4,360,704
Cash, cash equivalents and restricted cash at end of year	**$ 4,737,207**	**$ 2,090,551**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 57,393	$ 48,211
Supplemental disclosures of noncash investing and financing activities:		
Shares issued to settle obligations	$ 272,610	$ 133,245
Property and equipment acquired through capital lease	$ 706,778	$ —
Conversion of accounts payable to capital lease	$ 156,775	$ —
Unpaid deferred offering costs	$ —	$ 48,398

See accompanying notes to consolidated financial statements.

Note 1 - Organization

OpGen, Inc. ("OpGen" or the "Company") was incorporated in Delaware in 2001. References in this report to the "Company" include OpGen and its wholly-owned subsidiaries. The Company's headquarters are in Gaithersburg, Maryland, and its principal operations are in Gaithersburg, Maryland. The Company also has operations in Woburn, Massachusetts, Copenhagen, Denmark, and Bogota, Colombia. The Company operates in one business segment.

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

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

- The Company's Acuitas molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include its Acuitas antimicrobial resistance, or AMR, Gene Panel (Urine) test in development for patients at risk for complicated urinary tract infection, or cUTI, and its Acuitas AMR Gene Panel (Isolates) test in development for testing bacterial isolates, and its QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of the Acuitas AMR Gene Panel tests is available for sale for research use only, or RUO.
- The Company's Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that combine clinical lab test results with patient and hospital information to provide analytics and actionable insights to help manage MDROs in the hospital and patient care environment. Components of the informatics systems include the Acuitas Lighthouse Knowledgebase and the Acuitas Lighthouse Software. The Acuitas Lighthouse Knowledgebase is a relational database management system and a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens. The Acuitas Lighthouse Software system includes the Acuitas Lighthouse Portal, a suite of web applications and dashboards, the Acuitas Lighthouse Prediction Engine, which is a data analysis software, and other supporting software components. The Acuitas Lighthouse Software can be customized and made specific to a healthcare facility or collaborator, such as a pharmaceutical company. The Acuitas Lighthouse Software is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

The Company's operations are subject to certain risks and uncertainties. The risks include the risk that the Company will not receive 510(k) clearance for its Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software on a timely basis, or at all, rapid technology changes, the need to retain key personnel, the need to protect intellectual property and the need to raise additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop, obtain regulatory approval for and commercialize its proprietary technology as well as raise additional capital.

Note 2 - Going Concern and Management's Plans

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Since inception, the Company has incurred, and continues to incur, significant losses from operations. The Company has funded its operations primarily through external investor financing arrangements and significant actions taken by the Company to reduce costs, including:

- On October 22, 2018, the Company closed a public offering (the "October 2018 Public Offering") of 2,220,000 shares of its common stock at a public offering price of $1.45 per share. The offering raised gross proceeds of approximately $3.2 million and net proceeds of approximately $2.8 million.
- On June 11, 2018, the Company executed an Allonge (the "Allonge") to its Second Amended and Restated Senior Secured Promissory Note, dated June 28, 2017, with a principal amount of $1,000,000 issued to Merck Global Health Innovation Fund, LLC ("MGHIF"). The Allonge provided that accrued and unpaid interest of $285,512 due as of July 14, 2018, the original maturity date, be paid through the issuance of shares of OpGen's common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021. On July 30, 2018, the

Company issued 144,238 shares of common stock to MGHIF in a private placement transaction for $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

- On February 6, 2018, the Company closed a public offering (the "February 2018 Public Offering") of 2,841,152 units at $3.25 per unit, and 851,155 pre-funded units at $3.24 per pre-funded unit, raising gross proceeds of approximately $12 million and net proceeds of approximately $10.7 million. Each unit included one share of common stock and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. As of April 19, 2018, all 851,155 pre-funded warrants issued in the February 2018 Public Offering have been exercised.
- On July 18, 2017, the Company closed a public offering (the "July 2017 Public Offering") of 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million. jVen Capital, LLC ("jVen Capital") was one of the investors participating in the offering. jVen Capital is an affiliate of Evan Jones, the Company's Chairman of the Board and Chief Executive Officer. Each unit included one twenty-fifth of a share of common stock and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. Each pre-funded unit included one pre-funded warrant to purchase one twenty-fifth of a share of common stock for an exercise price of $0.25 per share, and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. Approximately $1 million of the gross proceeds was used to repay the outstanding Bridge Financing Notes to jVen Capital in July 2017.
- In early June 2017, the Company commenced a restructuring of its operations to improve efficiency and reduce its cost structure. Under the restructuring plan the Company is consolidating its operations, including manufacturing, for its FDA-cleared and CE marked QuickFISH and PNA FISH families of products and research and development activities for the Acuitas AMR Gene Panel products and services, in Gaithersburg, Maryland, and reducing the size of its commercial organization while the Company works to complete the development of its Acuitas AMR Gene Panel and Acuitas Lighthouse Knowledgebase products and services in development.
- On May 31, 2017, the Company entered into a Note Purchase Agreement with jVen Capital, under which jVen Capital agreed to provide bridge financing in an aggregate principal amount of up to $1,500,000 to the Company in up to three separate tranches of $500,000 (each, a "Bridge Financing Note" and collectively, the "Bridge Financing Notes"). In connection with the issuance of Bridge Financing Notes, in June and July 2017, the Company issued jVen Capital stock purchase warrants to acquire 5,634 shares with an exercise price of $19.50 per share, and warrants to acquire 6,350 shares with an exercise price of $17.25 per share. The Company drew down on two of three Bridge Financing Notes during June and July 2017, and repaid such outstanding Bridge Financing Notes in full upon the closing of the July 2017 Public Offering.
- On September 13, 2016, the Company entered into the Sales Agreement (the "Sales Agreement") with Cowen and Company LLC ("Cowen") pursuant to which the Company may offer and sell from time to time, up to an aggregate of $25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of $11.5 million. As of December 31, 2018, the Company sold an aggregate of 690,247 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $8.8 million, and gross proceeds of $9.4 million. During the year ended December 31, 2018, the Company has sold 318,236 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $0.6 million, and gross proceeds of $0.6 million. In connection with the October 2018 Public Offering, the Company terminated the at the market offering.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, strategic financings or other transactions, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements and business combination transactions. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. The Company believes that current cash will be sufficient to fund operations into the second quarter of 2019. This has led management to conclude that substantial doubt about the Company's ability to continue as a going concern exists. In the event the Company is unable to successfully raise additional capital during or before the second quarter of 2019, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to immediately reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing. If such sufficient financing is not received on a timely basis, the Company would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

Note 3 - Summary of Significant Accounting Policies

Basis of Presentation

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

Foreign Currency

The Company has subsidiaries located in Copenhagen, Denmark, and Bogota, Colombia, both of which use currencies other than the U.S. dollar as their functional currency. As a result, all assets and liabilities are translated into U.S. dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the average exchange rates prevailing during the reporting period. Translation adjustments are reported in accumulated other comprehensive (loss)/income, a component of stockholders' equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive (loss)/income at December 31, 2018 and 2017.

Foreign currency transaction gains and losses, excluding gains and losses on intercompany balances where there is no current intent to settle such amounts in the foreseeable future, are included in the determination of net loss. Unless otherwise noted, all references to "$" or "dollar" refer to the United States dollar.

Use of Estimates

In preparing financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, liquidity assumptions, revenue recognition, share-based compensation, allowances for doubtful accounts and inventory obsolescence, and valuation of derivative financial instruments measured at fair value on a recurring basis, deferred tax assets and liabilities and related valuation allowance, depreciation and amortization and estimated useful lives of long-lived assets. Actual results could differ from those estimates.

Fair value of financial instruments

Financial instruments classified as current assets and liabilities (including cash and cash equivalent, receivables, accounts payable, deferred revenue and short-term notes) are carried at cost, which approximates fair value, because of the short-term maturities of those instruments.

For additional fair value disclosures, see Note 12.

Cash and cash equivalents and restricted cash

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. The Company has cash and cash equivalents deposited in financial institutions in which the balances occasionally exceed the federal government agency (FDIC) insured limits of $250,000. The Company has not experienced any losses in such accounts, and management believes it is not exposed to any significant credit risk.

As of December 31, 2018 and 2017, the Company had funds totaling $164,720 and $243,380, respectively, which are required as collateral for letters of credit benefiting its landlords and for credit card processors. These funds are reflected in other noncurrent assets on the accompanying consolidated balance sheets.

Accounts Receivable

The Company's accounts receivable result from revenues earned but not collected from customers. Credit is extended based on an evaluation of a customer's financial condition and, generally, collateral is not required. Accounts receivable are due within 30 to 60 days and are stated at amounts due from customers. The Company evaluates if an allowance is necessary by considering a number of factors, including the length of time accounts receivable are past due, the Company's previous loss history and the customer's current ability to pay its obligation. If amounts become uncollectible, they are charged to operations when that determination is made. The allowance for doubtful accounts was $18,332 and $31,278 as of December 31, 2018 and 2017, respectively.

At December 31, 2018, the Company had accounts receivable from one customer which individually represented 12% of total accounts receivable. At December 31, 2017, the Company had accounts receivable from one customer which individually represented 41% of total accounts receivable. For the year ended December 31, 2018, revenue earned from one customer represented 17% of total revenues. For the year ended December 31, 2017, revenue earned from one customer represented 11% of total revenues.

Inventory

Inventories are valued using the first-in, first-out method and stated at the lower of cost or net realizable value and consist of the following:

	December 31,	
	2018	2017
Raw materials and supplies	$ 368,438	$ 360,134
Work-in process	58,402	51,233
Finished goods	116,907	122,058
Total	$ 543,747	$ 533,425

Inventory includes reagents and components for QuickFISH and PNA FISH kit products, and reagents and supplies used for the Company's laboratory services. Inventory reserves for obsolescence and expirations were $71,270 and $155,507 at December 31, 2018 and 2017, respectively.

Long-lived assets

Property and equipment

Property and equipment is stated at cost and depreciated on a straight-line basis over the estimated useful lives of the related assets. The estimated service lives approximate three to five years. Depreciation expense was $463,068 and $401,272 for the years ended December 31, 2018 and 2017, respectively. Property and equipment consisted of the following at December 31, 2018 and 2017:

	December 31,	
	2018	2017
Laboratory and manufacturing equipment	$ 4,829,323	$ 4,109,367
Office furniture and equipment	700,299	700,299
Computers and network equipment	1,520,713	1,505,651
Leasehold improvements	745,800	729,504
	7,796,135	7,044,821
Less accumulated depreciation	(6,574,308)	(6,209,284)
Property and equipment, net	$ 1,221,827	$ 835,537

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the years ended December 31, 2018 and 2017, the Company determined that its property and equipment was not impaired.

Intangible assets and goodwill

Intangible assets and goodwill as of December 31, 2018 and 2017 were acquired as part of a July 2015 merger transaction in which the Company acquired AdvanDx, Inc. and its subsidiary (the "Merger") and consist of finite-lived intangible assets and goodwill.

Finite-lived intangible assets

Finite-lived intangible assets include trademarks, developed technology and customer relationships, and consisted of the following as of December 31, 2018 and 2017:

	December 31, 2018			December 31, 2017	
	Cost	Accumulated Amortization	Net Balance	Accumulated Amortization	Net Balance
Trademarks and tradenames	$ 461,000	$ (159,783)	$ 301,217	$ (113,679)	$ 347,321
Developed technology	458,000	(226,746)	231,254	(161,322)	296,678
Customer relationships	1,094,000	(541,105)	552,895	(384,817)	709,183
	$ 2,013,000	$ (927,634)	$ 1,085,366	$ (659,818)	$ 1,353,182

Finite-lived intangible assets are amortized over their estimated useful lives. The estimated useful life of trademarks is 10 years, developed technology is 7 years, and customer relationships is 7 years. The Company reviews the useful lives of intangible assets when events or changes in circumstances occur which may potentially impact the estimated useful life of the intangible assets.

Total amortization expense of intangible assets was $267,816 and $267,816 for the years ended December 31, 2018 and 2017, respectively. Expected amortization of intangible assets for each of the next five fiscal years is as follows.

Year Ending December 31,	
2019	$ 267,816
2020	267,816
2021	267,816
2022	165,117
2023	46,104
Thereafter	70,697
Total	$ 1,085,366

Finite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any. During the years ended December 31, 2018 and 2017, the Company determined that its finite-lived intangible assets were not impaired.

In accordance with ASC 360-10, the Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that long-lived assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. During 2018, events and circumstances indicated the Company's intangible assets might be impaired. However, management's estimate of undiscounted cash flows indicated that such carrying amounts were expected to be recovered. Nonetheless, it is reasonably possible that the estimate of undiscounted cash flows may change in the near term, resulting in the need to write down those assets to fair value.

Goodwill

Goodwill represents the excess of the purchase price for AdvanDx, Inc. and subsidiary (collectively, "AdvanDx") over the fair values of the acquired tangible or intangible assets and assumed liabilities. Goodwill is not tax deductible in any relevant jurisdictions.

The Company conducts an impairment test of goodwill on an annual basis as of October 1 of each year, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value. As of December 31, 2018, the Company determined that its goodwill was not impaired.

Deferred rent

Deferred rent is recorded and amortized to the extent the total minimum rental payments allocated to the current period on a straight-line basis exceed or are less than the cash payments required.

Revenue recognition

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

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

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

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

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

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

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

Research and development costs

Research and development costs are expensed as incurred. Research and development costs primarily consist of salaries and related expenses for personnel, other resources, laboratory supplies, fees paid to consultants and outside service partners.

Share-based compensation

Share-based compensation expense is recognized at fair value. The fair value of share-based compensation to employees and directors is estimated, on the date of grant, using the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option. For all time-vesting awards granted, expense is amortized using the straight-line attribution method. The Company accounts for forfeitures as they occur.

Option valuation models, including the Black-Scholes model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award. A discussion of management's methodology for developing each of the assumptions used in the Black-Scholes model is as follows:

Fair value of common stock

For periods prior to the Company's IPO in May 2015, given the lack of an active public market for the common stock, the Company's board of directors determined the fair value of the common stock. In the absence of a public market, and as an emerging company with no significant revenues, the Company believed that it was appropriate to consider a range of factors to determine the fair market value of the common stock at each grant date. The factors included: (1) the achievement of clinical and operational milestones by the Company; (2) the status of strategic relationships with collaborators; (3) the significant risks associated with the Company's stage of development; (4) capital market conditions for life science and medical diagnostic companies, particularly similarly situated, privately held, early stage companies; (5) the Company's available cash, financial condition and results of operations; (6) the most recent sales of the Company's preferred stock; and (7) the preferential rights of the outstanding preferred stock. Since the IPO, the Company uses the quoted market price of its common stock as its fair value.

Expected volatility

Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. Until a significant trading history for its common stock develops, the Company has identified several public entities of similar size, complexity and stage of development; accordingly, historical volatility has been calculated using the volatility of this peer group.

Expected dividend yield

The Company has never declared or paid dividends on its common stock and has no plans to do so in the foreseeable future.

Risk-free interest rate

This is the U.S. Treasury rate for the day of each option grant during the year, having a term that most closely resembles the expected term of the option.

Expected term

This is the period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of 10 years. The Company estimates the expected term of the option to be 6.25 years for options with a standard four-year vesting period, using the simplified method. Over time, management will track actual terms of the options and adjust their estimate accordingly so that estimates will approximate actual behavior for similar options.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the expected future tax consequences attributable to temporary differences between financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred income tax assets to the amount expected to be realized.

Tax benefits are initially recognized in the financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially, and subsequently, measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts.

The Company had federal net operating loss ("NOL") carryforwards of $178,163,456 and $165,981,195 at December 31, 2018 and 2017, respectively. Despite the NOL carryforwards, which begin to expire in 2022, the Company may have future tax liability due to alternative minimum tax or state tax requirements. Also, use of the NOL carryforwards may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"). To date, the Company has not performed a formal study to determine if any of its remaining NOL and credit attributes might be further limited due to the ownership change rules of Section 382 or Section 383 of the Code. The Company will continue to monitor this matter going forward. There can be no assurance that the NOL carryforwards will ever be fully utilized.

Loss per share

Basic loss per share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options and stock purchase warrants using the treasury stock method, and convertible preferred stock and convertible debt using the if-converted method.

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The number of anti-dilutive shares, consisting of (i) common stock options, (ii) stock purchase warrants, and (iii) restricted stock units representing the right to acquire shares of common stock which have been excluded from the computation of diluted loss per share, was 3.7 million shares and 1.6 million shares as of December 31, 2018 and 2017, respectively.

Adopted accounting pronouncements

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

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

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

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the statements of cash flows:

	December 31, 2018	December 31, 2017	December 31, 2016
Cash and cash equivalents	$ 4,572,487	$ 1,847,171	$ 4,117,324
Restricted cash	164,720	243,380	243,380
Total cash, cash equivalents and restricted cash in the consolidated statements of cash flows	$ 4,737,207	$ 2,090,551	$ 4,360,704

Accounting pronouncements not yet adopted

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

The new standard provides a number of optional practical expedients in transition. The Company expects to elect: (1) the 'package of practical expedients', which permits it not to reassess under the new standard its prior conclusions about lease identification, lease classification, and initial direct costs; (2) the use-of-hindsight; and (3) the practical expedient pertaining to land easements. In addition, the new standard provides practical expedients for an entity's ongoing accounting that the Company anticipates making, such

as the (1) the election for certain classes of underlying asset to not separate non-lease components from lease components and (2) the election for short-term lease recognition exemption for all leases that qualify.

The Company will adopt ASC 842 as of January 1, 2019, using the alternative modified transition method. In preparation of adopting ASC 842, the Company is implementing additional internal controls to enable future preparation of financial information in accordance with ASC 842. The Company has also substantially completed its evaluation of the impact on the Company's lease portfolio. The Company believes the largest impact will be on the consolidated balance sheets for the accounting of facilities-related leases, which represents a majority of its operating leases it has entered into as a lessee. These leases will be recognized under the new standard as ROU assets and operating lease liabilities. The Company will also be required to provide expanded disclosures for its leasing arrangements. As of December 31, 2018, the Company had $2.8 million of undiscounted future minimum operating lease commitments that are not recognized on its consolidated balance sheets as determined under the current standard. For a lessor, the results of operations are not expected to significantly change after adoption of the new standard.

While substantially complete, the Company is still in the process of finalizing its evaluation of the effect of ASC 842 on the Company's consolidated financial statements and disclosures. The Company will finalize its accounting assessment and quantitative impact of the adoption during the first quarter of fiscal year 2019. As the Company completes its evaluation of this new standard, new information may arise that could change the Company's current understanding of the impact to leases. Additionally, the Company will continue to monitor industry activities and any additional guidance provided by regulators, standards setters, or the accounting profession, and adjust the Company's assessment and implementation plans accordingly.

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

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

Note 4 - Revenue from Contracts with Customers

Disaggregated Revenue

The Company provides diagnostic test products, laboratory services to hospitals, clinical laboratories and other healthcare provider customers, and enters into collaboration agreements with government agencies and healthcare providers. The revenues by type of service consist of the following:

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

Deferred Revenue

Changes in deferred revenue for the period were as follows:

Balance at December 31, 2017	$ 24,442
Revenue recognized in the current period from the amounts in the beginning balance	(14,450)
New deferrals, net of amounts recognized in the current period	5,832
Balance at December 31, 2018	$ 15,824

Contract Assets

The Company had no contract assets as of December 31, 2018, which are generated when contractual billing schedules differ from revenue recognition timing. Contract assets represent a conditional right to consideration for satisfied performance obligations that becomes a billed receivable when the conditions are satisfied.

Unsatisfied Performance Obligations

The Company had no unsatisfied performance obligations related to its contracts with customers at December 31, 2018.

Note 5 - MGHIF Financing

In July 2015, in connection with the Merger, the Company entered into a Purchase Agreement with MGHIF, pursuant to which MGHIF purchased 45,454 shares of common stock of the Company at $110.00 per share for gross proceeds of $5.0 million. Pursuant to the Purchase Agreement, the Company also issued to MGHIF an 8% Senior Secured Promissory Note (the "MGHIF Note") in the principal amount of $1.0 million with a two-year maturity date from the date of issuance. Also in July 2015, the Company entered into a Registration Rights Agreement with MGHIF and certain stockholders, which will require the Company to register for resale by such holders in the future, such shares of Company common stock that cannot be sold under an exemption from such registration. The Company's obligations under the MGHIF Note are secured by a lien on all of the Company's assets.

On June 28, 2017, the MGHIF Note was amended and restated, and the maturity date of the MGHIF Note was extended by one year to July 14, 2018. As consideration for the agreement to extend the maturity date, the Company issued an amended and restated secured promissory note to MGHIF that (1) increased the interest rate to ten percent (10%) per annum and (2) provided for the issuance of common stock warrants to purchase 13,120 shares of its common stock to MGHIF.

On June 11, 2018, the Company executed an Allonge to the MGHIF Note. The Allonge provided that accrued and unpaid interest of $285,512 due as of July 14, 2018, the original maturity date, be paid through the issuance of shares of OpGen's common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021.

On July 30, 2018, the Company issued 144,238 shares of common stock to MGHIF in a private placement transaction for $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

The Allonge to the MGHIF Note was treated as a debt modification and as such the unamortized issuance costs of approximately $7,000 as of June 11, 2018 is deferred and amortized as incremental expense over the term of the MGHIF Note.

Note 6 - Debt

As of December 31, 2018, the Company's outstanding short-term debt consisted of approximately $333,000 due under the MGHIF Note, as well as, the financing arrangements for the Company's insurance with note balances of approximately $65,000 with a final payment scheduled for April 2019. The Company's outstanding long-term debt as of December 31, 2018 consisted of approximately $660,000 due under the MGHIF Note, net of discounts and financing costs (see Note 5 "MGHIF Financing"). As of December 31, 2017, the Company's outstanding short-term debt consisted of the $1.0 million MGHIF Note, net of discounts and financing costs, as well as the financing arrangements for the Company's insurance with note balances of approximately $56,000. The Company did not have any long-term debt as of December 31, 2017. Total principal payments of approximately $333,000 are due annually in 2019, 2020, and 2021.

The Company drew down on two of three Bridge Financing Notes (see discussion in Note 2 "Going Concern and Management's Plans") during June and July of 2017. The outstanding Bridge Financing Notes were repaid in full subsequent to the closing of the July 2017 Public Offering.

The Company accounted for the embedded conversion option granted to jVen Capital in the Bridge Financing Notes as a mark-to-market derivative financial instrument carried at fair value. Changes in fair value of the embedded conversion option were reflected in earnings during the period of change. The embedded conversion option was expensed along with the remaining unamortized discount at the date of the Bridge Financing Notes repayment. The warrants issued to jVen Capital and MGHIF are classified as mark-to-market liabilities under ASC 480 due to certain put features that allow the holder to put the warrant back to the Company for cash equal to the Black-Scholes value of the warrant upon a change of control or fundamental transaction.

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $191,195 and $233,505 for the years ended December 31, 2018 and 2017, respectively.

Note 7 - Stockholders' Equity

As of December 31, 2018, the Company has 50,000,000 shares of authorized common shares and 8,645,720 shares issued and outstanding, and 10,000,000 of authorized preferred shares, of which none were issued or outstanding.

In September 2016, the Company entered into the Sales Agreement with Cowen pursuant to which the Company may offer and sell from time to time, up to an aggregate of $25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of $11.5 million. Pursuant to the Sales Agreement, Cowen may sell the shares of common stock by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including, without limitation, sales made by means of ordinary brokers' transactions on The Nasdaq Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by the Company. The Company pays Cowen compensation equal to 3.0% of the gross proceeds from the sales of common stock pursuant to the terms of the Sales Agreement. As of December 31, 2018, the Company has sold an aggregate of 690,247 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $8.8 million, and gross proceeds of $9.4 million. During the year ended December 31, 2018, the Company sold 318,236 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $0.6 million, and gross proceeds of $0.6 million. In connection with the October 2018 Public Offering, the Company terminated the at the market offering.

In the July 2017 Public Offering, the Company issued 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million. jVen Capital was one of the investors participating in the offering. Each unit included one twenty-fifth of a share of common stock and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. Each pre-funded unit included one pre-funded warrant to purchase one twenty-fifth of a share of common stock for an exercise price of $0.25 per share, and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of $10.625 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. At closing, the outstanding Bridge Financing Notes issued to jVen Capital, were repaid in the principal amount of $1 million plus accrued interest of $6,438. All pre-funded warrants issued in the July 2017 Public Offering were exercised during the year ended December 31, 2017.

In connection with the July 2017 Public Offering, the Company issued to its placement agent warrants to purchase 50,000 shares of common stock. The warrants issued to the Placement Agent have an exercise price of $12.50 per share and are exercisable for five years.

In September 2017, the Company issued 15,843 shares of its common stock with an aggregate value of $110,000 to settle a dispute related to pre-Merger AdvanDx activities. In October 2017, the Company issued 2,898 shares of its common stock with an aggregate value of $23,245 to a vendor in exchange for consulting services.

Following receipt of approval from stockholders at a special meeting of stockholders held on January 17, 2018, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to effect a reverse stock split of the issued and outstanding shares of common stock, at a ratio of one share for twenty-five shares, and to reduce the authorized shares of common stock from 200,000,000 to 50,000,000 shares. All share amounts and per share prices in this Annual Report have been adjusted to reflect the reverse stock split.

In the February 2018 Public Offering, the Company issued 2,841,152 units at $3.25 per unit, and 851,155 pre-funded units at $3.24 per pre-funded unit, raising gross proceeds of approximately $12 million and net proceeds of approximately $10.7 million. Each unit included one share of common stock and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one common warrant to purchase 0.5 share of common stock at an exercise price of $3.25 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. All 851,155 pre-funded warrants issued in the February 2018 Public Offering were exercised during the year ended December 31, 2018.

In connection with the February 2018 Public Offering, the Company issued to its placement agent warrants to purchase 184,615 shares of common stock. The warrants issued to the Placement Agent have an exercise price of $4.0625 per share and are exercisable for five years.

On October 22, 2018, the Company closed the October 2018 Public Offering of 2,220,000 shares of its common stock at a public offering price of $1.45 per share. The offering raised gross proceeds of approximately $3.2 million and net proceeds of approximately $2.8 million.

Stock options

In 2008, the Board adopted, and the stockholders approved, the 2008 Stock Option and Restricted Stock Plan (the "2008 Plan"), pursuant to which the Company's Board of Directors may grant either incentive or non-qualified stock options or shares of restricted stock to directors, key employees, consultants and advisors.

In April 2015, the Board adopted, and the Company's stockholders approved, the 2015 Equity Incentive Plan (the "2015 Plan"); the 2015 Plan became effective upon the execution and delivery of the underwriting agreement for the Company's IPO. Following the effectiveness of the 2015 Plan, no further grants have been made under the 2008 Plan. The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for the grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants.

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 54,200 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date, that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by the Company's Board of Directors. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled, or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. As of December 31, 2018, 50,863 shares remain available for issuance under the 2015 Plan.

For the years ended December 31, 2018 and 2017, the Company recognized stock compensation expense as follows:

	Year Ended December 31,	
	2018	2017
Cost of services	$ 964	$ 13,776
Research and development	241,122	237,103
General and administrative	574,244	603,787
Sales and marketing	45,951	56,732
	$ 862,281	$ 911,398

No income tax benefit for stock-based compensation arrangements was recognized in the consolidated statements of operations due to the Company's net loss position.

As of December 31, 2018, the Company had unrecognized expense related to its stock options of $0.5 million, which will be recognized over a weighted average period of 7.6 years.

A summary of the status of options granted is presented below as of and for the years ended December 31, 2018 and 2017:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2017	119,106	$ 44.00	8.6	$ 663,298
Granted	58,324	$ 17.58		
Exercised	(1,167)	$ 7.01		$ 11,256
Forfeited	(24,538)	$ 36.31		
Expired	(12,330)	$ 83.49		
Outstanding at December 31, 2017	139,395	$ 31.16	8.3	$ 37,339
Granted	95,800	$ 3.84		
Exercised	—	—		
Forfeited	(18,812)	$ 11.98		
Expired	(4,824)	$ 56.12		
Outstanding at December 31, 2018	211,559	$ 20.58	7.6	$ 522
Vested and expected to vest	211,559	$ 20.58	7.6	$ 522
Exercisable at December 31, 2018	10,445	$ 1.25	5.3	$ 522

The total fair value of options vested in the years ended December 31, 2018 and 2017 was $930,921 and $2,086,843, respectively. The fair value of each option grant was estimated at the date of grant using the Black-Scholes option pricing model based on the assumptions below:

	Year Ended December 31,	
	2018	2017
Annual dividend	—	—
Expected life (in years)	5.25 - 6.25	5.25 - 6.25
Risk free interest rate	2.5 - 2.9%	1.8 - 2.3%
Expected volatility	46.0 - 49.6%	44.2 - 53.0%

Restricted stock units

A summary of the status of restricted stock units granted is presented below as of and for the years ended December 31, 2018 and 2017:

	Number of Options	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2017	750	$ 42.50
Granted	11,175	$ 6.93
Vested	(6,025)	$ 8.01
Forfeited	—	—
Unvested at December 31, 2017	5,900	$ 31.16
Granted	—	—
Vested	(5,650)	$ 8.93
Forfeited	—	—
Unvested at December 31, 2018	250	$ 42.50

As of December 31, 2018, there was approximately $9,000 of unrecognized compensation cost related to restricted stock units, which is expected to be recognized over a weighted average period of 0.92 years.

Stock purchase warrants

At December 31, 2018 and 2017, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at December 31, 2018 (1)	Outstanding at December 31, 2017 (1)
March 2008	$ 19,763.50	March 2018	—	2
November 2009	$ 197.75	November 2019	270	270
January 2010	$ 197.75	January 2020	270	270
March 2010	$ 197.75	March 2020	55	55
November 2011	$ 197.75	November 2021	212	212
December 2011	$ 197.75	December 2021	27	27
March 2012	$ 2,747.50	March 2019	165	165
February 2015	$ 165.00	February 2025	9,001	9,001
May 2015	$ 165.00	May 2020	138,310	138,310
May 2016	$ 32.81	May 2021	189,577	189,577
June 2016	$ 32.81	May 2021	82,035	82,035
June 2017	$ 19.50	June 2022	18,754	18,754
July 2017	$ 17.25	July 2022	6,350	6,350
July 2017	$ 12.50	July 2022	50,000	50,000
July 2017	$ 10.625	July 2022	1,000,003	1,000,003
February 2018	$ 4.06	February 2023	184,615	—
February 2018	$ 3.25	February 2023	1,846,153	—
			3,525,797	1,495,031

The warrants listed above were issued in connection with various equity, debt, preferred stock or development contract agreements.

(1) Warrants to purchase fractional shares of common stock resulting from the reverse stock split on January 17, 2018 were rounded up to the next whole share of common stock on a holder by holder basis.

Note 8 - Income Taxes

At December 31, 2018 and 2017, the Company had net deferred tax assets of $52,348,036 and $49,251,408, respectively, primarily consisting of NOL carryforwards, research and experimental ("R&E") credits, and differences between depreciation and amortization recorded for financial statement and tax purposes. The Company's net deferred tax assets at December 31, 2018 and 2017 have been offset by a valuation allowance of $52,348,036 and $49,251,408, respectively. The valuation allowance has been recorded due to the uncertainty of realization of the deferred tax assets. The Company's deferred tax assets and liabilities as of December 31, 2018 and 2017 are as follows:

	December 31, 2018	December 31, 2017
Deferred tax assets:		
NOL carryforward	$ 49,480,731	$ 46,326,407
R&E credit carryforward	2,559,479	2,559,479
Share-based compensation	329,796	345,088
Inventory reserve	19,068	45,338
Depreciation	—	71,756
Interest expense	51,152	—
Accruals and other	284,662	247,093
Total deferred tax assets	52,724,888	49,595,161
Valuation allowance	(52,348,036)	(49,251,408)
Deferred tax liabilities:		
Intangible assets	(256,011)	(343,753)
Depreciation	(120,841)	—
Net	$ —	$ —

The difference between the Company's expected income tax provision (benefit) from applying federal statutory tax rates to the pre-tax loss and actual income tax provision (benefit) relates to the effect of the following:

	2018	2017
Federal income tax benefit at statutory rates	21.0%	34.0%
Permanent adjustment	(1.4)%	—
Provision to return adjustment	(0.2)%	—
State income tax benefit, net of Federal benefit	(6.4)%	6.8%
Tax reform impact	—	(134.5)%
Change in valuation allowance	(13.0)%	93.0%
Change in state tax rates and other	—	0.7%
	0.0%	0.0%

The Company has federal NOL carryforwards of $178,163,456 and $165,981,195 at December 31, 2018 and 2017, respectively. The NOL carryforwards incurred prior to 2018 begin to expire in 2022. Under the Tax Cuts and Jobs Act (the Tax Act), the amount of post 2017 NOLs that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. In addition, the Tax Act generally eliminates the ability to carry back any NOL to prior taxable years, while allowing post 2017 unused NOLs to be carried forward indefinitely. Utilization of the NOL carryforward may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code. There can be no assurance that the NOL carryforward will ever be fully utilized. To date, the Company has not performed a formal study to determine if any of its remaining NOL and credit attributes might be further limited due to the ownership change rules of Section 382 or Section 383 of the Internal Revenue Code of 1986, as amended. The Company will continue to monitor this matter going forward. There can be no assurance that the NOL carryforwards will ever be fully utilized.

In December 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"), most of the provisions of which took effect starting in 2018. The Tax Act made broad and complex changes to the U.S. tax code, including, but not limited to: (i) reducing the U.S. federal corporate tax rate from 35 percent to 21 percent; (ii) eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; (iii) creating a new limitation on deductible interest expense; and (iv) changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017; and (v) changing the U.S. federal taxation of earnings of foreign subsidiaries. The U.S. change in federal taxation for foreign subsidiary earnings included a one-time toll charge on deemed repatriated earnings of foreign subsidiaries as of December 31, 2017. As a result of the accumulated losses in the Company's foreign subsidiary, the Company had no toll tax liability for the tax year ended December 31, 2017. For 2018, the Company considered in its estimated annual effective tax rate additional provisions of Tax Reform including changes to the deduction for interest expense pursuant to IRC Section 163(j) interest limitation.

As a result, the most significant impact on the Company's consolidated financial statements was the reduction of approximately $14.6 million of the deferred tax assets related to net operating losses and other deferred tax assets. Such reduction is offset by a change in the Company's valuation allowance. Additionally, the Company has foreign subsidiaries. At December 31, 2017 and November 2, 2017, the cumulative earnings and profits of these entities were negative. Accordingly, the Company was not liable for the transition tax on foreign earnings enacted under the Tax Act.

Note 9 - Commitments

Operating leases

The Company leases a facility in Gaithersburg, Maryland under an operating lease that expires January 31, 2021, with one additional five-year renewal at the Company's election. The Company also leases a facility in Woburn, Massachusetts under an operating lease that expires January 30, 2022. Additionally, the Company leases office space in Denmark; this lease is currently on a month-to-month basis.

Rent expense under the Company's facility operating leases for the year ended December 31, 2018 and 2017 was $984,639 and $949,244, respectively.

Capital leases

The Company leases lab equipment, office furniture, and computer equipment under various capital leases. The leases expire at various dates through 2021. The leases require monthly principal and interest payments. Following is a schedule by year of the estimated future minimum payments under all operating and capital leases as of December 31, 2018:

Year ending December 31,	Capital Leases	Operating Leases	Total
2019	$ 508,114	$ 1,107,565	$ 1,615,679
2020	408,264	1,125,940	1,534,204
2021	104,579	535,250	639,829
2022	—	40,080	40,080
2023 and thereafter	—	—	—
Total	1,020,957	$ 2,808,835	$ 3,829,792
Less: amount representing interest	(96,251)		
Less: amount representing service costs	(88,172)		
Net present value of future minimum lease payments	836,534		
Current maturities	(399,345)		
Long-term maturities	$ 437,189		

Assets under capital leases were included in the following balance sheet categories as of December 31:

	2018	2017
Laboratory and manufacturing equipment	$ 1,563,346	$ 850,792
Office furniture and equipment	64,790	64,790
Computers and network equipment	24,350	24,350
Less accumulated amortization	(749,480)	(454,471)
Capital lease assets, net	$ 903,006	$ 485,461

Amortization expense associated with equipment under capital leases for the years ended December 31, 2018 and 2017 was $295,009 and $161,606, respectively, and is included within depreciation and amortization expense in the consolidated statements of operations.

Registration and other stockholder rights

In connection with the various investment transactions, the Company entered into registration rights agreements with stockholders, pursuant to which the investors were granted certain demand registration rights and/or piggyback and/or resale registration rights in connection with subsequent registered offerings of the Company's common stock.

Restructuring

In early June 2017, the Company commenced a restructuring of its operations to improve efficiency and reduce its cost structure. The restructuring plans anticipate that the Company will consolidate operations for FDA-cleared and CE marked products and research and development activities for the Acuitas Rapid Test in Gaithersburg, Maryland, and reduce the size of its commercial organization while the Company works to complete the development of its Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase products and services in development.

There were approximately $121,000 of one-time termination benefits that were recognized during the year ended December 31, 2017 related to the restructuring. The Company does not anticipate any further one-time termination benefits related to the restructuring plan. Retention agreements were issued to certain employees in which retention bonuses are earned and paid upon the completion of a designated service period. The service periods ended in December 2017. The Company incurred total retention expense of approximately $68,000 during the year ended December 31, 2017. The future minimum lease payments for the Woburn facility were approximately $1.4 million as of December 31, 2018. A liability for costs that will continue to be incurred under a contract for its remaining term without economic benefit to the entity shall be recognized at the cease-use date. If the contract is an operating lease the fair value of the liability at the cease-use date shall be determined based on the remaining lease rentals, adjusted for the effects of any prepaid or deferred items recognized under the lease, and reduced by estimated sublease rentals that could be reasonably obtained for the property. The Company expects the cease-use date for the Woburn facility to be in the first quarter of 2019. We do not believe there will be significant additional costs related to restructuring outside of what is described herein.

Supply Agreements

In June 2017, the Company entered into an agreement with Life Technologies Corporation, a subsidiary of Thermo Fisher Scientific ("LTC") to supply the Company with Thermo Fisher Scientific's QuantStudio 5 Real-Time PCR Systems ("QuantStudio 5") to be used to run OpGen's Acuitas AMR Gene Panel tests. Under the terms of the agreement the Company must notify LTC of the number of QuantStudio 5s that it commits to purchase in the following quarter. As of December 31, 2018 the Company has acquired fifteen QuantStudio 5s including eleven in the twelve months ended December 31, 2018. As of December 31, 2018 the Company has committed to acquiring an additional three QuantStudio 5s at a total cost of approximately $135,000 in the next three months.

Note 10 - License Agreements, Research Collaborations and Development Agreements

The Company is a party to one license agreement to acquire certain patent rights and technologies related to its FISH product line. Royalties are incurred upon the sale of a product or service which utilizes the licensed technology. Certain of the agreements require the Company to pay minimum royalties or license maintenance fees. The Company recognized net royalty expense of $250,000 and $257,186 for the years ended December 31, 2018 and 2017, respectively. Annual future minimum royalty fees are $250,000 under these agreements.

In September 2017, the Company was awarded a contract from the Centers for Disease Control and Prevention ("CDC") to develop smartphone-based clinical decision support solutions for antimicrobial stewardship, or AMS, and infection control in low- and middle-income countries. The one-year $860,000 award began September 30, 2017 and funds development and evaluation of cloud-based mobile software. The Company worked with subcontractors Ilúm, LLC, an affiliate of Merck, and Universidad El Bosque ("UEB") of Bogota, Colombia under this CDC contract. During the years ended December 31, 2018 and 2017, the Company recognized $503,881 and $357,178 of revenue related to the contract, respectively.

In June 2016, the Company entered into a license agreement with Hitachi, pursuant to which it resolved various matters with respect to previously delivered milestones under the technology development agreement and provided a development license and commercial products license to certain technology. The license agreement contains non-contingent multiple elements (the licenses) that the Company determined did not have stand alone value, and a contingent substantive milestone. The licenses are treated as a single unit of accounting and the Company will recognize the revenue associated with that unit of accounting over the applicable license period. During the years ended December 31, 2018 and 2017, the Company recognized $12,397 and $25,000 of revenue related to the license agreement, respectively.

Note 11 - Related Party Transactions

In October 2016, the Company entered into an agreement with Merck Sharp & Dohme, a wholly-owned subsidiary of Merck Co. & Inc. ("Merck"), an affiliate of MGHIF, a principal stockholder of the Company and a related party to the Company. Under the agreement, Merck provided access to its archive of over 200,000 bacterial pathogens. The Company is initially performing molecular analyses on up to 10,000 pathogens to identify markers of resistance to support rapid decision making using the Acuitas Lighthouse, and to speed development of its rapid diagnostic products. Merck gains access to the high-resolution genotype data for the isolates as well as access to the Acuitas Lighthouse informatics to support internal research and development programs. The Company is required to expend up to $175,000 for the procurement of materials related to the activities contemplated by the agreement. Contract life-to-date, the Company has incurred $171,646 of procurement costs which have been recognized as research and development expense, including $22,603 and $146,177 during the years ended December 31, 2018 and 2017.

In December 2017, we entered into a subcontractor agreement with ILÚM Health Solutions, LLC, an entity created by Merck's Healthcare Services and Solutions division, whereby ILÚM Health Solutions provided services to the Company in the performance of the Company's CDC contract to deploy ILÚM's commercially-available cloud- and mobile-based software platform for infectious disease management in up to three medical sites in Colombia with the aim of improving antibiotic use in resource-limited settings. During the years ended December 31, 2018 and 2017, the Company recognized $329,162 and $210,180 of cost of services expense related to the contract, respectively.

Note 12 - Fair Value Measurements

The Company classifies its financial instruments using a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 - defined as observable inputs such as quoted prices in active markets;
- Level 2 - defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and
- Level 3 - defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions such as expected revenue growth and discount factors applied to cash flow projections.

Financial assets and liabilities measured at fair value on a recurring basis

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the hierarchy.

As part of the Company's bridge financing and amendment to the MGHIF Note, the Company issued stock purchase warrants that the Company considers to be mark-to-market liabilities due to certain put features that allow the holder to put the warrant back to the Company for cash equal to the Black-Scholes value of the warrant upon a change of control or fundamental transaction. The Company determines the fair value of the warrant liabilities using the Black-Scholes option pricing model. Using this model, level 3 unobservable inputs include the estimated volatility of the Company's common stock, estimated terms of the instruments, and estimated risk-free interest rates.

The Company originally accounted for the conversion option embedded in the Bridge Financing Notes as a mark-to-market derivative financial instrument. The Company determined the fair value of the embedded conversion option liability using a probability-weighted expected return method. Using this method, level 3 unobservable inputs include the probability of default, the probability of a qualified financing, the probability of conversion, the estimated volatility of the Company's common stock, estimated terms of the instruments, and estimated risk-free interest rates, among other inputs. The fair value of the conversion option was expensed at the time of repayment of the Bridge Financing Notes.

The following table sets forth a summary of changes in the fair value of level 3 liabilities measured at fair value on a recurring basis for the year ended December 31, 2018:

Description	Balance at December 31, 2017	Change in Fair Value	Balance at December 31, 2018
Warrant liability	$ 8,453	$ (8,386)	$ 67

Financial assets and liabilities carried at fair value on a non-recurring basis

The Company does not have any financial assets and liabilities measured at fair value on a non-recurring basis.

Non-financial assets and liabilities carried at fair value on a recurring basis

The Company does not have any non-financial assets and liabilities measured at fair value on a recurring basis.

Non-financial assets and liabilities carried at fair value on a non-recurring basis

The Company measures its long-lived assets, including property and equipment and intangible assets (including goodwill), at fair value on a non-recurring basis when they are deemed to be impaired. No such fair value impairment was recognized in the year ended December 31, 2018.

Exhibit 4.1

NUMBER
OP

SHARES
SPECIMEN

OpGen, Inc.

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

SEE REVERSE FOR CERTAIN DEFINITIONS

COMMON STOCK

CUSIP 68373L 20 8

THIS CERTIFIES THAT:

SPECIMEN - NOT NEGOTIABLE

IS THE OWNER OF

FULLY PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK OF $.01 PAR VALUE EACH OF

OPGEN, INC.

transferable on the books of the Corporation in person or by duly authorized attorney upon surrender of this certificate duly endorsed or assigned. This certificate and the shares represented hereby are subject to the laws of the State of Delaware, and to the Certificate of Incorporation and Bylaws of the Corporation, as now or hereafter amended. This certificate is not valid until countersigned by the Transfer Agent.

WITNESS the facsimile seal of the Corporation and the facsimile signatures of its duly authorized officers.

DATED:

OPGEN, INC. CORPORATE SEAL 2001 DELAWARE

COUNTERSIGNED:
PHILADELPHIA STOCK TRANSFER, INC.
2320 HAVERFORD RD., SUITE 230, ARDMORE, PA 19003
TRANSFER AGENT

BY:

AUTHORIZED SIGNATURE

SPECIMEN NOT NEGOTIABLE

CHIEF FINANCIAL OFFICER

CEO/PRESIDENT

Exhibit 21.1

OPGEN, INC.

The following is a list of subsidiaries of OpGen, Inc. as of December 31, 2018:

Name	**Jurisdiction of Incorporation**
AdvanDx, Inc.	Delaware
AdvanDx A/S	Denmark
OpGen Colombia SAS	Colombia

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statements No. 333-224035, No. 333-216932, No. 333-216929, No. 333-210489, and No. 333-205864 on Form S-8 and Registration Statements and Registration Statements No. 333-213356 and No. 333-211996 on Form S-3 of OpGen, Inc. of our report, which includes an explanatory paragraph related to OpGen, Inc.'s ability to continue as a going concern, dated February 27, 2019, on our audits of the consolidated financial statements of OpGen, Inc. as of December 31, 2018 and 2017 and for the years then ended, included in this Annual Report on Form 10-K of OpGen, Inc. for the year ended December 31, 2018.

/s/ CohnReznick LLP

Tysons, Virginia
February 27, 2019

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13A-14(A)/15D-14(A)

I, Evan Jones, certify that:

1. I have reviewed this Annual Report on Form 10-K of OpGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2019

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13A-14(A)/15D-14(A)

I, Timothy C. Dec, certify that:

1. I have reviewed this Annual Report on Form 10-K of OpGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2019

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

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of OpGen, Inc. (the "Company") for the year ended December 31, 2018 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is provided solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Date: February 27, 2019

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

Date: February 27, 2019

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

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.