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, 2017

☐ **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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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, 2017, was $11,102,412 (based upon the last reported sale price of $16.005 per share on June 30, 2017, on The Nasdaq Capital Market, as the stock price and number of shares is adjusted to reflect the one-for-twenty-five reverse stock split effected on January 17, 2018).

As of March 26, 2018, 5,289,919 shares of common stock of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2018 annual meeting of stockholders to be filed by April 30, 2018, are incorporated by reference into Part III of this Annual Report on Form 10-K.

OPGEN, INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2017

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K for the year ended December 31, 2017 (the "Annual Report") and certain information incorporated herein by reference contain 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 AMR Gene Panel for cUTI 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® Argus®, 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 using 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 offerings combine our Acuitas® DNA tests 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 DNA tests provide rapid microbial identification and antibiotic resistance gene information. These products include our Acuitas antimicrobial resistance, or AMR, Gene Panel u5.47 for complicated urinary tract infections in development as a clinical diagnostic test and available for Research Use Only, the QuickFISH® family of FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures, and our Acuitas Resistome Tests for genetic analysis of hospital surveillance isolates.
- 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.

We have established a number of collaborative 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 collaboration 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 will provide services to the Company in the performance of the Company's CDC contract to deploy ILÚM's commercially-available cloud- and mobile-based software platform for infectious disease management in up to three medical sites in Colombia with the aim of improving antibiotic use in resource-limited settings.

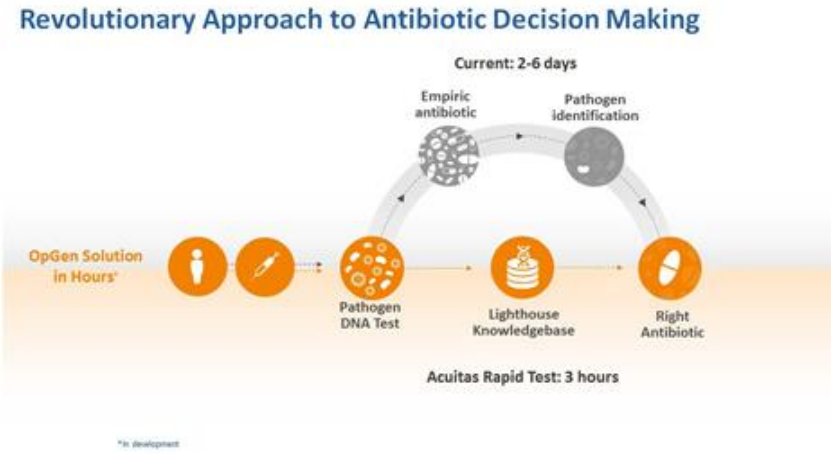
In June 2017, we entered into a global supply agreement to provide customer access to Thermo Fisher Scientific's products to support the commercialization of our Acuitas Rapid Test and Acuitas Lighthouse Software products in development to combat MDROs. We have worked closely with Intermountain Healthcare, or IHC, a leading integrated health system, to complete a comprehensive retrospective study to evaluate the burden and costs of antibiotic resistance at IHC. We are working to expand 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 a new high resolution AMR Gene Panel designed to determine pathogen levels in clinical specimens and the key drug resistance gene profiles of Gram-negative organisms. Following completion of our research and development efforts and receipt of appropriate regulatory approvals, we anticipate the AMR Gene Panel will be used in the clinical setting to provide pathogen and antibiotic resistance gene information to aid in decision-making for patients with complicated urinary tract infections, or cUTI, lower respiratory tract infections, and blood stream infections.

Lead Rapid Diagnostic and Acuitas Lighthouse Software

Our lead product in development is the Acuitas AMR Gene Panel u5.47 for patients at risk for cUTI. The AMR Gene Panel u5.47 is a direct test that will be able to be performed in under three hours to identify five pathogens associated with urinary tract infections 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. Preliminary performance data for E. coli and K. pneumonia in our Acuitas Lighthouse Software algorithms was presented at the ASM Microbe meeting in June 2017. Accuracy of prediction ranged from 77% to 96%. These data and additional data from our research combined with the anticipated results from the AMR Gene Panel u5.47 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 potential workflow and anticipated results from our new testing approach.



Current Diagnostic Tests and Informatics Offerings

Our suite of DNA-based products and products in development are intended to provide actionable, precise diagnostic information supported by the proprietary genomic Acuitas Lighthouse Knowledgebase to facilitate data interpretation. The Acuitas DNA tests use multiplex PCR to help provide reliable and accurate detection of drug resistance. The QuickFISH tests are powered by PNA technology and provide rapid pathogen identification, typically in less than 30 minutes from a positive blood culture result. The Acuitas MDRO Gene Test is used for determining if acute care patients are colonized with MDROs. Positive samples are confirmed using microbiological methods and the Acuitas Resistome Test for high resolution genotyping. Test results are maintained in the Acuitas Lighthouse data warehouse for subsequent interpretation by physicians and healthcare providers.

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 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 will 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.

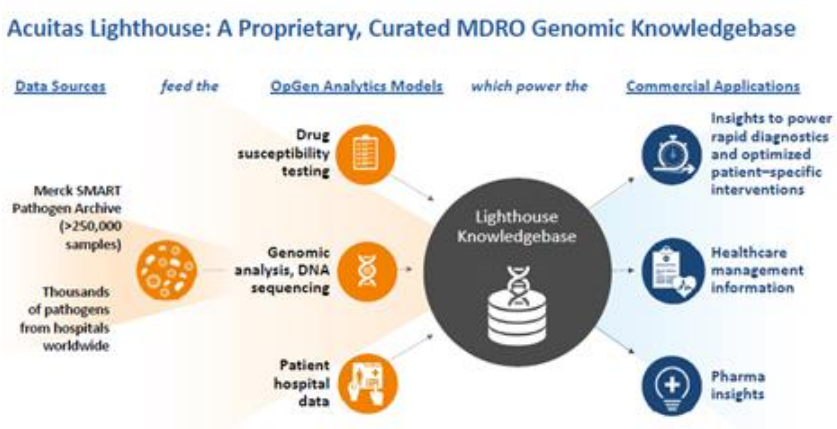
- **Acuitas Lighthouse informatics and services** – We are pursuing commercial opportunities to provide our Acuitas Lighthouse informatics and companion genomic testing to pharmaceutical companies and CROs, health systems, third party in vitro diagnostic companies, and government agencies. Through our Pharmaceutical/CRO services we are working to help accelerate clinical trials and new product launches and to establish early access for diagnostic tests to help guide decision-making for new antibiotics. 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 AMR Gene Panel u5.47 for cUTI with a goal of achieving three-hour antibiotic resistance analysis from the time of specimen collection;
- continue clinical evaluations for the AMR Gene Panel u5.47 in the first half of 2018; in January 2018 we introduced the AMR Gene Panel u5.47 as an RUO test and have a goal of making a FDA 510(k) submission in the fourth quarter of 2018 to support commercial launch;
- obtain third party funding to expand our AMR Gene Panel 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 and CLIA lab-based MDRO surveillance tests 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.



The lead products from our initial development work are the Acuitas AMR Gene Panel u5.47, which is in development as a clinical diagnostic for complicated urinary tract infections and clinical isolates and was released as a ROU product in the first quarter of 2018, and the Acuitas Lighthouse Software for managing and evaluating results from the AMR Gene Panel test. In conjunction with these development programs we have added and tested approximately 9,500 bacterial isolates from the SMART pathogen archive and added the results to the Lighthouse Knowledgebase which includes data from 15,000 bacterial isolates. In the future we anticipate developing additional AMR Gene Panel tests and expanding our software offerings.

Recent Events

Business Initiatives

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 Acuitas Rapid Test 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 early June 2017, the Company commenced a restructuring of its operations to improve efficiency and reduce its cost structure. To date, the Company has achieved a reduction in operating expenses of approximately 31 percent. The restructuring plans included work to consolidate the Company's operations for FDA-cleared and CE marked products and research and development activities for the Acuitas AMR Gene Panel products and Acuitas Lighthouse Software in Gaithersburg, Maryland, and reduce the size of its commercial organization while the Company focused on development work. The restructuring process was substantially completed by year-end, and is expected to be completed in the first quarter of 2018.

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 funds development and evaluation of cloud-based mobile software. The Company will work with partners ILÚM Health Solutions and Universidad El Bosque, or UEB, of Bogota, Colombia. The Company's teaming partner ILÚM is providing 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 will be 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. The software will be translated to Spanish and will support WHONET data integration. WHONET is an information system developed to support the World Health Organization's goal of global surveillance of bacterial resistance to antimicrobial agents. WHONET analyzes the data of over 4,000 laboratories worldwide and is used in more than 120 countries.

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 February 7, 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, LLC, a Delaware limited liability company and principal stockholder of the Company and an affiliate of Evan Jones, the Company's Chairman of the Board and Chief Executive Officer, or 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. The purpose of the bridge financing was to provide capital while the Company pursued a public offering described below. The interest rate on each Bridge Financing Note was ten percent (10%) per annum (subject to increase upon an event of default). The Bridge Financing Notes were prepayable by the Company at any time without penalty, and had a maturity date of September 30, 2017, which could be accelerated upon the closing of a qualified financing (any equity or debt financing that raised net proceeds of $5 million or more). The Bridge Financing Notes were contingently convertible at the option of the holder upon an event of default into shares of the Company's convertible Series B preferred stock. 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, and repaid such outstanding Bridge Financing Notes 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 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. Pursuant to the Sales Agreement, Cowen may sell the shares of the Company's 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, 2017, the Company has sold an aggregate of approximately 372 thousand shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $8.2 million, and gross proceeds of $8.8 million. As of December 31, 2017, remaining availability under the at the market offering is $2.7 million. During the year ended December 31, 2017, the Company sold approximately 227 thousand shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $3.8 million, and gross proceeds of $4.0 million.

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 WHO. 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.

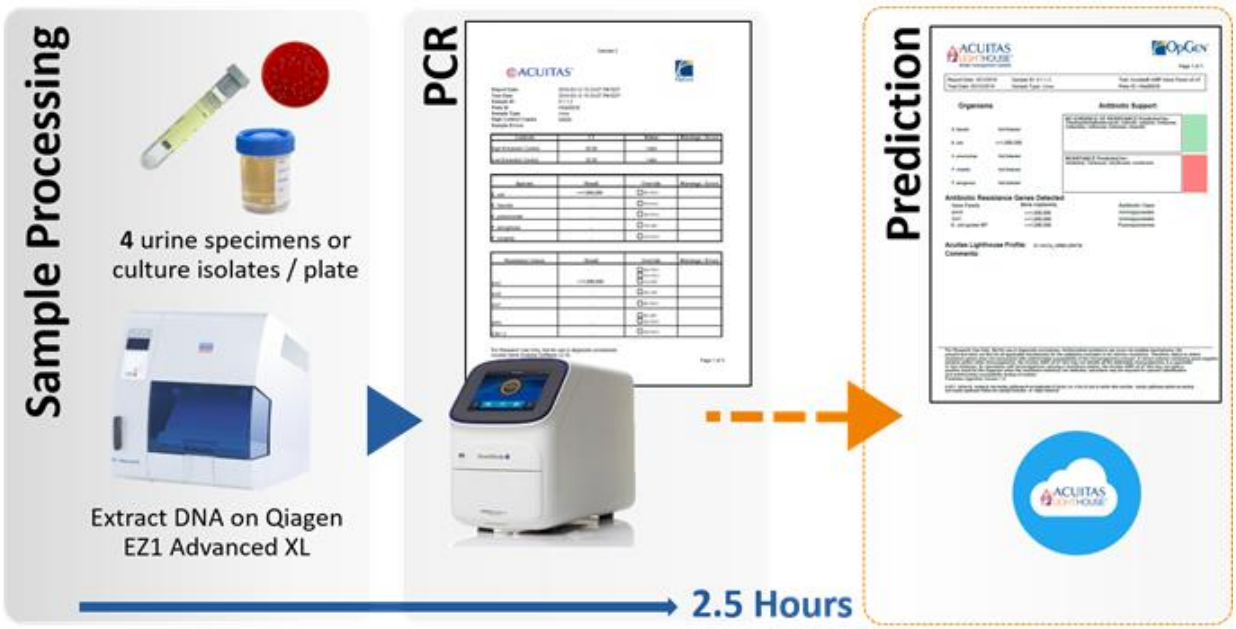
Based on industry analyses, we believe the global HAI market is a $2 billion dollar market with the molecular diagnostic segment representing a fast growing segment of such market with multiple high acuity patients and significant infectious sites, including urinary tract infections, surgical site infections,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

Products

Our lead product are the Acuitas® AMR Gene Panel u5.47 and the Acuitas Lighthouse Software. The Acuitas AMR Gene Panel u5.47 was introduced as an RUO test in the first quarter of 2018 and is under development as an in vitro diagnostic test to detect the most common bacterial causes of cUTI directly from urine. Our current product offerings include our QuickFISH and PNA FISH which are FDA-cleared, CE-marked IVD tests designed to rapidly identify antimicrobial- resistant pathogens significantly earlier than currently available conventional methods, our Acuitas MDRO Gene Test, Acuitas CR Elite Test and Acuitas Resistome Test, each a CLIA lab-based laboratory developed tests, or LDT, service that provides a profile of MDRO-resistant genes for surveillance and response to outbreaks, and our Acuitas Lighthouse informatics.

Acuitas AMR Gene Panel and Acuitas Lighthouse Software

The Acuitas® AMR Gene Panel u5.47 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. The Acuitas AMR Gene Panel u5.47 is intended as an aid in the diagnosis of specific agents of urinary tract infections, or UTI, for patients at risk of complicated urinary tract infection. The Acuitas AMR Gene Panel u5.47 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 u5.47 RUO test detects 47 gene targets which span 600 subtypes and convey resistance to 9 classes of antibiotics directly from urine and isolated colonies. 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 u5.47 RUO 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 5 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. The figure below describes the workflow for the Acuitas AMR Gene Panel u5.47 test and the Acuitas Lighthouse Software.



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. All components of this 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 u5.47 test through the Acuitas AMR Gene Panel u5.47 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 u5.47 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 u5.47 was the result of a comprehensive, multi-year development effort to help address urgent clinical needs for improved rapid antibiotic decision-making capabilities.

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 80 U.S. hospital customers purchased our FISH products over the past twelve months, and we sell our FISH products to hospitals in 15 countries with antibiotic stewardship programs. Our hospital customers include academic medical centers, tertiary care hospitals and community hospitals.

Other Acuitas Products

Our high resolution DNA tests are marketed under the Acuitas trade name. We have developed Acuitas DNA tests, such as the Acuitas MDRO Gene Test, for use in our CLIA laboratory,

- Our Acuitas MDRO Gene Test, launched in 2014, is, to our knowledge, the first CLIA lab-based test able to provide information regarding the presence of ten MDRO resistance genes from one patient specimen. The ten drug-resistant genes identified by our Acuitas MDRO Gene Test are associated with CRE, ESBL and VRE organisms, and are gastrointestinal organisms frequently associated with antibiotic-resistant infections. The test results can be used by healthcare providers to identify patients colonized with organisms expressing the drug-resistant genes or who are actively infected.
- Our Acuitas CR Elite Test, launched in 2014, adds the ability for the healthcare provider to order a microbiology culture screen to be performed from the same specimen sent for our Acuitas MDRO Gene Test, thereby providing additional information about the organism(s) associated with an active infection, as well as an antibiotic susceptibility profile for such organism(s).
- Our Acuitas Resistome Test, launched in the second quarter of 2015, is a more comprehensive MDRO molecular test which detects 49 genes covering over 900 subtypes associated with antibiotic resistance. The test includes additional resistance genes for carbapenemases, ESBLs and AmpC genes, in replacement of the Vancomycin resistant genes found in the Acuitas MDRO Gene Test. We use Acuitas Resistome Test results for Acuitas Lighthouse profiling of specimens collected in hospitals and clinical isolates from infected patients. Information from our Acuitas Resistome Test provides additional gene detection information to supplement our Acuitas MDRO Gene Test.

Acuitas Resistome Test results can be used in conjunction with the Acuitas CR Elite Test to provide high resolution Acuitas Lighthouse profiles. Our goal is to provide DNA test-based Acuitas Lighthouse profiles, within 24 hours of sample receipt, and, using the Acuitas CR Elite Test to supplement our Acuitas Lighthouse profiles, with biologically derived, phenotypic antibiotic susceptibility data within 48 hours. We anticipate improving the accuracy, over time, of our Acuitas Resistome Test by performing DNA sequence analysis of microbial isolates characterized within our Acuitas Lighthouse Knowledgebase. We believe our menu of genotypic and phenotypic tests along with our Acuitas Lighthouse informatics platform, will enable better surveillance and epidemiology, improved infection control practices, improved antibiotic stewardship and individualized patient care, as well as help to facilitate outbreak detection and response in healthcare settings.

Acuitas Lighthouse

Our Acuitas Lighthouse informatics platform enables proactive MDRO management to prevent in-hospital transmission events and to help improve patient outcomes. Using our Acuitas Lighthouse informatics, launched in December 2015, we offer trend analysis of patient specific data, data specific to individual hospital facilities and health systems, which can be accessed safely and confidentially by healthcare providers. Our Acuitas Lighthouse's dynamic profiling incorporates identity, phenotype and MDRO gene presence and assigns unique microbe identifiers, or Acuitas Lighthouse profiles, based on MDRO gene composition, and antibiotic susceptibility, or AST, data. We believe our Acuitas Lighthouse profiling will provide a comprehensive diagnostic tracking tool for MDRO infections in the hospital setting. It is based on our CLIA- and HIPAA-compliant LIMS database system. We have developed a web-based portal to allow our customers access to LIMS-based lab reports and Acuitas Lighthouse data reports.

Research and Development

For the years ended December 31, 2017 and 2016, our research and development expenses were $6.9 million and $8.6 million, respectively. 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 u5.47 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.

Our ongoing and anticipated research and development efforts include:

- development of the Acuitas AMR Gene Panel tests for additional indications, and clinical trial work to support a 510(k) application for commercial launch of the Acuitas AMR Gene Panel 5u.47;
- 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;
- working with pharmaceutical companies to add new or recently FDA approved antibiotics to the Acuitas Lighthouse Software
- further development of our Acuitas MDRO Gene Test, Acuitas Resistome Test and Acuitas Whole Genome Sequence Analysis; and
- converting our CLIA lab-based products to IVD kits that can be sold, upon receipt of FDA clearance and other approvals, directly to our customers and to other clinical reference laboratories.

During 2018 we anticipate finalizing the regulatory approach for commercializing the Acuitas AMR Gene Panel u5.47 and the Acuitas Lighthouse Software. We believe that separate FDA 510(k) regulatory submissions will be required for both of these products. The objective is to complete clinical trials and analytical validation work to support FDA submissions during the fourth quarter of 2018. We anticipate the clinical trial will involve 4-5 clinical sites and the testing of approximately 5,000 clinical samples and bacterial isolates. The final scope of the clinical trial will be finalized following pre-submission meetings with the FDA.

Sales and Marketing

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 11 countries. We operate a subsidiary in Denmark that provides support for our European customers and to distributors in other parts of the world. We anticipate expanding our commercial organization in conjunction with the anticipated FDA clearance to commercialize our Acuitas AMR Gene Panel u5.47 and Acuitas Lighthouse Software products. During 2018 our strategy to build demand for our products following receipt of such regulatory clearance includes completing clinical verification studies, sales of the AMR Gene Panel for Research Use Only, 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 u5.47 and Acuitas Lighthouse Software products through a structured clinical verification program including academic medical centers and clinical collaborators. In March 2018 we announced the first of these agreements with Beth Israel Deaconess Medical Center in Boston. Participants in our clinical verification program will potentially participate in our FDA clinical trials. Results from these activities will support publications and peer to peer medical communications.

In the first quarter of 2018, we introduced the Acuitas AMR Gene Panel u5.47 for infection control purposes and pharmaceutical surveillance research as a Research Use Only test for cUTI. The Acuitas AMR Gene Panel u5.47 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 product in 2019. Our rapid pathogen identification FISH products are used by nearly 100 customers in the US and internationally. Many of these customers are potential customers for our FDA-cleared Acuitas AMR Gene Panel u5.47 test. 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. Total revenues from customers for the years ended December 31, 2017 and 2016 were $3.2 million and $4.0 million, respectively. Net loss for the years ended December 31, 2017 and 2016 was $15.4 million and $19.2 million, respectively. Total assets at December 31, 2017 and 2016 were $6.6 million and $9.0 million, respectively.

For the year ended December 31, 2017, revenue earned under the CDC contract represented 11% of total revenues. No individual customer represented in excess of 10% of revenues for the year ended December 31, 2016.

Competition

We believe we are currently the only company 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 DNA tests developed in our CLIA laboratory, FDA-cleared and CE-marked rapid diagnostics, and 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 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.

Laboratory Operations

Our laboratory operations are headquartered at our CLIA-certified laboratory in Gaithersburg, Maryland, where we perform all Acuitas MDRO tests. Samples are transported to the laboratory by FedEx or by courier. Once received, samples are assessed for acceptability, accessioned into our LIMS, prepared for processing and analyzed with traditional microbiology culture methods or using molecular testing instrumentation. Laboratory test data is housed in a proprietary LIMS database that is CLIA and HIPAA compliant. Customers access CLIA laboratory test results through individual PDF test reports and through our Acuitas Lighthouse informatics. Our laboratory also performs testing for research and development, quality control, and for both the creation and ongoing maintenance of our Acuitas Lighthouse data warehouse.

We believe we have sufficient laboratory capacity to perform Acuitas testing for at least the next 24 months.

Manufacturing

During 2017, we manufactured our FDA-cleared and CE-marked QuickFISH and PNA FISH products in our Woburn, Massachusetts facility. We are currently in the process of transferring these manufacturing operations to 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. Our Woburn, Massachusetts facility was inspected by the FDA in 2015. Following such inspection, the FDA issued a report of its findings and observations, typically referred to as "Form 483 observations," primarily related to our quality systems and testing policies and documentation. We have responded to all inspection observations within the required timeframe and have worked with the FDA's Office of Compliance to satisfy all identified deficiencies.

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 procure reagents, equipment, chips and other materials we use to perform our Acuitas MDRO Gene Test from sole suppliers such as Fluidigm Corporation. 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 perform our Acuitas MDRO Gene Test or manufacture 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, the Acuitas Lighthouse Software, MDRO test products, and our 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. Hospitals that purchase MDRO services from our CLIA laboratory are billed on a per test basis. 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, 2017, we had total ownership rights to 35 patents, including 19 pending United States non-provisional patent applications, and 16 issued United States patents. More specifically, as of December 31, 2017, related to our FISH products, we had ownership rights to 11 patents, including 3 pending United States non-provisional patent applications, and 8 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, 2017, related to our Acuitas products, we had ownership rights to 4 patents, including 4 pending United States non-provisional patent applications and no issued United States patents. As of December 31, 2017, related to our other products, we had ownership rights to 20 patents, including 12 pending United States non-provisional patent applications, and 8 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 five years. The remaining 14 exclusively licensed United States FISH patents expire between 2018 and 2023.

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.

Clinical Laboratory Improvement Amendments of 1988

Congress passed CLIA in 1988, which provided CMS authority over all laboratory testing, except research that is performed on humans in the United States. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations, has the responsibility for implementing the CLIA program.

The CLIA program is designed to establish quality laboratory testing by ensuring the accuracy, reliability and timeliness of patient test results. Under CLIA, a laboratory is a facility that does laboratory testing on specimens derived from humans and used to provide information for the diagnosis, prevention or treatment of disease, or impairment of, or assessment of health. Under the CLIA program,

laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections and pay fees.

As a clinical reference laboratory, we are required to hold certain Federal, state and local licenses, certifications and permits to conduct our business. Under CLIA, we are required to hold a certificate applicable to the type of laboratory examinations we perform and to comply with standards covering personnel, facilities administration, quality systems and proficiency testing.

We have a current Certificate of Compliance under CLIA and a Medical Laboratory Permit from the State of Maryland to perform clinical testing at our Gaithersburg, Maryland laboratory. To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business. Our current CLIA certificate expires on October 1, 2019, and our Medical Laboratory Permit expires on June 30, 2018.

If our clinical laboratory is out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificate, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties. We must maintain CLIA compliance and certification in order to perform clinical laboratory tests and report patient test results. If we were to be found out of compliance with CLIA requirements and subjected to sanction, our business could be harmed.

Federal Oversight of Laboratory Developed Tests and Research-Use-Only Products

Clinical laboratory tests, like our Acuitas MDRO Gene Test, are regulated under CLIA, as well as by applicable state laws. Historically, most laboratory developed tests, or LDTs, were not subject to FDA regulations applicable to medical devices, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. The FDA defines the term “laboratory developed test” as an IVD test that is intended for clinical use and designed, manufactured and used within a single laboratory. We believe that our Acuitas MDRO test products are LDTs. Currently, the FDA exercises enforcement discretion with respect to LDTs such that it does not enforce provisions of the Food, Drug and Cosmetic Act applicable to IVD devices. In July 2014, due to the increased proliferation of LDTs for complex diagnostic testing, and concerns with several high-risk LDTs related to lack of evidentiary support for claims, erroneous results and falsification of data, the FDA notified Congress that it would issue guidance that, when finalized, would adopt a risk-based framework that would increase FDA oversight of LDTs. As part of this developing framework, the FDA issued draft guidance in October 2014, informing manufacturers of LDTs of its intent to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. In November 2016, the FDA announced that a final LDT Policy guidance would not be issued to allow for further public discussion on an appropriate oversight approach, to give FDA’s congressional authorizing committees the opportunity to develop a legislative solution to LDT regulation. The FDA further elaborated in January 2017 through a discussion paper the agency’s intended framework for potential regulation while also confirming that the FDA intends to continue to exercise enforcement discretion over LDTs at this time.

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.

We cannot predict the potential effect the FDA’s current and forthcoming guidance on LDTs and IUOs/RUOs will have on our product offerings or materials used to perform our diagnostic services. While we qualify all materials used in our diagnostic services according to CLIA regulations, 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 FDCA, 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 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. At this time our CLIA lab in Maryland is not required to register and list with the FDA; however, the Medical Device User Fee Act IV, or MFUFA IV, negotiations currently taking place between the FDA and medical device manufacturers include discussions regarding user fees for clinical laboratories running LDTs. This new fee would be in addition to the user fees required to operate a clinical laboratory.

The FDA has issued a regulation outlining specific requirements for "specimen transport and storage containers." "Specimen transport and storage containers" are medical devices if "intended to contain biological specimens, body waste, or body exudate during storage and transport" so that the specimen can be used effectively for diagnostic examination. Since medical devices are subject to registration and listing requirements, the reporting of corrections and removals, and responsible for medical device reporting requirements, if the FDA were to determine that our sample collection container is a medical device, the manufacturer would be required to register and list with the FDA for us to use the container for diagnostic purposes. The specimen collection device would be exempt from premarket review, and from Quality System Regulation, or QSR, requirements except for recordkeeping and complaint handling requirements, so long as no sterility claims are made, but the manufacturer would still be required to comply with applicable regulations.

510(k) Clearance Pathway

If required to obtain 510(k) clearance for our future products or conversion of our Acuitas MDRO test products to diagnostic kits, such tests would be classified as medical devices and we would 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.

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 Woburn, Massachusetts facility is currently registered as an establishment with the FDA. If the LDTs performed in OpGen's CLIA-certified lab were deemed medical devices by the FDA, then we and any third-party manufacturers of such devices would need to register with the FDA as medical device manufacturers and obtain all necessary state permits or licenses to operate our business. We and any third-party manufacturers would be subject to announced and unannounced inspections by the FDA to determine our compliance with quality system regulation and other regulations. Our Woburn, Massachusetts facility was inspected by the FDA in 2015. Following such inspection, the FDA issued a report of its findings and observations, typically referred to as "Form 483 observations," primarily related to our quality systems and testing policies and documentation. We have responded to all inspection observations within the required time frame and are working with the FDA's Office of Compliance to satisfy the identified deficiencies.

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 clinical laboratory, and 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, including a laboratory, 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.

Maryland Laboratory Licensing

Maryland requires that any site that performs clinical laboratory testing located in the state of Maryland, with limited exceptions, must be licensed by the state, in addition to meeting Federal CLIA requirements. As such, our laboratory in Gaithersburg, Maryland holds a current Maryland license and is subject to on-site surveys by Maryland’s Office of Health Care Quality. Our license was renewed in 2016 and will expire in June 2018.

Other States’ Laboratory Licensing

In addition to Maryland, other states including California, Florida, New York, Pennsylvania, Rhode Island, and the District of Columbia, require licensing of out-of-state laboratories under certain circumstances. We have obtained licenses to receive specimens from Pennsylvania, Florida, and New York. We intend to obtain licenses from additional states and jurisdictions where we believe we are required to be licensed, and believe we are in compliance with applicable licensing laws.

From time to time, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states do have such requirements or will have such requirements in the future. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to comply with such requirements.

International Regulation

Sales of diagnostic tests like our Acuitas MDRO test 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’s Woburn, Massachusetts facility is currently ISO 13485 certified; the facility passed an inspection by our Notified Body in January 2017. While such certification is not required to distribute products internationally, the ISO 13485 certification implies that we are in compliance with the applicable regulatory requirements to distribute our medical devices internationally. OpGen currently distributes 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 u5.47" 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 CR Elite" is a comprehensive test for detection of CRE including our Acuitas MDRO gene test, culture-based detection, and Acuitas resistome testing on positive specimens.

"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.

"Acuitas MDRO Gene Test" means our internally developed test that detects ten critical MDRO genes, including CRE (7 genes), ESBL (2 genes) and VRE-resistant organisms, from one patient swab.

"Acuitas MDRO test products" means our Acuitas MDRO Gene Test, Acuitas CR Elite Test and Acuitas Resistome Test.

"Acuitas Resistome Test" means our rapid, high resolution test that includes additional resistance genes for carbapenems, ESBLs and AmpC.

"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.

"CLIA" means the Clinical Laboratory Improvements Act of 1988, as amended.

"CLIA lab" means a clinical or reference laboratory meeting the requirements of the Clinical Laboratory Improvements Act of 1988, as amended.

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

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

"CRO" means carbapenem-resistant organisms, 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.

“LIMS” means a laboratory information management system.

“MDRO” means a multidrug-resistant organism.

“PCR” means polymerase chain reaction.

“QSR” means Quality System Regulation.

“SEC” means the U.S. Securities and Exchange Commission.

“Securities Act” means the Securities Act of 1933, as amended.

“WHO” means the World Health Organization.

Employees

As of December 31, 2017, we had 43 employees worldwide, with 42 employed in the United States and 1 employed in Denmark. There are 35 full-time employees. The 42 employees in the United States primarily work in our Gaithersburg, Maryland and Woburn, Massachusetts locations. 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 are in Gaithersburg, Maryland, and its principal operations are in Gaithersburg, Maryland and Woburn, Massachusetts. The Company also has operations in Copenhagen, Denmark.

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 and copied at the Public Reference Room of the SEC at 100 F Street, N.E., Washington D.C. 20549. The SEC also maintains an internet website that contains reports, proxy statements, and other information about issuers, like OpGen who file electronically with the SEC. The address of the site is 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, 2017 and 2016 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, 2017 and 2016, we had net losses of $15.4 million and $19.2 million, respectively. From our inception through December 31, 2017, we had an accumulated deficit of $148.7 million. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2017 and 2016 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. We completed a number of financings in 2018, 2017, and 2016, including the February 2018 Public Offering, the July 2017 Public Offering, a private investment in public equity, or PIPE, in May and June 2016 to members of management, employees and accredited investors, including MGHIF and jVen Capital, and an at-the-market, or ATM, public offering commenced in September 2016. The net proceeds from such financings were approximately $37.1 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, and our automated rapid molecular diagnostic products;
- commercializing our rapid pathogen identification and Acuitas MDRO and Acuitas Lighthouse informatics services;
- developing, presenting and publishing additional clinical and economic utility data intended to increase clinician adoption of our current and future products and services;
- expansion of our operating capabilities;
- development of collaborative arrangements during 2018;
- maintenance, expansion and protection of our intellectual property portfolio and trade secrets;
- future clinical trials as we seek regulatory approval for some of our product offerings;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize potential future products and services; and
- continued focus on recruiting and retaining our quality assurance and compliance personnel and activities.

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 including the February 2018 Public Offering will be sufficient to fund operations into the first quarter of 2019. In the event we are unable to successfully raise additional capital during or before the first 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, Acuitas MDRO tests and Acuitas Lighthouse bioinformatics services in order to make our business profitable. We have identified potential synergies for future rapid diagnostic test developments based on our existing product and service offerings, but 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. In September 2016, we filed a shelf registration statement on Form S-3 to offer for sale and sell, from time to time, up to $50 million of shares of our common stock. As a smaller reporting company, we are limited to sales under such shelf registration statement, or similar offerings, of no more than one-third of our public float over a rolling twelve-month period. In September 2016, we commenced an "at the market," or ATM, offering under the shelf registration statement to raise up to $11.5 million. As of December 31, 2017, we have raised approximately $8.8 million under the ATM offering. 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 including the February 2018 Public Offering will be sufficient to fund operations into the first quarter of 2019. In the event we are unable to successfully raise additional capital during or before the first 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 July 2018. 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.

Our restructuring plans may not produce the cost savings we anticipate, and we may encounter difficulties associated with the related organizational change.

In June 2017, we commenced a restructuring of our operations to improve efficiency and reduce our cost structure. To date, we have achieved a reduction in operating expenses of approximately 31 percent. The restructuring plan anticipates that we will consolidate operations for our FDA-cleared and CE marked products and research and development activities for the Acuitas AMR Gene Panel in Gaithersburg, Maryland, and reduce the size of our commercial organization while we work to complete the development of our Acuitas AMR Gene Panel u5.47 test and Acuitas Lighthouse Software in development.

The restructuring is substantially complete, however, if we are unable to complete the objectives of the restructuring, our business and results of operations may be materially and adversely affected. We may not fully realize the anticipated benefits from our restructuring plans. Our restructuring plans may not adequately reduce expenses or produce the cost savings we anticipate or in the time frame we expect. Further restructuring activities may also be required in the future beyond what is currently planned, which could enhance the risks associated with these activities.

Moreover, the costs associated with the closing of our facility in Woburn, Massachusetts and consolidating our operations in Gaithersburg, Maryland are significant. In addition, our Gaithersburg facility may not meet the FDA and CE marked requirements. If we are unable to consolidate our operations, receive the necessary regulatory approvals for our Gaithersburg facility, or sufficiently reduce our cash burn it could have a material adverse effect on our business, operating results and financial condition.

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 management 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 automate and expand our current product offerings. We may not be successful in developing such automated rapid pathogen identification products, which would 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 one to 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 by 2019. Any significant delays or failures in this process could have a material adverse effect on our business and financial condition.

We may offer these products in development to the research use only market or 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 will 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 have been awarded a contract by the CDC, and may enter into additional 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 September 2017, we were awarded a contract by the CDC to assess use of smartphone-based clinical decision support tools for antimicrobial stewardship and infection control in low- and middle-income countries. Receipt of this funding is contingent on our successful implementation of the grant agreement with our collaboration partners. If we fail to meet the obligations under the contract, our financial condition could be adversely affected.

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.

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.

The sales cycles for our Acuitas AMR Gene Panel and Acuitas Lighthouse Software is lengthy, which makes 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 may enter into collaborations with third parties to develop product and services candidates. If these collaborations are not successful, our business could be adversely affected.

We may enter into collaborations related to our MDRO and informatics products and services. Such collaborations may be with pharmaceutical companies, platform companies or other participants in our industry. We would 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 future 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 future 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, the Acuitas MDRO 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. We have experienced very limited revenue and customer adoption for our Acuitas MDRO products and services to date. 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 and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians, particularly as we seek to further integrate operations of the combined company. 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 laboratory and field 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 and Acuitas Lighthouse Software, our QuickFISH products, and our Acuitas Lighthouse surveillance product and services offerings. 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. As a result, we believe it is necessary to maintain a sales force that includes sales representatives with specific technical backgrounds that can support our customers' needs. We will also 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 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 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.

The performance of clinical and economic utility studies is expensive and demands significant attention from our management team.

The performance of clinical and economic utility studies is expensive and demands significant attention from our management team. Data collected from these studies may not be positive or consistent with our existing data, or may not be statistically significant or compelling to the medical community. If the results obtained from our ongoing or future studies are inconsistent with certain results obtained from our previous studies, adoption of our current and future products and services would suffer and our business would be harmed.

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. The recent 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.

If our sole laboratory facility or manufacturing facility becomes inoperable, we will be unable to perform Acuitas MDRO test services, or manufacture our QuickFISH and PNA Fish products, and our business will be harmed.

We perform all of our Acuitas MDRO and Acuitas Lighthouse testing services in our CLIA-compliant laboratory located in Gaithersburg, Maryland. We do not have redundant laboratory facilities. Our facility and the equipment we use to perform our diagnostic and screening assays 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 to perform our tests for some period of time. The inability to perform our tests 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 laboratory 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 clinical laboratory facility opened by us would be required to be certified under CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. In addition to a CLIA certification, we would also be required to secure and maintain state licenses required by several states, including Maryland, California, Florida, New York and Pennsylvania which can take a significant amount of time and result in delays in our ability to begin operations at that facility. We currently have active licenses in Maryland, Florida, New York and Pennsylvania. If we failed to secure any such licenses, we would not be able to process samples from recipients in such states. If we fail to maintain our CLIA certification or if our CLIA certification is suspended, limited or revoked, we would not be able to process human-derived samples from recipients that are not for research purposes. We also expect that it would be difficult, time-consuming and costly to train, equip and use a third-party to perform tests on our behalf. We could only use another facility with the established state licensures and CLIA certification necessary to perform our current or future tests following validation and other required procedures. We cannot assure you that we would be able to find another CLIA-certified facility willing or able to adopt our current or future tests and comply with the required procedures, or that this laboratory would be willing or able to perform the tests for us on commercially reasonable terms.

We are completing the process of re-locating the manufacturing our QuickFISH and PNA Fish products from our leased facility located in Woburn, Massachusetts to our Gaithersburg, Maryland facility. If demand for these products increase beyond our current forecasts or, regulatory requirements arise, we may not be able to meet our obligations to produce these products, and backlog or reduced demand for such products could occur. We are in the process of obtaining all necessary FDA certifications with respect to such relocation. If we are not successful in obtaining all necessary FDA certifications, it could delay our ability to manufacture these products. If any of these issues occur, it could have a material adverse effect on our financial condition and results of operations.

In order to meet the turn-around time required for our Acuitas MDRO test services, we rely on transport of specimens to our sole laboratory facility; any disruption in such transport could significantly adversely affect our business.

Our current customers for our Acuitas MDRO test services are located near our sole laboratory facility in Gaithersburg, Maryland. As we expand our customer base, and the jurisdictions where we are licensed to provide our CLIA laboratory services, we will need to secure the proper licenses for shipment of specimens and rely on accurate and timely delivery of the specimens by overnight delivery services such as FedEx. Any failure to procure the proper licenses, to comply with the license regulations or to receive undamaged specimens from overnight delivery services could adversely affect our business and reputation.

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

We rely on several sole suppliers and manufacturers, including Fluidigm Corporation, for supplying certain laboratory reagents, raw materials, supplies and substances which we use in our laboratory operations and products and 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.

We believe that there are only a few other equipment manufacturers that are currently capable of supplying and servicing the equipment and other supplies and materials necessary for our laboratory operations. The use of equipment or materials furnished by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our products. There can be no assurance that we will be able to secure alternative equipment and other materials, and bring such equipment and materials on line and revalidate them without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the equipment we require for our products, our business, financial condition, results of operations and reputation could be adversely affected.

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

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

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

We also face competition from commercial laboratories, such as Bio-Reference Laboratories, Inc., Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated 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.

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 test at the research or development stage;
- lack of clinical validation data to support the effectiveness of the test;
- 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 2018 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 $165.5 million and research and development tax credits of $2.6 million as of December 31, 2017, that may already be or could be limited if we experience an ownership change. In addition, the Tax Cuts and Jobs Act may limit 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.

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 March 26, 2018, the market price of our common stock fluctuated from a high of $136.00 per share to a low of $1.75 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.

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. Currently, approximately 9% of our common stock, on a fully diluted basis, is held by officers, directors and their affiliates, each of whom is subject to certain restrictions with regard to trading our common stock. This ownership may result in different prices for our common stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and asked prices for our common stock. In addition, following the 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.

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 March 26, 2018, we had outstanding warrants to acquire 4,198,876 shares of our common stock, and stock options to purchase 221,194 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 have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

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

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

If we fail to comply with federal, state and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA for our Acuitas MDRO tests, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payors. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories.

We are also required to maintain state licenses to conduct testing in our laboratories. Maryland law requires that we maintain a state license and establishes standards for the day-to- day operation of our clinical reference laboratory in Gaithersburg, including the training and skills required of personnel and quality control matters. In addition, our clinical reference laboratory is required to be licensed on a test-specific basis by New York State. New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether such laboratories are located in New York. Moreover, several other states including California, Pennsylvania, and Florida require that we hold licenses to test samples from patients in those states. Other states may adopt similar requirements in the future.

If we were to lose, or have restrictions imposed on, our CLIA certificate or Maryland license for our Gaithersburg laboratory, whether as a result of revocation, suspension or limitation, we would no longer be able to perform our test products, which would eliminate our primary source of revenue and harm our business. If we cannot secure a license from states where we are required to hold licenses, we will not be able to test specimens from those states.

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 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.

If the FDA were to begin regulating our laboratory tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or other approvals.

Clinical laboratory tests, like our Acuitas MDRO Gene Test, are regulated under CLIA, as well as by applicable state laws. Historically, most LDTs were not subject to FDA regulations applicable to medical devices, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. The FDA defines the term "laboratory developed test" as an IVD test that is intended for clinical use and designed, manufactured and used within a single laboratory. We believe that our Acuitas MDRO test products are LDTs. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug, and Cosmetic Act (the "FDA Act") with respect to LDTs. In July 2014, due to the increased proliferation of LDTs for complex diagnostic testing and concerns with several high-risk LDTs related to lack of evidentiary support for claims, erroneous results and falsification of data, the FDA issued a Notification to Congress that it intended to issue a draft guidance that, when and if finalized, would likely adopt a risk-based framework that would increase FDA oversight of LDTs. The FDA issued draft guidance in October 2014, informing manufacturers of LDTs of its intent to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. The FDA will use this information to classify LDTs and to prioritize enforcement of premarket review requirements for categories of LDTs based on risk, using a public process. Specifically, the FDA plans to use advisory panels to provide recommendations to the agency on LDT risks, classification and prioritization of enforcement of applicable regulatory requirements on certain categories of LDTs, as appropriate. In November 2016, the FDA announced that a final LDT Policy guidance would not be issued to allow for further public discussion on an appropriate oversight approach, to give the FDA's congressional authorizing committees the opportunity to develop a legislative solution to LDT regulation. The FDA further elaborated in January 2017, through a discussion paper, the agency's intended framework for potential regulation while also confirming that the FDA intends to continue to exercise enforcement discretion over LDTs at this time.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. We cannot predict the timing or content of future legislation enacted, regulations promulgated or guidance issued regarding LDTs, or how it will affect our business.

If FDA premarket review, including clearance or approval, is required for our Acuitas MDRO test products or any of our future tests (either alone or together with sample collection devices), products or services we may develop, or we decide to voluntarily pursue FDA clearance or approval, we may be forced to stop selling our tests while we work to obtain such FDA clearance or approval. Our business would be negatively affected until such review was completed and clearance to market or approval was obtained. The regulatory process may involve, among other things, successfully completing additional clinical studies and submitting premarket notification or filing a premarket approval application with the FDA. If premarket review is required by the FDA or if we decide to voluntarily pursue FDA premarket review of our tests, there can be no assurance that our Acuitas MDRO Gene Test or any tests, products or services we may develop in the future will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of our tests. If our tests are allowed to remain on the market but there is uncertainty in the marketplace about our tests, if we are required by the FDA to label them investigational, or if labeling claims the FDA allows us to make are limited, orders may decline. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements.

If we are required to but fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our products or product enhancements, our ability to commercially distribute and market our products could suffer.

If the FDA determines that enforcement discretion is not appropriate or that LDTs are generally subject to FDA regulation and that premarket review, including clearance or approval, is required for our Acuitas MDRO Gene Test or any of our future tests, diagnostic test kits that we may develop, or other products that would be classified as medical devices, the process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the FDA Act, or is the subject of an approved PMA, unless the device is specifically exempt from those requirements. 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. Our currently commercialized products have not received FDA clearance or approval, as they are marketed under the FDA's enforcement discretion for LDTs or are class I medical devices, which are exempt from the requirement for FDA clearance or approval.

Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

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 are required to obtain 510(k) clearance or PMA approval for any of our current or future products, any modification to those products 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 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.

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

Some of our future products may require 510(k) clearance from the FDA. Other products, potentially, could require PMA approval. In addition, some of our new products may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products. Failure to receive a required clearance or approval for our new products would have an adverse effect on our ability to expand our business.

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 and LDT manufacturers are required to report to the FDA information that a device or LDT 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 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 believe that our Acuitas MDRO test products are LDTs, subject to the FDA's enforcement discretion. To remain within the FDA's enforcement discretion, we are restricted in the ways we can promote and market our products. We believe that our promotional activities for our products fall 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 MDRO products in certain ways unless and until we obtain FDA clearance or approval for them, or our FDA-cleared products for unapproved or "off-label" uses unless and until we obtain FDA clearance or approval for those uses. In addition, because our Acuitas MDRO products are not currently cleared or approved by the FDA, if the FDA determines that our promotional materials constitute promotion of a use for which premarket clearance or approval is required, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions, 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.

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. 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 Other 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 subjects manufacturers of medical devices to an excise tax of 2.3% on certain U.S. sales of medical devices beginning in January 2013. This excise tax has been suspended currently, and we anticipate that this may be repealed. If eventually implemented, this excise tax will likely increase our expenses in the future.

Further, 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. We have provided reports under the Open Payments Act to the CMS since 2013. 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.

Failure in our information technology, storage systems or our digital platform technology 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 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 digital immunoassay platform, could adversely affect our ability to operate our business. Any interruption in the operation of our digital immunoassay platform, 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.

Payments for our tests and other services could decline because of factors beyond our control.

If hospital patient volumes drop as a result of severe economic conditions, or other unforeseen changes in healthcare provision or affordability, individual hospitals and health systems may be less willing to invest in our products and services. In addition, state and federal funds that are anticipated to be invested in the National Strategy for Combating Antibiotic-Resistant Bacteria could be reduced. If such funds are reduced, the market for our products would be impacted, which may affect our ability to generate revenues.

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. Several clinical diagnostic laboratories and members of their management have been the subject of this enforcement scrutiny, which has resulted in very significant civil and criminal settlement payments. 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 have compliance policies and are in the process of adopting a written compliance plan based on the Health and Human Services' Office of the Inspector General guidance set forth in its model compliance plan for clinical laboratories, and federal and state fraud and abuse laws. We will monitor changes in government enforcement, particularly in these areas, 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, 2017 and 2016 were $949,244 and $1,000,726, 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. The following table shows the high and low sales price for our common stock and IPO warrants as reported by The Nasdaq Capital Market for the periods indicated:

	High	Low
Common Stock:		
Year Ended December 31, 2017		
Fourth Quarter	$ 10.25	$ 3.78
Third Quarter	$ 16.76	$ 5.30
Second Quarter	$ 31.25	$ 13.00
First Quarter	$ 46.25	$ 24.50
IPO Warrants:		
Year Ended December 31, 2017		
Fourth Quarter	$ 2.10	$ 0.25
Third Quarter	$ 4.88	$ 1.50
Second Quarter	$ 10.00	$ 0.88
First Quarter	$ 4.50	$ 1.50

	High	Low
Common Stock:		
Year Ended December 31, 2016		
Fourth Quarter	$ 77.50	$ 21.75
Third Quarter	$ 116.25	$ 34.00
Second Quarter	$ 54.50	$ 25.50
First Quarter	$ 49.20	$ 34.00
IPO Warrants:		
Year Ended December 31, 2016		
Fourth Quarter	$ 7.48	$ 2.01
Third Quarter	$ 17.00	$ 3.13
Second Quarter	$ 11.50	$ 2.80
First Quarter	$ 9.25	$ 4.61

Stockholder Information

As of March 26, 2018, there were approximately 34 stockholders of record of our common stock, which does not include stockholders that beneficially own shares held in a "nominee" or in "street" name.

Dividends

We have not paid cash dividends in the years ended December 31, 2017 and 2016. We do not anticipate paying cash dividends in the foreseeable future, as we intend to use our revenue and capital to advance our product development and commercialization activities.

Sales of Unregistered Securities

In July 2017, the Company issued one Bridge Financing Notes to jVen Capital and warrants to purchase shares of common stock to jVen Capital and MGHIF in a private placement transactions as described in this Annual Report on Form 10-K and in the Form D filed on June 20, 2017. The private placement was made in accordance with Rule 506 promulgated under the Securities Act.

In September 2017, we issued 15,482 shares of common stock to settle a dispute related to pre-Merger AdvanDx activities. A Form D was filed on September 21, 2017. The private placement was made in accordance with Rule 506 promulgated under the Securities Act.

Use of Proceeds from the Sale of Registered Securities

As of December 31, 2017, we have used all of the net cash proceeds from our July 2017 Public Offering for sales and marketing, research and development and working capital purposes. There has been no material change in our planned use of the balance of the net proceeds from the July 2017 Public Offering as described in our final prospectus dated July 12, 2017 and filed with the SEC pursuant to Rule 424(b) under the Securities Act on July 14, 2017.

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data

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

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our audited consolidated financial statements and the accompanying notes thereto included elsewhere in this Annual Report. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth in the section titled "Risk Factors" included under Part I, Item 1A of this Annual Report.

Overview

OpGen was incorporated in Delaware in 2001. On July 14, 2015, OpGen completed the Merger with AdvanDx ("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 are in Gaithersburg, Maryland, and its principal operations are in Gaithersburg, Maryland and Woburn, Massachusetts. The Company also has operations in Copenhagen, Denmark. The Company operates in one business segment.

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

The Company's molecular diagnostics and informatics offerings combine its Acuitas DNA tests 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 DNA tests provide rapid microbial identification and antibiotic resistance gene information. These products include the Acuitas AMR Gene Panel u5.47 for complicated urinary tract infections in development as a clinical diagnostic test and available for Research Use Only, the QuickFISH® family of FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures, and the Acuitas Resistome Tests for genetic analysis of hospital surveillance isolates.
- 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.

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

2017 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 2017:

- 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 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.
- 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, each a Bridge Financing Note. 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 5,633 shares with an exercise price of $19.50 per share, and stock purchase warrants to acquire 6,349 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.
- During the year ended December 31, 2017, the Company sold approximately 227 thousand 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.

Results of Operations for the Years Ended December 31, 2017 and 2016

Revenues

	Year Ended December 31,	
	2017	2016
Revenue		
Product sales	$ 2,771,869	$ 3,524,178
Laboratory services	41,960	228,904
Collaboration revenue	397,178	272,603
Total revenue	$ 3,211,007	$ 4,025,685

Our total revenue for the year ended December 31, 2017 decreased 20%, to $3.2 million from $4.0 million, when compared to the same period in 2016. This decrease is primarily attributable to:

- Product Sales: the decrease in revenue of 21% in 2017 as compared to 2016 is primarily attributable to a reduction in the sale of our legacy Argus Whole Genome Mapping System, or Argus, products, as we transitioned from our legacy mapping products to the introduction of Acuitas MDRO products sales, and a reduction in the sale of our rapid pathogen ID testing products;
- Laboratory Services: the decrease in revenue of 82% in 2017 as compared to 2016 is a result of decreases in sales of our Acuitas MDRO test products; and
- Collaboration Revenue: the increase in collaboration revenue of 46% in 2017 as compared to 2016 is primarily the result of increased revenue associated with our CDC contract

Operating expenses

	Year Ended December 31,	
	2017	2016
Cost of products sold	$ 1,612,838	$ 1,658,571
Cost of services	520,338	631,333
Research and development	6,883,293	8,613,236
General and administrative	6,692,659	6,602,608
Sales and marketing	2,767,670	5,529,274
Total operating expenses	$ 18,476,798	$ 23,035,022

The Company's total operating expenses for the year ended December 31, 2017 decreased 20%, to $18.5 million from $23.0 million, when compared to the same period in 2016. This decrease is primarily attributable to:

- Costs of products sold: expenses for the year ended December 31, 2017 decreased approximately 3% when compared to the same period in 2016. The change in costs of products sold is primarily attributable to the decrease in legacy Argus sales offset by increased payroll and facility costs;
- Costs of services: expenses for the year ended December 31, 2017 decreased approximately 18% when compared to the same period in 2016. The change in costs of services is primarily attributable to a decrease in sales of Acuitas Lighthouse services;
- Research and development: expenses for the year ended December 31, 2017 decreased approximately 20% when compared to the same period in 2016, primarily due to a decrease in costs related to the automated rapid pathogen identification project;
- General and administrative: expenses for the year ended December 31, 2017 increased approximately 1% when compared to the same period in 2016, primarily due to legal costs
- Sales and marketing: expenses for the year ended December 31, 2017 decreased approximately 50% when compared to the same period in 2016, primarily due to costs associated with marketing studies conducted in the first half of 2016 and the reductions in the size of our commercial organization that occurred in June through December 2017.

Other income (expense)

	Year Ended December 31,	
	2017	2016
Interest expense	$ (233,505)	$ (143,347)
Foreign currency transaction gains/(losses)	23,179	(8,102)
Change in fair value of derivative financial instruments	144,064	-
Interest and other expense	(87,255)	(5,967)
Total other expense	$ (153,517)	$ (157,416)

Other expense for the year ended December 31, 2017 decreased to a net expense of $153,517 from a net expense of $157,416 in the same period of 2016. The decrease was primarily a result of gains recognized due to the change in fair value of warrant liabilities offset by an increase in interest expense due to the issuance of the Bridge Financing Notes and modification of the MGHIF Note in June 2017 as well as the expense of the unamortized discount on the Bridge Financing Notes at repayment.

Liquidity and capital resources

On February 7, 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.

At December 31, 2017, the Company had cash and cash equivalents of $1.8 million, compared to $4.1 million at December 31, 2016. The Company has funded its operations primarily through external investor financing arrangements and has raised significant funds in 2017 and 2016, including:

On July 18, 2017, the Company closed a public offering of 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million as described above under "2017 Financing Transactions."

On May 31, 2017, the Company entered the bridge financing transaction with jVen Capital described above under "2017 Financing Transactions."

A condition to the receipt of the bridge financing was an extension of 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 issued the amended and restated MGHIF Note to increase the interest rate to 10% 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 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, 2017, the Company has sold an aggregate of approximately 372 thousand shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $8.2 million, and gross proceeds of $8.8 million. As of December 31, 2017, remaining availability under the at the market offering is $2.7 million. During the year ended December 31, 2017, the Company sold approximately 227 thousand shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $3.8 million, and gross proceeds of $4.0 million.

To meet its capital needs, the Company is 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. 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 on hand including the February 2018 Public Offering will be sufficient to fund operations into the first quarter of 2019. This has led management to conclude that there is substantial doubt about the Company's ability to continue as a going concern. In the event the Company is unable to successfully raise additional capital during or before the first 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.

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,	
	2017	2016
Net cash used in operating activities	$ (14,303,880)	$ (17,250,637)
Net cash used in investing activities	(276,950)	(123,514)
Net cash provided by financing activities	12,348,194	13,664,690

Net cash used in operating activities

Net cash used in operating activities in 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 of $0.9 million, partially offset by the net change in operating assets and liabilities of $0.6 million. Net cash used in operating activities for 2016 consists primarily of our net loss of $19.2 million, reduced by certain non-cash items, including depreciation and amortization expense of $0.7 million, share-based compensation expense of $0.9 million, and the net change in operating assets and liabilities of $0.2 million.

Net cash used in investing activities

Net cash used in investing activities in 2017 and 2016 consisted solely of the purchase of property and equipment.

Net cash provided by financing activities

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. Net cash provided by financing activities in 2016 of $13.7 million consisted primarily of the net proceeds from our private placement of common stock, non-voting convertible preferred stock and stock purchase warrants and issuance of common stock under the ATM offering.

Critical accounting policies and use of estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our audited consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our audited consolidated financial statements, estimates are used for, but not limited to, share-based compensation, allowances for doubtful accounts and inventories, valuation of derivative financial instruments, beneficial conversion features of convertible debt, deferred tax assets and liabilities and related valuation allowance, and 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

Revenue for the sales of QuickFISH and PNA FISH diagnostic test products is recognized upon shipment to the customer.

The Company recognizes revenue associated with laboratory services contracts when the service has been performed and reports are made available to the customer.

The Company recognizes revenue primarily from sales of AdvanDx diagnostic products, providing laboratory services, and from “funded software development” arrangements with collaborative parties. Revenue is recognized when the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the selling price is fixed or determinable; and collectability is reasonably assured. At times, the Company sells products and services, or performs software development, under multiple-element arrangements with separate units of accounting; in these situations, total consideration is allocated to the identified units of accounting based on their relative fair value and revenue is then recognized for each unit based on its specific characteristics.

The Company’s funded software development arrangements generally consist of multiple elements. Total arrangement consideration is allocated to the identified units of accounting based on their relative selling prices and revenue is then recognized for each unit based on its specific characteristics. When funded software development arrangements include substantive research and development milestones, revenue is recognized for each such milestone when the milestone is achieved and is due and collectible. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with achievement of the milestone.

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 FASB issued an Accounting Standards Update ("ASU") for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the identification of performance obligations and licensing arrangements. In May 2016, the FASB issued guidance addressing the presentation of sales and other similar taxes collected from customers, providing clarification of the collectability criterion assessment, as well as clarifying certain transition requirements. The Company has identified its major revenue streams and has completed its formal contract review and the Company will adopt this guidance effective January 1, 2018. The Company will adopt this guidance using the modified retrospective method. The adoption of this new guidance will not have a material impact on the Company's consolidated financial statements.

In July 2015, the FASB issued accounting guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using LIFO or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The standard is effective for reporting periods beginning after December 15, 2016. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. The Company adopted this guidance effective January 1, 2017 on a prospective basis. The adoption of this new guidance did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued guidance for the accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the consolidated balance sheets and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its consolidated financial statements.

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

Off-Balance Sheet Arrangements

As of December 31, 2017 and 2016, 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 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, 2017. 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, 2017.

Changes in Internal Control over Financial Reporting

As of December 31, 2017, 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, 2017. 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, 2017, internal control over financial reporting is effective based on these criteria.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item is incorporated herein by reference to the similarly named section of our Definitive Proxy Statement for our 2018 Annual Meeting of Stockholders.

Item 11. Executive Compensation

Information required by this item is incorporated herein by reference to the similarly named section of our Definitive Proxy Statement for our 2018 Annual Meeting of Stockholders.

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

Information required by this item is incorporated herein by reference to the similarly named section of our Definitive Proxy Statement for our 2018 Annual Meeting of Stockholders.

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

Information required by this item is incorporated herein by reference to the similarly named section of our Definitive Proxy Statement for our 2018 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services

Information required by this item is incorporated herein by reference to the similarly named section of our Definitive Proxy Statement for our 2018 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements.

The consolidated balance sheets of the Company as of December 31, 2017 and 2016, 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
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 of the Amended and Restated Certificate of Incorporation of the Registrant (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 (incorporated by reference to Exhibit 4.1 of Form S-1, Amendment No. 6, File No. 333-202478, filed on April 28, 2015)
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 Pre-Funded 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 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 Common Stock Purchase 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)
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)

Exhibit Number	Description
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
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 10.9.14 to the Registrant's Annual Report on Form 10-K, 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 10.9.24 to the Registrant's Annual Report on Form 10-K, 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 10.9.34 to the Registrant's Annual Report on Form 10-K, filed on March 24, 2017)
10.8 !	Form of Restricted Stock Unit Award Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.410 to the Registrant's Annual Report on Form 10-K, 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)
10.11	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, filed on August 14, 2015)

Exhibit Number	Description
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, 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	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 Current Report on Form 8-K, Amendment No.1, filed on June 28, 2017)
10.23±	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)
10.24	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)
10.25	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)
10.26 !	Amended and Restated Executive Change in Control and Severance Benefits Agreement, dated January 29, 2018, by and between the Registrant and Vadim Sapiro (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on January 29, 2018)
10.27 !	Executive Change in Control and Severance Benefits Agreement, dated January 29, 2018, by and between the Registrant and Timothy C. Dec (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 29, 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)
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)
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: March 29, 2018

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

Date: March 29, 2018

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Evan Jones Evan Jones	Chief Executive Officer and Director (principal executive officer)	March 29, 2018
/s/ Timothy C. Dec Timothy C. Dec	Chief Financial Officer (principal financial officer and principal accounting officer)	March 29, 2018
/s/ Harry J. D'Andrea Harry J. D'Andrea	Director	March 29, 2018
/s/ Timothy J.R. Harris Timothy J.R. Harris	Director	March 29, 2018
/s/ Tina S. Nova Tina Nova	Director	March 29, 2018
/s/ David M. Rubin David M. Rubin	Director	March 29, 2018
/s/ Misti Ushio Misti Ushio	Director	March 29, 2018

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. (the "Company") as of December 31, 2017 and 2016, 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, 2017 and 2016, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United Stated 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.

Vienna, Virginia
March 29, 2018

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

	2017	2016
Assets		
Current assets		
Cash and cash equivalents	$ 1,847,171	$ 4,117,324
Accounts receivable, net	809,540	542,420
Inventory, net	533,425	692,368
Prepaid expenses and other current assets	311,644	329,646
Total current assets	**3,501,780**	**5,681,758**
Property and equipment, net	835,537	800,723
Goodwill	600,814	600,814
Intangible assets, net	1,353,182	1,620,998
Other noncurrent assets	328,601	279,752
Total assets	**$ 6,619,914**	**$ 8,984,045**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,691,712	$ 2,232,563
Accrued compensation and benefits	746,924	578,480
Accrued liabilities	1,160,714	1,215,283
Deferred revenue	24,442	37,397
Short-term notes payable	1,010,961	1,023,815
Current maturities of long-term capital lease obligation	154,839	184,399
Total current liabilities	**4,789,592**	**5,271,937**
Deferred rent	290,719	398,084
Warrant liability	8,453	—
Long-term capital lease obligation and other noncurrent liabilities	130,153	146,543
Total liabilities	**5,218,917**	**5,816,564**
Commitments (Note 8)		
Stockholders' equity		
Common stock, $0.01 par value; 200,000,000 shares authorized; 2,265,320 and 1,012,171 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	22,653	10,122
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2017 and December 31, 2016, respectively	—	—
Additional paid-in capital	150,114,671	136,442,302
Accumulated other comprehensive (loss)/income	(25,900)	6,176
Accumulated deficit	(148,710,427)	(133,291,119)
Total stockholders' equity	**1,400,997**	**3,167,481**
Total liabilities and stockholders' equity	**$ 6,619,914**	**$ 8,984,045**

See accompanying notes to consolidated financial statements.

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

	2017	2016
Revenue		
Product sales	$ 2,771,869	$ 3,524,178
Laboratory services	41,960	228,904
Collaboration revenue	397,178	272,603
Total revenue	**3,211,007**	**4,025,685**
Operating expenses		
Cost of products sold	1,612,838	1,658,571
Cost of services	520,338	631,333
Research and development	6,883,293	8,613,236
General and administrative	6,692,659	6,602,608
Sales and marketing	2,767,670	5,529,274
Total operating expenses	**18,476,798**	**23,035,022**
Operating loss	**(15,265,791)**	**(19,009,337)**
Other income/(expense)		
Interest and other expense	(87,255)	(5,967)
Interest expense	(233,505)	(143,347)
Foreign currency transaction gains/(losses)	23,179	(8,102)
Change in fair value of derivative financial instruments	144,064	—
Total other expense	**(153,517)**	**(157,416)**
Loss before income taxes	**(15,419,308)**	**(19,166,753)**
Provision for income taxes	—	—
Net loss	**(15,419,308)**	**(19,166,753)**
Preferred stock dividends and beneficial conversion	—	(332,550)
Net loss available to common stockholders	**$ (15,419,308)**	**$ (19,499,303)**
Net loss per common share - basic and diluted	**$ (9.80)**	**$ (27.59)**
Weighted average shares outstanding - basic and diluted	1,573,769	706,702
Net loss	$ (15,419,308)	$ (19,166,753)
Other comprehensive (loss)/income - foreign currency translation	(32,076)	7,235
Comprehensive loss	**$ (15,451,384)**	**$ (19,159,518)**

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, 2015	**501,907**	**$ 5,019**	**—**	**—**	**$ 121,611,452**	**$ (1,059)**	**$ (114,124,366)**	**$ 7,491,046**
Stock option exercises	2,660	27	—	—	23,744	—	—	23,771
Private offering of common stock, preferred stock and warrants, net of issuance costs	269,765	2,697	2,309,428	23,094	9,434,958	—	—	9,460,749
Preferred stock conversion	92,377	924	(2,309,428)	(23,094)	22,170	—	—	(0)
At the market offering, net of offering costs	144,795	1,448	—	—	4,404,525	—	—	4,405,973
Issuance of RSUs	667	7	—	—	(8)	—	—	(1)
Stock compensation expense	—	—	—	—	945,461	—	—	945,461
Foreign currency translation	—	—	—	—	—	7,235	—	7,235
Net loss	—	—	—	—	—	—	(19,166,753)	(19,166,753)
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**

See accompanying notes to consolidated financial statements.

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

	2017	2016
Cash flows from operating activities		
Net loss	$ (15,419,308)	$ (19,166,753)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	669,088	656,047
Loss on disposal of property and equipment	—	6,309
Noncash interest expense	185,294	4,527
Share-based compensation	911,398	945,461
Inventory obsolescence	—	113,465
Change in fair value of warrant liabilities	(144,064)	—
Unamortized discount on bridge loan at repayment	85,932	—
Changes in operating assets and liabilities:		
Accounts receivable	(260,471)	136,226
Inventory	161,027	20,179
Other assets	(315,688)	263,882
Accounts payable	(563,357)	(53,229)
Accrued compensation and other liabilities	399,224	(163,223)
Deferred revenue	(12,955)	(13,528)
Net cash used in operating activities	**(14,303,880)**	**(17,250,637)**
Cash flows from investing activities		
Purchases of property and equipment (net of proceeds on disposals)	(276,950)	(123,514)
Net cash used in investing activities	**(276,950)**	**(123,514)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	3,808,836	4,405,973
Proceeds from issuance of promissory notes, net of issuance costs	—	204,895
Proceeds from private offering of common stock, preferred stock and warrants, net of issuance costs	—	9,460,749
Proceeds from issuance of units, net of selling costs	8,754,882	—
Proceeds from exercise of stock options and warrants	76,537	23,771
Proceeds from debt, net of issuance costs	1,168,222	—
Payments on debt	(1,255,198)	(178,997)
Payments on capital lease obligations	(205,085)	(251,701)
Net cash provided by financing activities	**12,348,194**	**13,664,690**
Effects of exchange rates on cash	(37,517)	12,565
Net decrease in cash and cash equivalents	(2,270,153)	(3,696,896)
Cash and cash equivalents at beginning of year	4,117,324	7,814,220
Cash and cash equivalents at end of year	**$ 1,847,171**	**$ 4,117,324**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 48,211	$ 58,564
Supplemental disclosures of noncash investing and financing activities:		
Unpaid deferred offering costs	$ 48,398	$ —
Shares issued to settle obligations	$ 133,245	$ —
Issuance of placement agent warrant	$ 93,677	$ —

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 and Woburn, Massachusetts. The Company also has operations in Copenhagen, Denmark. The Company operates in one business segment.

OpGen is a precision medicine company using molecular diagnostics and informatics to help combat infectious disease. The Company is developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. 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 offerings combine its Acuitas DNA tests and Acuitas Lighthouse informatics platform for use with its proprietary, curated MDRO knowledgebase. The Company is working to deliver our products and services, some in development, to a global network of customers and partners. These include:

- Its Acuitas DNA tests provide rapid microbial identification and antibiotic resistance gene information. These products include our Acuitas Rapid Test for complicated urinary tract infection in development, the QuickFISH family of FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures, and its Acuitas Resistome Tests for genetic analysis of hospital surveillance isolates.
- Its 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 its informatics systems are the Acuitas Lighthouse Knowledgebase, a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens and its Acuitas Lighthouse informatics, which can be 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 rapid technology changes, the need to manage growth, the need to retain key personnel, the need to protect intellectual property and the need to raise additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop and commercialize its proprietary technology as well as raise additional capital.

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 February 7, 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.

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. 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.

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. The interest rate on each Bridge Financing Note was ten percent (10%) per annum (subject to increase upon an event of default). The Bridge Financing Notes were prepayable by the Company at any time without penalty, and had a maturity date of September 30, 2017, which could be accelerated upon the closing of a qualified financing (any equity or debt financing that raised net proceeds of $5 million or more). The Bridge Financing Notes were contingently convertible at the option of the holder upon an event of default into shares of the Company's convertible Series B preferred stock. 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, and repaid such outstanding Bridge Financing Notes in full upon the closing of the July 2017 Public Offering.

As a condition to the receipt of the bridge financing, the Company issued an amended and restated Senior Secured Promissory Note to Merck Global Health Innovation Fund ("MGHIF"), an affiliate of Merck & Co., Inc. ("Merck"), 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 September 13, 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, 2017, the Company has sold an aggregate of approximately 372 thousand shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $8.2 million, and gross proceeds of $8.8 million. As of December 31, 2017, under the initial sales agreement, remaining availability under the at the market offering is $2.7 million.

In May and June 2016, the Company offered and sold units in a private offering to members of management and employees and to accredited investors, including MGHIF and jVen Capital, each unit consisting of either (i) one twenty-fifth of a share of common stock and a detachable stock purchase warrant to purchase an additional 0.03 shares of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.03 shares of common stock, at a price of $1.14 per unit. The total net proceeds to the Company, after deducting offering commissions and expenses, was $9.5 million. Pursuant to the private placement the Company issued 269,765 shares of common stock, 2,309,428 of Series A non-voting convertible preferred stock and stock purchase warrants to acquire an additional 271,606 shares of common stock. Under the purchase agreement, the Company granted registration rights to the investors in the private financing.

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 on hand including the February 2018 Public Offering will be sufficient to fund operations into the first 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 first 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 generally accepted accounting standards in the United States ("U.S. GAAP"). The consolidated financial statements consolidate the operations of all controlled subsidiaries; all intercompany activity is eliminated.

Foreign Currency

One of the Company's subsidiaries is located in Copenhagen, Denmark and uses the Danish Krone as its 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, 2017 and 2016.

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

Use of Estimates

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

Fair value of financial instruments

All financial instruments classified as current assets and liabilities are carried at cost, which approximates fair value, because of the short-term maturities of those instruments.

For additional fair value disclosures, see Note 11.

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, 2017 and 2016, the Company has funds totaling $243,380, 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 $31,278 and $26,716 as of December 31, 2017 and 2016, respectively.

At December 31, 2017, the Company had accounts receivable from one customer which individually represented 41% of total accounts receivable. At December 31, 2016, the Company had accounts receivable from one customer which individually represent 25% of total accounts receivable. For the year ended December 31, 2017, revenue earned from one customer represented 11% of total revenues. No individual customer represented in excess of 10% of revenues for year ended December 31, 2016.

Inventory

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

	December 31,	
	2017	2016
Raw materials and supplies	$ 360,134	$ 479,479
Work-in process	51,233	27,422
Finished goods	122,058	185,467
Total	$ 533,425	$ 692,368

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 $155,507 and $704,516 at December 31, 2017 and 2016, respectively. The primary driver of the decrease in the inventory reserves for obsolescence and expirations is the disposal of legacy Argus Whole Genome Mapping System ("Argus") and the portion of the reagents and supplies used for Argus consumable kits. All items disposed in the year ended December 31, 2017 related to Argus were fully reserved for as of December 31, 2016.

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 $401,272 and $388,231 for the years ended December 31, 2017 and 2016, respectively. Property and equipment consisted of the following at December 31, 2017 and 2016:

	December 31,	
	2017	2016
Laboratory and manufacturing equipment	$ 4,109,367	$ 3,785,133
Office furniture and equipment	700,299	688,952
Computers and network equipment	1,505,651	1,472,144
Leasehold improvements	729,504	662,506
	7,044,821	6,608,735
Less accumulated depreciation	(6,209,284)	(5,808,012)
Property and equipment, net	$ 835,537	$ 800,723

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, 2017 and 2016, the Company determined that its property and equipment was not impaired.

Intangible assets and goodwill

Intangible assets and goodwill as of December 31, 2017 and 2016 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, 2017 and 2016:

	December 31, 2017			December 31, 2016	
	Cost	Accumulated Amortization	Net Balance	Accumulated Amortization	Net Balance
Trademarks and tradenames	$ 461,000	$ (113,679)	$ 347,321	$ (67,575)	$ 393,425
Developed technology	458,000	(161,322)	296,678	(95,898)	362,102
Customer relationships	1,094,000	(384,817)	709,183	(228,529)	865,471
	$ 2,013,000	$ (659,818)	$ 1,353,182	$ (392,002)	$ 1,620,998

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, 2017 and 2016, respectively. Expected amortization of intangible assets for each of the next five fiscal years is as follows.

Year Ending December 31,	
2018	$ 267,816
2019	267,816
2020	267,816
2021	267,816
2022	165,117
Thereafter	116,801
Total	$ 1,353,182

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, 2017 and 2016, 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 the fourth quarter of 2017, 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, 2017, 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

The Company recognizes revenue primarily from sales of its products and services when the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the selling price is fixed or determinable; and collectability is reasonably assured. At times, the Company sells products and services, or performs software development, under multiple-element arrangements with separate units of accounting; in these situations, total consideration is allocated to the identified units of accounting based on their relative selling prices and revenue is then recognized for each unit based on its specific characteristics.

Amounts billed to customers for shipping and handling are included in revenue when the related product or service revenue is recognized. Shipping and handling costs are included in cost of products sold.

Revenue from sales of QuickFISH and PNA FISH diagnostic test products

Revenue is recognized upon shipment to the customer.

Revenue from providing laboratory services

The Company recognizes revenue associated with laboratory services contracts when the service has been performed and reports are made available to the customer.

Revenue from funded software development arrangements

The Company's funded software development arrangements generally consist of multiple elements. Total arrangement consideration is allocated to the identified units of accounting based on their relative selling prices and revenue is then recognized for each unit based on its specific characteristics. When funded software development arrangements include substantive research and development milestones, revenue is recognized for each such milestone when the milestone is achieved and is due and collectible. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with achievement of the milestone.

For any non-substantive milestones, the Company recognizes revenue as the underlying services are performed, using a proportional performance method based on inputs (cost to cost method percentage of completion method).

Revenue from license arrangements

The Company recognizes revenue from licenses of its technologies over the applicable license term.

Revenue from sales of the reagents and supplies used for Argus consumable kits

Revenue is recognized for sales of the reagents and supplies used for Argus consumable kits upon shipment to the customer.

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, 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 $165,544,893 and $150,950,436 at December 31, 2017 and 2016, 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 1.6 million shares and 0.5 million shares as of December 31, 2017 and 2016, respectively.

Recent accounting pronouncements

In May 2014, the FASB issued an Accounting Standards Update ("ASU") for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the identification of performance obligations and licensing arrangements. In May 2016, the FASB issued guidance addressing the presentation of sales and other similar taxes collected from customers, providing clarification of the collectability criterion assessment, as well as clarifying certain transition requirements. The Company has identified its major revenue streams and has completed its formal contract review and the Company will adopt this guidance effective January 1, 2018. The Company will adopt this guidance using the modified retrospective method. The adoption of this new guidance will not have a material impact on the Company's consolidated financial statements.

In July 2015, the FASB issued accounting guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using LIFO or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The standard is effective for reporting periods beginning after December 15, 2016. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. The Company adopted this guidance effective January 1, 2017 on a prospective basis. The adoption of this new guidance did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued guidance for the accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the consolidated balance sheets and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its consolidated financial statements.

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

Note 4 – 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. The Company's obligations under the MGHIF Note are secured by a lien on all of the Company's assets. Under the Purchase Agreement, MGHIF has the right to participate in future securities offerings made by the Company. 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 incurred issuance costs of approximately $50,000 related to the financing. Approximately $8,000 of the issuance costs were deferred as debt issuance costs and netted against notes payable in the accompanying condensed consolidated balance sheets as a result of the Company's adoption of the new accounting guidance in 2016, and are being amortized as interest expense over the life of the MGHIF Note. The remaining $42,000 of issuance costs were charged to additional paid-in capital.

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. The warrants issued to MGHIF each have a five year term from issuance, are first exercisable on the date that is six months after the date of issuance and have an exercise price equal to $19.50 which represents 110% of the closing price of the Company's common stock on the date of issuance.

The MGHIF Note, as amended and restated was treated as a debt modification and as such the issuance date fair value of the warrants is deferred and amortized as incremental interest expense over the term of the MGHIF Note. The warrants are classified as mark to market liabilities under ASC 480, Distinguishing Liabilities from Equity, 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, as defined in the agreement. The warrants had an issuance date fair value of approximately $0.1 million which was calculated using the Black-Scholes model.

The estimated fair value of the MGHIF Note was $1.0 million as of December 31, 2017 and 2016 which approximates the carrying value given the short time lapse since modification, prevailing interest rates and maturity date.

Note 5 – Debt

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 (see Note 4 " MGHIF Financing ") as well as, the financing arrangements for the Company's insurance with note balances of approximately $0.1 million with a final payment scheduled for April 2018. Total principal payments of $1.1 million are due in 2018. As of December 31, 2016, the Company's outstanding long-term debt consisted of the $1.0 million MGHIF Note, net of discounts and financing costs.

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 are 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 $233,505 and $143,347 for the years ended December 31, 2017 and 2016, respectively.

Note 6 - Stockholders' Equity

As of December 31, 2017, the Company has 200,000,000 shares of authorized common shares and 2,265,320 shares issued and outstanding, and 10,000,000 of authorized preferred shares, of which none were issued or outstanding.

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 were exercised during the year ended December 31, 2017

In connection with the July 2017 Public Offering, the Company issued to its placement agent 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 15,842 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.

On September 13, 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, 2017, the Company has sold an aggregate of approximately 372 thousand shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $8.2 million, and gross proceeds of $8.8 million. As of December 31, 2017, remaining availability under the at the market offering is $2.7 million.

In May and June 2016, the Company offered and sold units in a private offering to members of management and employees and to accredited investors, including MGHIF and jVen Capital, each unit consisting of either (i) one twenty-fifth of a share of common stock and a detachable stock purchase warrant to purchase an additional 0.03 shares of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.03 shares of common stock, at a price of $1.14 per unit. The total net proceeds to the Company, after deducting offering commissions and expenses was $9.5 million. Pursuant to the private placement the Company issued 269,765 shares of common stock, 2,309,428 of Series A non-voting convertible preferred stock and stock purchase warrants to acquire an additional 271,606 shares of common stock. Under the purchase agreement, the Company granted registration rights to the investors in the private financing.

Each share of Series A non-voting convertible preferred stock was convertible at the option of the holder in whole or in part and from time to time into one twenty-fifth of a share of common stock, was entitled to dividends on an "as converted basis" when and if dividends are issued to common stockholders, and would have participated in liquidation on a pari passu basis with common stockholders. The preferred stock was classified as permanent equity. The stock purchase warrants issued as part of the units are exercisable at $32.8125 per share beginning 90 days after closing for five years, expiring on May 18, 2021. The warrants are classified as permanent equity at December 31, 2017. In connection with the issuance of Series A non-voting convertible preferred stock, the Company recognized a beneficial conversion feature of $332,550 as a deemed dividend to the preferred shareholders. Holders of the Series A non-voting convertible preferred stock subsequently converted all 2,309,428 shares of preferred stock into 92,377 shares of common stock.

The Company filed a registration statement on Form S-3 on June 13, 2016 to register for resale by the investors, from time to time, of the shares of common stock acquired, or underlying the warrants issued, in the private offering. On July 20, 2016, the registration statement was declared effective by the SEC.

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, 2017, 32,411 shares remain available for issuance under the 2015 Plan.

For the years ended December 31, 2017 and 2016, the Company recognized stock compensation expense as follows:

	Year Ended December 31,	
	2017	2016
Cost of services	$ 13,776	$ 6,003
Research and development	237,103	236,341
General and administrative	603,787	599,550
Sales and marketing	56,732	103,567
	$ 911,398	$ 945,461

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, 2017, the Company had unrecognized expense related to its stock options of $1.3 million, which will be recognized over a weighted average period of 8.3 years.

A summary of the status of options granted is presented below as of and for the years ended December 31, 2017 and 2016:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2016	86,431	$ 65.00	9.1	$ 1,575,646
Granted	58,546	$ 35.25		
Exercised	(2,660)	$ 9.00		$ 79,406
Forfeited	(22,868)	$ 99.75		
Expired	(343)	$ 212.25		
Outstanding at December 31, 2016	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
Vested and expected to vest	139,395	$ 31.16	8.3	$ 37,339
Exercisable at December 31, 2017	63,365	$ 4.73	7.7	$ 33,575

The total fair value of options vested in the years ended December 31, 2017 and 2016 was $2,086,843 and $1,088,978, 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,	
	2017	2016
Annual dividend	—	—
Expected life (in years)	5.25 - 6.25	5.25 - 6.25
Risk free interest rate	1.8 - 2.3%	1.2 - 2.2%
Expected volatility	44.2 - 53.0%	42.0 - 49.8%

Restricted stock units

During the year ended December 31, 2017, the Company granted restricted stock units to acquire 11,175 shares of common stock, with a weighted average grant date fair value of $6.93 per share. 6,025 restricted stock units vested and no restricted stock units were forfeited during the year ended December 31, 2017. The Company had 5,900 total restricted stock units outstanding at December 31, 2017.

Stock purchase warrants

At December 31, 2017 and 2016, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at December 31, 2017	Outstanding at December 31, 2016
August 2007	$ 197.75	August 2017	-	357
March 2008	$ 19,763.50	March 2018	2	2
November 2009	$ 197.75	November 2019	267	267
January 2010	$ 197.75	January 2020	267	267
March 2010	$ 197.75	March 2020	51	51
November 2011	$ 197.75	November 2021	209	209
December 2011	$ 197.75	December 2021	27	27
March 2012	$ 2,747.50	March 2019	165	165
February 2015	$ 165.00	February 2025	9,000	9,000
May 2015	$ 165.00	May 2020	138,310	138,310
May 2016	$ 32.81	May 2021	189,574	189,574
June 2016	$ 32.81	May 2021	82,033	82,033
June 2017	$ 19.50	June 2022	18,754	-
July 2017	$ 17.25	July 2022	6,349	-
July 2017	$ 12.50	July 2022	50,000	-
July 2017	$ 10.63	July 2022	1,000,000	-
			1,495,008	420,262

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

Note 7 - Income Taxes

At December 31, 2017 and 2016, the Company had net deferred tax assets of $49,251,408 and $63,520,548, 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, 2017 and 2016 have been offset by a valuation allowance of $49,251,408 and $63,520,548, 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, 2017 and 2016 are as follows:

	December 31, 2017	December 31, 2016
Deferred tax assets:		
NOL carryforward	$ 46,326,407	$ 60,357,220
R&E credit carryforward	2,559,479	2,559,479
Share-based compensation	345,088	448,534
Inventory reserve	45,338	269,708
Depreciation	71,756	117,629
Accruals and other	247,093	333,126
Total deferred tax assets	49,595,161	64,085,696
Valuation allowance	(49,251,408)	(63,520,548)
Deferred tax liabilities:		
Intangible assets	(343,753)	(565,148)
Net deferred tax liability	$ —	$ —

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:

	2017	2016
Federal income tax benefit at statutory rates	34.0%	34.0%
State income tax benefit, net of Federal benefit	6.8%	6.5%
Tax reform impact	(134.5)%	0.0%
Change in valuation allowance	93.0%	(37.3)%
Change in state tax rates and other	0.7%	(3.2)%
	0.0%	0.0%

The Company has federal NOL carryforwards of $165,544,893 and $150,950,436 at December 31, 2017 and 2016, respectively. The NOL carryforwards begin to expire in 2022. 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"). The Tax Act makes 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 carryforwards created in tax years beginning after December 31, 2017; and (v) changing the U.S. federal taxation of earnings of foreign subsidiaries.

As a result, the Company believes the most significant impact on its consolidated financial statements will be 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 a foreign subsidiary. At December 31, 2017 and November 2, 2017, the cumulative earnings and profits of this entity was negative. Accordingly, the Company is not liable for the transition tax on foreign earnings enacted under the Tax Act.

The Company has completed the accounting for the impact of the Tax Act as of December 31, 2017 and has recorded no provisional amounts.

Note 8 - Commitments

Operating leases

The Company leases a facility in Woburn, Massachusetts under an operating lease that expires January 30, 2022.

During the second quarter of 2015, the Company extended the term of its Gaithersburg, Maryland office lease, effective May 7, 2015, through January 31, 2021, with one additional five-year renewal at the Company's election. The Company is responsible for all utilities, repairs, insurance, and taxes under this operating lease. Effective July 1, 2015, the Company further modified its lease agreement to add additional leased space to its headquarters. 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, 2017 and 2016 was $949,244 and $1,000,726, respectively.

Capital leases

The Company leases computer equipment, office furniture, and 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, 2017:

Year ending December 31,	Capital Leases	Operating Leases	Total
2018	$ 177,464	$ 1,041,323	$ 1,218,787
2019	85,393	1,054,374	1,139,767
2020	56,981	1,072,748	1,129,729
2021	1,773	482,058	483,830
2022 and thereafter	-	35,647	35,647
Total	321,611	$ 3,686,150	$ 4,007,760
Less: amount representing interest	(36,619)		
Net present value of future minimum lease payments	284,992		
Current maturities	(154,839)		
Long-term maturities	$ 130,153		

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

	2017	2016
Laboratory and manufacturing equipment	$ 850,792	$ 560,829
Office furniture and equipment	64,790	64,790
Computers and network equipment	24,350	24,350
Less accumulated amortization	(454,471)	(270,808)
Capital lease assets, net	$ 485,461	$ 379,161

Amortization expense associated with equipment under capital leases for the years ended December 31, 2017 and 2016 was $183,663 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 $1.8 million as of December 31, 2017. 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 second quarter of 2018. We have not estimated the contract termination costs associated with this lease given that we have not yet reached the cease use date and given that we have only begun sublease pursuit activities. We do not believe there will be significant additional costs related to restructuring outside of what is described herein.

Note 9 - 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 $257,186 and $290,491 for the years ended December 31, 2017 and 2016, 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 will work with subcontractors Ilúm, LLC, an affiliate of Merck, and Universidad El Bosque ("UEB") of Bogota, Colombia under this CDC contract. During the year ended December 31, 2017, the Company recognized $357,178 of revenue related to the contract.

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 year ended December 31, 2017, the Company recognized $25,000 of revenue related to the license agreement.

Note 10 – Related Party Transactions

In March 2014, the Company entered into a supply agreement with Fluidigm Corporation ("Fluidigm") under which Fluidigm supplies the Company with its microfluidic test platform for use in manufacturing the Acuitas MDRO Gene Test. The Company's CEO and Chairman of the Board of Directors is a director of Fluidigm. On July 12, 2015, the Company entered into a letter agreement (the "Fluidigm Agreement") with Fluidigm to expand the companies' existing relationship to include collaborating on the development of test kits and custom analytic instruments for identification, screening and surveillance testing of MDROs. The Fluidigm Agreement also expands the existing Supply Agreement between the Company and Fluidigm, and provides for expansion of the gene targets and organisms to be tested on the Company's existing CLIA lab-based tests, the Acuitas MDRO Gene Test and the Acuitas Resistome Test, using Fluidigm technologies and products. Additionally, Fluidigm has agreed not to develop or directly collaborate with any third party to develop an FDA approved or CE marked diagnostic test for the purpose of detecting resistance genes for identified MDROs if the Company meets certain minimum purchase commitments and other requirements. The initial term of the Fluidigm Agreement is five years. Both parties have the ability to extend the term for an additional five years. Under the expanded Supply Agreement, the term was extended until March 17, 2018, and the Company has the right to extend the term of the Supply Agreement for up to two additional three-year terms. The Company paid $123,067 related to these agreements in the year ended December 31, 2017. The Company paid $183,713 related to these agreements in the year ended December 31, 2016.

Under the agreements with Fluidigm, the Company had purchases of $135,415 in the year ended December 31, 2017. The Company had purchases of $91,399 related to these agreements in the year ended December 31, 2016.

In addition, the Company has several capital lease arrangements for laboratory equipment manufactured by Fluidigm. The Company paid $91,882 related to the leased equipment in the year ended December 31, 2017. The Company paid $175,475 related to the leased equipment in the year ended December 31, 2016.

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 $146,177 of procurement costs which have been recognized as research and development expense, including $113,907 and $32,270 during the years ended December 31, 2017 and 2016.

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 will provide services to the Company in the performance of the Company's CDC contract to deploy ILÚM's commercially-available cloud- and mobile-based software platform for infectious disease management in up to three medical sites in Colombia with the aim of improving antibiotic use in resource-limited settings. During the year ended December 31, 2017, the Company recognized $210,180 of cost of services expense related to the contract.

Note 11 – 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, 2017:

Description	Balance at December 31, 2016	Established in 2017	Change in Fair Value	Expensed	Balance at December 31, 2017
Embedded conversion option liability	$ -	$ 4,500	$ -	$ (4,500)	$ -
Warrant liability	$ -	$ 152,517	$ (144,064)	$ -	$ 8,453

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, 2017.

Note 12 – Subsequent events

On January 5, 2018, the Company entered into a supply agreement with Life Technologies Corporation. The term of the agreement is three years and the Company must make annual minimum purchases of $100,000 per year.

On January 17, 2018, the Board of Directors of the Company approved a one-for-twenty-five reverse stock split. All share and per share information in these consolidated financial statements, except for par value and authorized shares, have been amended to reflect the reverse stock split.

In addition, on January 17, 2018, the stockholders of the Company approved an Amendment to the Amended and Restated Certificate of Incorporation to reduce the number of authorized shares of common stock from 200,000,000 to 50,000,000.

On February 7, 2018, the Company closed a 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.

Exhibit 10.4

OPGEN, INC.

2015 EQUITY INCENTIVE PLAN,
as Amended and Restated

ARTICLE 1.
PURPOSE

The purpose of the OpGen, Inc. 2015 Equity Incentive Plan, as amended and restated (as it may be further amended or restated from time to time, the "Plan") is to promote the success and enhance the value of OpGen, Inc. (the "Company") by aligning the individual interests of the members of the Board, Employees, and Consultants with those of Company stockholders and by providing such individuals with an equity-based incentive for outstanding performance. The Plan is further intended to provide flexibility to the Company in its ability to motivate, attract, and retain the services of members of the Board, Employees, and Consultants upon whose judgment, interest and special effort the successful conduct of the Company's operation is largely dependent.

ARTICLE 2.
DEFINITIONS AND CONSTRUCTION

Wherever the following terms are used in the Plan they have the meanings specified below, unless the context clearly indicates otherwise. The singular pronoun shall include the plural where the context so indicates.

2.1 "Administrator" means the entity that conducts the general administration of the Plan as provided in Article 12. With reference to the duties of the Committee under the Plan which have been delegated to one or more persons pursuant to Section 12.6, or which the Board has assumed, the term "Administrator" shall refer to such person(s) unless the Committee or the Board has revoked such delegation or the Board has terminated the assumption of such duties.

2.2 "Applicable Accounting Standards" means Generally Accepted Accounting Principles in the United States, International Financial Reporting Standards or such other accounting principles or standards as may apply to the Company's financial statements under United States federal securities laws from time to time.

2.3 "Applicable Law" means any applicable law, including without limitation: (a) provisions of the Code, the Securities Act, the Exchange Act and any rules or regulations thereunder; (b) corporate, securities, tax or other laws, statutes, rules, requirements or regulations, whether federal, state, local or foreign; and (c) rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded.

2.4 "Award" means an Option, a Restricted Stock award, a Restricted Stock Unit award, a Performance award, a Dividend Equivalent award, a Stock Payment award or a Stock Appreciation Right, which may be awarded or granted under the Plan (collectively, "Awards").

2.5 "Award Agreement" means any written notice, agreement, terms and conditions, contract or other instrument or document evidencing an Award, including through electronic medium, which shall contain such terms and conditions with respect to an Award as the Administrator shall determine consistent with the Plan.

2.6 "Board" means the Board of Directors of the Company.

2.7 "Change in Control" means and includes each of the following:

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission) 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

(b) 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:

(i) 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 Entity")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this Section 2.7(b)(ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction; or

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

In addition, if a Change in Control constitutes a payment event with respect to any portion of an Award that provides for the deferral of compensation and is subject to Section 409A of the Code, the transaction or event described in subsection (a), (b), (c) or (d) with respect to such Award (or portion thereof) must also constitute a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5) to the extent required by Section 409A.

The Board shall have full and final authority, which shall be exercised in its sole discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, and the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

2.8 "Code" means the Internal Revenue Code of 1986, as amended from time to time, together with the regulations and official guidance promulgated thereunder.

2.9 "Committee" means the Compensation Committee of the Board, or another committee or subcommittee of the Board or the Compensation Committee of the Board, appointed as provided in Section 12.1.

2.10 "Common Stock" means the common stock of the Company, $0.01 par value per share.

2.11 "Company" has the meaning set forth in Article 1.

2.12 "Consultant" means any consultant or adviser engaged to provide services to the Company or any Subsidiary that qualifies as a consultant under the applicable rules of the Securities and Exchange Commission for registration of shares on a Form S-8 Registration Statement.

2.13 "Director" means a member of the Board, as constituted from time to time.

2.14 "Dividend Equivalent" means a right to receive the equivalent value (in cash or Shares) of dividends paid on Shares, awarded under Section 9.2.

2.15 "DRO" means a domestic relations order as defined by the Code or Title I of the Employee Retirement Income Security Act of 1974, as amended from time to time, or the rules thereunder.

2.16 "Effective Date" means the day prior to the Public Trading Date.

2.17 "Eligible Individual" means any person who is an Employee, a Consultant or a Non-Employee Director, as determined by the Committee.

2.18 "Employee" means any officer or other employee (as determined in accordance with Section 3401(c) of the Code and the Treasury Regulations thereunder) of the Company or of any Subsidiary.

2.19 "Equity Restructuring" means a nonreciprocal transaction between the Company and all of its then-current stockholders, such as a stock dividend, stock split, spin-off, or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other securities of the Company) or the share price of Common Stock (or other securities) and causes a change in the per-share value of the Common Stock underlying outstanding Awards.

2.20 "Exchange Act" means the Securities Exchange Act of 1934, as amended from time to time.

2.21 "Expiration Date" has the meaning given to such term in Section 13.1.

2.22 "Fair Market Value" means, as of any given date, the value of a Share determined as follows:

(a) If the Common Stock is listed on any (i) established securities exchange (such as the New York Stock Exchange, the NASDAQ Global Market, the NASDAQ Global Select Market and the NASDAQ Capital Market), (ii) national market system or (iii) automated quotation system on which the Shares are listed, quoted or traded, its Fair Market Value shall be the closing sales price for a Share as quoted on such exchange or system for such date or, if there is no closing sales price for a Share on the date in question, the closing sales price for a Share on the last preceding date for which such quotation exists, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable;

(b) If the Common Stock is not listed on an established securities exchange, national market system or automated quotation system, but the Common Stock is regularly quoted by a recognized securities dealer, its Fair Market Value shall be the mean of the high bid and low asked prices for such date or, if there are no high bid and low asked prices for a Share on such date, the high bid and low asked prices for a Share on the last preceding date for which such information exists, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable; or

(c) If the Common Stock is neither listed on an established securities exchange, national market system or automated quotation system nor regularly quoted by a recognized securities dealer, its Fair Market Value shall be established by the Board or Committee in good faith.

2.23 "Greater Than 10% Stockholder" means an individual then owning (within the meaning of Section 424(d) of the Code) more than 10% of the total combined voting power of all classes of stock of the Company or any subsidiary corporation (as defined in Section 424(f) of the Code) or parent corporation thereof (as defined in Section 424(e) of the Code).

2.24 "Holder" means a person who has been granted an Award.

2.25 "Incentive Stock Option" means an Option that is intended to qualify as an incentive stock option and conforms to the applicable provisions of Section 422 of the Code.

2.26 "Non-Employee Director" means a Director of the Company who is not an Employee.

2.27 "Non-Employee Director Compensation Program" has the meaning set forth in Section 4.5.

2.28 "Non-Qualified Stock Option" means an Option that is not an Incentive Stock Option.

2.29 "Option" means a right to purchase Shares at a specified exercise price, granted under Article 5. An Option shall be either a Non-Qualified Stock Option or an Incentive Stock Option; provided, however, that Options granted to Non-Employee Directors and Consultants shall only be Non-Qualified Stock Options.

2.30 "Option Term" has the meaning set forth in Section 5.4.

2.31 "Performance Award" means a cash bonus award, stock bonus award, performance award or incentive award that is paid in cash, Shares or a combination of both, awarded under Section 9.1.

2.32 "Performance Goals" means, for a Performance Period, one or more goals established by the Administrator for the Performance Period. The Performance Goals may be expressed in terms of overall Company performance or the performance of a Subsidiary, division, business unit, or an individual.

2.33 "Performance Period" means one or more periods of time, which may be of varying and overlapping durations, as the Administrator may select, over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Holder's right to, and the payment of, an Award.

2.34 "Performance Stock Unit" means a Performance Award awarded under Section 9.1 which is denominated in units of value including dollar value of Shares.

2.35 "Permitted Transferee" means, with respect to a Holder, any "family member" of the Holder, as defined in the instructions to Form S-8 under the Securities Act, or any other transferee specifically approved by the Administrator, after taking into account Applicable Law.

2.36 "Plan" has the meaning set forth in Article 1.

2.37 "Prior Plan" means the OpGen, Inc. 2008 Stock Option and Restricted Stock Plan, as such plan may be amended from time to time.

2.38 "Prior Plan Award" means an award outstanding under the Prior Plan as of the Effective Date.

2.39 "Program" means any program adopted by the Administrator pursuant to the Plan containing the terms and conditions intended to govern a specified type of Award granted under the Plan and pursuant to which such type of Award may be granted under the Plan.

2.40 "Public Trading Date" means the first date upon which Common Stock is listed (or approved for listing) upon notice of issuance on any securities exchange or designated (or approved for designation) upon notice of issuance as a national market security on an interdealer quotation system.

2.41 "Restricted Stock" means Common Stock awarded under Article 7 that is subject to certain restrictions and may be subject to risk of forfeiture or repurchase.

2.42 "Restricted Stock Units" means the right to receive Shares awarded under Article 8.

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

2.44 "Shares" means shares of Common Stock.

2.45 "Stock Appreciation Right" means a stock appreciation right granted under Article 10.

2.46 "Stock Appreciation Right Term" has the meaning set forth in Section 10.5.

2.47 "Stock Payment" means (a) a payment in the form of Shares, or (b) an option or other right to purchase Shares, as part of a bonus, deferred compensation or other arrangement, awarded under Section 9.3.

2.48 "Subsidiary" means any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least fifty percent (50%) of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.49 "Substitute Award" means an Award granted under the Plan upon the assumption of, or in substitution for, outstanding equity awards previously granted by a company or other entity in connection with a corporate transaction, such as a merger, combination, consolidation or acquisition of property or stock; provided, however, that in no event shall the term "Substitute Award" be construed to refer to an award made in connection with the cancellation and repricing of an Option or Stock Appreciation Right.

2.50 "Termination of Service" means:

(a) As to a Consultant, the time when the engagement of a Holder as a Consultant to the Company or a Subsidiary is terminated for any reason, with or without cause, including, without limitation, by resignation, discharge, death or retirement, but excluding a

termination where the Consultant simultaneously commences or remains in employment or service with the Company or any Subsidiary.

(b) As to a Non-Employee Director, the time when a Holder who is a Non-Employee Director ceases to be a Director for any reason, including, without limitation, a termination by resignation, failure to be elected, death or retirement, but excluding terminations where the Holder simultaneously commences or remains in employment or service with the Company or any Subsidiary.

(c) As to an Employee, the time when the employee-employer relationship between a Holder and the Company or any Subsidiary is terminated for any reason, including, without limitation, a termination by resignation, discharge, death, disability or retirement; but excluding terminations where the Holder simultaneously commences or remains in employment or service as a Consultant or Non-Employee Director with the Company or any Subsidiary.

The Administrator, in its sole discretion, shall determine the effect of all matters and questions relating to any Termination of Service, including, without limitation, the question of whether a Termination of Service resulted from a discharge for "cause" and all questions of whether particular leaves of absence constitute a Termination of Service; provided, however, that, with respect to Incentive Stock Options, unless the Administrator otherwise provides in the terms of the Program, the Award Agreement or otherwise, or as otherwise required by Applicable Law, a leave of absence, change in status from an employee to an independent contractor or other change in the employee-employer relationship shall constitute a Termination of Service only if, and to the extent that, such leave of absence, change in status or other change interrupts employment for the purposes of Section 422(a)(2) of the Code and the then-applicable regulations and revenue rulings under said Section. For purposes of the Plan, a Holder's employee-employer relationship or consultancy relations shall be deemed to be terminated in the event that the Subsidiary employing or contracting with such Holder ceases to remain a Subsidiary following any merger, sale of stock or other corporate transaction or event (including, without limitation, a spin-off).

ARTICLE 3.
SHARES SUBJECT TO THE PLAN

3.1 Number of Shares.

(a) Subject to adjustment as provided in Sections 3.1(b) and 13.2, as of March 29, 2018, the aggregate number of Shares which may be issued or transferred pursuant to Awards under the Plan is the sum of (i) 205,374 plus (ii) any Shares which as of the Effective Date are subject to awards granted under the Prior Plan which are forfeited, or lapse unexercised; and (iii) an annual increase on the first day of each calendar year beginning January 1, 2019 and ending on and including January 1, 2025 equal to the lesser of (A) four percent (4%) of the Shares outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year, and (B) such smaller number of Shares as determined by the Board; provided, however, no more than 160,000 Shares may be issued upon the exercise of Incentive Stock Options. From and after the Effective Date, no future awards shall be granted under the Prior Plan; however, any Prior Plan Award shall continue to be subject to the terms and conditions of the Prior

Plan. The share numbers in this Section 3.1(a) have been adjusted, in accordance with Section 13.2, to reflect a one-for-twenty-five reverse stock split of the Common Stock effected on January 17, 2018.

(b) To the extent all or a portion of an Award is forfeited, expires or lapses for any reason, or is settled for cash without delivery of Shares to the Holder, any Shares subject to such Award, or portion thereof, to the extent of such forfeiture, expiration, lapse or cash settlement, shall again be or shall become, as applicable, available for the future grant of an Award pursuant to the Plan. Any Shares repurchased by or surrendered to the Company pursuant to Section 7.4 or in connection with any Prior Plan Award so that such Shares are returned to the Company shall again be or shall become, as applicable, available for the future grant of an Award pursuant to the Plan. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards shall not be counted against the Shares available for issuance under the Plan. Any shares acquired by the Company from the net settlement of an Award as contemplated by Section 11.2 of this Plan or in connection with any Prior Plan Award shall not be available for future grant of an Award pursuant to the Plan. Notwithstanding the provisions of this Section 3.1(b), no Shares may again be or, as applicable, may become eligible to be, optioned, granted or awarded if such action would cause an Incentive Stock Option to fail to qualify as an incentive stock option under Section 422 of the Code.

(c) Substitute Awards shall not reduce the Shares authorized for grant under the Plan. Additionally, in the event that a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines has shares available under a pre-existing plan approved by stockholders and not adopted in contemplation of such acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not reduce the Shares authorized for grant under the Plan; provided that Awards using such available Shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not employed by or providing services to the Company or its Subsidiaries immediately prior to such acquisition or combination.

3.2 Stock Distributed. Any Shares distributed pursuant to an Award may consist, in whole or in part, of authorized and unissued Common Stock, treasury Common Stock or Common Stock purchased on the open market.

ARTICLE 4.
GRANTING OF AWARDS

4.1 Participation. The Administrator may, from time to time, select from among all Eligible Individuals, those to whom an Award shall be granted and shall determine the nature and amount of each Award, which shall not be inconsistent with the requirements of the Plan. Except as provided in Section 4.5 regarding the grant of Awards pursuant to the Non-

Employee Director Compensation Program, no Eligible Individual has any right to be granted an Award pursuant to the Plan.

4.2 Award Agreement. Each Award shall be evidenced by an Award Agreement that sets forth the terms, conditions and limitations for such Award, which may include the term of the Award, the provisions applicable in the event of the Holder's Termination of Service, to the extent different from those set forth herein, and the Company's authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind an Award. Award Agreements evidencing Incentive Stock Options shall contain such terms and conditions as may be necessary to meet the applicable provisions of Section 422 of the Code.

4.3 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan, the Plan, and any Award granted or awarded to any individual who is then subject to Section 16 of the Exchange Act, shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including Rule 16b-3 of the Exchange Act and any amendments thereto) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

4.4 At-Will Employment; Voluntary Participation. Nothing in the Plan or in any Program or Award Agreement hereunder shall confer upon any Holder any right to continue in the employ of, or as a Director or Consultant for, the Company or any Subsidiary, or shall interfere with or restrict in any way the rights of the Company and any Subsidiary, which rights are hereby expressly reserved, to discharge any Holder at any time for any reason whatsoever, with or without cause, and with or without notice, or to terminate or change all other terms and conditions of employment or engagement, except to the extent expressly provided otherwise in a written agreement between the Holder and the Company or any Subsidiary. Participation by each Holder in the Plan shall be voluntary and nothing in the Plan shall be construed as mandating that any Eligible Individual shall participate in the Plan.

4.5 Non-Employee Director Awards. The Administrator, in its sole discretion, may provide that Awards granted to Non-Employee Directors shall be granted pursuant to a written nondiscretionary formula established by the Administrator (the "Non-Employee Director Compensation Program"), subject to the limitations of the Plan. The Non-Employee Director Compensation Program shall set forth the type of Award(s) to be granted to Non-Employee Directors, the number of Shares to be subject to Non-Employee Director Awards, the conditions on which such Awards shall be granted, become exercisable and/or payable and expire, and such other terms and conditions as the Administrator shall determine in its sole discretion. The Non-Employee Director Compensation Program may be modified by the Administrator from time to time in its sole discretion.

4.6 Stand-Alone and Tandem Awards. Awards granted pursuant to the Plan may, in the sole discretion of the Administrator, be granted either alone, in addition to, or in tandem with, any other Award granted pursuant to the Plan. Awards granted in addition to or in tandem with other Awards may be granted either at the same time as or at a different time from the grant of such other Awards.

ARTICLE 5.
GRANTING OF OPTIONS

5.1 Granting of Options to Eligible Individuals. The Administrator is authorized to grant Options to Eligible Individuals from time to time, in its sole discretion, on such terms and conditions as it may determine, which shall not be inconsistent with the Plan.

5.2 Qualification of Incentive Stock Options. No Incentive Stock Option shall be granted to any person who is not an Employee. No person who qualifies as a Greater Than 10% Stockholder may be granted an Incentive Stock Option unless such Incentive Stock Option conforms to the applicable provisions of Section 422 of the Code. Any Incentive Stock Option granted under the Plan may be modified by the Administrator, with the consent of the Holder, to disqualify such Option from treatment as an "incentive stock option" under Section 422 of the Code. To the extent that the aggregate Fair Market Value of stock with respect to which "incentive stock options" (within the meaning of Section 422 of the Code, but without regard to Section 422(d) of the Code) are exercisable for the first time by a Holder during any calendar year under the Plan, and all other plans of the Company and any parent or subsidiary corporation thereof (each as defined in Section 424(e) and 424(f) of the Code, respectively), exceeds $100,000, the Options shall be treated as Non-Qualified Stock Options to the extent required by Section 422 of the Code. The rule set forth in the immediately preceding sentence shall be applied by taking Options and other "incentive stock options" into account in the order in which they were granted and the Fair Market Value of stock shall be determined as of the time the respective options were granted.

5.3 Option Exercise Price. The exercise price per Share subject to each Option shall be set by the Administrator, but shall not be less than 100% of the Fair Market Value of a Share on the date the Option is granted (or, as to Incentive Stock Options, on the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code). In addition, in the case of Incentive Stock Options granted to a Greater Than 10% Stockholder, such price shall not be less than 110% of the Fair Market Value of a Share on the date the Option is granted (or the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code).

5.4 Option Term.

(a) The term of each Option (the "Option Term") shall be set by the Administrator in its sole discretion; provided, however, that the Option Term shall not be more than ten (10) years from the date the Option is granted, or five (5) years from the date an Incentive Stock Option is granted to a Greater Than 10% Stockholder. The Administrator shall determine the time period, including the time period following a Termination of Service, to the extent different from that set forth herein, during which the Holder has the right to exercise the vested Options, which time period may not extend beyond the last day of the Option Term. Except as limited by the requirements of Section 409A or Section 422 of the Code and regulations and rulings thereunder or the first sentence of this Section 5.4, the Administrator may extend the Option Term of any outstanding Option, and may extend the time period during which vested Options may be exercised, in connection with any Termination of Service of the Holder,

and may amend, subject to Section 13.1, any other term or condition of such Option relating to such a Termination of Service.

(b) Unless the Administrator expressly provides otherwise in an Award Agreement or by action following the grant of the Option, immediately upon the Termination of Service of a Holder, the unvested portion of any Option held by such Holder or such Holder's Permitted Transferee will terminate. The vested balance of any Option, to the extent exercisable, will remain exercisable for the lesser of: (i) a period ending on the latest date on which such Option could have been exercised without regard to the Termination of Service and (ii)(A) with respect to a Termination of Service of a Holder who was a Non-Employee Director, a period of one year, (B) with respect to a Termination of Service of a Holder in connection with the death or disability of the Holder, a period of one hundred eighty (180) days, and (C) with respect to any other Termination of Service, a period of ninety (90) days. Notwithstanding the foregoing, the Administrator may determine in its sole discretion that the reasons for a Termination of Service justify immediate termination of an Option.

5.5 Option Vesting.

(a) The period during which the right to exercise, in whole or in part, an Option vests in the Holder shall be set by the Administrator and the Administrator may determine that an Option may not be exercised in whole or in part for a specified period after it is granted. Such vesting may be based on service with the Company or any Subsidiary or any performance criteria selected by the Administrator, and, except as limited by the Plan, at any time after the grant of an Option, the Administrator, in its sole discretion and subject to whatever terms and conditions it selects, may accelerate the period during which an Option vests.

(b) No portion of an Option which is unexercisable at a Holder's Termination of Service shall thereafter become exercisable, except as may be otherwise provided by the Administrator either in the applicable Program, the Award Agreement evidencing the grant of an Option, or by action of the Administrator following the grant of the Option.

(c) Notwithstanding any provisions of this Agreement, any acceleration of vesting provisions in an employment agreement with respect to Options will supersede the provisions of this Plan and the related Award Agreement, unless the employment agreement specifically states otherwise.

5.6 Substitute Awards. Notwithstanding the foregoing provisions of this Article 5 to the contrary, in the case of an Option that is a Substitute Award, the price per share of the Shares subject to such Option may be less than the Fair Market Value per share on the date of grant; provided that the excess of: (a) the aggregate Fair Market Value (as of the date such Substitute Award is granted) of the Shares subject to the Substitute Award, over (b) the aggregate exercise price thereof does not exceed the excess of: (x) the aggregate fair market value (as of the time immediately preceding the transaction giving rise to the Substitute Award, such fair market value to be determined by the Administrator) of the shares of the predecessor entity that were subject to the grant assumed or substituted for by the Company, over (y) the aggregate exercise price of such shares.

5.7 Substitution of Stock Appreciation Rights. The Administrator may provide in the applicable Program or the Award Agreement evidencing the grant of an Option that the Administrator, in its sole discretion, shall have the right to substitute a Stock Appreciation Right for such Option at any time prior to or upon exercise of such Option; provided that such Stock Appreciation Right shall be exercisable with respect to the same number of Shares for which such substituted Option would have been exercisable, and shall also have the same exercise price, vesting schedule and remaining term as the substituted Option.

ARTICLE 6.
EXERCISE OF OPTIONS

6.1 Partial Exercise. An exercisable Option may be exercised in whole or in part. However, an Option shall not be exercisable with respect to fractional Shares and the Administrator may require that, by the terms of the Option, a partial exercise must be with respect to a minimum number of Shares.

6.2 Manner of Exercise. All or a portion of an exercisable Option shall be deemed exercised upon delivery of all of the following to the Secretary of the Company, the stock plan administrator of the Company or such other person or entity designated by the Administrator, or his, her or its office, as applicable:

(a) A written or electronic notice complying with the applicable rules established by the Administrator stating that the Option, or a portion thereof, is exercised. The notice shall be signed by the Holder or other person then entitled to exercise the Option or such portion of the Option;

(b) Such representations and documents as the Administrator, in its sole discretion, deems necessary or advisable to effect compliance with Applicable Law. The Administrator, in its sole discretion, may also take whatever additional actions it deems appropriate to effect such compliance including, without limitation, placing legends on share certificates and issuing stop-transfer notices to agents and registrars;

(c) In the event that the Option shall be exercised pursuant to Section 11.3 by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Option, as determined in the sole discretion of the Administrator; and

(d) Full payment of the exercise price and applicable withholding taxes to the stock plan administrator of the Company for the Shares with respect to which the Option, or portion thereof, is exercised, in a manner permitted by Sections 11.1 and 11.2.

6.3 Notification Regarding Disposition. The Holder shall give the Company prompt written or electronic notice of any disposition of Shares acquired by exercise of an Incentive Stock Option which occurs within (a) two years from the date of grant (including the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code) of such Option to such Holder, or (b) one year after the transfer of such Shares to such Holder.

ARTICLE 7.
AWARD OF RESTRICTED STOCK

7.1 Award of Restricted Stock.

(a) The Administrator is authorized to grant Restricted Stock to Eligible Individuals, and shall determine the terms and conditions, including the restrictions applicable to each award of Restricted Stock, which terms and conditions shall not be inconsistent with the Plan, and may impose such conditions on the issuance of such Restricted Stock as it deems appropriate.

(b) The Administrator shall establish the purchase price, if any, and form of payment for Restricted Stock; provided, however, that if a purchase price is charged, such purchase price shall be no less than the par value, if any, of the Shares to be purchased, unless otherwise permitted by Applicable Law. In all cases, legal consideration shall be required for each issuance of Restricted Stock.

7.2 Rights as Stockholder. Subject to Section 7.4, upon issuance of Restricted Stock, the Holder shall have, unless otherwise provided by the Administrator, all the rights of a stockholder with respect to said Shares, subject to the restrictions in the applicable Program or in each individual Award Agreement, including the right to receive all dividends and other distributions paid or made with respect to the Shares; provided, however, that, in the sole discretion of the Administrator, any extraordinary distributions with respect to the Shares shall be subject to the restrictions set forth in Section 7.3.

7.3 Restrictions. All shares of Restricted Stock (including any shares received by Holders thereof with respect to shares of Restricted Stock as a result of stock dividends, stock splits or any other form of recapitalization) shall, in the terms of the applicable Program or in each individual Award Agreement, be subject to such restrictions and vesting requirements as the Administrator shall provide. Such restrictions may include, without limitation, restrictions concerning voting rights and transferability and such restrictions may lapse separately or in combination at such times and pursuant to such circumstances or based on such criteria as selected by the Administrator, including, without limitation, criteria based on the Holder's duration of employment, directorship or consultancy with the Company, Company performance, individual performance or other criteria selected by the Administrator. By action taken after the Restricted Stock is issued, the Administrator may, on such terms and conditions as it may determine to be appropriate, accelerate the vesting of such Restricted Stock by removing any or all of the restrictions imposed by the terms of the applicable Program or Award Agreement. Restricted Stock may not be sold or encumbered until all restrictions are terminated or expire. Notwithstanding any provisions of this Agreement, any acceleration of vesting provisions in an employment agreement with respect to Restricted Stock will supersede the provisions of this Plan and the related Award Agreement, unless the employment agreement specifically states otherwise.

7.4 Repurchase or Forfeiture of Restricted Stock. Except as otherwise determined by the Administrator at the time of the grant of the Award or thereafter, if no price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable

restriction period, the Holder's rights in unvested Restricted Stock then subject to restrictions shall lapse, and such Restricted Stock shall be surrendered to the Company and cancelled without consideration. If a price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Company shall have the right to repurchase from the Holder the unvested Restricted Stock then subject to restrictions at a cash price per share equal to the price paid by the Holder for such Restricted Stock or such other amount as may be specified in the applicable Program or Award Agreement. Notwithstanding the foregoing, the Administrator, in its sole discretion, may provide that upon certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service or any other event, the Holder's rights in unvested Restricted Stock shall not lapse, such Restricted Stock shall vest and, if applicable, the Company shall not have a right of repurchase.

7.5 Certificates for Restricted Stock. Restricted Stock granted pursuant to the Plan may be evidenced in such manner as the Administrator shall determine. Certificates or book entries evidencing shares of Restricted Stock shall include an appropriate legend referring to the terms, conditions, and restrictions applicable to such Restricted Stock. The Company, in its sole discretion, may (a) retain physical possession of any stock certificate evidencing shares of Restricted Stock until the restrictions thereon shall have lapsed and/or (b) require that the stock certificates evidencing shares of Restricted Stock be held in custody by a designated escrow agent (which may but need not be the Company) until the restrictions thereon shall have lapsed, and that the Holder deliver a stock power, endorsed in blank, relating to such Restricted Stock.

7.6 Section 83(b) Election. If a Holder makes an election under Section 83(b) of the Code to be taxed with respect to the Restricted Stock as of the date of transfer of the Restricted Stock rather than as of the date or dates upon which the Holder would otherwise be taxable under Section 83(a) of the Code, the Holder shall be required to deliver a copy of such election to the Company promptly after filing such election with the Internal Revenue Service along with proof of the timely filing thereof with the Internal Revenue Service.

ARTICLE 8.
AWARD OF RESTRICTED STOCK UNITS

8.1 Grant of Restricted Stock Units. The Administrator is authorized to grant Awards of Restricted Stock Units to any Eligible Individual selected by the Administrator in such amounts and subject to such terms and conditions as determined by the Administrator.

8.2 Purchase Price. The Administrator shall specify the purchase price, if any, to be paid by the Holder to the Company with respect to any Restricted Stock Unit award; provided, however, that value of the consideration shall not be less than the par value of a Share, unless otherwise permitted by Applicable Law.

8.3 Vesting of Restricted Stock Units. At the time of grant, the Administrator shall specify the date or dates on which the Restricted Stock Units shall become fully vested and nonforfeitable, and may specify such conditions to vesting as it deems appropriate, including, without limitation, vesting based upon the Holder's duration of service to the Company or any

Subsidiary, Company performance, individual performance or other specific criteria, in each case on a specified date or dates or over any period or periods, as determined by the Administrator. Without limiting the foregoing, the vesting period shall be at least one (1) year after the date of grant for Employees.

8.4 Maturity and Payment. At the time of grant, the Administrator shall specify the maturity date applicable to each grant of Restricted Stock Units, which shall be no earlier than the vesting date or dates of the Award and may be determined at the election of the Holder (if permitted by the applicable Award Agreement); provided that, except as otherwise determined by the Administrator, set forth in any applicable Award Agreement, and subject to compliance with Section 409A of the Code, in no event shall the maturity date relating to each Restricted Stock Unit occur following the later of (a) the 15th day of the third month following the end of calendar year in which the applicable portion of the Restricted Stock Unit vests; or (b) the 15th day of the third month following the end of the Company's fiscal year in which the applicable portion of the Restricted Stock Unit vests. On the maturity date, the Company shall, subject to Section 11.4(e), transfer to the Holder one unrestricted, fully transferable Share for each Restricted Stock Unit scheduled to be paid out on such date and not previously forfeited, or in the sole discretion of the Administrator, an amount in cash equal to the Fair Market Value of such Shares on the maturity date or a combination of cash and Common Stock as determined by the Administrator. Notwithstanding any provisions of this Agreement, any acceleration of vesting provisions in an employment agreement with respect to Restricted Stock Units will supersede the provisions of this Plan and the related Award Agreement, unless the employment agreement specifically states otherwise.

8.5 No Rights as a Stockholder. Unless otherwise determined by the Administrator, a Holder of Restricted Stock Units shall possess no incidents of ownership with respect to the Shares represented by such Restricted Stock Units, unless and until such Shares are transferred to the Holder pursuant to the terms of this Plan and the applicable Award Agreement.

8.6 Dividend Equivalents. Subject to Section 9.2, the Administrator, in its sole discretion, may provide that Dividend Equivalents shall be earned by a Holder of Restricted Stock Units based on dividends declared on the Common Stock, to be credited as of dividend payment dates during the period between the date an Award of Restricted Stock Units is granted to a Holder and the maturity date of such Award.

ARTICLE 9.
AWARD OF PERFORMANCE AWARDS, DIVIDEND EQUIVALENTS, STOCK PAYMENTS

9.1 Performance Awards.

(a) The Administrator is authorized to grant Performance Awards, including Awards of Performance Stock Units, to any Eligible Individual. The value of Performance Awards, including Performance Stock Units, may be linked to specific performance criteria determined by the Administrator on a specified date or dates or over any period or periods and in such amounts as may be determined by the Administrator. Performance Awards, including

Performance Stock Unit awards, may be paid in cash, Shares, or a combination of cash and Shares, as determined by the Administrator.

(b) Without limiting Section 9.1(a), the Administrator may grant Performance Awards to any Eligible Individual in the form of a cash bonus payable upon the attainment of objective Performance Goals, or such other criteria, whether or not objective, which are established by the Administrator, in each case on a specified date or dates or over any period or periods determined by the Administrator.

9.2 Dividend Equivalents. Dividend Equivalents may be granted by the Administrator based on dividends declared on the Common Stock, to be credited as of dividend payment dates with respect to dividends with record dates that occur during the period between the date an Award is granted to a Holder and the date such Award vests, is exercised, is distributed or expires, as determined by the Administrator. Such Dividend Equivalents shall be converted to cash or additional Shares by such formula and at such time and subject to such restrictions and limitations as may be determined by the Administrator.

9.3 Stock Payments. The Administrator is authorized to make Stock Payments to any Eligible Individual. The number or value of Shares of any Stock Payment shall be determined by the Administrator and may be based upon one or more specific performance criteria, including service to the Company or any Subsidiary, determined by the Administrator. Shares underlying a Stock Payment which is subject to a vesting schedule or other conditions or criteria set by the Administrator shall not be issued until those conditions have been satisfied. Unless otherwise provided by the Administrator, a Holder of a Stock Payment shall have no rights as a Company stockholder with respect to such Stock Payment until such time as the Stock Payment has vested and the Shares underlying the Award have been issued to the Holder. Stock Payments may, but are not required to, be made in lieu of base salary, bonus, fees or other cash compensation otherwise payable to such Eligible Individual.

9.4 Term. The term of a Performance Award, Dividend Equivalent award, and/or Stock Payment award shall be established by the Administrator in its sole discretion.

9.5 Purchase Price. The Administrator may establish the purchase price of a Performance Award or Shares distributed as a Stock Payment award; provided, however, that value of the consideration shall not be less than the par value of a Share, unless otherwise permitted by Applicable Law.

9.6 Termination of Service. A Performance Award, Dividend Equivalent award, and/or Stock Payment award is distributable only while the Holder is an Employee, Director or Consultant, as applicable. The Administrator, however, in its sole discretion, may provide that the Performance Award, Dividend Equivalent award, and/or Stock Payment award may be distributed subsequent to the Holder’s Termination of Service subject to terms and conditions determined by the Administrator.

ARTICLE 10.
AWARD OF STOCK APPRECIATION RIGHTS

10.1 Grant of Stock Appreciation Rights.

(a) The Administrator is authorized to grant Stock Appreciation Rights to Eligible Individuals from time to time, in its sole discretion, on such terms and conditions as it may determine, which shall not be inconsistent with the Plan.

(b) A Stock Appreciation Right shall entitle the Holder (or other person entitled to exercise the Stock Appreciation Right pursuant to the Plan) to exercise all or a specified portion of the Stock Appreciation Right (to the extent then exercisable pursuant to its terms) and to receive from the Company an amount determined by multiplying the difference obtained by subtracting the exercise price per share of the Stock Appreciation Right from the Fair Market Value on the date of exercise of the Stock Appreciation Right by the number of Shares with respect to which the Stock Appreciation Right shall have been exercised, subject to any limitations the Administrator may impose. Except as described in (c) below, the exercise price per Share subject to each Stock Appreciation Right shall be set by the Administrator, but shall not be less than 100% of the Fair Market Value on the date the Stock Appreciation Right is granted.

(c) Notwithstanding the foregoing provisions of Section 10.1(b) to the contrary, in the case of a Stock Appreciation Right that is a Substitute Award, the exercise price per share of the Shares subject to such Stock Appreciation Right may be less than 100% of the Fair Market Value per share on the date of grant; provided that the excess of: (i) the aggregate Fair Market Value (as of the date such Substitute Award is granted) of the Shares subject to the Substitute Award, over (ii) the aggregate exercise price thereof does not exceed the excess of: (x) the aggregate fair market value (as of the time immediately preceding the transaction giving rise to the Substitute Award, such fair market value to be determined by the Administrator) of the shares of the predecessor entity that were subject to the grant assumed or substituted for by the Company, over (y) the aggregate exercise price of such shares.

10.2 Stock Appreciation Right Vesting.

(a) The period during which the right to exercise, in whole or in part, a Stock Appreciation Right vests in the Holder shall be set by the Administrator and the Administrator may determine that a Stock Appreciation Right may not be exercised in whole or in part for a specified period after it is granted. Such vesting may be based on service with the Company or any Subsidiary or any other criteria selected by the Administrator. Except as limited by the Plan, at any time after grant of a Stock Appreciation Right, the Administrator, in its sole discretion and subject to whatever terms and conditions it selects, may accelerate the period during which a Stock Appreciation Right vests.

(b) No portion of a Stock Appreciation Right which is unexercisable at a Holder's Termination of Service shall thereafter become exercisable, except as may be otherwise provided by the Administrator in the applicable Program, the Award Agreement evidencing the

grant of a Stock Appreciation Right, or by action of the Administrator following the grant of the Stock Appreciation Right.

10.3 Manner of Exercise. All or a portion of an exercisable Stock Appreciation Right shall be deemed exercised upon delivery of all of the following to the Secretary of the Company, the stock plan administrator of the Company, or such other person or entity designated by the Administrator, or his, her or its office, as applicable:

(a) A written or electronic notice complying with the applicable rules established by the Administrator stating that the Stock Appreciation Right, or a portion thereof, is exercised. The notice shall be signed by the Holder or other person then entitled to exercise the Stock Appreciation Right or such portion of the Stock Appreciation Right;

(b) Such representations and documents as the Administrator, in its sole discretion, deems necessary or advisable to effect compliance with Applicable Law. The Administrator, in its sole discretion, may also take whatever additional actions it deems appropriate to effect such compliance, including, without limitation, placing legends on share certificates and issuing stop-transfer notices to agents and registrars;

(c) In the event that the Stock Appreciation Right shall be exercised pursuant to this Section 10.3 by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Stock Appreciation Right, as determined in the sole discretion of the Administrator; and

(d) Full payment of the exercise price (if any) and applicable withholding taxes to the stock plan administrator of the Company for the Shares with respect to which the Stock Appreciation Right, or portion thereof, is exercised, in a manner permitted by Sections 11.1 and 11.2.

10.4 Exercise following Termination of Service. Unless varied in an Award Agreement, the Holder shall have ninety (90) days following a Termination of Service, other than for "cause" (as such term is defined in the sole discretion of the Administrator, or as set forth in the Award Agreement relating to such Award) to exercise any vested portion of a Stock Appreciation Right. All unvested portions of any Stock Appreciation Rights held shall automatically be forfeited upon a Termination of Service.

10.5 Stock Appreciation Right Term. The term of each Stock Appreciation Right (the "Stock Appreciation Right Term") shall be set by the Administrator in its sole discretion; provided, however, that the Stock Appreciation Right Term shall not be more than ten (10) years from the date the Stock Appreciation Right is granted. The Administrator shall determine the time period, including the time period following a Termination of Service, during which the Holder has the right to exercise the vested Stock Appreciation Rights, which time period may not extend beyond the last day of the Stock Appreciation Right Term applicable to such Stock Appreciation Right. Except as limited by the requirements of Section 409A of the Code and regulations and rulings thereunder or the first sentence of this Section 10.5, the Administrator may extend the Stock Appreciation Right Term of any outstanding Stock Appreciation Right, and may extend the time period during which vested Stock Appreciation

Rights may be exercised, in connection with any Termination of Service of the Holder, and may amend, subject to Section 13.1, any other term or condition of such Stock Appreciation Right relating to such a Termination of Service.

10.6 Payment. Payment of the amounts payable with respect to Stock Appreciation Rights pursuant to this Article 10 shall be in cash, Shares (based on its Fair Market Value as of the date the Stock Appreciation Right is exercised), or a combination of both, as determined by the Administrator.

ARTICLE 11.
ADDITIONAL TERMS OF AWARDS

11.1 Payment. The Administrator shall determine the methods by which payments by any Holder with respect to any Awards granted under the Plan shall be made, including, without limitation: (a) cash or check, (b) Shares (including, in the case of payment of the exercise price of an Award, Shares issuable pursuant to the exercise of the Award) or Shares held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences, in each case, having a Fair Market Value on the date of delivery equal to the aggregate payments required, (c) delivery of a written or electronic notice that the Holder has placed a market sell order with a broker acceptable to the Company with respect to Shares then issuable upon exercise or vesting of an Award, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the aggregate payments required; provided that payment of such proceeds is then made to the Company upon settlement of such sale, or (d) other form of legal consideration acceptable to the Administrator in its sole discretion. The Administrator shall also determine the methods by which Shares shall be delivered or deemed to be delivered to Holders. Notwithstanding any other provision of the Plan to the contrary, no Holder who is a Director or an "executive officer" of the Company within the meaning of Section 13(k) of the Exchange Act shall be permitted to make payment with respect to any Awards granted under the Plan, or continue any extension of credit with respect to such payment, with a loan from the Company or a loan arranged by the Company in violation of Section 13(k) of the Exchange Act.

11.2 Tax Withholding. The Company or any Subsidiary shall have the authority and the right to deduct or withhold, or require a Holder to remit to the Company, an amount sufficient to satisfy federal, state, local and foreign taxes (including the Holder's FICA, employment tax or other social security contribution obligation) required by law to be withheld with respect to any taxable event concerning a Holder arising as a result of the Plan. The Administrator, in its sole discretion and in satisfaction of the foregoing requirement, may withhold, or allow a Holder to elect to have the Company withhold, Shares otherwise issuable under an Award (or allow the surrender of Shares). The number of Shares which may be so withheld or surrendered shall be limited to the number of Shares which have a Fair Market Value on the date of withholding or repurchase equal to the aggregate amount of such liabilities based on the applicable statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such supplemental taxable income without leading to any avoid adverse accounting consequences. The Administrator shall determine the Fair Market Value of the Shares, consistent with applicable provisions of

the Code, for tax withholding obligations due in connection with a broker-assisted cashless Option or Stock Appreciation Right exercise involving the sale of Shares to pay the Option or Stock Appreciation Right exercise price or any tax withholding obligation.

11.3 Transferability of Awards.

(a) Except as otherwise provided in Sections 11.3(b) and 11.3(c):

(i) No Award under the Plan may be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a DRO, unless and until such Award has been exercised, or the Shares underlying such Award have been issued, and all restrictions applicable to such Shares have lapsed;

(ii) No Award or interest or right therein shall be liable for the debts, contracts or engagements of the Holder or the Holder's successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, hypothecation, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect, except to the extent that such disposition is permitted by Section 11.3(a)(i); and

(iii) During the lifetime of the Holder, only the Holder may exercise an Award (or any portion thereof) granted to such Holder under the Plan, unless it has been disposed of pursuant to a DRO; after the death of the Holder, any exercisable portion of an Award may, prior to the time when such portion becomes unexercisable under the Plan or the applicable Program or Award Agreement, be exercised by the Holder's personal representative or by any person empowered to do so under the deceased Holder's will or under the then-applicable laws of descent and distribution.

(b) Notwithstanding Section 11.3(a), the Administrator, in its sole discretion, may determine to permit a Holder to transfer an Award other than an Incentive Stock Option to any one or more Permitted Transferees, subject to the following terms and conditions: (i) an Award transferred to a Permitted Transferee without the consent of the Administrator shall not be assignable or transferable by the Permitted Transferee other than by will or the laws of descent and distribution or pursuant to a DRO; (ii) an Award transferred to a Permitted Transferee shall continue to be subject to all the terms and conditions of the Award as applicable to the original Holder (other than the ability to further transfer the Award); and (iii) the Holder and the Permitted Transferee shall execute any and all documents requested by the Administrator, including, without limitation documents to (A) confirm the status of the transferee as a Permitted Transferee, (B) satisfy any requirements for an exemption for the transfer under Applicable Law and (C) evidence the transfer.

(c) Notwithstanding Section 11.3(a), a Holder may, in the manner determined by the Administrator, designate a beneficiary to exercise the rights of the Holder and to receive any distribution with respect to any Award upon the Holder's death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject

to all terms and conditions of the Plan and any Program or Award Agreement applicable to the Holder, except to the extent the Plan, any Program or any Award Agreement otherwise provides, and to any additional restrictions deemed necessary or appropriate by the Administrator. If the Holder is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than the Holder's spouse or domestic partner, as applicable, as the Holder's beneficiary with respect to more than 50% of the Holder's interest in the Award shall not be effective without the prior written or electronic consent of the Holder's spouse or domestic partner. If no beneficiary has been designated or survives the Holder, payment shall be made to the person entitled thereto pursuant to the Holder's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by a Holder at any time; provided that the change or revocation is filed with the Administrator prior to the Holder's death.

11.4 Conditions to Issuance of Shares.

(a) Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates or make any book entries evidencing Shares pursuant to the exercise of any Award, unless and until the Board or the Committee has determined, with advice of counsel, that the issuance of such Shares is in compliance with Applicable Law and the Shares are covered by an effective registration statement or applicable exemption from registration. In addition to the terms and conditions provided herein, the Board or the Committee may require that a Holder make such reasonable covenants, agreements and representations as the Board or the Committee, in its sole discretion, deems advisable in order to comply with Applicable Law.

(b) All share certificates delivered pursuant to the Plan and all Shares issued pursuant to book entry procedures may be subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with Applicable Law. The Administrator may place legends on any share certificate or book entry to reference restrictions applicable to the Shares.

(c) The Administrator shall have the right to require any Holder to comply with any timing or other restrictions with respect to the settlement, distribution or exercise of any Award, including a window-period limitation, as may be imposed in the sole discretion of the Administrator.

(d) No fractional Shares shall be issued and the Administrator, in its sole discretion, shall determine whether cash shall be given in lieu of fractional Shares or whether such fractional Shares shall be eliminated by rounding down.

(e) Notwithstanding any other provision of the Plan, unless otherwise determined by the Administrator or required by Applicable Law, the Company shall not deliver to any Holder certificates evidencing Shares issued in connection with any Award and instead such Shares shall be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator).

11.5 Forfeiture and Claw-Back Provisions. Pursuant to its general authority to determine the terms and conditions applicable to Awards under the Plan, the Administrator shall have the right to provide, in an Award Agreement or otherwise, or to require a Holder to agree by separate written or electronic instrument, that:

(a) (i) Any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of the Award, or upon the receipt or resale of any Shares underlying the Award, shall be paid to the Company, and (ii) the Award shall terminate and any unexercised portion of the Award (whether or not vested) shall be forfeited, if (x) a Termination of Service occurs prior to a specified date, or within a specified time period following receipt or exercise of the Award, or (y) the Holder at any time, or during a specified time period, engages in any activity in competition with the Company, or which is inimical, contrary or harmful to the interests of the Company, as further defined by the Administrator or (z) the Holder incurs a Termination of Service for "cause" (as such term is defined in the sole discretion of the Administrator, or as set forth in the Award Agreement relating to such Award); and

(b) All Awards (including any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of any Award or upon the receipt or resale of any Shares underlying the Award) shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with the requirements of Applicable Law, including without limitation the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder, to the extent set forth in such claw-back policy and/or in the applicable Award Agreement.

ARTICLE 12.
ADMINISTRATION

12.1 Administrator. The Compensation Committee of the Board (or another committee or a subcommittee of the Board or the Compensation Committee of the Board assuming the functions of the Committee under the Plan) shall administer the Plan (except as otherwise permitted herein). To the extent necessary to comply with Rule 16b-3 of the Exchange Act, the Compensation Committee of the Board (or another committee or subcommittee of the Board or the Compensation Committee of the Board assuming the functions of the Committee under the Plan) shall take all action with respect to such Awards, and the individuals taking such action shall consist solely of two or more Non-Employee Directors appointed by and holding office at the pleasure of the Board, each of whom is intended to qualify as a "non-employee director" as defined by Rule 16b-3 of the Exchange Act or any successor rule. Additionally, to the extent required by Applicable Law, each of the individuals constituting the Compensation Committee of the Board (or another committee or subcommittee of the Board or the Compensation Committee of the Board assuming the functions of the Committee under the Plan) shall be an "independent director" under the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded. Notwithstanding the foregoing, any action taken by the Committee shall be valid and effective, whether or not members of the Committee at the time of such action are later determined not to have satisfied the requirements for membership set forth in this Section

12.1 or otherwise provided in any charter of the Committee. Except as may otherwise be provided in any charter of the Committee, appointment of Committee members shall be effective upon acceptance of appointment. Committee members may resign at any time by delivering written or electronic notice to the Board. Vacancies in the Committee may only be filled by the Board. Notwithstanding the foregoing, (a) the full Board, acting by a majority of its members in office, shall conduct the general administration of the Plan with respect to Awards granted to Non-Employee Directors and, with respect to such Awards, the terms "Administrator" and "Committee" as used in the Plan shall be deemed to refer to the Board and (b) the Board or Committee may delegate its authority hereunder to the extent permitted by Section 12.6.

12.2 Duties and Powers of Committee. It shall be the duty of the Committee to conduct the general administration of the Plan in accordance with its provisions. The Committee has the power to interpret the Plan, the Programs and the Award Agreements, and to adopt such rules for the administration, interpretation and application of the Plan as are not inconsistent therewith, to interpret, amend or revoke any such rules and to amend any Program or Award Agreement; provided that the rights or obligations of the Holder of the Award that is the subject of any such Program or Award Agreement are not affected adversely by such amendment, unless the consent of the Holder is obtained or such amendment is otherwise permitted under Section 11.5 or Section 13.10. Any such grant or award under the Plan need not be the same with respect to each Holder. Any such interpretations and rules with respect to Incentive Stock Options shall be consistent with the provisions of Section 422 of the Code. In its sole discretion, the Board may at any time and from time to time exercise any and all rights and duties of the Committee under the Plan, except with respect to matters which under Rule 16b-3 under the Exchange Act or any successor rule, or the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded, are required to be determined in the sole discretion of the Committee.

12.3 Action by the Committee. Unless otherwise established by the Board or in any charter of the Committee, a majority of the Committee shall constitute a quorum and the acts of a majority of the members present at any meeting at which a quorum is present, and acts approved in writing by all members of the Committee in lieu of a meeting, shall be deemed the acts of the Committee. Each member of the Committee is entitled to, in good faith, rely or act upon any report or other information furnished to that member by any Employee, the Company's independent certified public accountants, or any executive compensation consultant or other professional retained by the Company to assist in the administration of the Plan.

12.4 Authority of Administrator. Subject to the Company's Amended and Restated Bylaws, the charter of the Committee and any specific designation in the Plan, the Administrator has the exclusive power, authority and sole discretion to:

(a) Designate Eligible Individuals to receive Awards;

(b) Determine the type or types of Awards to be granted to each Eligible Individual;

(c) Determine the number of Awards to be granted and the number of Shares to which an Award will relate;

(d) Determine the terms and conditions of any Award granted pursuant to the Plan, including, but not limited to, the exercise price, grant price, purchase price, any restrictions or limitations on the Award, any schedule for vesting, lapse of forfeiture restrictions or restrictions on the exercisability of an Award, and accelerations or waivers thereof, and any provisions related to non-competition and recapture of gain on an Award, based in each case on such considerations as the Administrator in its sole discretion determines;

(e) Determine whether, to what extent, and pursuant to what circumstances an Award may be settled in, or the exercise price of an Award may be paid in cash, Shares, other Awards, or other property, or an Award may be canceled, forfeited, or surrendered;

(f) Prescribe the form of each Award Agreement, which need not be identical for each Holder;

(g) Decide all other matters that must be determined in connection with an Award;

(h) Establish, adopt, or revise any rules and regulations as it may deem necessary or advisable to administer the Plan;

(i) Interpret the terms of, and any matter arising pursuant to, the Plan, any Program or any Award Agreement;

(j) Make all other decisions and determinations that may be required pursuant to the Plan or as the Administrator deems necessary or advisable to administer the Plan; and

(k) Accelerate wholly or partially the vesting or lapse of restrictions of any Award or portion thereof at any time after the grant of an Award, subject to whatever terms and conditions it selects and Section 13.2.

12.5 Decisions Binding. The Administrator's interpretation of the Plan, any Awards granted pursuant to the Plan, any Program, any Award Agreement and all decisions and determinations by the Administrator with respect to the Plan are final, binding and conclusive on all parties.

12.6 Delegation of Authority. To the extent permitted by Applicable Law, the Board or Committee may from time to time delegate to a committee of one or more members of the Board or one or more officers of the Company the authority to grant or amend Awards or to take other administrative actions pursuant to this Article 12; provided, however, that in no event shall an officer of the Company be delegated the authority to grant awards to, or amend awards held by, the following individuals: (a) individuals who are subject to Section 16 of the Exchange Act or (b) officers of the Company (or Directors) to whom authority to grant or amend Awards has been delegated hereunder; provided, further, that any delegation of administrative authority shall only be permitted to the extent it is permissible under Applicable Law. Any delegation hereunder shall be subject to the restrictions and limits that the Board or

Committee specifies at the time of such delegation, and the Board may at any time rescind the authority so delegated or appoint a new delegatee. At all times, the delegatee appointed under this Section 12.6 shall serve in such capacity at the pleasure of the Board and the Committee (to the extent the Committee delegated its authority to the delegatee).

ARTICLE 13.
MISCELLANEOUS PROVISIONS

13.1 Amendment, Suspension or Termination of the Plan. Except as otherwise provided in this Section 13.1, the Plan may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Board or the Committee. However, without approval of the Company's stockholders given within twelve (12) months before or after the action by the Administrator, no action of the Administrator may, except as provided in Section 13.2, increase the limits imposed in Section 3.1 on the maximum number of Shares which may be issued under the Plan, or otherwise amend or modify the Plan in a manner requiring stockholder approval under Applicable Law. Except as provided in Section 11.5 and Section 13.10, no amendment, suspension or termination of the Plan shall, without the consent of the Holder, materially impair any rights or obligations under any Award theretofore granted or awarded, unless the Award itself otherwise expressly so provides. No Awards may be granted or awarded during any period of suspension or after termination of the Plan, and notwithstanding anything herein to the contrary, in no event may any Award be granted under the Plan after the tenth (10th) anniversary of the date the Plan is first adopted by the Board (the "Expiration Date"). Any Awards that are outstanding on the Expiration Date shall remain in force according to the terms of the Plan and the applicable Award Agreement.

13.2 Changes in Common Stock or Assets of the Company, Acquisition or Liquidation of the Company and Other Corporate Events.

(a) In the event of any stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the Shares of the Company's stock or the share price of the Company's stock other than an Equity Restructuring, the Administrator shall make equitable adjustments, if any, to reflect such change with respect to: (i) the aggregate number and kind of Shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Section 3.1 on the maximum number and kind of Shares which may be issued under the Plan); (ii) the number and kind of Shares (or other securities or property) subject to outstanding Awards; (iii) the terms and conditions of any outstanding Awards (including, without limitation, any applicable performance targets or criteria with respect thereto); and (v) the grant or exercise price per share for any outstanding Awards under the Plan.

(b) In the event of any transaction or event described in Section 13.2(a) or any unusual or nonrecurring transactions or events affecting the Company, any Subsidiary of the Company, or the financial statements of the Company or any Subsidiary, or of changes in Applicable Law or accounting principles, the Administrator, in its sole discretion, and on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken

prior to the occurrence of such transaction or event and either automatically or upon the Holder's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any Award under the Plan, to facilitate such transactions or events or to give effect to such changes in laws, regulations or principles:

(i) To provide for either (A) termination of any such Award in exchange for an amount of cash, if any, equal to the amount that would have been attained upon the exercise of such Award or realization of the Holder's rights (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction or event described in this Section 13.2 the Administrator determines in good faith that no amount would have been attained upon the exercise of such Award or realization of the Holder's rights, then such Award may be terminated by the Company without payment) or (B) the replacement of such Award with other rights or property selected by the Administrator, in its sole discretion, having an aggregate value not exceeding the amount that could have been attained upon the exercise of such Award or realization of the Holder's rights had such Award been currently exercisable or payable or fully vested;

(ii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by similar options, rights or awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices;

(iii) To make adjustments in the number and type of Shares of the Company's stock (or other securities or property) subject to outstanding Awards, and in the number and kind of outstanding Restricted Stock and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards and Awards which may be granted in the future;

(iv) To provide that such Award shall be exercisable or payable or fully vested with respect to all Shares covered thereby, notwithstanding anything to the contrary in the Plan or the applicable Program or Award Agreement; and

(v) To provide that the Award cannot vest, be exercised or become payable after such event.

(c) In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in Sections 13.2(a) and 13.2(b), the Administrator shall equitably adjust each outstanding Award, which adjustments may include adjustments to the number and type of securities subject to each outstanding Award and/or the exercise price or grant price thereof, if applicable, the grant of new Awards, and/or the making of a cash payment. The Administrator shall make such equitable adjustments, if any, as the Administrator, in its sole discretion, may deem appropriate to reflect such Equity Restructuring with respect to the aggregate number and kind of Shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Section 3.1 on the maximum number and kind of

Shares which may be issued under the Plan). The adjustments provided under this Section 13.2(c) shall be nondiscretionary and shall be final and binding on the affected Holder and the Company.

(d) Notwithstanding any other provision of the Plan, in the event of a Change in Control, unless the Administrator elects to (i) terminate an Award in exchange for cash, rights or property, or (ii) cause an Award to become fully exercisable and no longer subject to any forfeiture restrictions prior to the consummation of a Change in Control, pursuant to Section 13.2, (A) such Award (other than any portion subject to performance-based vesting) shall continue in effect or be assumed or an equivalent Award substituted by the successor corporation or a parent or subsidiary of the successor corporation and (B) the portion of such Award subject to performance-based vesting shall be subject to the terms and conditions of the applicable Award Agreement and, in the absence of applicable terms and conditions, the Administrator's discretion.

(e) In the event that the successor corporation in a Change in Control refuses to assume or substitute for an Award (other than any portion subject to performance-based vesting), the Administrator may cause any or all of such Award (or portion thereof) to (i) terminate in exchange for cash, rights or other property pursuant to Section 13.2(b)(i) or (ii) become fully exercisable immediately prior to the consummation of such transaction and all forfeiture restrictions on any or all of such Award to lapse. If any such Award is exercisable in lieu of assumption or substitution in the event of a Change in Control, the Administrator shall notify the Holder that such Award shall be fully exercisable for a period of fifteen (15) days from the date of such notice, contingent upon the occurrence of the Change in Control, and such Award shall terminate upon the expiration of such period.

(f) The Administrator, in its sole discretion, may include such further provisions and limitations in any Award, agreement or certificate, as it may deem equitable and in the best interests of the Company that are not inconsistent with the provisions of the Plan.

(g) No adjustment or action described in this Section 13.2 or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause the Plan to violate Section 422(b)(1) of the Code. Furthermore, no such adjustment or action shall be authorized to the extent such adjustment or action would result in short-swing profits liability under Section 16 or violate the exemptive conditions of Rule 16b-3 unless the Administrator determines that the Award is not to comply with such exemptive conditions.

(h) The existence of the Plan, a Program, an Award Agreement and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, warrants or rights to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

(i) No action shall be taken under this Section 13.2 which shall cause an Award to fail to be exempt from or comply with Section 409A of the Code or the Treasury Regulations thereunder.

(j) In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other extraordinary transaction or change affecting the Shares or the share price of the Common Stock including any Equity Restructuring, for reasons of administrative convenience, the Company, in its sole discretion, may refuse to permit the exercise of any Award during a period of up to sixty (60) days prior to the consummation of any such transaction.

13.3 Approval of Plan by Stockholders. The Plan shall be submitted for the approval of the Company's stockholders within twelve (12) months after the date of the Board's initial adoption of the Plan.

13.4 No Stockholders Rights. Except as otherwise provided herein, a Holder shall have none of the rights of a stockholder with respect to Shares covered by any Award until the Holder becomes the record owner of such Shares.

13.5 Paperless Administration. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, then the paperless documentation, granting or exercise of Awards by a Holder may be permitted through the use of such an automated system.

13.6 Effect of Plan upon Other Compensation Plans. The adoption of the Plan shall not affect any other compensation or incentive plans in effect for the Company or any Subsidiary. Nothing in the Plan shall be construed to limit the right of the Company or any Subsidiary: (a) to establish any other forms of incentives or compensation for Employees, Directors or Consultants of the Company or any Subsidiary, or (b) to grant or assume options or other rights or awards otherwise than under the Plan in connection with any proper corporate purpose including without limitation, the grant or assumption of options in connection with the acquisition by purchase, lease, merger, consolidation or otherwise, of the business, stock or assets of any corporation, partnership, limited liability company, firm or association.

13.7 Compliance with Laws. The Plan, the granting and vesting of Awards under the Plan and the issuance and delivery of Shares and the payment of money under the Plan or under Awards granted or awarded under the Plan are subject to compliance with all Applicable Law (including but not limited to state, federal and foreign securities law and margin requirements), and to such approvals by any listing, regulatory or governmental authority as may, in the opinion of counsel for the Company, be necessary or advisable in connection therewith. Any securities delivered under the Plan shall be subject to such restrictions, and the person acquiring such securities shall, if requested by the Company, provide such assurances and representations to the Company as the Company may deem necessary or desirable to assure compliance with all Applicable Law. To the extent permitted by Applicable Law, the

Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to Applicable Law.

13.8 Titles and Headings, References to Sections of the Code or Exchange Act. The titles and headings of the Sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control. References to sections of the Code or the Exchange Act shall include any amendment or successor thereto.

13.9 Governing Law. The Plan and any agreements hereunder shall be administered, interpreted and enforced under the internal laws of the State of Delaware without regard to conflicts of laws thereof or of any other jurisdiction.

13.10 Section 409A. To the extent that the Administrator determines that any Award granted under the Plan is subject to Section 409A of the Code, the Program pursuant to which such Award is granted and the Award Agreement evidencing such Award shall incorporate the terms and conditions required by Section 409A of the Code. To the extent applicable, the Plan, the Program and any Award Agreements shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Effective Date. Notwithstanding any provision of the Plan to the contrary, in the event that following the Effective Date the Administrator determines that any Award may be subject to Section 409A of the Code and related Department of Treasury guidance (including such Department of Treasury guidance as may be issued after the Effective Date), the Administrator may adopt such amendments to the Plan and the applicable Program and Award Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Administrator determines are necessary or appropriate to (a) exempt the Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Award, or (b) comply with the requirements of Section 409A of the Code and related Department of Treasury guidance and thereby avoid the application of any penalty taxes under such Section.

13.11 No Right to Awards. No Eligible Individual or other person shall have any claim to be granted any Award pursuant to the Plan, and neither the Company nor the Administrator is obligated to treat Eligible Individuals, Holders or any other persons uniformly.

13.12 Unfunded Status of Awards. The Plan is intended to be an “unfunded” plan for incentive compensation. With respect to any payments not yet made to a Holder pursuant to an Award, nothing contained in the Plan or any Program or Award Agreement shall give the Holder any rights that are greater than those of a general creditor of the Company or any Subsidiary.

13.13 Indemnification. To the extent allowable pursuant to Applicable Law, each member of the Committee or of the Board shall be indemnified and held harmless by the Company from any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by such member in connection with or resulting from any claim, action, suit, or

proceeding to which he or she may be a party or in which he or she may be involved by reason of any action or failure to act pursuant to the Plan and against and from any and all amounts paid by him or her in satisfaction of judgment in such action, suit, or proceeding against him or her; provided he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such persons may be entitled pursuant to the Company's Amended and Restated Bylaws, as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

13.14 Relationship to other Benefits. No payment pursuant to the Plan shall be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary except to the extent otherwise expressly provided in writing in such other plan or an agreement thereunder.

13.15 Expenses. The expenses of administering the Plan shall be borne by the Company and its Subsidiaries.

Last amended and restated: March 29, 2018

Exhibit 21.1

OPGEN, INC.

The following is a list of subsidiaries of OpGen, Inc. as of December 31, 2017:

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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statements No. 333-210489, No. 333-205864, No. 333-216929, and No. 333-216932 on Form S-8 and Registration Statements No. 333-218392 and No. 333-222140 on Form S-1 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 March 29, 2018, on our audits of the consolidated financial statements of OpGen, Inc. as of December 31, 2017 and 2016 and for the years then ended, included in this Annual Report on Form 10-K of OpGen, Inc. for the year ended December 31, 2017.

/s/ CohnReznick LLP

Vienna, Virginia
March 29, 2018

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: March 29, 2018

/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: March 29, 2018

/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, 2017 (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: March 29, 2018

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

Date: March 29, 2018

/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.