

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

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AMENDMENT NO. 2  
TO  
FORM S-1  
REGISTRATION STATEMENT

Under  
The Securities Act of 1933

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**OPGEN, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation or  
organization)

**8071**  
(Primary Standard Industrial  
Classification Code Number)

**06-1614015**  
(I.R.S. Employer  
Identification Number)

**708 Quince Orchard Road, Suite 205**  
**Gaithersburg, MD 20878**  
**(240) 813-1260**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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**Evan Jones**  
**Chief Executive Officer**  
**708 Quince Orchard Road**  
**Gaithersburg, MD 20878**  
**(301) 869-9683**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the 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   
Non-Accelerated Filer

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 to Section 7(a)(2)(B) of the Securities Act.

#### CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)(2)	Amount of Registration Fee
Units, each Unit consisting of one share of Common Stock, par value \$0.01 per share and one common warrant to purchase one share of Common Stock (3)	\$ 11,000,000	\$ 1,274.90
(i) Common Stock included in the Units (4)	-	-
(ii) Common warrants included in the Units (4)	-	-
Pre-funded Units, each Pre-funded Unit consisting of one pre-funded warrant to purchase one share of Common Stock and one common warrant to purchase one share of Common Stock (3)	\$ 10,800,000	\$ 1,251.72
(i) Pre-funded warrants included in the Pre-funded Units (4)	-	-
(ii) Common warrants included in the Pre-funded Units (4)	-	-
Shares of Common Stock underlying pre-funded warrants included in the Pre-funded Units (3)	\$ 200,000	\$ 23.18
Shares of Common Stock underlying common warrants included in the Units and the Pre-funded Units (3)	\$ 11,000,000	\$ 1,274.90
Placement Agent's warrants (6)	\$ 687,500	\$ 79.68
Common Stock issuable upon exercise of Placement Agent's warrants (5)(6)	-	-
<b>Total</b>	<b>\$ 33,687,500</b>	<b>\$ 3,904.38<sup>(7)</sup></b>

- (1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
- (2) Pursuant to Rule 416 under the Securities Act of 1933, as amended, the shares of common stock registered hereby also include an indeterminate number of additional shares of common stock as may, from time to time, become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.
- (3) The proposed maximum aggregate offering price of the Units proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any Pre-funded Units offered and sold in the offering, and as such the proposed maximum aggregate offering price of the Units and Pre-funded Units (including the common stock issuable upon exercise of the pre-funded warrants included in the Pre-funded Units), if any, is \$11,000,000 .
- (4) No additional registration fee is payable pursuant to Rule 457(i) under the Securities Act of 1933, as amended.
- (5) No additional registration fee is payable pursuant to Rule 457(g) under the Securities Act of 1933, as amended.
- (6) Represents warrants to purchase a number of shares of common stock equal to 5% of the number of shares of common stock (i) included within the Units and (ii) issuable upon the exercise of the pre-funded warrants included within the Pre-funded Units placed in this offering at an exercise price equal to 125% of the offering price per unit (excluding any shares of common stock underlying the common warrants included in the units and the pre-funded units placed in this offering).
- (7) The Registrant previously paid \$1,810.94 as a registration fee in connection with this registration statement.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**Subject to Completion: Dated July 11, 2017**

Preliminary Prospectus



**Up to 20,000,000 Units (each Unit contains 1 Share of Common Stock and 1 Common Warrant to purchase 1 Share of Common Stock)**

**or**

**Up to 20,000,000 Pre-funded Units (each Pre-funded Unit contains 1 Pre-funded Warrant to Purchase 1 Share of Common Stock and 1 Common Warrant to purchase 1 Share of Common Stock)  
(Shares of Common Stock Underlying the Pre-funded Warrants) and  
(Shares of Common Stock Underlying the Common Warrants)**

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We are offering up to 20,000,000 units (each unit consisting of one share of our common stock and one common warrant to purchase one share of our common stock). Each common warrant contained in a unit has an exercise price of \$ per share. The common warrants contained in the units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the units.

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

For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. Units and the pre-funded units will not be issued or certificated. The shares of common stock or pre-funded warrants, as the case may be, and the common warrants can only be purchased together in this offering but the securities contained in the units or pre-funded units will be issued separately.

Our common stock is listed on The NASDAQ Capital Market under the symbol "OPGN." On July 7, 2017, the last reported sale price of our common stock on The NASDAQ Capital Market was \$0.55 per share. The public offering price per unit or pre-funded unit, as the case may be, will be determined between us and the placement agent based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. We do not intend to apply for listing of the pre-funded warrants or common warrants on any securities exchange or other nationally recognized trading system. There is no established public trading market for the pre-funded warrants or common warrants, and we do not expect a market to develop .

We are an "emerging growth company" as the term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. See "Prospectus Summary – Implications of Being an Emerging Growth Company."

**Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 13.**

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



jVen Capital, LLC, a principal stockholder of the Company and an affiliate of Evan Jones, the Company’s Chairman of the Board and Chief Executive Officer, has committed to a bridge financing of up to \$1,500,000 to the Company in the form of short-term secured promissory notes and has provided \$1,000,000 pursuant to the bridge financing as of the date of this prospectus. Upon the closing of this offering, if at least \$5,000,000 in net cash proceeds to the Company is raised, defined as a qualified financing, the maturity date of each outstanding bridge financing note will be accelerated to the date that is five business days after the closing of the qualified financing. If this offering is a qualified financing, the Company will use a portion of the proceeds to repay the outstanding bridge financing notes (up to \$1,500,000 plus accrued interest).

jVen Capital, LLC has informed the Company that it intends to participate in this offering in an amount up to \$1,000,000. However, because indications of interest are not binding agreements or commitments to purchase, jVen Capital LLC may determine to purchase fewer securities than it indicates an interest in purchasing or not to purchase any securities in this offering.

	<b>Per Unit</b>	<b>Per Pre-funded Unit</b>	<b>Total</b>
Public offering price	\$	\$	\$
Placement agent’s fees <sup>(1)</sup>	\$	\$	\$
Proceeds, before expenses, to OpGen, Inc.	\$	\$	\$

We have retained H.C. Wainwright & Co., LLC as our exclusive placement agent to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent's fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above.

We have agreed to pay the placement agent a total cash fee equal to 6.5% of the gross proceeds of this offering and a management fee of 1% of the gross proceeds of this offering (which fees may be reduced under certain circumstances). In addition to the placement agent’s fees, we have agreed to pay the placement agent a non-accountable expense allowance of \$50,000, to reimburse the placement agent for fees and expenses of its legal counsel in an amount up to \$100,000 and to reimburse the placement agent for any escrow or settlement fees in an amount not to exceed \$10,000. As additional compensation, we plan to issue the placement agent warrants to purchase a number of shares of common stock equal to 5% of the number of shares of common stock (i) included within the units and (ii) issuable upon the exercise of the pre-funded warrants included within the pre-funded units that are, in each case, placed in this offering to investors. The exercise price for these warrants will be \$ per share, which represents 125% of the public offering price per unit. See “Plan of Distribution.”

We expect to deliver the securities to investors on or about , 2017.

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**H.C. Wainwright & Co.**

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Prospectus dated , 2017

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You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell securities in any state where the offer or solicitation is not permitted. The information contained in this prospectus is complete and accurate as of the date on the front cover of this prospectus, but information may have changed since that date. We are responsible for updating this prospectus to ensure that all material information is included and will update this prospectus to the extent required by law.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data and we do not make any representation as to the accuracy of the information.

We own various U.S. federal trademark registrations and applications and unregistered trademarks and servicemarks, including OpGen®, Acuitas®, Acuitas Lighthouse®, Argus®, AdvanDx®, QuickFISH® and PNA FISH®. All other trademarks, servicemarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are sometimes referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law,

their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies, products or services.

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## PROSPECTUS SUMMARY

*This summary highlights information contained in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. You should read the entire prospectus carefully before making an investment in our common stock. You should carefully consider, among other things, our financial statements and the related notes and the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this prospectus. When we refer to OpGen, Inc. we use the terms “OpGen,” “the Company,” “us,” “we” and “our.”*

***Please refer to the Glossary on page 84 of this prospectus for definitions of scientific, health care, regulatory and OpGen-specific terms used in this prospectus.***

### 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 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 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 are the Acuitas Lighthouse Knowledgebase, a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens and our Acuitas Lighthouse informatics, which can be 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. The potential market is discussed in the publication “Hospital Acquired Infection Testing Market – Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2013-2019.” Our relationship with Merck & Co., Inc., or Merck, includes investment from the Merck Global Health Innovation Fund; and a research collaboration with Merck Sharp & Dohme, or MSD, to provide access to MSD’s 200,000 clinical isolate SMART bacterial surveillance archive. 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 Knowledgebase 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 Acuitas Rapid Test 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 Acuitas Rapid Test 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.

### **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 DNA tests for use on the Thermo Fisher Scientific 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 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 Knowledgebase 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:

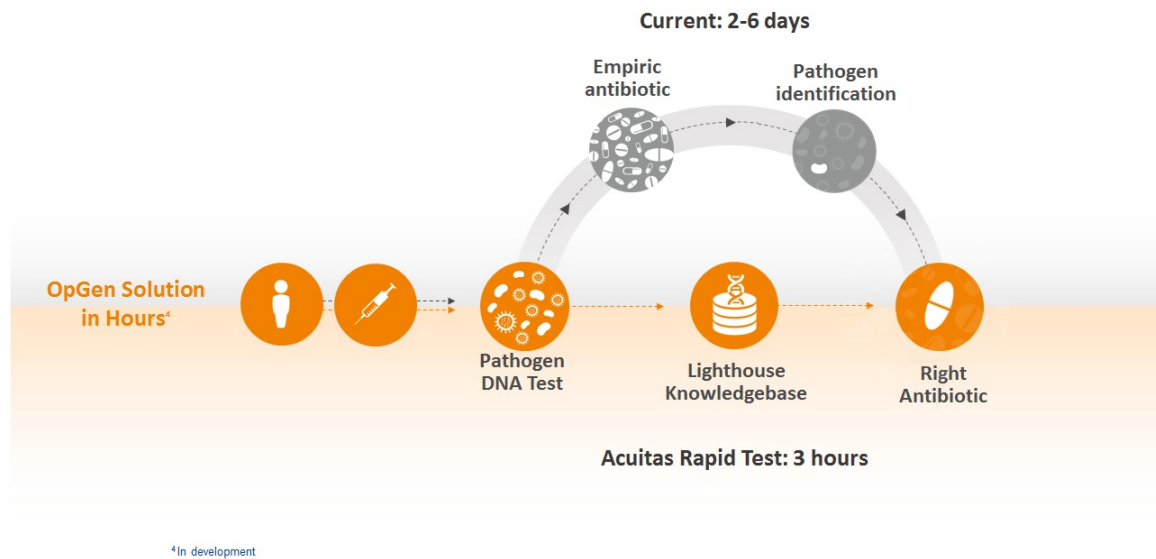
- complete development, clinical evaluations, obtain necessary regulatory approvals, and successfully commercialize our Acuitas Rapid Test for cUTI with a goal of achieving three-hour antibiotic resistance analysis from the time of specimen collection;
- begin clinical evaluations for the Acuitas Rapid Test for cUTI in the second half of 2017 with a goal of initial commercialization in the first half of 2018 as an RUO test;
- obtain third party funding to expand our Acuitas Rapid Test development and access to additional third party rapid testing platforms;
- expand our business collaborations with Merck and other pharmaceutical companies;
- capitalize on opportunities to deploy our Acuitas Lighthouse informatics and genomic testing for Pharmaceutical/CRO services;
- complete testing and initial development of the Acuitas Lighthouse Knowledgebase in 2017 using 10,000 clinical isolates from the Merck SMART bacterial surveillance network;

- 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 informatics and decision-making software and work to install Acuitas Lighthouse access to customer sites in the United States and globally.

**Lead Rapid Diagnostic and Acuitas Lighthouse Informatics Product**

Our lead product in development is the Acuitas Rapid Test for patients at risk for cUTI. The Acuitas Rapid Test for cUTI is a direct test that will be able to be performed in 2 ½ hours to identify five pathogens associated with urinary tract infections and their levels and 39 genes associated with antibiotic resistance. We anticipate that the Acuitas Lighthouse Knowledgebase will be used to provide additional interpretation of test results including probability of resistance for fourteen antibiotics commonly used to treat cUTI. Approximately 9,000 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 antibiotic resistance prediction decision-making algorithms. Preliminary performance data for E. coli and K. pneumonia Acuitas Lighthouse 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 Acuitas Rapid Test for cUTI support the potential for the Acuitas Lighthouse Knowledgebase 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.

**Revolutionary Approach to Antibiotic Decision Making**



**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.

## **Current Status**

As of July 7, 2017, our cash and cash equivalents on hand were approximately \$622,000. Since April 1, 2017, through the date of this prospectus, we raised \$1,372,576 in net proceeds through the sale of 1,971,451 shares of our common stock in our at-the-market offering and \$1,000,000 from a bridge financing discussed below.

### ***Bridge Financing***

On May 31, 2017, the Company entered into a Note Purchase Agreement with jVen Capital, LLC, a Delaware limited liability company, or jVen Capital, under which jVen Capital agreed to lend up to \$1,500,000 to the Company in the form of three \$500,000 secured convertible promissory notes. The Note Purchase Agreement was amended and restated by the parties on July 10, 2017. jVen Capital is an affiliate of Evan Jones, the Company's Chairman of the Board and Chief Executive Officer. The principal terms of the bridge financing provided under the amended and restated Note Purchase Agreement, or the Note Purchase Agreement, are:

- the Company may access the bridge financing facility by providing five business days' notice to jVen Capital
- secured bridge financing notes will be issued in three \$500,000 increments
- the bridge financing notes carry an interest rate of 10% per annum (increased to 15% in an event of default)
- the Note Purchase Agreement provides for the issuance of warrants to purchase common stock equal to 20% of the principal of each note being purchased at issuance of such note
- the maturity date for the up to \$1,500,000 principal amount of bridge financing notes is September 30, 2017, when all principal and interest will be due, subject to the following
  - o if the Company raises net proceeds of at least \$5 million in a qualified financing prior to September 30, 2017, the maturity date of the outstanding bridge financing notes will be accelerated to a date that is five business days after the qualified financing closes
  - o if the Company does not complete a qualified financing by September 30, 2017, but is working on a qualified financing transaction, the maturity date of the outstanding bridge financing notes can be extended, but not beyond December 31, 2017
- the bridge financing notes are secured by all of the Company's assets, but are subordinate to the existing first priority security interest of Merck Global Health Innovation Fund, or MGHIF, related to the July 2015 \$1,000,000 promissory note, or the MGHIF Note; if the Company seeks to liquidate or enters a bankruptcy proceeding, the MGHIF Note and the bridge financing notes will have equal secured status, and the maturity dates of all then-outstanding bridge financing notes and of the MGHIF Note will accelerate
- assuming that any bridge financing notes are then outstanding, if the Company does not pay any outstanding bridge financing notes on a timely basis, seeks to liquidate the Company, enters into a bankruptcy proceeding, or fails to timely pay any other outstanding indebtedness, the then-outstanding bridge financing notes would acquire a two times liquidation preference for unpaid principal and interest, unless jVen Capital exercises its option to convert the bridge financing notes to Series B convertible preferred stock, or Preferred Stock, at a ratio of one share of Preferred Stock per \$1.00 of principal and interest, which Preferred Stock would be convertible into 10 shares of voting common stock, otherwise no further preferences are provided to the Preferred Stock

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. To receive MGHIF's consent to such extension, we amended and restated the MGHIF Note to increase the interest rate to 10% and to issue 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.

If this offering is a qualified financing under the Note Purchase Agreement, and any bridge financing notes are outstanding, the Company will use a portion of the proceeds to repay the outstanding bridge financing notes (up to \$1,500,000 plus accrued interest).

The bridge financing notes, the warrants issued to jVen Capital and the Preferred Stock Certificate of Designation to be filed each includes a blocker provision that prevents any issuance of securities as repayment of the bridge financing notes, the exercise of the warrants issued to jVen Capital, the conversion of the bridge financing notes to Preferred Stock and/or the conversion of the Preferred Stock to common stock, if such repayment, exercise or conversion, when aggregated with the other issuances contemplated under the Note Purchase Agreement, would violate NASDAQ Listing Rule 5635, unless stockholder approval is first obtained by the Company.

As of the date of this prospectus, \$1,000,000 in bridge financing notes have been issued to jVen Capital, and warrants to purchase an aggregate of 627,570 shares of common stock have been issued to jVen Capital and MGHIF .

We believe that current cash on hand, plus the bridge financing, excluding any additional bridge financings, other financings, or further cash conservation measures will be sufficient to fund operations through end of July 2017.

### ***Restructuring***

In early June 2017, we commenced a restructuring of our operations to improve efficiency and reduce our cost structure. We expect these actions to reduce costs by 25-30 percent by the fourth quarter of 2017. The restructuring plans anticipate that we will consolidate operations for FDA-cleared and CE marked products in Gaithersburg, Maryland, and reduce the size of our commercial organization while we work to complete the development of our Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase products and services in development.

### **2016 Events**

#### ***Business Initiatives***

In May 2016, OpGen and the District of Columbia Hospital Association, or DCHA, announced the completion of the first citywide quantification of MDROs. The study was conducted with Washington D.C.'s public health departments to gauge the prevalence of the multidrug-resistant Gram-negative bacteria CRE in healthcare facilities throughout the District of Columbia. The results revealed the prevalence of CRE and other CRO was 5.1% and 6.4%, respectively. The study also reported a wide range of variability across the 16 institutions tested providing direction for concentrated intervention.

In July 2016, we completed the IHC Retrospective MDRO Health Outcome Study. The study was one of the largest of its kind ever conducted in an integrated health system. 900,000 hospital admissions were evaluated over an eight-year period at IHC, including 22 hospitals and affiliated clinics to help evaluate actual healthcare costs of MDRO and *C. difficile* infections and to provide proprietary data sets to help guide OpGen commercialization and R&D activities. The researchers found that a 222% increase was observed in the prevalence of *C. difficile* infections as well as a 322% increase in ESBL (extended spectrum beta lactamase) positive organisms. The study documented total costs of hundreds of millions of dollars and average individual patient costs of between \$25,000 and \$80,000. Total costs are projected to double over the next seven years.

In October 2016, we entered into a research collaboration with MSD to develop new rapid diagnostics and information technology products to help combat the threat of antimicrobial resistance. The collaboration with MSD will support OpGen's development of rapid DNA tests and a genomic knowledgebase of antibiotic-resistant pathogens for predicting antibiotic susceptibility based on test results. Under the terms of the agreement, MSD will provide access to its archive of over 200,000 bacterial pathogens gathered over the last 15 years through the Study for Monitoring Antimicrobial Resistance Trends known as "SMART," one of the world's largest surveillance studies of antimicrobial resistance supported by MSD in collaboration with International Health Management Associates, or IHMA. OpGen is performing genomic analysis, microbiology testing for drug resistance, and incorporate this information into its Acuitas Lighthouse Knowledgebase and the development of rapid DNA tests such as the Acuitas Rapid Test in development. OpGen will initially perform molecular analyses on up to 10,000 pathogens to identify markers of resistance to support rapid decision-making using the Acuitas Lighthouse data warehouse, and to speed development of OpGen's rapid diagnostic platforms. MSD will gain access to the high-resolution genotype data for the SMART isolates as well as access to Acuitas Lighthouse informatics to support internal research and development programs.

On June 15, 2017, the Company entered into a Supply Agreement with Life Technologies Corporation, a Thermo Fisher Scientific company, or LTC, pursuant to which the Company is authorized to lease or purchase LTC QuantStudio® 5 real-time PCR instruments for placement with the Company's research use only and, upon receipt of regulatory approval, commercial customers of the Company's Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase products and services in development. The Supply Agreement also contemplates the placement of the LTC instruments in Company customer locations using the Company's Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase products and services, once developed and offered. The Company currently expects such research use only, or RUO, customer sales to begin in the first half of 2018.

### ***Financings***

On May 19, 2016 and June 27, 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 share of common stock and a detachable stock purchase warrant to purchase an additional 0.75 of one share of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.75 of one share of common stock, at a price of \$1.14 per unit. The total net proceeds to the Company, after deducting offering commissions and expenses was \$9.5 million. The Company is using the proceeds for working capital and general corporate purposes. Pursuant to the private offering the Company issued 6,744,127 shares of common stock, 2,309,428 shares of Series A non-voting convertible preferred stock and stock purchase warrants to acquire an additional 6,790,169 shares of common stock. Each share of non-voting convertible preferred stock was convertible at the option of the holder in whole or in part and from time to time into one share of common stock, is entitled to dividends on as "as converted basis" when and if dividends are issued to common stockholders, and participates in liquidation on a *pari passu* basis with common stockholders. Holders of the Series A non-voting convertible preferred stock subsequently converted all 2,309,428 shares of preferred stock into 2,309,428 shares of common stock. The stock purchase warrants issued as part of the units are exercisable at \$1.3125 per share beginning 90 days after closing for five years, expiring on May 18, 2021. On July 20, 2016, the Company's registration statement on Form S-3, registering for resale by the holders of the shares of common stock acquired in the private offering was declared effective by the SEC.

In August 2016, the Company filed a shelf registration statement on Form S-3 registering \$50 million of common stock for future offerings. The shelf registration statement was declared effective by the SEC on September 9, 2016.

On September 13, 2016, the Company entered into 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 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 the date of this prospectus, the Company has sold an aggregate of approximately 7.7 million shares of its common stock under this at-the-market offering resulting in aggregate net proceeds to the Company of approximately \$7.8 million, and gross proceeds of \$8.4 million. Under the initial sales agreement, remaining availability under the at-the-market offering is \$3.1 million.

## **Risk Factors**

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

- We need to raise money in this offering to fund our operations.
- We needed to obtain bridge financing to allow us to complete this offering and fund our operations.
- We have a history of losses, and we expect to incur losses for the next several years. Substantial doubt exists about our ability to continue as a going concern.
- We expect to make significant additional investments 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 are an early stage company with a history of losses, and we expect to incur net losses for the foreseeable future and may never achieve or sustain profitability.
- Our products and services may never achieve significant commercial market acceptance.
- Our future success is dependent upon our ability to expand our customer base.
- We depend on our information technology systems, and any failure of these systems could harm our business.
- We face competition from large, well-capitalized companies who are developing rapid diagnostic systems for MDROs. If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenue or achieve and sustain profitability.

## THE OFFERING

Units offered by us in this offering:	20,000,000 units, each consisting of one share of our common stock and one common warrant to purchase one share of our common stock
Pre-funded units offered by us in this offering:	We are also offering to each purchaser whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock) in lieu of units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding common stock (or, at the election of the purchaser, 9.99%). The purchase price of each pre-funded unit will equal the price at which the units are being sold to the public in this offering, minus \$0.01, and the exercise price of each pre-funded warrant included in each pre-funded unit will be \$0.01 per share. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. Because we will issue a common warrant as part of each unit or pre-funded unit, the number of common warrants sold in this offering will not change as a result of a change in the mix of the units and pre-funded units sold.
Common warrants offered by us in the offering	Common warrants to purchase an aggregate of 20,000,000 shares of our common stock. Each unit and each pre-funded unit includes a common warrant to purchase one share of our common stock. Each common warrant will have an exercise price of \$ per share, will be immediately separable from the common stock or pre-funded warrant, as the case may be, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.
Common stock outstanding prior to this offering:	27,377,490 shares of common stock
Common stock outstanding after this offering:	47,377,490 shares of common stock (assuming no sale of any pre-funded units and assuming none of the common warrants issued in this offering are exercised).
Use of Proceeds:	We currently intend to use the net proceeds of this offering for general corporate purposes, including working capital and product development, particularly development of our one to three hour antibiotic resistance diagnostic product and repayment of all outstanding bridge financing notes (up to \$1,500,000 plus accrued interest). See "Use of Proceeds" on page 43 of this prospectus.
Risk Factors:	Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 13 of this prospectus and the other information included or incorporated by reference in this prospectus.
The NASDAQ Capital Market symbol	"OPGN" We do not plan on applying to list the pre-funded warrants or the common warrants on NASDAQ, any national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants or common warrants will be limited.

The number of shares of common stock to be outstanding immediately after this offering is based on 27,377,490 shares of our common stock outstanding as of March 31, 2017, and excludes:

- 1,971,451 shares of common stock issued under our at-the-market offering since March 31, 2017;
- 16,800 shares of common stock issued upon the exercise of outstanding options granted under our equity incentive plans since March 31, 2017;
- 3,514,071 shares of common stock issuable upon the exercise of outstanding options granted as of March 31, 2017, under our equity incentive plans at a weighted average exercise price of \$1.48 per share;
- 10,506,524 shares of common stock issuable upon the exercise of outstanding warrants issued as of March 31, 2017, at a weighted average exercise price of \$3.23 per share;
- 627,570 shares of common stock issuable upon exercise of warrants issued to jVen Capital and MGHIF since March 31, 2017;
- 18,750 shares of common stock issuable upon vesting of outstanding restricted stock units granted as of March 31, 2017;
- 1,145,402 shares of common stock available for future issuance under our equity incentive plans as of March 31, 2017;
- 20,000,000 shares of common stock issuable upon the exercise of common warrants to be issued to investors in this offering at an exercise price of \$ per share; and
- 1,000,000 shares of common stock issuable upon exercise of warrants to be issued to the placement agent as described in “Plan of Distribution.”

The number of outstanding options, restricted stock units and shares of common stock available for future issuances under our equity incentive plans do not reflect grants of 26,500 restricted stock units, grants of options to purchase 146,000 shares of our common stock with a weighted average exercise price of \$0.73 per share or forfeitures of options to purchase 303,047 shares of our common stock since March 31, 2017.

jVen Capital, LLC has informed the Company that it intends to participate in this offering in an amount up to \$1,000,000. However, because indications of interest are not binding agreements or commitments to purchase, jVen Capital LLC may determine to purchase fewer securities than it indicates an interest in purchasing or not to purchase any securities in this offering.



## **Company and Other Information**

OpGen, Inc. was incorporated in Delaware in 2001. On July 14, 2015, the Company acquired AdvanDx, Inc., a Delaware corporation, as a wholly owned subsidiary in a merger transaction, or the AdvanDx Merger. 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. Our principal executive office is located at 708 Quince Orchard Road, Gaithersburg, Maryland, 20878, and our telephone number is (240) 813-1260. Our website address is [www.opgen.com](http://www.opgen.com). We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

## **Implications of Being an Emerging Growth Company**

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. An “emerging growth company” may take advantage of exemptions from some of the reporting requirements that are otherwise applicable to public companies. These exceptions include:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering in May 2015. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenue exceeds \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

## SUMMARY FINANCIAL DATA

The following summary financial data should be read together with our financial statements and related notes, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” appearing elsewhere in this prospectus. The summary statements of operations data for the years ended December 31, 2016 and 2015 and the three months ended March 31, 2017 and 2016, and the balance sheet data as of March 31, 2017 have been derived from our audited financial statements and unaudited interim condensed financial statements included elsewhere in this prospectus. Historical results are not necessarily indicative of the results that may be expected in the future and results of interim periods are not necessarily indicative of the results for the entire year.

	Year Ended December 31,		Three Months Ended March 31,	
	2016	2015	2017	2016
	(In thousands, except per share data) (Unaudited)			
<b>Statements of Operations Data:</b>				
Revenue	\$ 4,026	\$ 3,158	\$ 772	\$ 1,077
Operating expenses:				
Cost of products sold	1,659	1,180	425	346
Cost of services <sup>(1)</sup>	631	368	100	316
Research and development <sup>(1)</sup>	8,613	6,003	2,123	1,953
General and administrative <sup>(1)</sup>	6,603	5,835	1,969	1,538
Sales and marketing <sup>(1)</sup>	5,529	4,305	1,106	1,400
Transaction expenses	-	526	-	-
Total operating expenses <sup>(1)</sup>	<u>23,035</u>	<u>18,217</u>	<u>5,723</u>	<u>5,553</u>
Operating loss	(19,009)	(15,059)	(4,951)	(4,476)
Interest and other (expense) income	(6)	26	-	-
Interest expense	(144)	(1,801)	(30)	(42)
Foreign currency transaction gains (losses)	(8)	-	3	12
Change in fair value of derivative financial instruments	-	(647)	-	-
Provision for income taxes	-	(129)	-	-
Net loss	<u>\$ (19,167)</u>	<u>\$ (17,352)</u>	<u>\$ (4,978)</u>	<u>\$ (4,506)</u>
Net loss available to common stockholders	<u>\$ (19,499)</u>	<u>\$ (17,596)</u>	<u>\$ (4,978)</u>	<u>\$ (4,506)</u>
Net loss per common share, basic and diluted	<u>\$ (1.10)</u>	<u>\$ (2.20)</u>	<u>\$ (0.19)</u>	<u>\$ (0.36)</u>
Weighted average shares outstanding – basic and diluted	<u>17,668</u>	<u>7,981</u>	<u>26,079</u>	<u>12,569</u>

(1) Includes stock-based compensation as follows:

	Year Ended December 31,		Three Months Ended March 31,	
	2016	2015	2017	2016
	(Unaudited)			
Cost of services	\$ 6,003	\$ -	\$ 1,823	\$ 4,312
Research and development	236,341	240,739	57,778	62,218
General and administrative	599,550	619,899	152,476	172,103
Sales and marketing	103,567	584,450	33,328	22,864
Total stock-based compensation	<u>\$ 945,461</u>	<u>\$ 1,445,088</u>	<u>\$ 245,405</u>	<u>\$ 261,497</u>

	<b>As of March 31, 2017</b>	
	<b>Actual</b>	<b>As Adjusted</b>
	<b>(In thousands) (Unaudited)</b>	
<b>Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 1,620	\$ 11,080
Working capital (deficit)	(2,160)	7,250
Total assets	6,157	15,567
Accumulated deficit	(138,269)	(138,269)
Total stockholders' equity	554	9,964

The preceding table presents a summary of our unaudited balance sheet data as of March 31, 2017:

- on an actual basis;
- on an as adjusted basis to give effect to the receipt of the estimated net proceeds from the sale of an aggregate of 20,000,000 units and no pre-funded units in this offering at the assumed offering price of \$0.55 per unit and the issuance of 20,000,000 shares of common stock included in the units.

A \$0.10 increase or decrease in the assumed public offering price of \$0.55 per unit, based on the last reported sale price for our common stock as reported on the NASDAQ Capital Market on July 7, 2017, would decrease or increase the number of shares of our common stock included in the units and issuable upon the exercise of pre-funded warrants included in the pre-funded units issued in this offering by approximately 4.4 million shares or 3.1 million shares, respectively.

## RISK FACTORS

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

### **Risks Related to this Offering and Our Securities**

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

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the three months ended March 31, 2017, we had a net loss of \$5.0 million. From our inception through March 31, 2017, we had an accumulated deficit of \$138.3 million. We believe that current cash on hand, plus the bridge financing, excluding any additional bridge financings, other financings, or further cash conservation measures will be sufficient to fund operations through the end of July 2017. In the event we are unable to successfully raise sufficient capital in this offering, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing. We have no additional committed sources of capital and may find it difficult to raise money on terms favorable to us or at all. The failure to obtain sufficient capital to support our operations would have a material adverse effect on our business, financial condition and results of operations. If such sufficient financing is not received timely, we would then need to pursue a plan to license or sell assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

***We needed bridge financing from a principal stockholder and an affiliate of our Chairman of the Board and Chief Executive Officer to provide us with financing in order to complete this offering and for our operations. If we are not able to complete this offering as a qualified financing we may be unable to repay the outstanding bridge financing notes, and our financial position will be materially adversely impacted.***

On May 31, 2017, the Company entered into a Note Purchase Agreement (amended and restated on July 10, 2017) with jVen Capital under which jVen Capital agreed to lend up to \$1,500,000 to the Company in the form of three \$500,000 secured convertible promissory notes to provide bridge financing for this offering and fund our operations. As of the date of this prospectus, \$1,000,000 principal amount of bridge financing notes and warrants to purchase 299,575 shares of common stock have been issued to jVen Capital. jVen Capital is an affiliate of Evan Jones, the Company's Chairman of the Board and Chief Executive Officer. The principal terms of the bridge financing provided under the amended and restated Note Purchase Agreement are described in the Prospectus Summary and include an interest rate of 10% per annum (increased to 15% in an event of default), the issuance of warrants to purchase common stock equal to 20% of the principal balance of each bridge financing note, and a maturity date of September 30, 2017, subject to acceleration or extension, and, in an event of default, the outstanding bridge financing notes will acquire a two times liquidation preference for unpaid principal and interest, unless jVen Capital exercises its option to convert the outstanding bridge financing notes to Preferred Stock at a ratio of one share of Preferred Stock per \$1.00 of principal and interest, which Preferred Stock shall be convertible into 10 shares of voting common stock, otherwise no further preferences are provided to the Preferred Stock. If the net proceeds in this offering are equal to or more than \$5,000,000, then the maturity date of the outstanding bridge financing notes will accelerate to the date that is five business days after the closing of this offering, and we will use net proceeds to repay the outstanding bridge financing notes up to \$1,500,000, plus accrued interest. If we are not successful in raising sufficient net proceeds, the secured bridge financing notes will mature on September 30, 2017, subject to extension to no later than December 31, 2017 if we are pursuing a qualified financing. We may be unable to repay the outstanding bridge financing notes at September 30, 2017 or any such extended maturity date. Such failure to repay the outstanding bridge financing notes could have a material adverse effect on our financial condition.

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

Our management will have broad discretion as to the application of the net proceeds and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not increase our results of operations or the market value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development and approval of our products and cause the price of our common stock to decline.

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

Because the effective price per share of common stock included in the units or issuable upon exercise of the preferred warrants included in the pre-funded units being offered may be higher than the net tangible book value per share of our common stock, you will experience dilution to the extent of the difference between the effective offering price per share of common stock you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value as of March 31, 2017, was approximately (\$1.6) million, or (\$0.06) per share of common stock. Net tangible book value per share is equal to our total tangible assets minus total liabilities, all divided by the number of shares of common stock outstanding. See “Dilution” on page 45 for a more detailed discussion of the dilution you will incur in this offering.

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

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

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

***There is no public market for the common warrants to purchase shares of our common stock included in the units and the pre-funded units being offered by us in this offering.***

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

***The common warrants are speculative in nature.***

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

***Directors, executive officers and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in the best interests of our stockholders.***

Our current officers, directors, their affiliated entities and affiliates collectively own approximately 32% of our outstanding common stock. In addition, under the bridge financing, if we default on repayment of the secured promissory notes, jVen Capital could obtain more significant ownership of the Company's securities. As a result, if some or all of our directors, executive officers and affiliated entities acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of the Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

***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 July 7, 2017, the market price of our common stock fluctuated from a high of \$4.85 per share to a low of \$0.54 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 32% of the issued and outstanding shares of our common stock is held by officers, directors and beneficial owners of at least 10% of our outstanding shares, each of whom is subject to certain restrictions with regard to trading our common stock. In addition, MGHIF became our principal stockholder following the 2016 PIPE financing transaction; as of July 7, 2017, it owns approximately 18.4% of our outstanding common stock, and has the right to acquire approximately 3.0 million additional shares upon the exercise of stock purchase warrants, which, if exercised, could put its ownership at approximately 25.9% of our outstanding shares. These factors may result in different prices for our common stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and asked prices for our common stock. In addition, without a large public float, our common stock is less liquid than the stock of companies with broader public ownership, and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future, if at all.

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

As of March 31, 2017, we had outstanding warrants to acquire 10,506,524 shares of our common stock, and stock options to purchase 3,514,071 shares of our common stock. The expiration of the term of such options and warrants range from June 2017 to February 2027. 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 committed to issue additional warrants to purchase common stock to jVen Capital and MGHIF to obtain bridge financing from jVen Capital and to restructure the MGHIF Note to extend the maturity date. As of the date of this prospectus, we have issued warrants to purchase an aggregate of 627,570 shares of common stock to jVen Capital and MGHIF. Such warrants add to the dilution impact if exercised.

***We received deficiency notices from The NASDAQ Capital Market. If we are unable to cure these deficiencies and meet the NASDAQ continued listing requirements, we could be delisted from the NASDAQ Capital Market which would negatively impact the trading of our common stock.***

On May 12, 2017, the Company received a written notice from The Nasdaq Stock Market LLC, or NASDAQ, notifying the Company that it fails to comply with NASDAQ's Marketplace Rule 5550(b)(1) because the Company's stockholders' equity as of March 31, 2017 fell below the required minimum of \$2,500,000, and, as of May 12, 2017, the Company does not meet the alternative compliance standards of market value of listed securities or net income from continuing operations for continued listing. In accordance with NASDAQ's listing requirements, the Company submitted a plan to regain compliance within 45 days after receipt of the notice. If the plan is accepted, NASDAQ can grant the Company an extension of up to 180 calendar days from the date it received the notification to evidence compliance. There can be no assurance that the Company's plan will be accepted or that if it is, the Company will be able to regain compliance.

On June 20, 2017, we received notice from NASDAQ that we had failed to maintain a bid price of at least \$1.00 per share for 30 successive trading days. We have a minimum of six months to regain compliance with the listing standard, and may be able to obtain an additional six-month compliance period. However, there can be no assurance that we will be able to maintain the NASDAQ Capital Market listing of our common stock in the future.

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

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

***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, the MGHIF Note and the bridge financing promissory notes and related security agreements restrict our ability to pay cash dividends on our common stock and 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.

### **Risks Related to Our Business**

***We have a history of losses, and we expect to incur losses for the next several years. 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 three months ended March 31, 2017, we had a net loss of \$5.0 million. From our inception through March 31, 2017, we had an accumulated deficit of \$138.3 million. We completed a number of financings in 2016, including a private investment in public equity, or PIPE, in May and June 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 2016 financings were approximately \$13.9 million. As of March 31, 2017, the Company has raised \$6.9 million in aggregate gross proceeds through the ATM. We expect to raise additional funds through capital transactions in 2017. We believe that current cash on hand, plus the bridge financing, excluding any additional bridge financings, other financings, or further cash conservation measures will be sufficient to fund operations through end of July 2017. In the event we are unable to successfully raise sufficient capital during this offering, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing. We have no 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.

With financing, we expect to continue to incur significant operating expenses relating to, among other things:

- commercializing our rapid pathogen identification and Acuitas MDRO and Acuitas Lighthouse informatics services;
- developing our Acuitas Rapid Test products and services for antibiotic resistance testing, and our automated rapid molecular diagnostic products;
- 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;
- 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 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 Rapid Test in development, Acuitas MDRO tests, informatics services and QuickFISH products and 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 the date of this prospectus, we have raised approximately \$8.4 million in gross proceeds 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.

In the event we are unable to successfully raise sufficient capital in this offering, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to 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. We amended and restated the MGHIF Note in June 2017 in connection with the bridge financing. The amended and restated MGHIF Note requires interest-only payments at a rate of 10% per annum, with the principal due and payable on July 14, 2018. We also provided secured creditor rights to jVen Capital in connection with the bridge financing described in the Prospectus Summary. Such secured creditor rights could negatively impact our ability to raise money in the future. If we default on payments under any of the secured promissory notes, MGHIF and jVen Capital have the rights of a secured creditor. If those rights are exercised, it could have a material adverse effect on our 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 informatics, 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 rapid pathogen identification and Acuitas MDRO 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 currently beginning development of 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. Our intent is to identify over 100 antibiotic resistance genes to help guide clinician antibiotic therapy decisions when test results are evaluated using the Acuitas Lighthouse. 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, identify and license a third-party rapid array platform, 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.

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

The sales cycles for our Acuitas MDRO test products and services and for our Acuitas Lighthouse services are 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 may enter into agreements with U.S. or other government agencies, which could be subject to uncertain future funding.***

The presence of MDROs and the need for antibiotic stewardship activities have prompted state, federal and international government agencies to develop programs to combat the effects of MDROs. In the future, we may seek to enter into agreements with governmental funding sources or contract with government healthcare organizations to sell our products and services. If we enter into such funding 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.

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

We rely principally on the commercialization of our QuickFISH and Acuitas MDRO test products and our Acuitas Lighthouse services 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 product 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 MDRO test products and services, which includes our QuickFISH products, and our Acuitas Lighthouse informatics services and 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.

***We may fail to realize some or all of the anticipated benefits of the business combination of OpGen and AdvanDx, which may adversely affect the value of our common stock.***

The success of the continued integration of AdvanDx will depend, in part, on our ability to realize the anticipated benefits and cost savings from combining the respective business and operations of OpGen and AdvanDx. To realize these anticipated benefits and cost savings, we must successfully combine the acquired business with our legacy operations and integrate our respective operations, technologies and personnel, which is particularly challenging given the geographic and cultural differences between the personnel and facilities based in Maryland and Massachusetts, plus the European operations of AdvanDx, and the lack of experience we have in combining businesses. If we are not able to fully achieve these objectives within the anticipated time frame or at all, the anticipated benefits and cost savings of the acquisition may not be realized fully or at all or may take longer to realize than expected, and the value of our common stock may be adversely affected. In addition, the overall integration of the businesses is a complex, time-consuming and expensive process that, without proper planning and effective and timely implementation, could significantly disrupt our operations.

Risks in integrating AdvanDx into our operations in order to realize the anticipated benefits of the acquisition include, among other factors:

- coordinating research and development activities to enhance the introduction of new diagnostic tests and technology of the combined business;
- failure to successfully integrate and harmonize financial reporting and information technology systems of the two companies;
- retaining each company's relationships with its partners;
- retaining and integrating key employees from OpGen and AdvanDx;
- managing effectively the diversion of management's attention from business matters to integration issues;
- combining research and development capabilities effectively and quickly;
- integrating partnership efforts so that new partners acquired can easily do business with us; and
- transitioning all facilities to a common information technology environment.

Actual cost synergies, if achieved at all, may be lower than we expect and may take longer to achieve than anticipated. If we are not able to adequately address these challenges, we may be unable to successfully integrate the operations of the business acquired from AdvanDx into our own, or to realize the anticipated benefits of the integration. The anticipated benefits and synergies assume a successful integration and are based on projections, which are inherently uncertain, and other assumptions. Even if integration is successful, anticipated benefits and synergies may not be achieved. An inability to realize the full extent of, or any of, the anticipated benefits of the acquisition, as well as any delays encountered in the integration process, could have an adverse effect on our business and results of operations, which may affect the value of the shares of our common stock.

***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 MDRO test and informatics products and services 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, PNA Fish and XpressFISH 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 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 manufacture our QuickFISH, PNA Fish and XpressFISH products in a leased facility located in Woburn, Massachusetts. 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. If we decide to relocate the facility, we will need to obtain all necessary FDA certifications, which 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 2017 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 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 further 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 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 \$151.0 million and research and development tax credits of \$2.6 million as of December 31, 2016, that may already be or could be limited if we experience an ownership change.

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

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

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

### **Risks Related to Our Public Company Status**

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

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

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

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

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

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

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

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

## **Risks Related to Regulation of Our Business**

***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 New York or from other 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. Furthermore, certain of our future products, including specimen transport containers we may develop such as Grow on the Go, might be regulated as Class I medical devices for which premarket clearance or approval may not be required, subject to certain limitations. 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, President Obama signed into law 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. 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 was suspended in December 2015 for two years, 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. In May 2017, we entered into a secured bridge financing facility with jVen Capital, which is also secured by a lien on our assets, including our intellectual property assets. If we default on our payment obligations under any of these secured promissory notes, the secured creditors have 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.

## INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect” or the negative version of these words and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors”. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to finance our operations;
- the completion of our development efforts for the Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase, 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;
- 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;



- changes in laws or regulations applicable to our business, including potential 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. These risks should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to the risk factors described in this prospectus. Other risks may be described from time to time in our filings made under the securities laws. New risks emerge from time to time. It is not possible for our management to predict all risks. All forward-looking statements in this prospectus speak only as of the date made and are based on our current beliefs and expectations. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to the risk factors described in this prospectus. Other risks may be described from time to time in our filings made under the securities laws. New risks emerge from time to time. It is not possible for our management to predict all risks. All forward-looking statements in this prospectus speak only as of the date made and are based on our current beliefs and expectations. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

## USE OF PROCEEDS

We estimate the net proceeds from this offering will be approximately \$9.4 million, from the sale of our securities in this offering, based on an assumed offering price of \$0.55 per unit and assuming the sale of 20,000,000 units and no sale of any pre-funded units in this offering, after deducting estimated placement agent's fees and expenses and our estimated offering expenses. The public offering price per unit or pre-funded unit will be determined between us and the placement agent based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. This estimate excludes the proceeds, if any, from the exercise of common warrants in this offering. If all of the common warrants sold in this offering were to be exercised in cash at an assumed exercise price of \$0.55 per share, we would receive additional net proceeds of approximately \$5 million. We cannot predict when or if these common warrants will be exercised. It is possible that these common warrants may expire and may never be exercised.

If this offering raises at least \$5 million in net proceeds we are obligated to use up to \$1,500,000, plus accrued interest, to pay off the outstanding bridge financing notes to jVen Capital. We currently intend to use the remaining net proceeds of this offering for research and development, including funding the continued development and manufacturing of our Acuitas Rapid Test that is expected to be released for RUO customers in the first half of 2018, support acquisitions of products and technologies, capital expenditures, working capital and other general corporate purposes .

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

- repayment of outstanding bridge financing notes, if this offering is a qualified offering ;
- completion of development of Acuitas Rapid Test for cUTI and Acuitas Lighthouse Knowledgebase;
- support of acquisitions of products and technologies;
- initial commercialization efforts for the Acuitas Rapid Test for cUTI and Acuitas Lighthouse Knowledgebase; and
- the balance for general corporate purposes, such as general and administrative expenses, capital expenditures and working capital needs.

The expected use of net proceeds of this offering represents our current intentions based upon our present plan and business conditions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. Our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

Pending specific utilization of the net proceeds described above, we intend to invest the net proceeds in United States government securities and other short term, investment grade, interest bearing securities.

A \$0.10 increase or decrease in the assumed public offering price of \$0.55 per unit, based on the last reported sale price for our common stock as reported on the NASDAQ Capital Market on July 7, 2017, would decrease or increase the number of shares of our common stock included in the units and issuable upon the exercise of pre-funded warrants included in the pre-funded units offered in this offering by approximately 4.4 million shares or 3.1 million shares, respectively.

Similarly, a one million unit or pre-funded unit increase or decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the net proceeds to us by approximately \$0.5 million, assuming the assumed public offering price of \$0.55 per unit and \$0.54 per pre-funded unit remains the same, and after deducting estimated placement agent fees and expenses and estimated offering expenses payable by us.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2017. As of July 7, 2017, our cash and cash equivalents are approximately \$622,000. You should read this table in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this prospectus.

	As of March 31, 2017	
	Actual	As Adjusted
	(In thousands, except share and per share data)	
	(Unaudited)	
Cash and cash equivalents	\$ 1,670	\$ 11,080
Short-term debt, net of discount	\$ 999	\$ 999
Stockholder's (deficit) equity:		
Common stock, par value \$0.01 per share: 200,000,000 shares authorized, 27,377,490 shares issued and outstanding, actual; 200,000,000 shares authorized, 47,377,490 issued and outstanding, as adjusted	274	474
Preferred stock, par value \$0.01 per share; 10,000,000 shares authorized, no shares outstanding, actual and as adjusted		
Additional paid-in capital	138,547	147,757
Accumulated other comprehensive income	2	2
Accumulated deficit	(138,269)	(138,269)
Total stockholders' (deficit) equity	554	9,964
Total capitalization	\$ 1,553	\$ 10,963

A \$0.10 increase or decrease in the assumed public offering price of \$0.55 per unit, based on the last reported sale price for our common stock as reported on the NASDAQ Capital Market on July 7, 2017, would decrease or increase the number of shares of our common stock included in the units and issuable upon the exercise of pre-funded warrants included in the pre-funded units offered in this offering by approximately 4.4 million shares or 3.1 million shares, respectively.

The number of shares of common stock outstanding in the table above excludes options and warrants to purchase an aggregate of 14,020,595 shares of our common stock at exercise prices ranging from \$0.05 to \$790.54 per share with a weighted average exercise price of \$2.80 per share outstanding as of March 31, 2017, 18,750 restricted stock units outstanding at March 31, 2017, 26,500 restricted stock units granted since March 31, 2017, options to purchase 146,000 shares of common stock with a weighted average exercise price of \$0.73 per share granted since March 31, 2017, warrants to purchase an aggregate of 627,570 issued to jVen Capital and MGHIF since March 31, 2017, and forfeitures of stock options to purchase 303,047 shares of our common stock since March 31, 2017, in addition to 20,000,000 shares of common stock issuable upon the exercise of common warrants to be issued in this offering and 1,000,000 shares of common stock issuable upon the exercise of common warrants to be issued to the placement agent in connection with this offering.

## DILUTION

Our net tangible book value as of March 31, 2017 was approximately (\$1.6) million, or (\$0.06) per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of March 31, 2017. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the assumed sale of 20,000,000 units in this offering at an assumed offering price of \$0.55 per unit, based on the last reported sale price of our common stock on The NASDAQ Capital Market on July 7, 2017, assuming no sale of any pre-funded units in this offering and after deducting estimated placement agent's fees and estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2017 would have been approximately \$7.8 million, or \$0.16 per share, which excludes the common warrants to purchase 20,000,000 shares of our common stock to be issued to investors in this offering. This represents an immediate increase in net tangible book value of \$0.22 per share to existing stockholders and immediate dilution of \$0.39 per share to investors purchasing our securities in this offering at the public offering price. The following table illustrates this dilution on a per share basis:

Assumed public offering price per unit		\$	0.55
Net tangible book value per share of as March 31, 2017		\$	(0.06)
Increase in net tangible book value per share attributable to this offering		\$	<u>0.22</u>
As adjusted net tangible book value per share as of March 31, 2017, after giving effect to this offering		\$	<u>0.16</u>
Dilution per share to new investors purchasing our common stock in this offering		\$	0.39

The above discussion and table are based on 27,377,490 shares outstanding as of March 31, 2017, and excludes:

- 1,971,451 shares of common stock issued under our at-the-market offering since March 31, 2017;
- 16,800 shares of common stock issued upon the exercise of outstanding options granted under our equity incentive plans since March 31, 2017;
- 3,514,071 shares of common stock issuable upon the exercise of outstanding options granted as of March 31, 2017, under our equity incentive plans at a weighted average exercise price of \$1.48 per share;
- 10,506,524 shares of common stock issuable upon the exercise of outstanding warrants issued as of March 31, 2017, at a weighted average exercise price of \$3.23 per share;
- 627,570 shares of common stock issuable upon exercise of warrants issued to jVen Capital and MGHIF since March 31, 2017;
- 18,750 shares of common stock issuable upon vesting of outstanding restricted stock units as of March 31, 2017;
- 1,145,402 shares of common stock available for future issuance under our equity incentive plans as of March 31, 2017;
- 20,000,000 shares of common stock issuable upon the exercise of common warrants to be issued to investors in this offering at an exercise price of \$ per share; and
- 1,000,000 shares of common stock issuable upon exercise of warrants to be issued to the placement agent as described in "Plan of Distribution."

The number of outstanding options, restricted stock units and shares of common stock available for future issuances under our equity incentive plans do not reflect grants of 26,500 restricted stock units, grants of options to purchase 146,000 shares of common stock with a weighted average exercise price of \$0.73 per share or forfeitures of stock options to purchase 303,047 shares of our common stock since March 31, 2017. To the extent that options or warrants outstanding as of March 31, 2017 have been or may be exercised or other shares issued, investors purchasing the units in this offering may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

**PRICE RANGE FOR OUR COMMON EQUITY AND RELATED SHAREHOLDER MATTERS**

**Market Information**

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

	<u>High</u>	<u>Low</u>
<b>Common Stock:</b>		
<b>Year Ended December 31, 2015</b>		
Second Quarter (beginning May 5, 2015)	\$ 5.43	\$ 3.12
Third Quarter	\$ 4.43	\$ 2.21
Fourth Quarter	\$ 2.79	\$ 1.45

<b>IPO Warrants:</b>		
<b>Year Ended December 31, 2015</b>		
Second Quarter (beginning May 5, 2015)	\$ 0.95	\$ 0.50
Third Quarter	\$ 0.84	\$ 0.30
Fourth Quarter	\$ 0.59	\$ 0.25

	<u>High</u>	<u>Low</u>
<b>Common Stock:</b>		
<b>Year Ended December 31, 2016</b>		
First Quarter	\$ 1.96	\$ 1.36
Second Quarter	\$ 1.78	\$ 1.03
Third Quarter	\$ 3.70	\$ 1.36
Fourth Quarter	\$ 1.76	\$ 0.89

<b>IPO Warrants:</b>		
<b>Year Ended December 31, 2016</b>		
First Quarter	\$ 0.35	\$ 0.19
Second Quarter	\$ 0.46	\$ 0.11
Third Quarter	\$ 0.49	\$ 0.13
Fourth Quarter	\$ 0.26	\$ 0.09

	<u>High</u>	<u>Low</u>
<b>Common Stock:</b>		
<b>Year Ending December 31, 2017</b>		
First Quarter	\$ 1.50	\$ 0.99
Second Quarter	\$ 1.18	\$ 0.54
Third Quarter (through July 7, 2017)	\$ 0.63	\$ 0.55

<b>IPO Warrants:</b>		
<b>Year Ending December 31, 2017</b>		
First Quarter	\$ 0.17	\$ 0.07
Second Quarter	\$ 0.14	\$ 0.04
Third Quarter (through July 7, 2017)	\$ 0.1395	\$ 0.111

**Stockholder Information**

As of June 15, 2017, there were approximately 65 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**

No cash dividends have been declared or paid on our common stock to date. 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. In addition, the MGHIF Note and the bridge financing notes prohibit us from declaring or paying cash dividends or making cash distributions on any class of our capital stock.

## DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 200,000,000 shares of common stock, par value \$0.01 per share, and 10,000,000 shares of preferred stock, par value \$0.01 per share, of which 7,690,572 shares are available for issuance. The following is a summary of the rights of our common and preferred stock and the warrants offered hereby, and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws and the Delaware General Corporation Law. Because it is only a summary, it does not contain all of the information that may be important to you. Such summary is subject to and qualified in its entirety by our amended and restated certificate of incorporation and our amended and restated bylaws, a copy of each of which has been incorporated as an exhibit to the registration statement of which this prospectus forms a part.

### **Common Stock**

Of the authorized common stock, as of July 7, 2017, there were 29,365,741 shares outstanding. As of July 7, 2017, there were 14,519,568 shares of our common stock reserved for the exercise of outstanding stock options, warrants and restricted stock units. There were approximately 65 record holders as of July 7, 2017. The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by the Board of Directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions .

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

### **Preferred Stock**

#### ***Series A Convertible Preferred Stock***

Of the authorized preferred stock, the Company issued 2,309,428 shares of Series A Convertible Preferred Stock. As of August 10, 2016, no shares of the Series A Convertible Preferred Stock were outstanding. The holder of the Series A Convertible Preferred Stock converted all 2,309,428 shares of Series A Convertible Preferred Stock into 2,309,428 shares of common stock. All such converted shares of Series A Convertible Preferred Stock were canceled and will not be reissued.

#### ***Additional Series of Preferred Stock***

Our Board of Directors has the authority, without further action by our stockholders, to issue from time to time 7,690,572 shares of preferred stock in one or more series. Our Board of Directors will have the authority to establish the number of shares to be included in each series and fix the powers, preferences and rights of the shares of each wholly unissued series and any of its qualifications, limitations or restrictions. Our Board of Directors will also be able to increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by the stockholders.

The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of common stock or adversely affect the rights and powers, including voting rights, of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our Company, which could depress the market price of our common stock. We have no current plans to issue any additional shares of preferred stock.

## **Outstanding Warrants**

### ***IPO Warrants***

The warrants to purchase common stock that we issued in our initial public offering, or the IPO Warrants, entitle the registered holder to purchase one share of common stock at a price equal to \$6.60 per share, subject to adjustment as discussed below, immediately following the issuance of such IPO Warrants and terminate at 5:00 p.m., New York City time, on May 8, 2020 or earlier upon the dissolution or winding up of the Company. We have listed the IPO Warrants on the NASDAQ Capital Market, as a standalone security under the symbol "OPGNW."

The IPO Warrants were issued pursuant to a Warrant Agreement between us and our transfer agent as the Warrant Agent. The exercise price and number of shares of common stock issuable upon exercise of the IPO Warrants may be adjusted in certain circumstances, including in the event of a stock dividend or recapitalization, reorganization, merger or consolidation.

The IPO Warrants may be exercised upon surrender of the applicable Warrant Certificate on or prior to the applicable expiration date at the offices of the Warrant Agent, with the exercise form on the reverse side of the Warrant Certificate completed and executed as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, unless such holders are willing to exercise their IPO Warrants on a cashless basis, as further described in this Warrant Agreement, for the number of IPO Warrants being exercised. Under the terms of the Warrant Agreement, we have agreed to use our reasonable best efforts to maintain the effectiveness of a registration statement and prospectus relating to common stock issuable upon exercise of the IPO Warrants until the expiration of the IPO Warrants. The Offered Warrant holders do not have the rights or privileges of holders of common stock or any voting rights until they exercise their IPO Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the IPO Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

A holder may not exercise any portion of an Offered Warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would own more than 4.99% of the outstanding common stock after exercise, as such percentage ownership is determined in accordance with the terms of the Offered Warrant. The foregoing limitation on exercise shall not apply to any registered holder of an Offered Warrant who, together with his, her or its affiliates, and any persons acting as a group together with such registered holder and such registered holder's affiliates, owns in excess of 4.99% immediately prior to the closing of this offering. In addition, upon at least 61 days' prior notice from the holder to us, the holder may waive such limitation.

No fractional shares of common stock will be issued upon exercise of the IPO Warrants. If, upon exercise of the Offered Warrant, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round to the nearest whole number of shares of common stock to be issued to the Offered Warrant holder. If multiple IPO Warrants are exercised by the holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all the IPO Warrants.

### ***2016 PIPE Warrants***

Pursuant to the terms of the Amended & Restated Purchase Agreement, dated as of May 18, 2016, by and among the Company and the purchasers party thereto, the purchasers purchased 9,053,556 warrants, or the PIPE Warrants, exercisable for an aggregate of 6,790,169 shares of common stock, or the PIPE Warrant Shares, in the PIPE Financing. The PIPE Warrants are exercisable at an exercise price of \$1.3125 per share of common stock, became exercisable 90 days after the date of issuance, and may be exercised for five years from the date of issuance. The exercise price and the number of PIPE Warrant Shares will be adjusted to account for the subdivision or combination by the Company of outstanding shares of common stock. The exercise price may, at any time, also be voluntarily reduced at the discretion of the Board of Directors of the Company. The PIPE Warrants may be exercised pursuant to a cashless exercise, but only if a registration statement covering the resale of the PIPE Warrant Shares that are the subject of an exercise notice is not available for the resale of such PIPE Warrant Shares.

The PIPE Warrants also contain certain provisions providing for liquidated damages to be paid by the Company in the event the Company does not timely deliver registered shares of common stock to the holder upon exercise of a PIPE Warrant. Specifically, in addition to the PIPE Warrant holder's other available remedies, if the Company fails to issue and deliver (or cause to be delivered) to a holder by the required delivery date a certificate representing the shares so delivered to the Company by such holder that is free from all restrictive and other legends, the Company shall pay to a holder in cash, as partial liquidated damages and not as a penalty, an amount equal to 1% of the product of (A) the aggregate number of shares of common stock not issued to the holder on a timely basis and to which the holder is entitled and (B) the closing sale price on the trading day immediately preceding the required delivery date of the certificate, per trading day for each trading day after such required delivery date until such securities are delivered to the holder. In addition, if the Company fails to (i) issue and deliver (or cause to be delivered) to a holder by the required delivery date a certificate representing the shares so delivered to the Company by such holder that is free from all restrictive and other legends or (ii) if after the required delivery date such holder purchases (in an open market transaction or otherwise) shares of common stock to deliver in satisfaction of a sale by such holder of all or any portion of the number of shares of common stock, or a sale of a number of shares of common stock equal to all or any portion of the number of shares of common stock that such holder anticipated receiving from the Company without any restrictive legend, then, the Company shall either (y) pay cash to the holder in an amount equal to the holder's total purchase price (including brokerage commissions and other out-of-pocket expenses, if any) for the shares of Common Stock so purchased, or the Buy-In Price, at which point the Company's obligation to deliver such shares shall terminate, or (z) promptly honor its obligation to deliver to the holder a certificate or certificates representing such shares and pay cash to the holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (1) such number of shares of common stock that the Company was required to deliver multiplied by (2) the lowest closing sale price of the common stock on any trading day during the period commencing on the date of the delivery by such holder to the Company of the applicable shares (as the case may be) and ending on the date of such delivery and payment under this clause (z).

### ***Warrants issued in Bridge Financing***

Pursuant to the Note Purchase Agreement and the underlying transactions, the Company has issued warrants to purchase shares of its common stock to jVen Capital in an amount equal to twenty percent (20%) of the principal of each of the two bridge financing notes issued as of the date of this prospectus, or the jVen Capital Warrants, and warrants to purchase shares of its common stock to MGHIF in an amount equal to twenty percent (20%) of the outstanding principal and accrued interest under the amended and restated MGHIF Note on June 28, 2017, the date of issuance. The warrants each have a five year term from issuance, are first exercisable on the date that is six months after the date of issuance and have an exercise price equal to 110% of the closing price of the Company's common stock on the date immediately prior to the date of issuance. If this offering closes, the terms of these issued warrants (other than the exercise price and the number of shares) can be amended, in the discretion of the holder, to reflect the terms of the warrants issued in this offering.

The jVen Warrants each include a blocker provision that prevents the exercise of the jVen Warrants if such exercise, when aggregated with the other issuances contemplated under the Note Purchase Agreement, would violate NASDAQ Listing Rule 5635, unless stockholder approval is first obtained by the Company.

### **Registration Rights**

#### ***Investors' Rights Agreement***

Under the Third Amended and Restated Investors' Rights Agreement, dated as of December 18, 2013, among the Company and certain investors, or the investors' rights agreement, we granted registration rights to the holders of shares acquired prior to our initial public offering, or their permitted transferees. These rights are provided under the terms of the investors' rights agreement, and include demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered. As of the date of this prospectus, the holders of 6,490,971 shares of our common stock have registration rights under the investors' rights agreement. The investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable shares in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them. The registration rights granted under the investors' rights agreement will terminate at the earlier of the closing of a deemed liquidation event and when all of the holders of registrable securities are eligible to be sold without restrictions under Rule 144 promulgated under the Securities Act within any 90-day period.

#### ***AdvanDx Merger and MGHIF Investment***

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

#### ***Bridge Financing Registration Rights***

In connection with the bridge financing the Company entered into a registration rights agreement with jVen Capital and with MGHIF, pursuant to which the investors were granted certain demand registration rights and piggyback registration rights in connection with subsequent registered offerings of the Company's common stock. The registrable securities include the shares of common stock underlying the warrants issued to jVen Capital and to MGHIF, and the shares of common stock underlying the Series B Preferred Stock, if issued, under the terms of the bridge financing promissory notes.



## DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering (i) 20,000,000 units, each unit consisting of one share of our common stock and one common warrant to purchase one share of our common stock, or (ii) pre-funded units, each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock. For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. The share of common stock and accompanying common warrant included in each unit will be issued separately, and the pre-funded warrant to purchase one share of common stock and the accompanying common warrant included in each pre-funded unit will be issued separately. Units will not be issued or certificated. We are also registering the shares of common stock included in the units and the shares of common stock issuable from time to time upon exercise of the pre-funded warrants included in pre-funded units and common warrants included in the units and the pre-funded units offered hereby.

### **Common Stock**

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

### **Pre-Funded Warrants**

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

#### ***Duration and Exercise Price***

Each pre-funded warrant will have an initial exercise price per share equal to \$0.01. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The pre-funded warrants will be issued separately from the accompanying common warrants included in the pre-funded units, and may be transferred separately immediately thereafter.

#### ***Exercisability***

The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded units in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

### ***Cashless Exercise***

If, at the time a holder exercises its pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

### ***Transferability***

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

### ***Fractional Shares***

No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

### ***Trading Market***

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

### ***Right as a Stockholder.***

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

### ***Common Warrants***

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

### ***Duration and Exercise Price***

Each common warrant included in the units and the pre-funded units offered hereby will have an initial exercise price per share equal to \$ . The common warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The common warrants will be issued separately from the common stock included in the units, or the pre-funded warrants included in the pre-funded units, as the case may be, and may be transferred separately immediately thereafter. A common warrant to purchase one share of our common stock will be included in each unit or pre-funded unit purchased in this offering.

### ***Exercisability***

The common warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the common warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's common warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common warrants.

### ***Cashless Exercise***

If, at the time a holder exercises its common warrants, a registration statement registering the issuance of the shares of common stock underlying the common warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the common warrants.

### ***Fractional Shares***

No fractional shares of common stock will be issued upon the exercise of the common warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

### ***Transferability***

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

### ***Exchange Listing***

We do not intend to list the common warrants on any securities exchange or nationally recognized trading system.

### ***Right as a Stockholder***

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

### ***Fundamental Transaction***

In the event of a fundamental transaction which is approved by our Board, the holders of the common warrants have the right to require us or a successor entity to redeem the common warrant for cash in the amount of the Black Scholes value of the unexercised portion of the common warrant on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by our Board, the holders of the common warrants have the right to require us or a successor entity to redeem the common warrant for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the common warrant on the date of the consummation of the fundamental transaction.

### ***Anti-Takeover Effects of Our Certificate of Incorporation, Bylaws and Delaware Law***

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our Board of Directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below. The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation and amended and restated bylaws. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

### ***Meetings of Stockholders***

Our certificate of incorporation and bylaws provide that only the Chair of the Board, the Chief Executive Officer or a majority of the members of our Board of Directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

### ***Advance Notice Requirements***

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

### ***Amendment to Certificate of Incorporation and Bylaws***

Any amendment of our certificate of incorporation must first be approved by a majority of our Board of Directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our certificate of incorporation must be approved by not less than 66 2/3% of the outstanding shares entitled to vote on the amendment, and not less than 66 2/3% of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least 66 2/3% of the outstanding shares entitled to vote on the amendment, or, if our Board of Directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

### ***Undesignated Preferred Stock***

Our Board of Directors has the authority, without further action by our stockholders, to issue from time to time 7,690,572 shares of preferred stock in one or more series. The existence of authorized but unissued shares of preferred stock may enable our Board of Directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our Board of Directors were to determine that a takeover proposal is not in the best interests of our stockholders, our Board of Directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our Board of Directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

### ***Exclusive Jurisdiction for Certain Actions***

Our certificate of incorporation provides that, once our common stock is a “covered security,” unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar exclusive forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could rule that this provision in our certificate of incorporation is inapplicable or unenforceable.

### ***Section 203 of the Delaware General Corporation Law***

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our Board of Directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our Board of Directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

### **Listing**

Our common stock is listed on the NASDAQ Capital Market under the symbol “OPGN” and our IPO Warrants are traded under the symbol “OPGNW.”

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Philadelphia Stock Transfer, Inc. The transfer agent's address is 2320 Haverford Rd., Suite 230, Ardmore, PA 19003.

## PLAN OF DISTRIBUTION

Pursuant to an engagement agreement, we have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent in connection with this offering of our securities pursuant to this prospectus on a reasonable best efforts basis. The engagement agreement does not give rise to any commitment by the placement agent to purchase any of our securities, and the placement agent will have no authority to bind us by virtue of the engagement agreement. The placement agent may engage sub-agents or selected dealers to assist with the offering.

Only certain institutional investors purchasing the securities offered hereby will execute a securities purchase agreement with us, providing such investors with certain representations, warranties and covenants from us, which representations, warranties and covenants will not be available to other investors who will not execute a securities purchase agreement in connection with the purchase of the securities offered pursuant to this prospectus. Therefore, those investors shall rely solely on this prospectus in connection with the purchase of securities in the offering.

The placement agent is not purchasing or selling any of the securities offered by us under this prospectus, nor is it required to arrange the purchase or sale of any specific number or dollar amount of securities. The placement agent has agreed to use reasonable best efforts to arrange for the sale of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Further, the placement agent does not guarantee that it will be able to raise new capital in any prospective offering.

The securities purchase agreement we entered with the investors provides that the obligations of the investors of the securities are subject to certain conditions precedent. We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on or about \_\_\_\_\_, 2017.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by the placement agent and any profit realized on the resale of our securities sold by the placement agent while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent acting as principal. Under these rules and regulations, the placement agent :

- may not engage in any stabilization activity in connection with our securities; and
- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

### Fees and Expenses

We have agreed to pay the placement agent a total cash fee equal to 6.5% of the gross proceeds of this offering and management fee of 1.0% of the gross proceeds of this offering (which fees may be reduced under certain circumstances). We will also pay the placement agent a reimbursement for non-accountable expenses of \$50,000 and reimbursement for the placement agent's legal fees and expenses in the amount of up to \$100,000 and to reimburse the placement agent for any escrow or settlement fees in an amount not to exceed \$10,000. This fee will be distributed among the placement agent and any selected-dealers that it has retained to act on their behalf in connection with this offering. We estimate the total offering expenses of this offering that will be payable by us, excluding the placement agent's fees and expenses, will be approximately \$612,500.

## **Placement Agent Warrants**

In addition, we have agreed to issue to the placement agent warrants to purchase up to 1,000,000 shares of common stock (which represents 5.0% of the number of shares of common stock (i) included within the units and (ii) issuable upon the exercise of the pre-funded warrants included within the pre-funded units that are, in each case, placed in this offering to investors) at an assumed exercise price of \$0.6875 per share (representing 125% of the assumed public offering price for the units), exercisable for five years from the date of the effectiveness of this offering. The placement agent warrants will have substantially the same terms as the common warrants being sold to the investors in this offering. Pursuant to FINRA Rule 5110(g), the placement agent warrants and any shares of common stock issued upon exercise of the placement agent warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the placement agent or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

## **Right of First Refusal**

We have also agreed to give the placement agent, subject to the completion of this offering, certain rights of first refusal for a period of twelve months with respect to certain transactions, including any further capital raising transactions undertaken by us.

## **Lock-up Agreements**

Our executive officers and directors have agreed, subject to certain exceptions, not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of shares of common stock or warrants or any other securities convertible into or exchangeable for shares of common stock except for the shares of common stock included in the units and the shares of common stock issuable upon exercise of the common warrants included in the units and the pre-funded units and the pre-funded warrants included in the pre-funded units offered in this offering without the prior written consent of the representative for a period of 90 days after the consummation of this offering. In addition, we have agreed, subject to certain exceptions, to not issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or common stock equivalents from the date of this prospectus until 60 days after the closing of this offering.

## **Indemnification**

We have agreed to indemnify the placement agent and specified other persons against certain liabilities relating to or arising out of the placement agent's activities under the engagement agreement and to contribute to payments that the placement agent may be required to make in respect of such liabilities.

## **Determination of Offering Price**

The offering price of the securities we are offering was negotiated between us and the investors, in consultation with the placement agent based on the trading of our securities prior to the offering, among other things. Other factors considered in determining the offering price of the securities we are offering include the history and prospects of the company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant .

## **Other Relationships**

From time to time, the placement agent has provided, and may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. However, except as disclosed in this prospectus, we have no present arrangements with the placement agent for any further services.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in "Risk Factors" included elsewhere in this prospectus. When we refer to OpGen, Inc. we use the terms "OpGen," "the Company," "us," "we" and "our."

### Overview

OpGen was incorporated in Delaware in 2001. 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 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 its products and services, some in development, to a global network of customers and partners.

- The Acuitas DNA tests provide rapid microbial identification and antibiotic resistance gene information. These products include the Acuitas Rapid Test for complicated urinary tract infections in development, 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 Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that combine clinical lab test results with patient and hospital information to provide analytics and actionable insights to help manage MDROs in the hospital and patient care environment. Components of the informatics systems are the Acuitas Lighthouse Knowledgebase, a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens and the 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.

### Recent Developments

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. As of the date of this prospectus, the Company raised \$7.8 million in net proceeds under the "at-the-market offering" program from the selling of approximately 7.7 million shares of its common stock. As of the date of this prospectus, the Company has issued \$1,000,000 principal amount of promissory notes to jVen Capital and warrants to purchase an aggregate of 627,570 shares of common stock have been issued to jVen Capital and MGHIF .

See "Liquidity and Capital Resources" below for a description of the Company's recent financing activities.



## Results of Operations for the Years Ended December 31, 2016 and 2015

### Revenues

	<b>Year Ended December 31,</b>	
	<b>2016</b>	<b>2015</b>
<i>Revenue</i>		
Product sales	\$ 3,524,178	\$ 2,701,142
Laboratory services	228,904	120,476
Collaboration revenue	272,603	336,102
Total revenue	<u>\$ 4,025,685</u>	<u>\$ 3,157,720</u>

Our total revenue for the year ended December 31, 2016 increased 27%, to \$4.0 million from \$3.2 million, when compared to the same period in 2015. This increase is primarily attributable to:

- **Product Sales:** the increase in revenue of 30% in 2016 as compared to 2015 is attributable to the inclusion of AdvanDx products sales subsequent to the Merger, offset in part by a reduction in the sale of our Argus products, as we transition from our legacy mapping products to the introduction of Acuitas MDRO products;
- **Laboratory Services:** the increase in revenue of 90% in 2016 as compared to 2015 is a result of increases in sales of our Acuitas MDRO test services and Acuitas Lighthouse services; and
- **Collaboration Revenue:** the decrease in collaboration revenue of 19% in 2016 as compared to 2015 is primarily the result of decreased revenue associated with our technology development agreement with Hitachi, partially offset by \$135,000 of revenue recognized related to the Company's agreement with Healthcare Services & Solutions LLC, an affiliate of MGHIF.

### Operating expenses

	<b>Year Ended December 31,</b>	
	<b>2016</b>	<b>2015</b>
Cost of products sold	\$ 1,658,571	\$ 1,179,771
Cost of services	631,333	367,802
Research and development	8,613,236	6,002,941
General and administrative	6,602,608	5,834,642
Sales and marketing	5,529,274	4,305,444
Transaction expenses	—	526,283
Total operating expenses	<u>\$ 23,035,022</u>	<u>\$ 18,216,883</u>

The Company's total operating expenses for the year ended December 31, 2016 increased 26%, to \$23.0 million from \$18.2 million, when compared to the same period in 2015. This increase is primarily attributable to:

- **Costs of products sold:** cost of products sales for the year ended December 31, 2016 increased approximately 41% when compared to the same period in 2015. The change in costs of products sold is primarily attributable to the inclusion of AdvanDx costs of products sold subsequent to the AdvanDx Merger, offset in part by a reduction in the costs of products sold of our Argus products, as we transition from our legacy mapping products to the introduction of Acuitas MDRO products;
- **Costs of services:** cost of services for the year ended December 31, 2016 increased approximately 72% when compared to the same period in 2015. The change in costs of services is primarily attributable to an increase in sales of our Acuitas MDRO test services and Acuitas Lighthouse services;

- Research and development: research and development expenses for the year ended December 31, 2016 increased approximately 43% when compared to the same period in 2015, primarily due to costs related to the automated pathogen identification project;
- General and administrative: general and administrative expenses for the year ended December 31, 2016 increased approximately 13% when compared to the same period in 2015, primarily due to a full-year of payroll and facility costs associated with the AdvanDx acquisition in 2015 and public company costs;
- Sales and marketing: sales and marketing expenses for the year ended December 31, 2016 increased approximately 28% when compared to the same period in 2015, primarily due to costs associated with our expanded sales and marketing team, the Intermountain Healthcare Retrospective study, and industry trade show expenses; and
- Transaction expenses: transaction expenses for the year ended December 31, 2016 decreased 100% when compared to the same period in 2015 due to the prior year acquisition of AdvanDx.

**Other income (expense)**

	<b>Year Ended December 31,</b>	
	<b>2016</b>	<b>2015</b>
Interest expense	\$ (143,347)	\$ (1,801,320)
Foreign currency transaction losses	(8,102)	—
Change in fair value of derivative financial instruments	—	(647,342)
Interest and other (expense)/income	(5,967)	26,657
<b>Total other expense</b>	<b>\$ (157,416)</b>	<b>\$ (2,422,005)</b>

Other expense for the year ended December 31, 2016 decreased to a net expense of \$157,416 from a net expense of \$2,422,005 in the same period of 2015, and was primarily the result of a reduction in interest expense due to the settlement of a significant portion of our debt upon the closing of our IPO and the reclassification of derivative warrant liabilities, which were reclassified to stockholders' equity upon the closing of our IPO when their net cash-settlement features lapsed.

The Company recognized a benefit for income taxes of \$0.1 million for the year ended December 31, 2015 (none in 2016) as a result of the net deferred tax liabilities in a U.S. taxing jurisdiction related to the AdvanDx Merger.

**Results of operations for the three months ended March 31, 2017 and 2016**

**Revenues**

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
<i>Revenue</i>		
Product sales	\$ 734,502	\$ 947,219
Laboratory services	16,105	129,420
Collaboration revenue	21,164	-
<b>Total revenue</b>	<b>\$ 771,771</b>	<b>\$ 1,076,639</b>

Our total revenue for the three months ended March 31, 2017 decreased approximately 28%. This decrease is primarily attributable to:

- Product Sales: the decrease in revenue of approximately 22% in the 2017 period compared to the 2016 period is primarily attributable to a reduction in the sale of our Argus products, as we transition 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 approximately 88% in the 2017 period compared to the 2016 period as a result of decreases in sales of our Acuitas MDRO test services and Acuitas Lighthouse services; and

Collaboration Revenue: the increase in revenue in the 2017 period compared to the 2016 period is primarily attributable to \$15,000 of revenue recognized related to the Company's agreement with Healthcare Services & Solutions LLC, an affiliate of MGHIIF, and revenue related to Hitachi contracts.

### **Operating expenses**

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
Cost of products sold	\$ 424,950	\$ 345,967
Cost of services	100,233	315,709
Research and development	2,122,515	1,953,429
General and administrative	1,969,216	1,538,046
Sales and marketing	1,105,586	1,399,435
Total operating expenses	<u>\$ 5,722,500</u>	<u>\$ 5,552,586</u>

The Company's total operating expenses for the three months ended March 31, 2017 increased approximately 3% when compared to the same period in 2016. This increase is primarily attributable to:

Costs of products sold: cost of products sales for the three months ended March 31, 2017 increased approximately 23% when compared to the same period in 2016. The change in costs of products sold is primarily attributable to increased payroll and facility costs;

Costs of services: cost of services for the three months ended March 31, 2017 decreased approximately 68% 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: research and development expenses for the three months ended March 31, 2017 increased approximately 9% when compared to the same period in 2016, primarily due to payroll costs;

General and administrative: general and administrative expenses for the three months ended March 31, 2017 increased approximately 28% when compared to the same period in 2016, primarily due to payroll and legal costs; and

Sales and marketing: sales and marketing expenses for the three months ended March 31, 2017 decreased approximately 21% when compared to the same period in 2016, primarily due to costs associated with marketing studies conducted in the first quarter of 2016 and payroll costs.

### **Other income (expense)**

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
Interest expense	\$ (29,844)	\$ (41,734)
Foreign currency transaction gains	2,620	11,328
Interest and other income	21	173
Total other expense	<u>\$ (27,203)</u>	<u>\$ (30,233)</u>

Other expense for the three months ended March 31, 2017 decreased when compared to the same period of 2016, and was primarily the result of a reduction in interest expense partially offset by foreign currency transaction losses.

## Liquidity and capital resources

At March 31, 2017, the Company had cash and cash equivalents of \$1.7 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 funds in 2017 and 2016, including:

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 the date of this prospectus, the Company has sold an aggregate of approximately 7.7 million shares of its common stock under this at-the-market offering resulting in aggregate net proceeds to the Company of approximately \$7.8 million, and gross proceeds of \$8.4 million. Under the initial sales agreement, remaining availability under the at-the-market offering is \$3.1 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 share of common stock and a detachable stock purchase warrant to purchase an additional 0.75 of one share of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.75 of one share of common stock, at a price of \$1.14 per unit. The total net proceeds to the Company, after deducting offering commissions and expenses were \$9.5 million. The Company has used the proceeds for working capital and general corporate purposes. Pursuant to the private placement, the Company issued 6,744,127 shares of common stock, 2,309,428 shares of non-voting convertible preferred stock and stock purchase warrants to acquire an additional 6,790,169 shares of common stock.

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, plus the bridge financing, excluding any additional bridge financings, other financings, or further cash conservation measures will be sufficient to fund operations through end of July, 2017. 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, 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 timely, 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. Furthermore, in May 2017 the Company entered into a bridge financing facility with jVen Capital (amended and restated on July 10, 2017) under which it could issue secured promissory notes of up to \$1,500,000. In addition, the Company amended and restated the \$1,000,000 MGHIF Note which matures in July 2018. If the Company is unable to repay any of these secured promissory notes, or negotiate conversion or extension of their respective terms at maturity, the assets of the Company may be seized, as the secured promissory notes are secured by a lien on all the Company's assets. Failure to repay any one secured promissory note when due is an event of default that accelerates the maturity date of all secured promissory notes.

## Sources and uses of cash

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

	Three Months Ended March 31,	
	2017	2016
Net cash used in operating activities	\$ (4,460,492)	\$ (3,795,817)
Net cash used in investing activities	(27,022)	(1,644)
Net cash provided by/(used in) financing activities	2,044,257	(54,056)

### *Net cash used in operating activities*

Net cash used in operating activities for the three months ended March 31, 2017 consists primarily of our net loss of \$5.0 million, reduced by certain noncash items, including depreciation and amortization expense of \$0.2 million, share-based compensation expense of \$0.2 million, and the net change in operating assets and liabilities of \$0.1 million. Net cash used in operating activities for the three months ended March 31, 2016 consists primarily of our net loss of \$4.5 million, reduced by certain noncash items, including depreciation and amortization expense of \$0.2 million, share-based compensation expense of \$0.3 million, and the net change in operating assets and liabilities of \$0.3 million.

### *Net cash used in investing activities*

Net cash used in investing activities in the three months ended March 31, 2017 and 2016 consisted solely of purchases of property and equipment.

### *Net cash provided by/(used in) financing activities*

Net cash provided by financing activities for the three months ended March 31, 2017 of \$2.0 million consisted primarily of the net proceeds from issuance of common stock. Net cash used in financing activities for the three months ended March 31, 2016 of \$0.1 million consisted primarily of payments on capital lease obligations.

## Contractual obligations and off-balance sheet arrangements

As of March 31, 2017 and December 31, 2016, we did not have any off-balance sheet arrangements.

## Critical accounting policies and use of estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited condensed 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.

### **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, PN FISH and XpressFISH 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.

#### 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.

### ***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.

### ***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.

## Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued guidance 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 it plans on completing formal contract reviews in the second half of 2017. While the Company continues to assess all of the potential impacts of these ASUs, the Company does not expect the implementation of these ASUs to have a significant impact on the Company's consolidated results of operations, financial position and cash flows. The Company will assess the disclosure requirements prescribed by these ASUs in the second half of 2017 and it may be required to expand its disclosures. The Company will assess the method of adoption in the second half of 2017.

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 Accounting Standards Updates and believes the adoption of these standards will not have a material impact on its results of operations, financial position, or cash flows.

## 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 relies on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. The Company will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which it has total annual gross revenues of \$1.07 billion or more; (ii) December 31, 2019; (iii) the date on which the Company has issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which the Company is deemed to be a large accelerated filer under the rules of the SEC.



*Please refer to the Glossary on page 84 of this prospectus for definitions of scientific, health care, regulatory and OpGen-specific terms used in this prospectus.*

## 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 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 Rapid Test for complicated urinary tract infections in development, 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 are the Acuitas Lighthouse Knowledgebase, a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens and our Acuitas Lighthouse informatics, which can be 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 MGHIF, and a research collaboration with Merck Sharp & Dohme to provide access to MSD's 200,000 clinical isolate SMART bacterial surveillance archive. 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 Knowledgebase products in development to combat MDROs. We have worked closely with Intermountain Healthcare, 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.

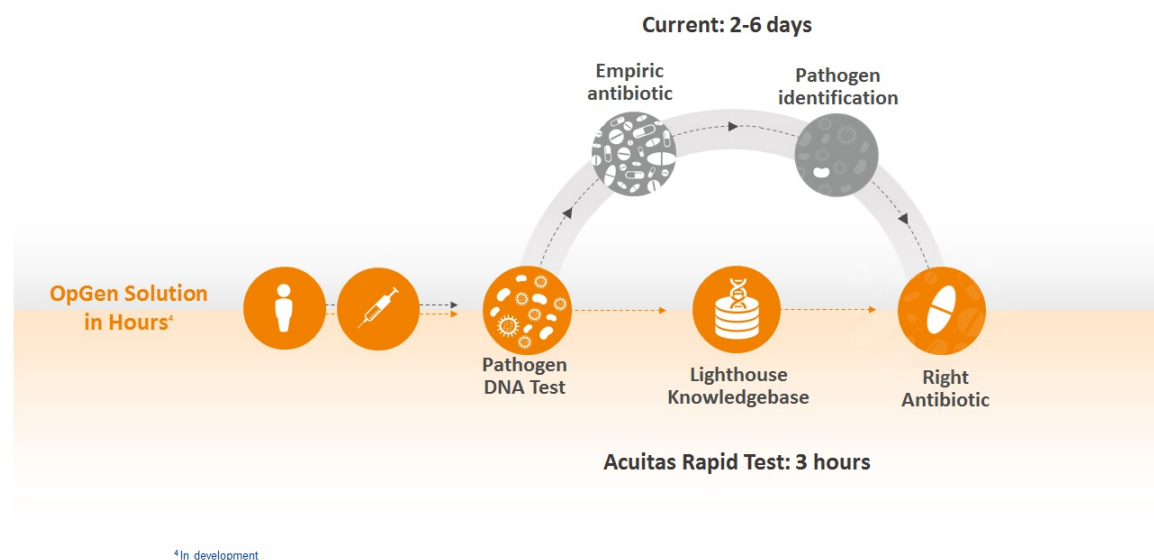
We believe more rapid genetic identification methods will reduce morbidity from MDROs, reduce healthcare costs through reduced length of stay, and assist in the identification of targeted antibiotic therapy. Current conventional microbiology, largely unchanged in 50 years, requires one to two days for 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 Acuitas Rapid Test 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 Acuitas Rapid Test will be used in the clinical setting to provide pathogen and antibiotic resistance gene information to aid in decision-making for patients with or cUTI, lower respiratory tract infections, and blood stream infections.

## Lead Rapid Diagnostic and Acuitas Lighthouse Informatics Product

Our lead product in development is the Acuitas Rapid Test for patients at risk for cUTI. The Acuitas Rapid Test for cUTI is a direct test that will be able to be performed in 2 ½ hours to identify five pathogens associated with urinary tract infections and their levels and 39 genes associated with antibiotic resistance. We anticipate that the Acuitas Lighthouse Knowledgebase will be used to provide additional interpretation of test results including probability of resistance for fourteen antibiotics commonly used to treat cUTI. Approximately 9,000 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 antibiotic resistance prediction decision-making algorithms. Preliminary performance data for E. coli and K. pneumonia Acuitas Lighthouse 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 Acuitas Rapid Test for cUTI support the potential for the Acuitas Lighthouse Knowledgebase 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.

## Revolutionary Approach to Antibiotic Decision Making



## 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 DNA tests for use on the Thermo Fisher Scientific 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 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 Knowledgebase 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.

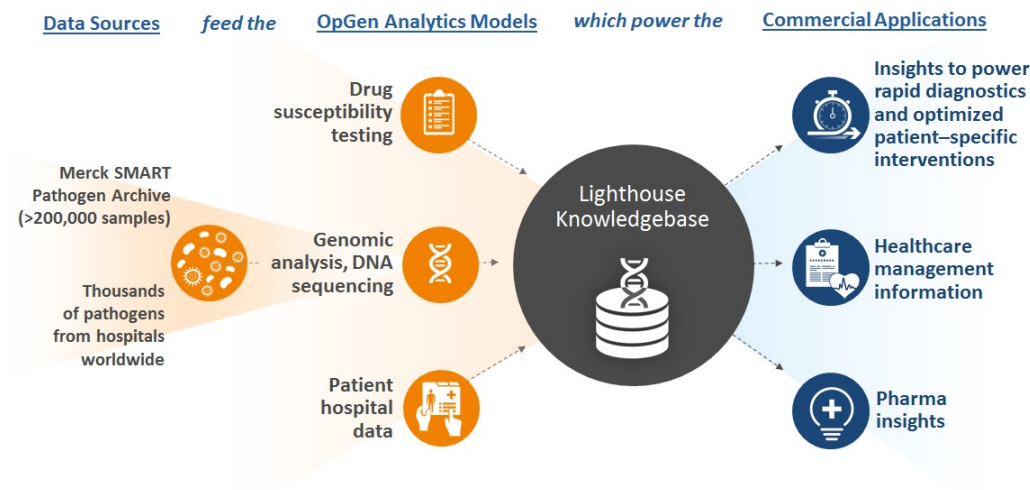
In support of our strategy we are working to:

- complete development, clinical evaluations, obtain necessary regulatory approvals, and successfully commercialize our Acuitas Rapid Test for cUTI with a goal of achieving three-hour antibiotic resistance analysis from the time of specimen collection;
- begin clinical evaluations for the Acuitas Rapid Test for cUTI in the second half of 2017 with a goal of initial commercialization in the first half of 2018 as an RUO test;
- obtain third party funding to expand our Acuitas Rapid Test development and access to additional third party rapid testing platforms;
- expand our business collaborations with Merck and other pharmaceutical companies;
- capitalize on opportunities to deploy our Acuitas Lighthouse informatics and genomic testing for Pharmaceutical/CRO services;
- complete testing and initial development of the Acuitas Lighthouse Knowledgebase in 2017 using 10,000 clinical isolates from the Merck SMART bacterial surveillance network;
- 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 informatics and decision-making software and work to install Acuitas Lighthouse access 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 informatics platform. 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, 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.

## Acuitas Lighthouse: A Proprietary, Curated MDRO Genomic Knowledgebase



## 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 President of the United States 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 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 current product offerings include our QuickFISH, PNA FISH and XpressFISH products, 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 LDT service that provides a profile of MDRO-resistant genes for surveillance and response to outbreaks, and our Acuitas Lighthouse informatics.

***FISH Products***

We have commercialized 15 QuickFISH, PNA FISH and XpressFISH 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	XpressFISH
Staphylococcus	Staphylococcus	MRSA
Enterococcus	Enterococcus	MSSA
Gram-negative bacteria	Gram-negative bacteria	
Gram –positive bacteria	Gram-positive bacteria	
Candida	Candida	

Our FISH products can provide pathogen identification and differentiation within 20 to 90 minutes of positive blood culture results. Differentiation of the pathogen, such as, for example differentiating a methicillin-resistant Staphylococcus aureus, or MRSA, infection from a methicillin-susceptible Staphylococcus aureus, or MSSA, infection provides actionable information that can be used by the healthcare provider to determine appropriate antibiotic therapy.

Approximately 100 U.S. hospital customers purchased our FISH products over the past twelve months, and we sell our FISH products to hospitals in 10 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 for use in our CLIA lab such as the Acuitas MDRO Gene Test and we are developing a rapid Acuitas DNA test for use in hospital laboratories that will combine rapid pathogen identification and detection of antibiotic resistance genes.

- Our Acuitas MDRO Gene Test 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 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.

We are also focused on further developing Acuitas Lighthouse into the Acuitas Lighthouse Knowledgebase, to provide an evergreen database for comprehensive testing and informatics analysis to help guide antibiotic therapy decision making with continual global pathogen data from our CLIA lab and hospital customers, with such data to be used to:

- assist in accelerating more rapid diagnosis with improved molecular susceptibility data;
- provide MDRO screening and surveillance capabilities to hospitals to identify pathogen and resistance profiles; and
- potentially accelerate new antibiotic development as the data are used to reveal genetic resistance patterns to direct drug discovery.

During 2016, we completed initial development of our genomic discovery engine including custom genotyping and DNA sequencing tests. We completed development of the informatics infrastructure including the data warehouse and portal to support large-scale pathogen testing for the Acuitas Lighthouse Knowledgebase.

## Research and Development

For the years ended December 31, 2016 and 2015, our research and development expenses were \$8.6 million and \$6.0 million, respectively. We intend to continue to invest in the development of additional Acuitas gene tests, 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 our product offerings to provide actionable, precise diagnostics powered by our Acuitas Lighthouse Knowledgebase 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 Rapid Test, capable of providing genetic resistance information for up to 150 drug resistance genes in one to three hours from specimen collection, and a cloud-based Acuitas Lighthouse Knowledgebase for interpretation of test results and clinical decision making support tools to help select appropriate antibiotic therapies;
- development of more rapid molecular diagnostic products to achieve actionable pathogen identification and differentiation in the first few hours of presentation or symptoms;
- automating our QuickFISH products through digital imaging and analysis, new formats requiring less hands on time to process samples, multiplex formats that allow for testing of a broader range of microorganisms;
- continued investments in our Acuitas Lighthouse informatics platform, focused on (i) data warehouse and portal for MDRO data and (ii) antibiotic analysis;
- 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.

On June 15, 2017, the Company entered into a Supply Agreement with Life Technologies Corporation, a Thermo Fisher Scientific company, or LTC, pursuant to which the Company is authorized to lease or purchase LTC QuantStudio® 5 real-time PCR instruments for placement with the Company's research use only and, upon receipt of regulatory approval, commercial customers of the Company's Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase products and services in development. The Supply Agreement also contemplates the placement of the LTC instruments in Company customer locations using the Company's Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase products and services, once developed and offered. The Company currently expects such RUO customer sales to begin in the first half of 2018.

## Sales and Marketing

We currently sell and market our products and services in the United States through a six-person sales and marketing organization including direct sales professionals and a dedicated marketing support organization. Internationally, we sell our products through a network of distributors in 16 countries. We operate a subsidiary in Denmark that provides support for our European customers and to distributors in other parts of the world. We are involved in pilot programs in approximately 10 countries to demonstrate the clinical and cost effectiveness of our FISH products. 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.

Our strategic focus is on selling to health systems and larger healthcare ecosystems such as individual cities or regions. The collaboration with Intermountain Healthcare in Utah and the HARP-DC study in Washington, DC are examples of company initiatives to deploy its technology across multi-hospital healthcare settings. We are working to expand this successful initial project to a funded pilot implementation across multiple healthcare facilities in the city. For more information, please see the description of these strategic initiatives under the heading “**2016 Events – Business Initiatives**” in the prospectus summary.

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, 2016 and 2015 were \$4.0 million and \$3.2 million, respectively. Net loss for the years ended December 31, 2016 and 2015 was \$19.2 million and \$17.4 million, respectively. Total assets at December 31, 2016 and 2015 were \$9.0 million and \$13.8 million, respectively.

No individual customer represented in excess of 10% of revenues for the year ended December 31, 2016. For the year ended December 31, 2015, revenue earned from Hitachi High-Technologies Corporation represented 11% of total revenues.

We anticipate that our direct sales organization, working in conjunction with our regional and health system high-level cooperation efforts, will sell and support our genomic diagnostic products, including MDRO surveillance and rapid diagnostics, and our Acuitas Lighthouse informatics offerings. In the United States, we anticipate that the Acuitas Rapid Test will become a lead product. As we work to gain appropriate regulatory approvals for this new product we plan to conduct clinical trial evaluations to document test performance and potential improved healthcare outcomes and reduced costs. Each testing site is anticipated to have access to our MDRO surveillance CLIA lab services and our Acuitas Lighthouse Knowledgebase.

## **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 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 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 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 testing. 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 purposes 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**

We manufacture our FDA-cleared and CE-marked QuickFISH, PNA FISH and XpressFISH products in our Woburn, Massachusetts facility. We are currently operating this facility under a five-year lease. Specialty reagents for our CLIA laboratory are manufactured at 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 reagents, equipment, chips and other materials we use to perform our Acuritas 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 Acuritas 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 MDRO test products, our Acuitas Lighthouse informatics and our QuickFISH tests are, and other future products and services will be, sold to hospitals and public health organizations 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. Currently, we provide access to our Acuitas Lighthouse informatics. The portal capability is provided to our test customers who have sufficient test volume as part of our MDRO test offerings.

In the future, we envision selling our Acuitas Lighthouse Knowledgebase to health systems, hospitals and long-term care facilities under capitated, flat-rate contracts. Health systems and hospitals absorb the costs of extended stay from HAIs and poor treatment outcomes. For healthcare providers to support the use of our tests and services, OpGen needs to demonstrate improved outcomes and reduced costs. Various studies have documented increased hospital stays of six days or more for patients infected with MDROs, resulting in increased costs of \$25,000 to \$82,000 per infected patient. Determining if an infection is hospital-acquired or was originally obtained from another source is an important issue for hospitals. We believe our tests may help adjudicate payment favorably for hospitals. Isolation procedures are also costly to hospitals, so it is critical that isolation/de-isolation decisions are made accurately. Two recent studies documented a daily extra cost of approximately \$101 for contact precaution equipment and approximately \$57 for nursing time and contact precaution supplies for each infected patient. In addition to costs to individual hospitals, estimates of the economic costs of antibiotic resistance to the U.S. economy range from \$20 billion to \$35 billion annually.

Our marketing strategy focuses on the rapid turn-around time of our Acuitas MDRO and QuickFISH test results and the panel of results available from one patient sample. We believe the combination of our Acuitas MDRO test products, including QuickFISH, and our Acuitas Lighthouse informatics differentiates us in the marketplace by offering a single sample process for identification and management of MDROs. Our approach can deliver a number of benefits to healthcare organizations including: (1) reduced lengths of stays; (2) cost savings and improved patient outcomes; and (3) avoidance of penalties by third-party payers for HAIs.

We employ diverse marketing programs to inform key stakeholders of the value of our products and services in order to drive adoption. As part of our marketing strategy, we educate hospitals, other healthcare institutions, and healthcare professionals about our value proposition. We intend to expand our marketing efforts using proceeds from this offering to increase these activities by expanding our sales and marketing efforts to microbiology and infection control professionals and hospital executives. We anticipate supporting efforts to advocate for expanded MDRO hospital surveillance, legislation at the state and federal level to encourage best practices for MDRO surveillance, and clinical practice guidelines. Finally, our website serves as a portal for educational material for hospitals, healthcare professionals and patients.

### Third-Party Payers

We do not currently rely on any third-party payers for payment or reimbursement to us for our Acuitas MDRO or QuickFISH test products. Although we do not anticipate seeking direct reimbursement to us, we do believe that Federal healthcare programs and other third-party payers may, in the future, reimburse hospitals for implementing institution-wide surveillance, infection control and antibiotic stewardship programs. Our management team has experience seeking reimbursement from Federal healthcare programs and other third-party payers, and would work to:

- meet the evidence standards necessary to be consistent with leading clinical guidelines. We believe demonstrating that our products and services meet leading clinical practice guidelines plays a critical role in payers' coverage decisions;
- engage reimbursement specialists to ensure the payor outreach strategy reacts to and anticipates the changing needs of our customer base. A customer service team would be an integral part of our reimbursement strategy, working with hospitals to navigate the claims process;
- cultivate a network of key opinion leaders. Key opinion leaders are able to influence clinical practice by publishing research and determining whether new tests should be integrated into practice guidelines. We would collaborate with key opinion leaders early in the development process to ensure our clinical studies are designed and executed in a way that clearly demonstrates the benefits of our tests to physicians and payers; and
- compile a library of peer-reviewed studies that demonstrate that our Acuitas MDRO test products are effective, accurate and faster than current methods.

## Intellectual Property

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.

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 of December 31, 2016, we had total license or ownership rights to 172 patents, including 12 pending United States non-provisional patent applications, and 68 issued United States patents. More specifically, as of December 31, 2016, related to our FISH products, we had license or ownership rights to 99 patents, including 1 pending United States non-provisional patent applications, and 45 issued United States patents. These issued patents began to expire in March 2017 and will be fully expired by January 2029. As of December 31, 2016, related to our Acuitas products, we had license or ownership rights to 22 patents, including 4 pending United States non-provisional patent applications and no issued United States patents. As of December 31, 2016, related to our other products, we had license or ownership rights to 51 patents, including 7 pending United States non-provisional patent applications, and 23 issued United States patents related to our other products. These issued patents begin to expire in April 2017 and will be fully expired by January 2032.

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, 2017, 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 Medical Device Regulation***

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 I 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 II devices may be required to file a Premarket Approval, or PMA, application.

Devices 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, are classified as Class 3 devices 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 501(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 be 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.

## ***21<sup>st</sup> Century Cures Act***

On December 13, 2016, President Obama signed into law the 21st Century Cures Act. The 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 21<sup>st</sup> 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 and Florida, and we have submitted an application to 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 prospectus:

“ACOs” means accountable care organizations, a voluntary combination of doctors, hospitals and other healthcare providers and other healthcare system participants, including insurers, formed under the PPACA, to provide coordinated healthcare to patients.

“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 a more comprehensive and global Acuitas Lighthouse Knowledgebase for use with our Acuitas Rapid Test 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 Rapid Test” mean our diagnostic test in development, capable of providing genetic Resistome information for up to 150 drug resistance genes in one to three hours from specimen collection.

“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.

”Argus System” means OpGen's proprietary system used to perform Whole Genome Mapping.

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

“C. difficile” means Clostridium difficile, an MDRO that causes intestinal tract infections that can lead to sepsis.

“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.

“hospital biome” is used in this prospectus to refer to the unique characteristic microbial environment found in a specific hospital or other healthcare setting, which could change from time to time based on the MDRO profile of the institution.

“ICU” means an intensive care unit in a health-care facility.

“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 prospectus, 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.

“microfluidic” means devices or processes that are designed, manufactured or formulated to accommodate applications that require very small volumes of fluid, on the order of nanoliters or picoliters.

“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.

“Whole Genome Mapping” means OpGen’s proprietary technology that provides a customer with a high resolution, ordered, whole genome restriction map generated from single DNA molecules extracted from organisms, such as bacteria, yeast or other fungi, plants or animals and humans. Whole Genome Mapping compliments genome assembly and enables scientist to identify highly repetitive regions, tandem repeats and translocations that are difficult to identify and clarify with sequencing alone.

## **Properties**

The Company leases 20,939 square feet of office and laboratory space at its 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, 2016 and 2015 were \$1,000,726 and \$683,519, 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.

## **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.

## **Employees**

As of July 7, 2017, we had 45 employees, 40 of whom are full-time.

## MANAGEMENT

### Directors and Executive Officers

The Board of Directors of the Company (the "Board") are elected at the annual meeting of the stockholders, and serve for the term for which each director is elected and until his or her successor is elected and qualified. Executive officers of the Company are elected by the Board, and serve for a term of one year and until their successors have been elected and qualified or until their earlier resignation or removal by the Board. There are no family relationships among any of the directors and executive officers of the Company. None of the executive officers or directors has been involved in any legal proceedings of the type requiring disclosure by the Company during the past ten years. On July 14, 2015, the Company entered into the Purchase Agreement with MGHIF. Pursuant to the Purchase Agreement, the Company's Board was expanded to seven members and MGHIF had the right, subject to the consent of the Company, to fill the new vacancy on the Board. Additionally, for as long as MGHIF holds at least five percent (5%) of the outstanding common stock of the Company, the Board is required to nominate MGHIF's designee, or any replacement, for election by the stockholders at each annual or special meeting of the stockholders at which directors are elected. MGHIF nominated, and the Board consented to, David M. Rubin Ph.D. serving as its designee on the Board. Otherwise, there are no arrangements or understandings between any director or executive officer and the Company pursuant to which he or she was selected as a director.

The following table sets forth the names and ages of all directors and executive officers of the Company and their respective positions with the Company as of the date of this prospectus:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<b><u>Directors</u></b>		
Evan Jones	60	Chief Executive Officer, Director and Chairman of the Board
Harry J. D'Andrea	60	Director
Timothy J.R. Harris, Ph.D., D.Sc	66	Director
Tina S. Nova, Ph.D.	63	Director
David M. Rubin, Ph.D.	52	Director
Misti Ushio, Ph.D.	45	Director
<b><u>Other Executive Officers</u></b>		
Timothy C. Dec	58	Chief Financial Officer and Corporate Secretary
Vadim Sapiro	46	Chief Information Officer

### Board of Directors

The following information summarizes, for each of our directors, his or her principal occupations and other public company directorships for at least the last five years and information regarding the specific experiences, qualifications, attributes and skills of such director:

**Evan Jones.** Mr. Jones has served as our Chief Executive Officer since October 2013 and as Chairman of our Board since September 2010. He served as our President from October 2013 until April 2015. Since 2007, Mr. Jones has served as managing member of jVen Capital, LLC, a life sciences investment company. Previously, he co-founded Digene Corporation, a publicly traded biotechnology company focused on women's health and molecular diagnostic testing that was sold to Qiagen N.V. (NASDAQ: QGEN) in 2007. He served as chairman of Digene's board of directors from 1995 to 2007, as Digene's chief executive officer from 1990 to 2006, and as Digene's president from 1990 to 1999. Mr. Jones currently serves on the board of directors of Fluidigm Corporation (NASDAQ: FLDM), a technology company that develops, manufactures and markets life science analytical and preparatory systems, since March 2011, Foundation Medicine, Inc. (NASDAQ: FMI), a cancer testing molecular informatics company, since January 2013, and Veracyte, Inc. (NASDAQ: VCYT), a leading genomic diagnostics company, since 2008. Mr. Jones received a B.A. from the University of Colorado and an M.B.A. from The Wharton School at the University of Pennsylvania. We believe that Mr. Jones' qualifications to serve as CEO of the Company and as Chairman of our Board include his extensive experience in the molecular diagnostic testing industry, including as chief executive officer of a public company focused on molecular diagnostic testing, as well as his service as a board member with other public and private companies and Vice Chair of the board at Children's National Medical Center in Washington, D.C.

**Harry J. D'Andrea.** Mr. D'Andrea has been a director of OpGen since April 2016. Mr. D'Andrea is managing general partner of Valhalla Partners, a venture capital firm, a position he has held since January 2012. He previously served as administrative general partner of Valhalla Partners since June 2002, and was a co-founder of Valhalla Partners in 2002. From June 1999 to February 2002, Mr. D'Andrea was Chief Financial Officer of Advanced Switching Communications, Inc., a Nasdaq-listed company that completed its IPO in October 2000. Prior thereto from 1989 to 1999 he held senior financial positions with a number of privately held and public companies. Mr. D'Andrea has served on the boards of two publicly traded companies in the past. He received his B.A. in Foreign Service from The Pennsylvania State University in 1978 and his MBA from Drexel University in 1980.

**Timothy J.R. Harris, Ph.D., D.Sc.** Dr. Harris has been a director of OpGen since April 2015. Dr. Harris is a science and business leader with nearly 40 years of experience guiding and leading laboratory work and scientists in a range of molecular research areas. He is a molecular biologist, biochemist and geneticist by training and is currently EVP R&D at Bioverativ Inc. and a Venture Partner at SV Health Investors, a position he has held since March 2016. He was the SVP for Precision Medicine at Biogen from March 2015 until February 2016, and prior to that SVP of Translational Medicine at Biogen Idec from June 2011 to February 2016. He was the Chief Technology Officer and Director of the Advanced Technology Program at SAIC-Frederick, Inc. in Maryland from January 2007 to June 2011, which operates the National Cancer Institute's leading center for cancer and AIDS research (now Frederick National Laboratory operated by Leidos Inc.). He has served as President and Chief Executive Officer of Novasite Pharmaceuticals, and he founded SGX Pharmaceuticals in 1999 (formerly Structural Genomix), where he built the company to more than 130 employees, raised \$85M in capital, and generated more than \$20M in revenue during six years as CEO before it was sold to Eli Lilly. Before founding SGX, Dr. Harris was Senior Vice President, Research and Development at Sequana/Axys. He began his scientific career working on animal viruses such as foot & mouth disease and was one of the first molecular biologists (1981) at Celltech (now UCB Pharma) in the United Kingdom. He subsequently spent nearly five years at Glaxo Group Research as Director of Biotechnology from 1989 to 1993. Dr. Harris received a Ph.D. and M.S. in General Virology and a B.Sc. in Biochemistry from the University of Birmingham in England and has an honorary doctorate (D.Sc.) from the University of Birmingham, UK awarded in July 2010. He is currently a visiting Professor at Columbia University.

**Tina S. Nova, Ph.D.** Dr. Nova has been a director of OpGen since April, 2017. Dr. Nova is a life science industry veteran with extensive experience building and leading novel genomics-based businesses. She currently serves as president and chief executive officer of Molecular Stethoscope, Inc., a newly formed molecular diagnostics company, a position she has held since October 2015. Prior thereto, she served as senior vice president and general manager of Illumina's oncology business unit from July 2014 to August 2015. From March 2000 to April 2014, Dr. Nova was a co-founder and director, president and chief executive officer of Genoptix Medical Laboratory, which was purchased by Novartis Pharmaceuticals Corporation for nearly \$0.5 billion in 2011. She has also held senior executive positions with Nanogen, Inc., Ligand Pharmaceuticals, Inc. and Hybritech, Inc. Dr. Nova currently serves on the board of directors for Arena Pharmaceuticals, Veracyte, Inc. and is vice chairman of the board of directors for the newly formed Rady Pediatric Genomics and Systems Medicine Institute, which is part of Rady Children's Hospital-San Diego. She holds a B.S. degree in Biological Sciences from the University of California, Irvine, and a Ph.D. in Biochemistry from the University of California, Riverside.

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

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

## Executive Officers

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

**Evan Jones.** See above under “Board of Directors.”

**Timothy C. Dec.** Mr. Dec joined OpGen as our interim Chief Financial Officer in April 2015 and became our Chief Financial Officer in May 2015. Prior to joining OpGen, Mr. Dec served as Senior Vice President and Chief Financial Officer for Clubwidesports, LLC, a start-up sports management software company, from January 2014 to April 2015. From December 2012 to the present, Mr. Dec is an adjunct professor at Mount St. Mary's University, where he teaches M.B.A. courses in Finance. From August 2007 to December 2012, Mr. Dec served as Senior Vice President and Chief Financial Officer of Fortress International Group, Inc., a publicly traded company. Mr. Dec has served in chief financial officer or other senior financial executive roles at companies in a number of industries from September 1986 through August 2007, including three publicly traded companies listed on NASDAQ or AMEX, such as Corvis Corporation, and with private equity-backed companies. Mr. Dec also has public accounting firm experience. Mr. Dec received his B.S. in Accounting from Mount St. Mary's University and an M.B.A. from American University.

**Vadim Sapiro.** Mr. Sapiro joined OpGen in December 2011 as Chief Information Officer. Mr. Sapiro is responsible for leading the development of the Company's informatics applications, software, databases and information technology operations. Prior to joining OpGen, Mr. Sapiro was Senior Vice President at SAIC-Frederick (now Leidos Biomedical Research Inc.) from June 2008 to December 2011, overseeing the Information Systems Program for the National Cancer Institute at SAIC-Frederick. From January 2007 to May 2008, Mr. Sapiro served as Vice President for Information Technology of J. Craig Venter Institute, a non-profit research institute. Mr. Sapiro served in other senior information technology roles from July 1999 through December 2006, including another non-profit research institute. Mr. Sapiro holds a B.S. in Mathematics and Computer Science from the University of Maryland.

## Independence of the Board of Directors Members

The Company defines “independent” as that term is defined in Rule 5605(a)(2) of the NASDAQ listing standards. The Board has determined that Mr. D'Andrea and Drs. Harris, Nova, Rubin and Ushio qualify as independent and none of them has any material relationship with the Company that might interfere with his or her exercise of independent judgment.



## EXECUTIVE COMPENSATION

### Compensation Tables

#### Summary Compensation Table—2016 and 2015 Fiscal Years

This table provides disclosure, for fiscal years 2016 and 2015 for the named executive officers, who are (1) any individual serving in the office of Chief Executive Officer during any part of 2016 and (2) the Company's two most highly compensated officers, other than the Chief Executive Officer, who were serving in such capacity on December 31, 2016, and one named executive officer for whom disclosure would be provided but for the fact that he was not serving as an executive officer at December 31, 2016.

Named Executive Officer and Principal Position	Year	Salary (\$)	Bonus (2) (\$)	Stock Awards (1)(\$)	Option Awards (1) (\$)	Non- Equity Incentive Plan Compensation (\$)	All Other Compensation (\$)	Total (\$)
Evan Jones Chief Executive Officer	2016	\$ 316,538	\$ -	\$ -	\$ 499,352	\$ -	\$ -	\$ 815,890
	2015	\$ 190,000	\$ -	\$ -	\$ 843,260	\$ -	\$ -	\$ 1,033,260
Timothy Dec Chief Financial Officer	2016	\$ 273,462	\$ 50,000	\$ -	\$ 44,996	\$ -	\$ -	\$ 368,458
	2015	\$ 182,050	\$ -	\$ 42,500	\$ 318,226	\$ -	\$ -	\$ 542,776
Vadim Sapiro Chief Information Officer	2016	\$ 280,385	\$ 50,500	\$ -	\$ 29,997	\$ -	\$ -	\$ 360,882
	2015	\$ 275,000	\$ -	\$ -	\$ 54,375	\$ -	\$ -	\$ 329,375
Kevin Krenitsky, M.D. Former President (3)	2016	\$ 233,263	\$ 61,000	\$ -	\$ 44,996	\$ -	\$ 53,364 (5)	\$ 392,623
	2015	\$ 194,950	\$ -	\$ 85,000	\$ 1,006,087	\$ -	\$ 10,891 (4)	\$ 1,296,928

- (1) The "Stock Awards column reflects the grant date fair value for all restricted stock units awarded under the 2015 Plan during 2016. The "Option Awards" column reflects the grant date fair value for all stock option awards granted under the 2015 Plan or the 2008 Plan during 2016 and 2015, respectively, except for Mr. Jones the 2016 stock option grant was made outside of the 2015 Plan, subject to stockholder approval that was obtained on June 22, 2016. These amounts are determined in accordance with FASB Accounting Standards Codification 718 (ASC 718), without regard to any estimate of forfeiture for service vesting. Assumptions used in the calculation of the amounts in these columns for 2016 and 2015 are included in footnote 8 to the Company's consolidated audited financial statements for the year ended December 31, 2016 included elsewhere in this prospectus.
- (2) Bonus amounts represent 2015 earned amounts that were not finalized until after the 2015 Annual Report and paid in 2016. No bonuses were earned for 2016.
- (3) Dr. Krenitsky resigned from his position on August 31, 2016.
- (4) Represents relocation expenses for which the Company reimbursed Dr. Krenitsky during the year ended December 31, 2015.
- (5) Represents severance related expenses.

#### Employment Agreements with Our Named Executive Officers

The Company has entered into employment agreements with, and provides post-employment benefits to, our named executive officers as follows:

**Evan Jones** - On March 3, 2014, we entered into an amended and restated employment agreement with Evan Jones, our Chief Executive Officer. The agreement provides that Mr. Jones will serve as our Chief Executive Officer at the equivalent of seventy percent of a full-time commitment. His initial base salary of \$190,000 reflected that pro rata adjustment. When he assumed the role of Chief Executive Officer, he agreed to receive base compensation for all of his positions through the issuance of restricted stock units, in lieu of cash salary, for the period from October 25, 2013 to June 30, 2014. In addition, Mr. Jones received an award of stock options to purchase three and one-half percent (3.5%) of the fully diluted equity of the Company following the closing of the 2014 Series A Convertible Preferred Stock offering, completed in February, April and May 2014. Mr. Jones receives annual bonus opportunities based on performance goals determined by our Board. The current maximum target opportunity is seventy percent of annual base salary. Under his employment agreement, Mr. Jones waived his rights to participate in any fringe benefit plans offered to the Company's employees, except for participation in the Company's 401(k) plan. Our agreement with Mr. Jones also includes standard confidentiality, general release and other provisions.

**Timothy C. Dec** - On April 17, 2015, we entered into an employment agreement with Timothy C. Dec, our Chief Financial Officer, with an initial base salary of \$260,000 and annual bonus opportunities based on performance goals determined by our Board, with a current target bonus of thirty percent (30%) of annual base salary. In addition, Mr. Dec received an award of stock options to purchase three-quarters of one percent (0.75%) of the fully diluted equity of the Company. The stock options will vest in equal monthly installments for an interim period, expected to last 90 days, and then vest in accordance with the Company's standard vesting practices. The agreement provides for the acceleration of the award if Mr. Dec's employment is terminated in connection with a change in control, if the award is not continued, assumed or substituted and would otherwise terminate and expire upon the change in control. In addition, the agreement provides for acceleration of the award, if the award is continued, assumed or substituted for in connection with a change in control, and, during the six (6) month period after the effective date of the change in control, Mr. Dec's employment with the Company is terminated without cause .

**Vadim Sapiro** – On January 27, 2012, we entered into an executive change in control and severance benefits agreement with Vadim Sapiro, our Chief Information Officer. Under the agreement, upon any termination of Mr. Sapiro's employment without "cause" that constitutes a "separation from service" under Section 409A of the Internal Revenue Code, he will receive severance compensation equal to his base salary at the time of termination for six months. The agreement provides for the acceleration of the vesting, or lapse of forfeiture restrictions on his outstanding equity awards that were granted on or prior to December 31, 2011, in the event of termination of employment in connection with a change in control. In addition, the agreement provides that, for 12 months following a change in control, if Mr. Sapiro terminates his employment with the Company for good reason and such termination constitutes a "separation from service" under Section 409A of the Code, Mr. Sapiro will receive severance compensation equal to his base salary at the time of termination for six months. On November 1, 2013, we amended the executive change in control and severance benefits agreement to add a provision providing the Company the ability to terminate the agreement upon sixty days (60) prior written notice.

For purposes of the employment and severance agreements, the following terms have the following meanings (where applicable):

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

"change in control" means (a) a merger or consolidation in which (i) the Company is a constituent party, or (ii) a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger or consolidation, except any such merger or consolidation involving the Company or a subsidiary in which the shares of capital stock of the Company outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation (taking into account all equity on a fully diluted and converted basis); or (b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company or any subsidiary of the Company of all or substantially all the assets of the Company and its subsidiaries taken as a whole, or the sale or disposition (whether by merger or otherwise) of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Company; provided that to the extent necessary for compliance with Section 409A of the Internal Revenue Code, no transaction will be a change in control for these purposes unless such transaction is also a change in the ownership or effective control of the Company, or a change in the ownership of a substantial portion of the Company's assets as described in Treasury Regulation Section 1.409A-3(i)(5).

“good reason” means any of the following, without the executive’s consent: (i) material diminution of executive’s responsibilities or duties (provided that the acquisition of the Company and subsequent conversion of the Company to a division or unit of the acquiring company will not by itself be deemed to be a diminution of executive’s responsibilities or duties); (ii) material reduction in the level of executive’s base salary (and any such reduction will be ignored in determining executive’s base salary for purposes of calculating the amount of severance pay); (iii) relocation of the office at which executive is principally based to a location that is more than fifty (50) miles from the location at which executive performed his or her duties immediately prior to the effective date of a change in control; (iv) failure of a successor in a change in control to assume the agreement; or (v) the Company’s material breach of any written agreement between executive and the Company. Notwithstanding the foregoing, any actions taken by the Company to accommodate a disability of executive or pursuant to the Family and Medical Leave Act shall not be a good reason for purposes of the agreement. Additionally, before executive may terminate employment for a good reason, executive must notify the Company in writing within thirty (30) days after the initial occurrence of the event, condition or conduct giving rise to good reason, the Company must fail to remedy or cure the alleged good reason within the thirty (30) day period after receipt of such notice if capable of being cured within such thirty-day period, and, if the Company does not cure the good reason (or it is incapable of being cured within such thirty-day period), then executive must terminate employment by no later than thirty (30) days after the expiration of the last day of the cure period (or, if the event condition or conduct is not capable of being cured within such thirty-day period, within thirty (30) days after initial notice to the Company of the violation). Transferring executive’s employment to a successor is not itself good reason to terminate employment under the agreement, provided, however, that subparagraphs (i) through (v) above shall continue to apply to executive’s employment by the successor. This definition is intended to constitute a “substantial risk of forfeiture” as defined under Treasury Regulation 1.409A-1(d).

**Outstanding Equity Awards at Fiscal Year-End Table—2016**

The following table shows the outstanding equity awards held by the named executive officers as of December 31, 2016.

Name	OPTION AWARDS					STOCK AWARDS			
	(1) Number of Securities Underlying Unexercised Options Exercisable	(1) Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options	Option Exercise Price (\$)	Option Expiration Date	Number of Shares of Stock that have not Vested	Market Value of Shares of Stock that have not Vested (\$)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that have not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or other Rights that have not Vested
Evan Jones(2)	89	-	-	79.05	7/23/2018	-	-	-	-
	1,847	-	-	110.68	9/21/2020	-	-	-	-
	108,896	65,339	-	0.05	4/24/2024	-	-	-	-
	100,000	100,000	-	0.61	10/23/2024	-	-	-	-
	-	766,500	-	1.55	4/28/2026	-	-	-	-
Timothy Dec(3)	50,015	64,305	-	6.00	5/4/2025	-	-	-	-
	15,625	34,375	-	1.70	11/10/2025	-	-	-	-
	-	60,000	-	1.55	6/13/2026	-	-	-	-
	-	-	-	-	-	18,750	21,563	-	-
Vadim Sapiro(4)	64	-	-	7.91	3/23/2022	-	-	-	-
	918	-	-	7.91	3/23/2022	-	-	-	-
	237	16	-	7.91	2/12/2023	-	-	-	-
	127	-	-	7.91	2/12/2023	-	-	-	-
	514	119	-	7.91	7/25/2023	-	-	-	-
	2,691	898	-	0.05	4/24/2024	-	-	-	-
	25,000	25,000	-	0.61	10/23/2024	-	-	-	-
	25,000	-	-	6.00	5/4/2025	-	-	-	-
-	40,000	-	1.55	6/13/2026	-	-	-	-	
Kevin Krenitsky(5)	95,266	-	-	6.00	2/28/2017	-	-	-	-
	20,833	-	-	1.70	2/28/2017	-	-	-	-

- The standard vesting schedule for all stock option grants is vesting over four years with twenty-five percent (25%) vesting on the first anniversary of the date of grant and six and one-quarter percent (6.25%) vesting on the last day of the next fiscal quarter over three years.
- The stock option awards made to Mr. Jones have the vesting schedule set forth in footnote (1) and were awarded on July 23, 2008 (89 shares), February 15, 2011 (1,847 shares), April 24, 2014 (174,235 shares), October 23, 2014 (200,000 shares) and April 28, 2016 (766,500 shares).
- Mr. Dec was granted stock option awards on May 4, 2015 (114,320 shares), November 10, 2015 (50,000 shares), and June 13, 2016 (60,000 shares). One-forty-eighth of Mr. Dec's stock option awards granted on May 4, 2015 vested on the one month anniversary of the date of grant and thereafter vest over four years with twenty-five percent (25%) vesting on the first yearly anniversary of the date of grant and six and one-quarter percent (6.25%) vesting on the last day of the next fiscal quarter over three years. Mr. Dec's stock option awards granted on November 10, 2015 and June 13, 2016 have the vesting schedule set forth in footnote (1). Mr. Dec was granted restricted stock units on November 10, 2015. Twenty-five percent (25%) of the entire Restricted Stock Units Award vest on the first four anniversaries of the date of grant.
- The stock option awards granted to Mr. Sapiro on March 23, 2012 (64 shares and 918 shares), February 12, 2013 (253 shares), July 25, 2013 (633 shares), October 23, 2014 (50,000 shares) and June 13, 2016 (40,000 shares) have the vesting schedule set forth in footnote (1). The stock option award granted to Mr. Sapiro on February 12, 2013 for 127 shares vested in full on the first anniversary of the date of grant, February 12, 2014. The stock option award granted to Mr. Sapiro on April 24, 2014 for 3,589 shares is vesting over four years with twenty-five percent (25%) vesting on December 31, 2014 and six and one-fourth percent (6.25%) vesting quarterly thereafter in equal proportions over the remaining three years. The stock option granted to Mr. Sapiro on May 4, 2015 vested quarterly over the first year following the date of grant.
- Dr. Krenitsky was granted stock option awards on May 4, 2015 (381,067 shares), November 10, 2015 (100,000 shares), and June 13, 2016 (60,000 shares). On August 31, 2016, Dr. Krenitsky resigned from his position as President. The Company entered into a Confidential Separation Agreement and General Release with Dr. Krenitsky on September 1, 2016 (the "Separation Agreement"). Pursuant to the Separation Agreement, the vesting of certain stock options set forth in this table was accelerated and Dr. Krenitsky had until February 28, 2017 to exercise his vested stock options. As of December 31, 2016, 116,099 options vested, including 95,266 options from the May 4, 2015 award, 20,833 options from the November 10, 2015 award and no options from the June 13, 2016 award.

## Director Compensation

Since May 2015, each non-employee director receives an annual cash retainer of \$25,000, payable quarterly, plus additional annual cash compensation for committee chairs (\$15,000 for Audit Committee, \$10,000 for Compensation Committee and \$7,500 for Compliance Committee) and for committee members (\$7,000 for Audit Committee, \$5,000 for Compensation Committee and \$3,500 for Compliance Committee). In addition, each new director receives an initial stock option grant to purchase 30,000 shares of common stock and each non-employee director receives an annual stock option grants to purchase 12,500 shares of common stock. All such awards are made under the 2015 Plan. The annual stock option awards may be pro-rated in the first year of service depending on when the non-employee director joins the Board. This compensation program was reviewed by the Compensation Committee in February 2017, and the determination was made to continue to the program without change.

Evan Jones, Chairman of the Board and CEO, does not receive additional compensation for service on our Board. See “Summary Compensation Table” for his 2016 compensation. Compensation for the non-employee directors for the year ended December 31, 2016 was:

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$)(1)	All Other Compensation (\$)	Total (\$)
Brian G. Atwood (2)	\$ 36,000	\$ 7,589	\$ -	\$ 43,589
Harry J. D'Andrea	\$ 24,167	\$ 26,114	\$ -	\$ 50,281
Timothy J.R. Harris	\$ 33,500	\$ 7,589	\$ -	\$ 41,089
Laurence R. McCarthy (2)	\$ 37,500	\$ 7,589	\$ -	\$ 45,089
David M. Rubin (3)	\$ -	\$ -	\$ -	\$ -
Misti Ushio	\$ 38,500	\$ 7,589	\$ -	\$ 46,089

- (1) The “Option Awards” column reflects the grant date fair value for all stock option awards granted under the 2015 Plan during 2016. These amounts are determined in accordance with FASB Accounting Standards Codification 718 (ASC 718), without regard to any estimate of forfeiture for service vesting. Assumptions used in the calculation of the amounts are included in footnote 8 to the Company's consolidated audited financial statements for the year ended December 31, 2016, included elsewhere in this prospectus.
- (2) Mr. Atwood and Dr. McCarthy did not stand for re-election at the 2017 Annual Meeting of the Stockholders.
- (3) As managing director of MGHIF, Dr. Rubin is precluded from receiving compensation for serving as a director of OpGen, Inc.

## Compensation Risk Assessment

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking. This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to recognize and support both short-term and long-term strategic goals, in particular in connection with our pay-for-performance compensation philosophy. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on us.

## Employee Incentive Plans

The following table shows, as of December 31, 2016, the Company's equity compensation plans under which the Company's equity securities are authorized for issuance:

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights(1)</b>	<b>Weighted average exercise price of outstanding options, warrants and rights(2)</b>	<b>Number of securities remaining available for future issuance</b>
Equity compensation plans approved by security holders	2,996,410	\$ 1.76	669,651
Equity compensation plans not approved by security holders	—	—	—
<b>Total</b>	<b>2,996,410</b>	<b>\$ 1.76</b>	<b>669,651</b>

(1) Includes 18,750 outstanding restricted stock units for which there is no exercise price.

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

### 2008 Plan

Our 2008 Stock Option and Restricted Stock Plan, as amended, or 2008 Plan, was approved by our Board and stockholders in April 2008; subsequent increases in the number of shares available for awards under the 2008 Plan were approved by our Board and stockholders in January 2009, February 2011, March 2012, December 2012, April 2014 and October 2014. A total of 1,447,791 shares of our common stock are reserved for issuance under the 2008 Plan.

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

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

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

### 2015 Plan

The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants. The 2015 Plan was amended by the Compensation Committee in February 2017 to revise the provisions with respect to net settlement of awards in response to change in regulations, and to establish standard periods for exercise of vested stock options following termination of service events.

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

*Authorized shares.* Under our 2015 Plan, the aggregate number of shares of our common stock authorized for issuance may not exceed (1) 1,355,000 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited or terminated for any reason before being exercised or settled, plus the number of shares subject to vesting restrictions under the 2008 Plan on the 2015 Plan's effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan 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 (i) 4% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year, and (ii) another lesser amount determined by our Board. Accordingly, on January 1, 2017, the number of shares authorized for issuance under the 2015 Plan increased by 1,012,171 shares such that, as of March 31, 2017, an aggregate of 3,928,390 shares are authorized for issuance under the 2015 Plan, with 1,148,050 shares remaining available for future awards under the 2015 Plan.

Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled, or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. No more than 4,000,000 shares may be delivered upon the exercise of incentive stock options granted under the 2015 Plan.

### ***Types of awards***

*Stock options.* A stock option is the right to purchase a certain number of shares of stock, at a certain exercise price, in the future. Under our 2015 Plan, incentive stock options and non-qualified options must be granted with an exercise price of at least 100% of the fair market value of our common stock on the date of grant. Incentive stock options granted to any holder of more than 10% of our voting shares must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. The stock option agreement specifies the date when all or any installment of the option is to become exercisable. Payment of the exercise price may be made in cash or, if provided for in the stock option agreement evidencing the award, (1) by surrendering, or attesting to the ownership of, shares which have already been owned by the optionee, (2) by delivery of an irrevocable direction to a securities broker to sell shares and to deliver all or part of the sale proceeds to us in payment of the aggregate exercise price, (3) by a "net exercise" arrangement, or (4) by any other form that is consistent with applicable laws, regulations and rules.

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

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

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

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

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

### ***Other plan features***

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

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

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

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

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



## CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Other than compensation arrangements, we describe below the transactions and series of similar transactions, during our last three fiscal years, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of \$120,000 or one percent of the average of the Company's total assets at year end for the past two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for our directors and named executive officers are described elsewhere in this prospectus.

### ***Contractual Relationships***

In December 2013, we purchased a BioMark HD DNA detection system and related instruments from Fluidigm Corporation for a purchase price of \$221,000. In March 2014, we entered into a supply agreement with Fluidigm under which Fluidigm supplies us with its microfluidic test platform for use in manufacturing our Acuitas MDRO Gene Test. In 2015, we entered into a collaboration agreement with Fluidigm that also extended the term of the supply agreement until March 2018. Evan Jones, our Chief Executive Officer and Chairman of the Board, is a director of Fluidigm. The Company paid \$183,713 related to these agreements in the year ended December 31, 2016. The Company paid \$295,442 related to these agreements in the year ended December 31, 2015. Under the agreements with Fluidigm, the Company had purchases of \$91,399 in the year ended December 31, 2016. The Company had purchases of \$370,539 related to these agreements in the year ended December 31, 2015. In addition, we have several capital lease arrangements for laboratory equipment manufactured by Fluidigm. Under the capital lease arrangements, we paid Fluidigm \$119,919 and \$175,475 related to leased equipment in 2015 and 2016, respectively. We believe that our transactions with Fluidigm were on commercially reasonable terms no less favorable to us than could have been obtained from unaffiliated third parties. The terms of our transactions with Fluidigm have been ratified and approved by the Board, without the participation of Mr. Jones. We intend that any future transactions with Fluidigm will be approved by the Board without the participation of Mr. Jones. Mr. Jones has no direct or indirect financial or pecuniary interest in these ordinary course business transactions between OpGen and Fluidigm.

In October 2016, the Company entered into an agreement with Merck Sharp & Dohme Corp., a wholly owned subsidiary of Merck, an affiliate of MGHIF, a principal stockholder of the Company and a related party. Under the agreement, Merck will provide access to its archive of over 200,000 bacterial pathogens. OpGen will initially perform molecular analyses on up to 10,000 pathogens to identify markers of resistance to support rapid decision making using the Acuitas Lighthouse MDRO Management System, and to speed development of OpGen's rapid diagnostic platforms. Merck will gain access to the high-resolution genotype data for the isolates as well as access to OpGen's Acuitas Lighthouse informatics to support internal research and development programs. OpGen is required to expend up to \$175,000 for the procurement of materials related to the activities contemplated by the agreement. As of December 31, 2016, the Company has incurred \$32,270 of procurement costs which have been recognized as research and development expense.

In December 2016, the Company entered into an agreement with Healthcare Services & Solutions LLC, an affiliate of MGHIF in which the Company will provide research analysis and reports to the third party on behalf of Healthcare Services & Solutions LLC. The agreement is worth up to \$150,000, of which \$135,000 has been recognized as of December 31, 2016.

## ***Sales and Purchases of Securities***

On May 19, 2016 and June 27, 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 share of common stock and a detachable stock purchase warrant to purchase an additional 0.75 of one share of common stock, or (ii) one share of non-voting convertible preferred stock a detachable stock purchase warrant to purchase an additional 0.75 of one share of common stock, at a price of \$1.14 per unit. The total net proceeds to the Company, after deducting offering commissions and expenses was \$9.5 million. The Company is using the proceeds for working capital and general corporate purposes. Pursuant to the private offering the Company issued 6,744,127 shares of common stock, 2,309,428 shares of Series A non-voting convertible preferred stock and stock purchase warrants to acquire an additional 6,790,169 shares of common stock. Each share of non-voting convertible preferred stock was convertible at the option of the holder in whole or in part and from time to time into one share of common stock, is entitled to dividends on as “as converted basis” when and if dividends are issued to common stockholders, and participates in liquidation on a pari passu basis with common stockholders. Holders of the Series A non-voting convertible preferred stock subsequently converted all 2,309,428 shares of preferred stock into 2,309,428 shares of common stock. The stock purchase warrants issued as part of the units are exercisable \$1.3125 per share beginning 90 days after closing for five years, expiring on May 18, 2021. Evan Jones, our Chief Executive Officer and Chairman of the Board is a managing member of jVen Capital, LLC and has voting and investment authority over the shares owned by jVen Capital; Timothy Harris, a director of the Company; and Timothy Dec and Vadim Sapiro, officers of the Corporation, were all investors in these offerings.

On May 31, 2017, the Company entered into the Note Purchase Agreement with jVen Capital, under which jVen Capital agreed to lend bridge financing in an aggregate principal amount of up to \$1,500,000 to the Company in the form of three \$500,000 secured convertible promissory notes. As of the date of this prospectus, \$1,000,000 principal amount of promissory notes have been issued to jVen Capital and warrants to purchase an aggregate of 627,570 shares of common stock have been issued to jVen Capital and MGHIF. The principal terms of the bridge financing are described above under “Prospectus Summary” and incorporated herein by reference.

## **Policies for Approval of Related Person Transactions**

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

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS

The number of shares of the Company's common stock outstanding at the close of business on July 7, 2017 was 29,365,741 shares. The following table sets forth the beneficial ownership of the Company's common stock as of July 7, 2017 by each Company director and executive officer, by all directors and executive officers as a group, and by each person who owned of record, or was known to own beneficially, more than 5% of the outstanding shares of our common stock. Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act. In computing the number of shares beneficially owned by a person or a group and the percentage ownership of that person or group, shares of our common stock subject to options and warrants currently exercisable or exercisable within 60 days after July 7, 2017 are deemed outstanding, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. To the knowledge of the directors and executive officers of the Company, as of July 7, 2017, there are no persons and/or companies who or which beneficially own, directly or indirectly, shares representing more than 5% of the voting rights attached to all outstanding shares of the Company, other than as set forth below. Unless otherwise indicated, the address of each beneficial owner listed below is c/o OpGen, Inc., 708 Quince Orchard Road, Suite 205, Gaithersburg, MD 20878.

jVen Capital, LLC has informed the Company that it intends to participate in this offering in an amount up to \$1,000,000. However, because indications of interest are not binding agreements or commitments to purchase, jVen Capital LLC may determine to purchase fewer securities than it indicates an interest in purchasing or not to purchase any securities in this offering.

Name and Address of Beneficial Owner	Number of Shares of Common Stock	Percentage of Outstanding Common Shares
<b>5% Stockholders</b>		
Merck Global Health Innovation Fund, LLC (1) One Merck Drive 2W116 Whitehouse Station, NJ 08889	8,364,270	25.9%
jVen Capital, LLC (2) 11009 Cripplegate Road Potomac, MD 20854	4,988,963	16.3%
Versant Ventures III, LLC (3) One Sansome Street Suite 3630 San Francisco, CA 94104	3,034,373	10.2%
<b>Directors and Executive Officers</b>		
Evan Jones (4)	5,638,103	18.2%
Harry D'Andrea (5)	25,625	*
Timothy J.R. Harris, Ph.D., D.Sc. (6)	133,211	*
Tina S. Nova, Ph.D. (7)	3,125	-
David M. Rubin, Ph.D. (8)	-	-
Misti Ushio, Ph.D. (9)	15,625	*
Timothy C. Dec (10)	195,683	*
Vadim Sapiro (11)	98,837	*
All Directors and Executive Officers as a group (8 individuals) (12)	6,110,209	19.5%

\* Constitutes less than 1%

- (1) Consists of (i) 5,413,449 shares of common stock and (ii) currently exercisable warrants to acquire an additional 2,950,821 shares of common stock.
- (2) Consists of (i) 3,805,604 shares of common stock, and (ii) currently exercisable warrants to acquire an additional 1,183,359 shares of common stock.
- (3) Consists of (i) 2,539,214 and 14,997 shares of common stock beneficially owned by Versant Venture Capital III, L.P., or Versant Capital III, and Versant Side Fund III, L.P., or Versant SF III, respectively, and (ii) currently exercisable warrants to acquire an additional 477,342 and 2,820 shares of common stock owned by Versant Capital III and Versant SF III, respectively. Versant Ventures III, LLC is the sole general partner of Versant Capital III and Versant SF III.

- (4) Consists of (i) 3,805,604 shares of common stock and currently exercisable warrants to acquire an additional 1,183,359 shares of common stock beneficially owned by jVen Capital, LLC, (ii) 131,156 shares of common stock and currently exercisable warrants to acquire an additional 20,841 shares of common stock owned by Mr. Jones' spouse, and (iii) stock options to purchase 497,143 shares of common stock that are currently vested or that will become vested within 60 days. Mr. Jones is a managing member of jVen Capital, LLC and has voting and investment authority over the shares owned by that entity (see footnote 2 above).
- (5) Consists of stock options to purchase 25,625 shares of common stock that are currently vested or that will become vested within 60 days.
- (6) Consists of (i) 50,116 shares of common stock, (ii) currently exercisable warrants to acquire an additional 39,187 shares of common stock, and (iii) stock options to purchase 43,908 shares of common stock that are currently vested or that will become vested within 60 days.
- (7) Consists of stock options to purchase 3,125 shares of common stock that are currently vested or that will become vested within 60 days.
- (8) Dr. Rubin is the managing director of MGHIF, but does not have nor share voting power over the shares of our common stock owned by MGHIF.
- (9) Consists of stock options to purchase 15,625 shares of common stock that are currently vested or that will become vested within 60 days.
- (10) Consists of (i) 53,966 shares of common stock, (ii) currently exercisable warrants to acquire an additional 36,787 shares of common stock, and (iii) stock options to purchase 104,930 shares of common stock that are currently vested or that will become vested within 60 days.
- (11) Consists of (i) 15,115 shares of common stock, (ii) currently exercisable warrants to acquire an additional 9,837 shares of common stock, and (iii) stock options to purchase 73,885 shares of common stock that are currently vested or that will become vested within 60 days.
- (12) See the beneficial ownership described in footnotes (4) through (11).

## LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Ballard Spahr LLP, Philadelphia, Pennsylvania. Haynes and Boone, LLP, New York, New York will pass upon certain legal matters for the placement agent in connection with the securities offered hereby.

## EXPERTS

The financial statements as of December 31, 2016 and 2015 and for the years then ended included in this prospectus have been audited by CohnReznick LLP, an independent registered public accounting firm, as stated in their report, which includes an explanatory paragraph relating to our ability to continue as a going concern, appearing elsewhere in this prospectus. Such financial statements are included in reliance upon the report of such firm given on the authority of said firm as experts in accounting and auditing.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We filed with the Securities and Exchange Commission a registration statement under the Securities Act of 1933 for the shares of common stock in this offering. This prospectus does not contain all of the information in the registration statement and the exhibits and schedule that were filed with the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits and schedule that were filed with the registration statement. Statements contained in this prospectus about the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and we refer you to the full text of the contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules that were filed with the registration statement may be inspected without charge at the Public Reference Room maintained by the Securities and Exchange Commission at 100 F Street, N.E. Washington, DC 20549, and copies of all or any part of the registration statement may be obtained from the Securities and Exchange Commission upon payment of the prescribed fee. Information regarding the operation of the Public Reference Room may be obtained by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission maintains a website that contains reports, proxy and information statements, and other information regarding registrants that file electronically with the SEC. The address of the website is [www.sec.gov](http://www.sec.gov).

We file periodic reports under the Securities Exchange Act of 1934, including annual, quarterly and special reports, and other information with the Securities and Exchange Commission. These periodic reports and other information are available for inspection and copying at the regional offices, public reference facilities and website of the Securities and Exchange Commission referred to above.

We make available free of charge on or through our internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission.

**OPGEN, INC.**  
**Index to Audited Consolidated Financial Statements**  
**Years Ended December 31, 2016 and 2015**

<a href="#"><u>Report of Independent Registered Public Accounting Firm</u></a>	<a href="#"><u>F-2</u></a>
<a href="#"><u>Consolidated Balance Sheets at December 31, 2016 and 2015</u></a>	<a href="#"><u>F-3</u></a>
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<a href="#"><u>Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015</u></a>	<a href="#"><u>F-6</u></a>
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## Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
OpGen, Inc.

We have audited the accompanying consolidated balance sheets of OpGen, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for the years then ended. OpGen, Inc.'s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of OpGen, Inc. as of December 31, 2016 and 2015, 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 States of America.

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in the Note 1 to the consolidated financial statements, the Company has incurred cumulative net losses 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.

/s/ CohnReznick LLP  
Vienna, Virginia  
March 23, 2017

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

	<u>2016</u>	<u>2015</u>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 4,117,324	\$ 7,814,220
Accounts receivable, net	542,420	678,646
Inventory, net	692,368	826,012
Prepaid expenses and other current assets	329,646	566,239
<b>Total current assets</b>	<b>5,681,758</b>	<b>9,885,117</b>
Property and equipment, net	800,723	1,074,710
Goodwill	600,814	637,528
Intangible assets, net	1,620,998	1,888,814
Other noncurrent assets	279,752	270,327
<b>Total assets</b>	<b>\$ 8,984,045</b>	<b>\$ 13,756,496</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 2,232,563	\$ 2,285,792
Accrued compensation and benefits	578,480	1,081,270
Accrued liabilities	1,215,283	920,286
Deferred revenue	37,397	50,925
Short-term notes payable	1,023,815	—
Current maturities of long-term capital lease obligation	184,399	251,800
<b>Total current liabilities</b>	<b>5,271,937</b>	<b>4,590,073</b>
Deferred rent	398,084	352,985
Note payable	—	993,750
Long-term capital lease obligation and other noncurrent liabilities	146,543	328,642
<b>Total liabilities</b>	<b>5,816,564</b>	<b>6,265,450</b>
<b>Commitments (Note 10)</b>		
<b>Stockholders' equity</b>		
Common stock, \$0.01 par value; 200,000,000 shares authorized; 25,304,270 and 12,547,684 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	253,042	125,477
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2016 and December 31, 2015, respectively	—	—
Additional paid-in capital	136,199,382	121,490,994
Accumulated other comprehensive income/(loss)	6,176	(1,059)
Accumulated deficit	(133,291,119)	(114,124,366)
<b>Total stockholders' equity</b>	<b>3,167,481</b>	<b>7,491,046</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 8,984,045</b>	<b>\$ 13,756,496</b>

See accompanying notes to consolidated financial statements.



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

	<u>2016</u>	<u>2015</u>
<b>Revenue</b>		
Product sales	\$ 3,524,178	\$ 2,701,142
Laboratory services	228,904	120,476
Collaboration revenue	272,603	336,102
<b>Total revenue</b>	<b>4,025,685</b>	<b>3,157,720</b>
<b>Operating expenses</b>		
Cost of products sold	1,658,571	1,179,771
Cost of services	631,333	367,802
Research and development	8,613,236	6,002,941
General and administrative	6,602,608	5,834,642
Sales and marketing	5,529,274	4,305,444
Transaction expenses	—	526,283
<b>Total operating expenses</b>	<b>23,035,022</b>	<b>18,216,883</b>
<b>Operating loss</b>	<b>(19,009,337)</b>	<b>(15,059,163)</b>
<b>Other expense</b>		
Interest and other (expense)/income	(5,967)	26,657
Interest expense	(143,347)	(1,801,320)
Foreign currency transaction losses	(8,102)	—
Change in fair value of derivative financial instruments	—	(647,342)
<b>Total other expense</b>	<b>(157,416)</b>	<b>(2,422,005)</b>
<b>Loss before income taxes</b>	<b>(19,166,753)</b>	<b>(17,481,168)</b>
<b>Provision for income taxes</b>	<b>—</b>	<b>(129,095)</b>
<b>Net loss</b>	<b>(19,166,753)</b>	<b>(17,352,073)</b>
Preferred stock dividends and beneficial conversion	(332,550)	(243,762)
<b>Net loss available to common stockholders</b>	<b>\$ (19,499,303)</b>	<b>\$ (17,595,835)</b>
Net loss per common share - basic and diluted	<b>\$ (1.10)</b>	<b>\$ (2.20)</b>
Weighted average shares outstanding - basic and diluted	17,667,557	7,980,995
Net loss	\$ (19,166,753)	\$ (17,352,073)
Other comprehensive income/(loss) - foreign currency translation	7,235	(1,059)
<b>Comprehensive loss</b>	<b>\$ (19,159,518)</b>	<b>\$ (17,353,132)</b>

See accompanying notes to consolidated financial statements.

**OpGen, Inc.**  
**Consolidated Statements of Stockholders' Equity (Deficit)**

	<u>Common Stock</u>		<u>Preferred Stock</u>		<u>Additional Paid- in Capital</u>	<u>Accumulated Other Comprehensive (Loss) / Income</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Number of Shares</u>	<u>Amount</u>	<u>Number of Shares</u>	<u>Amount</u>				
<b>Balances at December 31, 2014</b>	<b>493,178</b>	<b>\$ 4,932</b>	—	—	<b>\$ 88,701,737</b>	<b>\$ —</b>	<b>\$ (96,772,293)</b>	<b>\$ (8,065,624)</b>
Stock option exercises	11,472	114	—	—	2,189	—	—	2,303
Beneficial conversion feature	—	—	—	—	1,427,667	—	—	1,427,667
Reclassification of warrant liability to equity	—	—	—	—	719,675	—	—	719,675
Conversion of preferred stock into common shares	7,374,852	73,749	—	—	7,730,423	—	—	7,804,172
Demand notes tendered for IPO Units	350,000	3,500	—	—	2,096,500	—	—	2,100,000
Issuance of IPO units, net of offering costs	2,500,000	25,000	—	—	12,104,133	—	—	12,129,133
Additional IPO issuance costs	—	—	—	—	(58,566)	—	—	(58,566)
Common shares issued in business combination	681,818	6,818	—	—	2,577,272	—	—	2,584,090
Common shares issued in financing	1,136,364	11,364	—	—	4,988,638	—	—	5,000,002
Stock compensation expense	—	—	—	—	1,445,088	—	—	1,445,088
Accretion of Series A preferred stock	—	—	—	—	(243,762)	—	—	(243,762)
Foreign currency translation	—	—	—	—	—	(1,059)	—	(1,059)
Net loss	—	—	—	—	—	—	(17,352,073)	(17,352,073)
<b>Balances at December 31, 2015</b>	<b>12,547,684</b>	<b>\$ 125,477</b>	—	—	<b>121,490,994</b>	<b>(1,059)</b>	<b>(114,124,366)</b>	<b>7,491,046</b>
Stock option exercises	66,502	665	—	—	23,106	—	—	23,771
Private offering of common stock, preferred stock and warrants, net of issuance costs	6,744,127	67,441	2,309,428	23,094	9,370,214	—	—	9,460,749
Preferred stock conversion	2,309,428	23,094	(2,309,428)	(23,094)	—	—	—	(0)
At the market offering, net of offering costs	3,619,863	36,199	—	—	4,369,774	—	—	4,405,973
Issuance of RSUs	16,666	166	—	—	(167)	—	—	(1)
Stock compensation expense	—	—	—	—	945,461	—	—	945,461
Foreign currency translation	—	—	—	—	—	7,235	—	7,235
Net loss	—	—	—	—	—	—	(19,166,753)	(19,166,753)
<b>Balances at December 31, 2016</b>	<b><u>25,304,270</u></b>	<b><u>\$ 253,042</u></b>	<b><u>—</u></b>	<b><u>\$ -</u></b>	<b><u>\$ 136,199,382</u></b>	<b><u>\$ 6,176</u></b>	<b><u>\$ (133,291,119)</u></b>	<b><u>\$ 3,167,481</u></b>

See accompanying notes to consolidated financial statements.

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

	<u>2016</u>	<u>2015</u>
<b>Cash flows from operating activities</b>		
Net loss	\$ (19,166,753)	\$ (17,352,073)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	656,047	624,653
Loss on disposal of property and equipment	6,309	—
Deferred tax benefit	—	(129,095)
Noncash interest expense	4,527	1,598,312
Share-based compensation	945,461	1,445,088
Inventory obsolescence	113,465	—
Change in fair value of derivative financial instruments	—	647,342
Other non-cash items	—	24,010
Changes in operating assets and liabilities, net of effects of acquisition:		
Accounts receivable	136,226	359,298
Inventory	20,179	424,505
Other assets	263,882	(319,305)
Accounts payable	(53,229)	196,444
Accrued compensation and other liabilities	(163,223)	(1,508,937)
Deferred revenue	(13,528)	(288,246)
<b>Net cash used in operating activities</b>	<b>(17,250,637)</b>	<b>(14,278,004)</b>
<b>Cash flows from investing activities</b>		
Cash acquired in business combinations	—	1,367,211
Purchases of property and equipment (net of proceeds on disposals)	(123,514)	(185,296)
<b>Net cash (used in)/provided by investing activities</b>	<b>(123,514)</b>	<b>1,181,915</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock, net of issuance costs	4,405,973	17,366,620
Proceeds from issuance of convertible notes and warrants, net of issuance costs	—	1,388,815
Proceeds from issuance of promissory notes, net of issuance costs	204,895	1,741,667
Proceeds from exercise of stock options and warrants	23,771	2,293
Proceeds from private offering of common stock, preferred stock and warrants, net of issuance costs	9,460,749	—
Payments on debt	(178,997)	(155,000)
Payments on capital lease obligations	(251,701)	(175,317)
<b>Net cash provided by financing activities</b>	<b>13,664,690</b>	<b>20,169,078</b>
Effects of exchange rates on cash	12,565	(8,286)
Net (decrease)/increase in cash and cash equivalents	(3,696,896)	7,064,703
Cash and cash equivalents at beginning of period	7,814,220	749,517
<b>Cash and cash equivalents at end of period</b>	<b>\$ 4,117,324</b>	<b>\$ 7,814,220</b>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 58,564	\$ 194,288
<b>Supplemental disclosures of noncash investing and financing activities:</b>		
Acquisition of equipment purchased through capital leases	\$ —	\$ 580,477
Common stock issued in business combination	\$ —	\$ 2,584,090
Conversion of convertible promissory notes to Series A preferred stock	\$ —	\$ 3,000,000
Conversion of series A preferred stock into common shares	\$ —	\$ 8,183,661
Exchange of demand notes for IPO units	\$ —	\$ 2,100,000
Exchange of demand note for convertible debt	\$ —	\$ 300,000

See accompanying notes to consolidated financial statements.

## OpGen, Inc.

### Notes to Consolidated Financial Statements

#### Note 1 – Organization

OpGen, Inc. (“OpGen” of the “Company”) was incorporated in Delaware in 2001. On July 14, 2015, OpGen completed the strategic acquisition (the “Merger”) of AdvanDx, Inc. and its wholly owned subsidiary AdvanDx A/S (collectively, “AdvanDx”) (see Note 4). 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, Inc. with AdvanDx, Inc. surviving as OpGen’s wholly owned subsidiary. OpGen, AdvanDx, Inc. and AdvanDx A/S 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 bioinformatics to help combat infectious disease. The Company is developing molecular information products and services to combat infectious disease in global healthcare settings, helping to guide clinicians with more rapid information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms. Its proprietary DNA tests and bioinformatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize patient care decisions and protect the hospital biome through customized screening and surveillance products and services.

The Company’s molecular diagnostics and bioinformatics offerings combine its Acuitas DNA tests, Acuitas Lighthouse bioinformatics services, and CLIA lab services for MDRO surveillance. The Company is working to deliver its products and services, some in development, to a global network of customers and partners. These include:

- Its Acuitas DNA tests, which provide rapid microbial identification, and antibiotic resistance gene information. These products include the QuickFISH family of FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures, the Acuitas MDRO Gene Test to detect, type, track, and trend antibiotic resistant organisms in real-time and the Acuitas Rapid Test in development. The Company is working to provide actionable, precise diagnostic information powered by pathogen surveillance data collected through hospital screening programs and a network of hospital and public health laboratories globally.
- Its Acuitas Lighthouse bioinformatics systems, which are cloud-based HIPAA compliant bioinformatics offerings that combine clinical lab test results with patient and hospital information and provide analytics to help manage MDROs in the hospital and patient care environment. These include its Acuitas Lighthouse informatics, which can be specific to a healthcare facility, public health department or collaborator, such as a pharmaceutical company, and its Acuitas Lighthouse Knowledgebase, a proprietary data warehouse in development to include genomic data matched with antibiotic susceptibility information for microbes and patient information from healthcare providers, in which the Company is beginning to collect and store MDRO information from a variety of sources for use with its Acuitas Rapid Test in development.

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 has raised significant funds in 2016 and 2015, including:

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, 2016, the Company has sold an aggregate of approximately 3.6 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$4.4 million, and gross proceeds of \$4.7 million. As of December 31, 2016, under the initial sales agreement, remaining availability under the at the market offering is \$6.8 million. Subsequent to December 31, 2016, the Company has sold an aggregate of approximately 2.1 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$2.1 million, and gross proceeds of \$2.2 million. Under the initial sales agreement, remaining availability under the at the market offering is \$4.6 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 Merck GHI and jVen Capital, each unit consisting of either (i) one share of common stock and a detachable stock purchase warrant to purchase an additional 0.75 shares of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.75 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 6,744,127 shares of common stock, 2,309,428 of non-voting convertible preferred stock and stock purchase warrants to acquire an additional 6,790,169 shares of common stock.

In July 2015, the Company raised \$6.0 million by issuing 1,136,364 shares of common stock at \$4.40 per share and a \$1.0 million senior secured promissory note to Merck GHI. Under the Purchase Agreement, Merck GHI has the right to participate in future securities offerings made by the Company (see Note 5).

In May 2015, OpGen completed its IPO for total gross proceeds of \$17.1 million (see Note 8).

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 will be sufficient to fund operations into the second quarter of 2017. This has led management to conclude that substantial doubt about the Company's ability to continue as a going concern exists. In the event the Company is unable to successfully raise additional capital during or before the second quarter of 2017, 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 timely, 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. Furthermore, the \$1.0 million senior secured promissory note matures in July 2017. If the company is unable to repay the note, negotiate its conversion or extend its term, the assets of the company may be seized, as the note is secured by a lien on all the company's assets.

### **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. Certain prior period information has been reclassified to conform to the current period presentation.

#### **Foreign Currency**

AdvanDx A/S is located in Copenhagen, Denmark and uses the Danish Kroner 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 income/(loss), a component of stockholders' equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive loss at December 31, 2016 and 2015.

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 13.

#### **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, 2016 and 2015, 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 \$26,716 and \$15,596 as of December 31, 2016 and 2015, respectively.

At December 31, 2016, the Company had accounts receivable from one customer, a related party, which individually represented 25% of total accounts receivable. At December 31, 2015, the Company had accounts receivable from one customer which individually represent 25% of total accounts receivable. No individual customer represented in excess of 10% of revenues for year ended December 31, 2016. For the year ended December 31, 2015, revenue earned from Hitachi High-Technologies Corporation ("Hitachi") represented 11% of total revenues.

## 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:

	<b>December 31,</b> <b>2016</b>	<b>December 31,</b> <b>2015</b>
Raw materials and supplies	\$ 479,479	\$ 362,526
Work-in process	27,422	150,369
Finished goods	185,467	313,117
Total	<u>\$ 692,368</u>	<u>\$ 826,012</u>

Inventory includes reagents and components for QuickFISH and PNA FISH kit products, Argus Whole Genome Mapping Systems, reagents and supplies used for Argus consumable kits, and reagents and supplies used for the Company's laboratory services. Inventory reserves for obsolescence and expirations were \$704,516 and \$591,051 at December 31, 2016 and 2015, respectively.

## Long-lived assets

### Property and equipment

Property and equipment is stated at cost and depreciated on a straight-line basis over the estimated useful lives of the related assets. The estimated service lives approximate three to five years. Depreciation expense was \$388,231 and \$500,467 for the years ended December 31, 2016 and 2015, respectively. Property and equipment consisted of the following at December 31, 2016 and 2015:

	<b>December 31,</b>	
	<b>2016</b>	<b>2015</b>
Laboratory and manufacturing equipment	\$ 3,785,133	\$ 3,734,044
Office furniture and equipment	688,952	701,557
Computers and network equipment	1,472,144	1,563,177
Leasehold improvements	662,506	659,949
	<u>6,608,735</u>	<u>6,658,727</u>
Less accumulated depreciation	(5,808,012)	(5,584,017)
Property and equipment, net	<u>\$ 800,723</u>	<u>\$ 1,074,710</u>

In 2012, the Company began to provide Argus™ Whole Genome Systems under its Argus Reagent Rental Program to customers, in which the Company retains title without requiring customers to purchase the equipment or enter into an equipment lease or rental contract. The costs associated with these instruments are capitalized and charged to sales and marketing on a straight-line basis over the estimated useful life of the instrument, which is approximately four years. During the years ended December 31, 2016 and 2015, sales and marketing expenses related to these costs were \$0 and approximately \$175,000, respectively. The costs to maintain these systems are charged to operations as incurred.

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, 2016 and 2015, the Company determined that its property and equipment was not impaired.

#### Intangible assets and goodwill

Intangible assets and goodwill as of December 31, 2016 were acquired as part of 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, 2016 and 2015:

	December 31, 2016			December 31, 2015	
	Cost	Accumulated Amortization	Net Balance	Accumulated Amortization	Net Balance
Trademarks and tradenames	\$ 461,000	\$ (67,575)	\$ 393,425	\$ (21,471)	\$ 439,529
Developed technology	458,000	(95,898)	362,102	(30,474)	427,526
Customer relationships	1,094,000	(228,529)	865,471	(72,241)	1,021,759
	<u>\$ 2,013,000</u>	<u>\$ (392,002)</u>	<u>\$ 1,620,998</u>	<u>\$ (124,186)</u>	<u>\$ 1,888,814</u>

Finite-lived intangible assets are amortized over their estimated useful lives. The estimated useful life of trademarks was 10 years, developed technology was 7 years, and customer relationships was 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 \$124,186 for the years ended December 31, 2016 and 2015, respectively. Amortization of intangible assets is expected to be approximately \$268,000 per year for the next five years.

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 years ended December 31, 2016 and 2015, 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 2016, events and circumstances indicated the Company's intangible assets might be impaired. However, management's estimate of undiscounted cash flows indicated that such carrying amounts were expected to be recovered. Nonetheless, it is reasonably possible that the estimate of undiscounted cash flows may change in the near term resulting in the need to write down those assets to fair value. Management's estimate of cash flows might change if the development of the Company's automated rapid pathogen identification product technological advances does not progress as planned, the timeline of development is delayed, there are changes to the estimates of the future marketability of this product or if the Company cannot obtain sufficient funding to pay for its development.



## *Goodwill*

Goodwill represents the excess of the purchase price for 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, 2016, 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 fair value 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, PNA FISH and XpressFISH 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.

### Revenue from license arrangements

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

### Revenue from sales of the Argus System

When an Argus System is sold without the Genome Builder software, total arrangement consideration is recognized as revenue when the system is delivered to the customer. Ancillary performance obligations, including installation, limited customer training and limited consumables, are considered inconsequential and are combined with the Argus System as one unit of accounting.

When an Argus System is sold with the Genome Builder software in a multiple-element arrangement, total arrangement consideration is allocated to the Argus System and to the Genome Builder software based on their relative selling prices. Selling prices are determined based on sales of similar systems to similar customers and, where no sales have occurred, on management's best estimate of the expected selling price relative to similar products. Revenue related to the Argus System is recognized when it is delivered to the customer; revenue for the Genome Builder software is recognized when it is delivered to the customer.

### Revenue from sales of Genome Builder Software and consumables (on a stand-alone basis)

Revenue is recognized for Genome Builder Software and for consumables, when sold on a standalone basis, upon delivery to the customer.

### Revenue from extended warranty service contracts

The Company recognizes revenue associated with extended warranty service contracts over the service period in proportion to the costs expected to be incurred over that same period.

### **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 \$150,950,436 and \$132,359,334 at December 31, 2016 and 2015, 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 13.5 million shares and 6.0 million shares as of December 31, 2016 and 2015, respectively. The Company's convertible preferred stock, prior to its conversion, contained non-forfeitable rights to dividends, and therefore was considered to be a participating security; the calculation of basic and diluted income (loss) per share excludes net income (but not net loss) attributable to the convertible preferred stock from the numerator and excludes the impact of those shares from the denominator in periods prior to the IPO.

### **Recent accounting pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance 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 is currently evaluating the impact, if any, that this guidance will have on its consolidated financial statements.

In August 2014, the FASB issued guidance requiring management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity's ability to continue as a going concern. The guidance 1) provides a definition for the term "substantial doubt," 2) requires an evaluation every reporting period, interim periods included, 3) provides principles for considering the mitigating effect of management's plans to alleviate the substantial doubt, 4) requires certain disclosures if the substantial doubt is alleviated as a result of management's plans, 5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and 6) requires an assessment period of one year from the date the financial statements are issued. This guidance is effective for the annual periods ending after December 15, 2016 and for annual and interim reporting periods thereafter. The Company has made the appropriate disclosures required by this guidance. The adoption of this guidance has had no financial statement impact.

In April 2015, the FASB issued accounting guidance requiring that debt issuance costs related to a recognized liability be presented on the balance sheet as a direct reduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected. The standard is effective for reporting periods beginning after December 15, 2015. The Company adopted this guidance effective January 1, 2016 on a retrospective basis, and all periods are presented under this guidance.

In April 2015, the FASB issued guidance as to whether a cloud computing arrangement (e.g., software as a service, platform as a service, infrastructure as a service, and other similar hosting arrangements) includes a software license and, based on that determination, how to account for such arrangements. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The guidance is effective for reporting periods beginning after December 15, 2015, and can be adopted on either a prospective or retrospective basis. The Company adopted this guidance for the year ended December 31, 2016, on a prospective basis. The adoption of this new guidance did 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 is currently evaluating the impact, if any, that this new accounting pronouncement will have on its 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.

In March 2016, the FASB issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards. Under the guidance, all excess tax benefits and tax deficiencies related to stock-based compensation awards are to be recognized as income tax expenses or benefits in the income statement and excess tax benefits should be classified along with other income tax cash flows in the operating activities section of the statement of cash flows. Under the guidance, companies can also elect to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. In addition, the guidance amends some of the other stock-based compensation awards guidance to more clearly articulate the requirements and cash flow presentation for withholding shares for tax-withholding purposes. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted, though all amendments of the guidance must be adopted in the same period. The Company elected to adopt the guidance effective for the fiscal year ended December 31, 2016 and apply it retrospectively for all periods presented. This has not materially impacted the Company's consolidated results of operations, financial position or cash flows.

The Company has evaluated all other issued and unadopted Accounting Standards Updates 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 – Business Combination

On July 14, 2015, the Company acquired 100% of the capital stock of AdvanDx in the Merger in a taxable transaction. AdvanDx researches, develops and markets advanced IVD kits for the diagnosis and prevention of infectious diseases, and sells its products principally to hospitals and clinical laboratories in the United States and Europe. The Company acquired AdvanDx principally to use AdvanDx's diagnostic capabilities with respect to MDROs and leverage AdvanDx's relationships with hospitals and clinical laboratories to accelerate the sales of OpGen's products and services.

Pursuant to an Agreement and Plan of Merger (the "Merger Agreement"), Velox Acquisition Corp. merged with and into AdvanDx, Inc. with AdvanDx, Inc. surviving as a wholly owned subsidiary of the Company in accordance with the General Corporation Law of the State of Delaware. Under the terms of the Merger Agreement, the merger consideration consisted of an aggregate 681,818 shares of the Company's common stock with a value of \$2.6 million (the "Merger Consideration"), which Merger Consideration was distributed in accordance with the liquidation preferences set forth in the AdvanDx, Inc. Restated Certificate of Incorporation, as amended.

The Company accounted for its acquisition of AdvanDx by recording all tangible and intangible assets acquired and liabilities assumed at their estimated fair values on the acquisition date, with the remaining unallocated purchase price recorded as goodwill. The fair value assigned to identifiable intangible assets acquired was determined using an income approach for trade names and customer relationships, and a cost approach for technology. The Company received carryover tax basis in the acquired assets and liabilities and no tax basis in the intangible assets (including goodwill) established on the acquisition date. As a result, the Company recognized deferred tax assets related to foreign taxing jurisdictions of \$4.3 million (fully offset by a corresponding valuation allowance) and net deferred tax liabilities of \$0.1 million in the U.S. taxing jurisdiction. The net deferred tax liability in the U.S. taxing jurisdiction resulted in an income tax benefit related to a reduction in the Company's previously established valuation allowance (which reduction is accounted for outside of purchase accounting). The following represents the allocation of the purchase price (as adjusted for measurement period adjustments):

Total purchase price - fair value of common stock issued	\$ 2,584,090
Fair value of tangible assets acquired:	
Cash	\$ 1,367,211
Receivables	536,406
Inventory	881,273
Property and equipment	245,479
Other assets	359,587
Fair value of identifiable intangible assets acquired:	
Customer relationships	1,094,000
Developed technology	458,000
Trademarks and tradenames	461,000
Fair value of goodwill	600,814
Deferred tax liabilities, net	129,095
Fair value of liabilities assumed	3,290,585
	<u>\$ 2,584,090</u>

The total consideration paid in the acquisition exceeded the estimated fair value of the tangible and identifiable intangible assets acquired and liabilities assumed, resulting in approximately \$0.6 million of goodwill. Goodwill, primarily related to expected synergies gained from combining operations, sales growth from future product offerings and customers, together with certain intangible assets that do not qualify for separate recognition, including assembled workforce, is not tax deductible.

## Adjustments to goodwill

In the fourth quarter of 2015, the Company adopted new accounting guidance with respect to the accounting for measurement period adjustments resulting from business combinations. Under the new guidance, the Company is required to recognize adjustments to provisional amounts identified during the measurement period in the reporting period in which the adjustments are determined and disclose the portion of the amount recorded in current-period losses by line item that would have been recorded in previous reporting periods if the adjustment had been recognized as of the acquisition date.

During the fourth quarter of 2015, as a result of obtaining new information about facts and circumstances that existed as of the acquisition date, the Company adjusted the provisional estimated fair values of certain acquired assets and liabilities acquired in the Merger, resulting in an increase in goodwill recognized of \$345,781. During the first quarter of 2016, the Company identified an additional adjustment to the provisional estimated fair values, resulting in a decrease in goodwill recognized of \$36,714.

## Pro Forma Disclosures (unaudited)

The following unaudited pro forma financial information summarizes the results of operations for the year ended December 31, 2015 as if the Merger had been completed as of January 1, 2015. Pro forma information primarily reflects adjustments relating to (i) elimination of the interest on AdvanDx's outstanding debt, and (ii) the amortization of intangibles acquired. The pro forma amounts do not purport to be indicative of the results that would have actually been obtained if the acquisition occurred as of January 1, 2014 or that may be obtained in the future:

Unaudited pro forma results	December 31,
	2015
Revenues	\$ 5,231,844
Net loss	\$ (20,751,552)
Net loss per share	\$ (2.52)

## Note 5 – Merck GHI Financing

On July 14, 2015, as a condition of the Merger, the Company entered into the Purchase Agreement with Merck GHI, pursuant to which Merck GHI purchased 1,136,364 shares of common stock of the Company at \$4.40 per share for gross proceeds of \$5.0 million. Pursuant to the Purchase Agreement, the Company also issued to Merck GHI a 8% Senior Secured Promissory Note (the "Merck 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 Merck Note are secured by a lien on all of the Company's assets. Under the Purchase Agreement, Merck GHI 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 Merck GHI and the AdvanDx stockholders who received shares of the Company's common stock in the Merger, 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 consolidated balance sheets as a result of the Company's adoption of the new accounting guidance in 2016 (see Note 3), and are being amortized as interest expense over the life of the Merck Note. The remaining \$42,000 of issuance costs were charged to additional paid-in capital.

## Note 6 - Redeemable Convertible Preferred Stock

All shares of Series A Preferred Stock (including those shares issued in connection with the conversion of the 2014 and 2015 convertible debt) were converted into 7,374,852 shares of common stock in connection with the Company's IPO (see Notes 7 and 8). Before such conversion, the Series A Preferred Stock was redeemable at the option of the holders of 70% of the outstanding shares of Series A Preferred Stock, subject to certain additional requirements. The Company's redeemable convertible preferred stock was classified as temporary equity due to redemption provisions outside of the Company's control.

The Company issued 1,999,864 shares of Series A Preferred Stock in December 2013 at \$1.00 per share in exchange for \$1,999,864 in convertible promissory notes. In February 2014, the Company sold 1,405,096 shares of Series A redeemable convertible preferred stock for gross proceeds of \$1,405,096. In April 2014, the Company sold an additional 594,904 shares of Series A Preferred Stock for gross proceeds of \$594,904. The Company incurred issuance costs of \$62,098 related to the 2014 Series A Preferred Stock sales.

The following table presents the changes in the Series A Preferred Stock during 2015:

	<u>Shares</u>	<u>Amount</u>
Balance at December 31, 2014	3,999,864	\$ 4,564,899
2015 Accretion	—	243,762
2015 Conversions	<u>(3,999,864)</u>	<u>(4,808,661)</u>
Balance at December 31, 2015	<u>—</u>	<u>\$ —</u>

The Series A Preferred Stock had the right to receive non-cumulative dividends, at a rate of 8% per annum, when and if declared by the board of directors. The Series A Preferred Stock had preference of payment over all other classes and series of capital stock of the Company with respect to dividends, payment on liquidation and payment on redemption. The liquidation and redemption preferences were at two times the Series A Preferred Stock purchase price. The Series A preferred stockholders were entitled to vote on all matters that come to stockholders on an as-converted basis with holders of the common stock. In addition, the Series A Preferred Stock had broad based anti-dilution rights.

The holders of Series A Preferred Stock had the right to convert such shares, at their option and at any time, into shares of common stock at the then-applicable conversion rate, as defined. The initial conversion rate was one common share for each preferred share, which may be adjusted for specified dilutive transactions. Beginning in December 2019, the Company may have been obligated to redeem shares of Series A Preferred Stock, if requested, by holders of at least 70% of the then-outstanding shares of preferred stock. The redemption, if requested, would have taken place in three equal annual installments. Series A Preferred Stock would have been redeemed at two times the original issue price per share plus all accrued and unpaid dividends. The redemptions were subject to certain equity adjustments for specified anti-dilution transactions, as defined.

#### **Note 7 – Debt**

As of December 31, 2016, the Company's outstanding debt consisted of the \$1.0 million Merck Note that is due in July 2017 (see Note 5). As of December 31, 2015, debt outstanding consisted of the \$1.0 million Merck Note.

#### **Demand notes**

In the fourth quarter of 2014 and first quarter of 2015, the Company raised a total of \$2.3 million through the issuance of short-term demand notes. In the first quarter of 2015, \$0.3 million of demand notes, held by an entity controlled by our chief executive officer, were settled as partial payment for a 2015 convertible note. All then-outstanding demand notes were tendered as payment for 350,000 units in the Company's IPO (see Note 8). Prior to settlement, the demand notes bore interest at 8% per annum, had a first priority security interest in the assets of the Company, and a term of approximately four months.

#### **2014 convertible debt**

In July, August and September 2014, the Company raised \$1.5 million through the issuance of convertible debt. All outstanding 2014 convertible debt was converted into Series A redeemable convertible preferred stock and then into 1,500,000 shares of common stock in connection with the Company's IPO (see Note 8). Prior to its conversion, the debt was convertible, at the option of the holders or in certain cases at the Company's option, into shares of Series A redeemable convertible preferred stock or other potential equity securities, bore interest at 8% and was due in full on July 11, 2015.



## 2015 convertible debt

In February and March 2015, the Company raised \$1.5 million in capital through the issuance of 8% secured convertible notes with detachable stock purchase warrants. All outstanding 2015 convertible debt was converted into Series A redeemable convertible preferred stock and then into 1,875,000 shares of common stock in connection with the Company's IPO (see Note 8). Prior to its conversion, the 2015 convertible notes were prepayable by the Company without penalty at any time following the three-month anniversary of the closing of the IPO (provided that before the six-month anniversary of the closing of an IPO, the 2015 convertible notes could only be prepaid out of newly issued capital subsequent to the IPO), and were puttable by the holder to the Company in the event of a defined default. The 2015 convertible notes were each convertible, at the election of the holder, into (i) shares of Series A redeemable convertible preferred stock, at a conversion rate of 1.25 shares of Series A redeemable convertible preferred stock for each \$1.00 converted if the conversion occurs prior to closing of an IPO, or (ii) shares of common stock at a conversion rate of one share of common stock for each \$1.00 converted if the conversion occurs after the closing of an IPO.

The conversion option embedded in the convertible notes was determined to contain beneficial conversion features, resulting in the bifurcation of those features as an equity instrument (resulting in an additional debt discount) at issuance. After allocation of the gross proceeds to the detachable stock purchase warrants (discussed below) and beneficial conversion feature, the total debt discount recognized was equal to the face value of the 2015 convertible notes. Upon conversion in May 2015, the remaining unamortized beneficial conversion feature of approximately \$1.5 million was charged to interest expense in the accompanying condensed consolidated statements of operations and comprehensive loss. Remaining unamortized deferred financing costs of \$71,421 were also charged to interest expense upon conversion.

The 2015 convertible note holders also received detachable stock purchase warrants exercisable for 225,011 shares of common stock at 110% of the IPO price and exercisable only if the IPO occurred, and then exercisable beginning on the six-month anniversary of the closing of the IPO. Prior to the IPO, as a result of net settlement features, the stock purchase warrants were considered derivative liabilities, were initially recorded at fair value (resulting in a debt discount) and were marked-to-market at each balance sheet date through earnings. As a result of the elimination of the net settlement features in the IPO, the stock purchase warrants were marked to fair value of \$0.7 million on May 8, 2015 and then reclassified to equity.

Total interest expense on all debt instruments was \$143,347 for the year ended December 31, 2016. Total interest expense on all debt instruments was \$1,801,320 for year ended December 31, 2015.

## Note 8 - Stockholders' Equity

As of December 31, 2016, the Company has 200,000,000 shares of authorized common shares and 25,304,270 issued and outstanding, and 10,000,000 of authorized preferred shares, none of which were issued or outstanding.

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, 2016, the Company has sold an aggregate of approximately 3.6 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$4.4 million, and gross proceeds of \$4.7 million. As of December 31, 2016, remaining availability under the at the market offering is \$6.8 million. Subsequent to December 31, 2016, the Company has sold an aggregate of approximately 2.1 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$2.1 million, and gross proceeds of \$2.2 million. Under the initial sales agreement, remaining availability under the at the market offering is \$4.6 million.

On May 19, 2016 and June 27, 2016, the Company offered and sold units in a private offering to members of management and employees and to accredited investors, including Merck GHI and jVen Capital, each unit consisting of either (i) one share of common stock and a detachable stock purchase warrant to purchase an additional 0.75 shares of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.75 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 6,744,127 shares of common stock, 2,309,428 of Series A non-voting convertible preferred stock and stock purchase warrants to acquire an additional 6,790,169 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 share of common stock, was entitled to dividends on as "as converted basis" when and if dividends are issued to common stockholders, and participates in liquidation on a *pari passu* basis with common stockholders. The preferred stock was classified as permanent equity. The stock purchase warrants issued as part of the units are exercisable \$1.3125 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, 2016. 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 stockholders. Holders of the Series A non-voting convertible preferred stock subsequently converted all 2,309,428 shares of preferred stock into 2,309,428 shares of common stock in July 2016. The shares of preferred stock were retired and are no longer available for future issuance.

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.

In July 2015, the Company issued 1,136,364 shares of common stock to Merck GHI for cash consideration of \$5.0 million (see Note 5).

On May 8, 2015, the Company completed its IPO pursuant to which the Company offered and sold 2,850,000 units, each unit consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of \$6.00 per unit. Of the total gross proceeds of \$17.1 million, approximately \$2.1 million was used to satisfy outstanding demand notes by exchanging such notes for 350,000 units in the IPO. After considering the demand notes, and underwriting discounts, commissions and offering expenses of \$2.9 million (which were charged to additional paid-in capital), the total net cash proceeds to the Company was \$12.1 million. On the IPO closing date, the underwriters exercised a portion of their over-allotment option to acquire an additional 422,500 stock purchase warrants for cash of \$4,225.

In connection with the IPO, all of the Company's outstanding Series A redeemable convertible preferred stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,852 shares of common stock. Prior to the IPO, the carrying value of the Series A redeemable convertible preferred stock was increased by the accretion of related discounts, issuance costs and accrued but unpaid dividends so that the carrying amount would equal the redemption amount at the dates the stock becomes redeemable.

The stock purchase warrants issued as part of the units (including over-allotment option) are exercisable for 3,272,500 shares of common stock at \$6.60 per share beginning six months after the closing of the IPO for five years, expiring on May 8, 2020. Additionally, the Company issued additional warrants to its investment bankers to purchase 185,250 shares of common stock, on the same terms as the warrants issued with the units. The warrants were valued using the Black-Scholes option pricing model and are classified as equity.

## 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) 1,355,000 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, 2016, 669,651 shares remain available for issuance under the 2015 Plan.

For the years ended December 31, 2016 and 2015, the Company recognized stock compensation expense as follows:

	Year Ended December 31,	
	2016	2015
Cost of services	\$ 6,003	\$ —
Research and development	236,341	240,739
General and administrative	599,550	619,899
Sales and marketing	103,567	584,450
	<u>\$ 945,461</u>	<u>\$ 1,445,088</u>

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, 2016, the Company had unrecognized expense related to its stock options of \$2.2 million, which will be recognized over a weighted average period of 1.17 years.

A summary of the status of options granted is presented below as of and for the years ended December 31, 2016 and 2015:

	<b>Number of Options</b>	<b>Weighted- Average Exercise Price</b>	<b>Weighted- Average Remaining Contractual Life (in years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at January 1, 2015	404,272		9.3	\$ —
Granted	1,961,637	\$ 2.68		
Exercised	(11,472)	\$ 0.20		\$ 19,519
Forfeited	(193,657)	\$ 0.55		
Outstanding at December 31, 2015	2,160,780	\$ 2.60	9.1	\$ 1,575,646
Granted	1,463,650	\$ 1.41		
Exercised	(66,502)	\$ 0.36		\$ 79,406
Forfeited	(571,687)	\$ 3.99		
Expired	(8,581)	\$ 8.49		
Outstanding at December 31, 2016	2,977,660	\$ 1.76	8.6	\$ 663,298
Vested and expected to vest	2,977,660	\$ 1.76	8.6	\$ 663,298
Exercisable at December 31, 2016	1,098,504	\$ 0.22	8.0	\$ 421,621

The total fair value of options vested in the years ended December 31, 2016 and 2015, was \$1,088,978 and \$1,140,079, 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:

	<b>Year Ended December 31,</b>	
	<b>2016</b>	<b>2015</b>
Annual dividend	—	—
Expected life (in years)	5.25 - 6.25	5.5 - 6.25
Risk free interest rate	1.2 - 2.2%	1.5 - 1.9%
Expected volatility	42.0 - 49.8%	47.7 - 65.0%

The Company issued an annual grant on February 22, 2017 of 723,300 options to employees at an exercise price of \$1.03 per share.

#### Restricted stock units

In the fourth quarter of 2015, the Company granted restricted stock units to acquire 75,000 shares of common stock, with a weighted average grant date fair value of \$1.70 per share, 18,750 shares of which remain outstanding as of December 31, 2016. 16,666 restricted stock units vested and 39,584 restricted stock units were forfeited during the year ended December 31, 2016 at a weighted average grant date fair value of \$1.70 per share.

## Stock purchase warrants

At December 31, 2016 and 2015, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at December 31,	
			2016	2015
August 2007	\$ 7.91	August 2017	8,921	8,921
March 2008	\$ 790.54	March 2018	46	46
November 2009	\$ 7.91	November 2019	6,674	6,674
January 2010	\$ 7.91	January 2020	6,674	6,674
March 2010	\$ 7.91	March 2020	1,277	1,277
November 2011	\$ 7.91	November 2021	5,213	5,213
December 2011	\$ 7.91	December 2021	664	664
March 2012	\$ 109.90	March 2019	4,125	4,125
February 2015	\$ 6.60	February 2025	225,011	225,011
May 2015	\$ 6.60	May 2020	3,457,750	3,457,750
May 2016	\$ 1.31	May 2021	4,739,348	—
June 2016	\$ 1.31	May 2021	2,050,821	—
			<u>10,506,524</u>	<u>3,716,355</u>

The warrants listed above were issued in connection with various equity, debt, preferred stock or development contract agreements. The warrants issued in February 2015 were initially classified as a liability since the exercise price was variable. The exercise price became fixed as a result of the Company's IPO and, as such, the warrant liability was marked to fair value at that time and reclassified to equity (see Note 13).

## Note 9 - Income Taxes

At December 31, 2016 and 2015, the Company had net deferred tax assets of \$63,520,548 and \$41,554,045, respectively, primarily consisting of NOL carry forwards, 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, 2016 and 2015 have been offset by a valuation allowance of \$63,520,548 and \$41,554,045, 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, 2016 and 2015 are as follows:

	December 31,	
	2016	2015
<b>Deferred tax assets:</b>		
NOL carryforward	\$ 60,357,220	\$ 38,797,762
R&E credit carryforward	2,559,479	1,994,478
Share-based compensation	448,534	383,153
Inventory reserve	269,708	226,299
Depreciation	117,629	313,714
Accruals and other	333,126	495,640
Total deferred tax assets	<u>64,085,696</u>	<u>42,211,046</u>
Valuation allowance	<u>(63,520,548)</u>	<u>(41,554,045)</u>
<b>Deferred tax liabilities:</b>		
Intangible assets	(565,148)	(657,001)
Fixed assets	—	—
Net deferred tax liability	<u>\$ —</u>	<u>\$ —</u>

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:

	2016	2015
Federal income tax benefit at statutory rates	34.0%	34.0%
State income tax benefit, net of Federal benefit	6.5%	3.3%
Change in valuation allowance	(37.3)%	(32.1)%
Change in state tax rates and other	(3.2)%	(4.5)%
	<u>0.0%</u>	<u>0.7%</u>

Additionally, despite the NOL carryforwards, the Company may have future tax liability due to alternative minimum tax or state tax requirements. The Company has federal NOL carryforwards of \$150,950,436 and \$132,359,334 at December 31, 2016 and 2015, respectively. The NOL carry forwards 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.

#### Note 10 - 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, 2016 and 2015 was \$1,000,726 and \$683,519, 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, 2016:

Year ending December 31,	Capital Leases	Operating Leases	Total
2017	\$ 204,354	\$ 1,072,448	\$ 1,276,802
2018	113,337	1,205,263	1,318,600
2019	21,266	427,769	449,035
2020	21,266	427,769	449,035
2021 and thereafter	1,773	463,416	465,189
Total	<u>\$ 361,996</u>	<u>\$ 3,596,665</u>	<u>\$ 3,958,661</u>
Less: amount representing interest	(31,054)		
Net present value of future minimum lease payments	\$ 330,942		
Current maturities	(184,399)		
Long-term maturities	<u>\$ 146,543</u>		

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

	2016	2015
Laboratory and manufacturing equipment	\$ 560,829	\$ 803,500
Office furniture and equipment	64,790	89,140
Computers and network equipment	24,350	153,693
Less accumulated amortization	(270,808)	(402,066)
Capital lease assets, net	<u>\$ 379,161</u>	<u>\$ 644,267</u>

Amortization expense associated with equipment under capital leases for the years ended December 31, 2016 and 2015 was \$161,606 and \$157,036, 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.

#### Note 11 - License Agreements, Research Collaborations and Development Agreements

The Company is a party to five license agreements to acquire certain patent rights and technologies; two related to the FISH product line and three related to the Argus and MapIt product lines. 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 \$290,491 and \$205,147 for the years ended December 31, 2016 and 2015, respectively. Annual future minimum royalty fees are \$250,000 under these agreements.

In September 2013, the Company entered into a technology development agreement with Hitachi High-Technologies Corporation ("Hitachi") that included fixed milestone payments for meeting development milestones under the agreement. Since the milestones were substantive, the Company recognized revenue in the periods in which the substantive milestones were achieved. In addition, the Company received an upfront payment which was recognized on a straight-line basis over the term of the technology development agreement, which ended on December 31, 2015. The Company recognized total revenue of \$336,102 for the year ended December 31, 2015 (none in 2016), relating to this arrangement.

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, 2016, the Company recognized \$137,603 of revenue related to the license agreement.

#### Note 12 – 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 \$183,713 related to these agreements in the year ended December 31, 2016. The Company paid \$295,442 related to these agreements in the year ended December 31, 2015.

Under the agreements with Fluidigm, the Company had purchases of \$91,399 in the year ended December 31, 2016. The Company had purchases of \$370,539 related to these agreements in the year ended December 31, 2015.

In addition, the Company has several capital lease arrangements for laboratory equipment manufactured by Fluidigm. The Company paid \$175,475 related to the leased equipment in the year ended December 31, 2016. The Company paid \$119,919 related to the leased equipment in the year ended December 31, 2015.

In October 2016, the Company entered into an agreement with Merck Sharp & Dohme Corp., a wholly owned subsidiary of Merck Co. & Inc. ("Merck"), an affiliate of Merck Global Health Innovation Fund ("Merck GHI"), a principal stockholder of the Company and a related party to the Company. Under the agreement, Merck will provide access to its archive of over 200,000 bacterial pathogens. OpGen will initially perform 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 OpGen's rapid diagnostic products. Merck will gain access to the high-resolution genotype data for the isolates as well as access to OpGen's Acuitas Lighthouse informatics to support internal research and development programs. OpGen is required to expend up to \$175,000 for the procurement of materials related to the activities contemplated by the agreement. As of December 31, 2016, the Company has incurred \$32,270 of procurement costs which have been recognized as research and development expense.

In December 2016, the Company entered into an agreement with Healthcare Services & Solutions LLC, an affiliate of Merck GHI, in which the Company will provide research analysis and reports to the third party. The agreement is worth up to \$150,000, of which \$135,000 has been recognized as of December 31, 2016. At December 31, 2016, the Company had accounts receivable from this customer of \$135,000, which individually represented 25% of total accounts receivable.

### **Note 13 – 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.



Prior to its IPO, certain stock purchase warrants contained cash settlement features and, accordingly, the Company considered them to be derivative financial instruments and accounted for them at fair value using level 3 inputs. As a result of the Company's IPO and elimination of the cash settlement features pursuant to their terms, those stock purchase warrants were reclassified to equity. For periods prior to the IPO, the Company determined the fair value of these derivative liabilities using a hybrid valuation method that consisted of a probability weighted expected return method that values the Company's equity securities assuming various possible future economic outcomes while using an option pricing method (that treated all equity linked instruments as call options on the Company's equity value with exercise prices based on the liquidation preference of the Series A Preferred Stock ) to estimate the allocation of value within one or more of the scenarios. Using this hybrid method, unobservable inputs included the Company's equity value, the exercise price for each option value, expected timing of possible economic outcomes such as initial public offering, risk free interest rates and stock price volatility. The following tables set 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, 2015 (there has been no activity for the year ended December 31, 2016):

<b>Description</b>	<b>Balance at December 31, 2014</b>		<b>Established in 2015</b>		<b>Change in Fair Value</b>		<b>Reclassified to Equity</b>		<b>Balance at December 31, 2015</b>	
Derivative warrant liability	\$	—	\$	72,333	\$	647,342	\$	(719,675)	\$	—

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 2016 and 2015.

See Note 4 for a discussion of the fair value of assets acquired and liabilities assumed in the Merger.

**OPGEN, INC.**  
**Index to Unaudited Consolidated Interim Condensed Financial Statements**  
**Three Months Ended March 31, 2017 and 2016**

<a href="#">Condensed Consolidated Balance Sheets at March 31, 2017 and December 31, 2016</a>	<a href="#">F-30</a>
<a href="#">Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three-Month Periods ended March 31, 2017 and 2016</a>	<a href="#">F-31</a>
<a href="#">Condensed Consolidated Statements of Cash Flows for the Three-Month Periods ended March 31, 2017 and 2016</a>	<a href="#">F-32</a>
<a href="#">Unaudited Notes to Condensed Consolidated Financial Statements</a>	<a href="#">F-33</a>

**OpGen, Inc. and Subsidiaries**  
**Condensed Consolidated Balance Sheets**  
(unaudited)

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 1,670,311	\$ 4,117,324
Accounts receivable, net	379,246	542,420
Inventory, net	642,961	692,368
Prepaid expenses and other current assets	267,971	329,646
<b>Total current assets</b>	<b>2,960,489</b>	<b>5,681,758</b>
Property and equipment, net	743,521	800,723
Goodwill	600,814	600,814
Intangible assets, net	1,554,044	1,620,998
Other noncurrent assets	298,081	279,752
<b>Total assets</b>	<b>\$ 6,156,949</b>	<b>\$ 8,984,045</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 2,017,202	\$ 2,232,563
Accrued compensation and benefits	1,019,962	578,480
Accrued liabilities	883,105	1,215,283
Deferred revenue	31,233	37,397
Short-term notes payable	998,958	1,023,815
Current maturities of long-term capital lease obligation	170,297	184,399
<b>Total current liabilities</b>	<b>5,120,757</b>	<b>5,271,937</b>
Deferred rent	374,194	398,084
Long-term capital lease obligation and other noncurrent liabilities	107,940	146,543
<b>Total liabilities</b>	<b>5,602,891</b>	<b>5,816,564</b>
<b>Commitments (Note 8)</b>		
<b>Stockholders' equity</b>		
Common stock, \$0.01 par value; 200,000,000 shares authorized; 27,377,490 and 25,304,270 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	273,775	253,042
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at March 31, 2017 and December 31, 2016, respectively	—	—
Additional paid-in capital	138,546,915	136,199,382
Accumulated other comprehensive income	2,419	6,176
Accumulated deficit	(138,269,051)	(133,291,119)
<b>Total stockholders' equity</b>	<b>554,058</b>	<b>3,167,481</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 6,156,949</b>	<b>\$ 8,984,045</b>

*See accompanying notes to unaudited condensed consolidated financial statements.*

**OpGen, Inc. and Subsidiaries**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
(unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Revenue</b>		
Product sales	\$ 734,502	\$ 947,219
Laboratory services	16,105	129,420
Collaboration revenue	21,164	—
<b>Total revenue</b>	<b>771,771</b>	<b>1,076,639</b>
<b>Operating expenses</b>		
Cost of products sold	424,950	345,967
Cost of services	100,233	315,709
Research and development	2,122,515	1,953,429
General and administrative	1,969,216	1,538,046
Sales and marketing	1,105,586	1,399,435
<b>Total operating expenses</b>	<b>5,722,500</b>	<b>5,552,586</b>
<b>Operating loss</b>	<b>(4,950,729)</b>	<b>(4,475,947)</b>
<b>Other expense</b>		
Interest and other income	21	173
Interest expense	(29,844)	(41,734)
Foreign currency transaction gains	2,620	11,328
<b>Total other expense</b>	<b>(27,203)</b>	<b>(30,233)</b>
<b>Loss before income taxes</b>	<b>(4,977,932)</b>	<b>(4,506,180)</b>
<b>Provision for income taxes</b>	<b>—</b>	<b>—</b>
<b>Net loss</b>	<b>(4,977,932)</b>	<b>(4,506,180)</b>
Preferred stock dividends and beneficial conversion	—	—
<b>Net loss available to common stockholders</b>	<b>\$ (4,977,932)</b>	<b>\$ (4,506,180)</b>
Net loss per common share - basic and diluted	<b>\$ (0.19)</b>	<b>\$ (0.36)</b>
Weighted average shares outstanding - basic and diluted	26,079,461	12,568,941
Net loss	\$ (4,977,932)	\$ (4,506,180)
Other comprehensive loss - foreign currency translation	(3,757)	(1,112)
<b>Comprehensive loss</b>	<b>\$ (4,981,689)</b>	<b>\$ (4,507,292)</b>

*See accompanying notes to unaudited condensed consolidated financial statements.*

**OpGen, Inc. and Subsidiaries**  
**Condensed Consolidated Statements of Cash Flows**  
(unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (4,977,932)	\$ (4,506,180)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	159,863	168,440
Loss on disposal of property and equipment	—	6,068
Noncash interest expense	2,087	1,042
Share-based compensation	245,405	261,497
Changes in operating assets and liabilities:		
Accounts receivable	163,174	39,411
Inventory	49,407	(97,849)
Other assets	43,346	199,182
Accounts payable	(215,361)	(80,276)
Accrued compensation and other liabilities	75,683	211,979
Deferred revenue	(6,164)	869
<b>Net cash used in operating activities</b>	<b>(4,460,492)</b>	<b>(3,795,817)</b>
<b>Cash flows from investing activities</b>		
Purchases of property and equipment (net of proceeds on disposals)	(27,022)	(1,644)
<b>Net cash used in investing activities</b>	<b>(27,022)</b>	<b>(1,644)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock, net of issuance costs	2,122,861	—
Proceeds from exercise of stock options and warrants	—	9,271
Payments on debt	(25,898)	—
Payments on capital lease obligations	(52,706)	(63,327)
<b>Net cash provided by/(used in) financing activities</b>	<b>2,044,257</b>	<b>(54,056)</b>
Effects of exchange rates on cash	(3,756)	5,254
Net decrease in cash and cash equivalents	(2,447,013)	(3,846,263)
Cash and cash equivalents at beginning of period	4,117,324	7,814,220
<b>Cash and cash equivalents at end of period</b>	<b>\$ 1,670,311</b>	<b>\$ 3,967,957</b>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 10,702	\$ 13,021
<b>Supplemental disclosures of noncash investing and financing activities:</b>		
Property and equipment purchased on credit	\$ 8,685	\$ 27,767
Deferred and accrued financing costs	\$ —	\$ 52,210

*See accompanying notes to unaudited condensed consolidated financial statements.*

**OpGen, Inc.**  
**Notes to Unaudited Condensed Consolidated Financial Statements**  
**March 31, 2017**

**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 bioinformatics to help combat infectious disease. The Company is developing molecular information products and services to combat infectious disease in global healthcare settings, helping to guide clinicians with more rapid information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms ("MDROs"). Its proprietary DNA tests and bioinformatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize patient care decisions and protect the hospital biome through customized screening and surveillance products and services.

The Company's molecular diagnostics and bioinformatics offerings combine its Acuitas DNA tests, Acuitas Lighthouse bioinformatics services, and CLIA lab services for MDRO surveillance. The Company is working to deliver its products and services, some in development, to a global network of customers and partners. These include:

- Its Acuitas DNA tests, which provide rapid microbial identification, and antibiotic resistance gene information. These products include (i) the QuickFISH family of FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures, (ii) the Acuitas MDRO Gene Test to detect, type, track, and trend antibiotic resistant organisms in real-time and (iii) the Acuitas Rapid Test in development. The Company is working to provide actionable, precise diagnostic information powered by pathogen surveillance data collected through hospital screening programs and a network of hospital and public health laboratories globally.
- Its Acuitas Lighthouse bioinformatics systems, which are cloud-based HIPAA compliant bioinformatics offerings that combine clinical lab test results with patient and hospital information and provide analytics to help manage MDROs in the hospital and patient care environment. These include its Acuitas Lighthouse informatics, which can be specific to a healthcare facility, public health department or collaborator, such as a pharmaceutical company, and its Acuitas Lighthouse Knowledgebase, a proprietary data warehouse in development to include genomic data matched with antibiotic susceptibility information for microbes and patient information from healthcare providers, in which the Company is beginning to collect and store MDRO information from a variety of sources for use with its Acuitas Rapid Test in development.

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 – Liquidity and management's plans**

The accompanying unaudited condensed consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Since inception, the Company has incurred, and continues to incur, significant losses from operations. The Company has funded its operations primarily through external investor financing arrangements and has raised funds in 2017 and 2016, including:

In September 2016, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company LLC ("Cowen") pursuant to which the Company may offer and sell from time to time, up to an aggregate of \$25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of \$11.5 million. 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 of 1933, as amended (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 March 31, 2017, the Company has sold an aggregate of approximately 5.7 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$6.5 million, and gross proceeds of \$6.9 million. As of March 31, 2017, remaining availability under the at the market offering is \$4.6 million. For the three months ended March 31, 2017, the Company has sold approximately 2.1 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$2.1 million, and gross proceeds of \$2.2 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 Merck Global Health Innovation Fund, LLC ("Merck GHI") and jVen Capital, LLC ("jVen Capital"), each unit consisting of either (i) one share of common stock and a detachable stock purchase warrant to purchase an additional 0.75 shares of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.75 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 were \$9.5 million. The Company used the proceeds for working capital and general corporate purposes. Pursuant to the private placement, the Company issued 6,744,127 shares of common stock, 2,309,428 shares of non-voting convertible preferred stock and stock purchase warrants to acquire an additional 6,790,169 shares of common stock.

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 will be sufficient to fund operations through a portion of the second quarter of 2017. 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 the second quarter of 2017, 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 timely, 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. Furthermore, the \$1.0 million Merck Note (see Note 4) matures in July 2017. If the Company is unable to repay the note, negotiate its conversion or extend its term, the assets of the Company may be seized, as the note is secured by a lien on all the Company's assets.

### **Note 3 - Summary of significant accounting policies**

#### **Basis of presentation and consolidation**

The Company has prepared the following unaudited condensed, consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission and the standards of accounting measurement set forth in the Interim Reporting Topic of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"). Certain information and note disclosures normally included in annual financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP") have been condensed or omitted, although the Company believes that the disclosures made are adequate to make the information not misleading. The Company recommends that the following condensed, consolidated financial statements be read in conjunction with the consolidated financial statements and the notes thereto included in the Company's latest Annual Report on Form 10-K. In the opinion of management, all adjustments that are necessary for a fair presentation of the Company's financial position for the periods presented have been reflected. All adjustments are of a normal, recurring nature, unless otherwise stated. The interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2016 consolidated balance sheet included herein was derived from the audited consolidated financial statements, but do not include all disclosures including notes required by GAAP for complete financial statements.

The accompanying unaudited interim condensed consolidated financial statements include the accounts of OpGen and its wholly-owned subsidiaries; all intercompany transactions and balances have been eliminated. The Company operates in one business segment.

### **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 income, a component of stockholders' equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive loss at March 31, 2017 and December 31, 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 U.S. dollar.

### **Use of estimates**

In preparing financial statements in conformity with GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In the accompanying condensed 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, 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.

### **Cash and cash equivalents**

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.

At March 31, 2017 and December 31, 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 condensed 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 \$31,118 and \$26,716 as of March 31, 2017 and December 31, 2016, respectively.

No individual customer represented in excess of 10% of revenues for the three months ended March 31, 2017 and 2016. At March 31, 2017, no individual customer represented in excess of 10% of total accounts receivable.



## 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:

	<b>March 31, 2017</b>	<b>December 31, 2016</b>
Raw materials and supplies	\$ 410,945	\$ 479,479
Work-in process	68,031	27,422
Finished goods	163,985	185,467
Total	<u>\$ 642,961</u>	<u>\$ 692,368</u>

Inventory now 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 \$134,679 and \$704,516 at March 31, 2017 and December 31, 2016, respectively. The primary driver of the decrease in the inventory reserves for obsolescence and expirations is the scrapping of legacy Argus Whole Genome Mapping Systems and the portion of the reagents and supplies used for Argus consumable kits. All items scrapped in the three months ended March 31, 2017 were fully reserved for as of December 31, 2016.

## Long-lived assets

### Property and equipment

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 three months ended March 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 March 31, 2017 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 March 31, 2017 and December 31, 2016:

	March 31, 2017			December 31, 2016	
	Cost	Accumulated Amortization	Net Balance	Accumulated Amortization	Net Balance
Trademarks and tradenames	\$ 461,000	\$ (79,101)	\$ 381,899	\$ (67,575)	\$ 393,425
Developed technology	458,000	(112,254)	345,746	(95,898)	362,102
Customer relationships	1,094,000	(267,601)	826,399	(228,529)	865,471
	<u>\$ 2,013,000</u>	<u>\$ (458,956)</u>	<u>\$ 1,554,044</u>	<u>\$ (392,002)</u>	<u>\$ 1,620,998</u>

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

Total amortization expense of intangible assets was \$66,954 for each of the three months ended March 31, 2017 and 2016, respectively. The Company estimates amortization expense related to intangible assets will be \$268,000 per year for each of the next five years.

Finite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any. During the three months ended March 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 2016, events and circumstances indicated the Company's intangible assets might be impaired. However, management's estimate of undiscounted cash flows indicated that such carrying amounts were expected to be recovered. Nonetheless, it is reasonably possible that the estimate of undiscounted cash flows may change in the near term resulting in the need to write down those assets to fair value. Management's estimate of cash flows might change if the development of the Company's automated rapid pathogen identification product technological advances does not progress as planned, the timeline of development is delayed, there are changes to the estimates of the future marketability of this product or if the Company cannot obtain sufficient funding to pay for its development.

### Goodwill

Goodwill represents the excess of the purchase price paid in a July 2015 merger transaction in which the Company acquired AdvanDx, Inc. and its subsidiary (the "Merger") over the fair values of the acquired tangible or intangible assets and assumed liabilities. Goodwill is not tax deductible in any relevant jurisdictions. The Company's goodwill balance as of March 31, 2017 and December 31, 2016 was \$600,814.

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

### 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, PNA FISH and XpressFISH 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.

#### 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.

#### **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.

#### **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 \$151.0 million at December 31, 2016. 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 14.0 million shares and 5.9 million shares as of March 31, 2017 and 2016, respectively.

### **Recent accounting pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance 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 it plans on completing formal contract reviews in the second half of 2017. While the Company continues to assess all of the potential impacts of these ASUs, the Company does not expect the implementation of these ASUs to have a significant impact on the Company's consolidated results of operations, financial position and cash flows. The Company will assess the disclosure requirements prescribed by these ASUs in the second half of 2017 and it may be required to expand its disclosures. The Company will assess the method of adoption in the second half of 2017.

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 Accounting Standards Updates 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 – 2015 Merck GHI financing**

In July 2015, in connection with the Merger, the Company entered into a Purchase Agreement with Merck GHI, pursuant to which Merck GHI purchased 1,136,364 shares of common stock of the Company at \$4.40 per share for gross proceeds of \$5.0 million. Pursuant to the Purchase Agreement, the Company also issued to Merck GHI a 8% Senior Secured Promissory Note (the "Merck 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 Merck Note are secured by a lien on all of the Company's assets. Under the Purchase Agreement, Merck GHI 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 Merck GHI 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 Merck Note. The remaining \$42,000 of issuance costs were charged to additional paid-in capital.

#### **Note 5 - Fair value measurements**

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

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

For the three months ended March 31, 2017, the Company has not transferred any assets between fair value measurement levels.

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

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the hierarchy. The Company has no financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2017.

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

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

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

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

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

The Company measures its long-lived assets, including property and equipment and intangible assets (including goodwill), at fair value on a non-recurring basis when they are deemed to be impaired. No such fair value impairment was recognized in the three months ended March 31, 2017 and 2016.

**Note 6 - Debt**

As of March 31, 2017 and December 31, 2016, the Company's outstanding debt consisted of the \$1.0 million Merck Note that is due in July 2017 (see Note 4).

Total interest expense on all debt instruments was \$29,844 and \$41,734 for the three months ended March 31, 2017 and 2016, respectively.

**Note 7 - Stockholders' equity**

As of March 31, 2017, the Company has 200,000,000 shares of authorized common shares and 27,377,490 issued and outstanding, and 10,000,000 of authorized preferred shares, of which none were issued or outstanding.

In September 2016, the Company entered into the Sales Agreement with Cowen pursuant to which the Company may offer and sell from time to time, up to an aggregate of \$25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of \$11.5 million. Pursuant to the Sales Agreement, Cowen may sell the shares of common stock by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including, without limitation, sales made by means of ordinary brokers' transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by the Company. The Company pays Cowen compensation equal to 3.0% of the gross proceeds from the sales of common stock pursuant to the terms of the Sales Agreement. As of March 31, 2017, the Company has sold an aggregate of approximately 5.7 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$6.5 million, and gross proceeds of \$6.9 million. As of March 31, 2017, remaining availability under the at the market offering is \$4.6 million. For the three months ended March 31, 2017, the Company has sold approximately 2.1 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$2.1 million, and gross proceeds of \$2.2 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 Merck GHI and jVen Capital, each unit consisting of either (i) one share of common stock and a detachable stock purchase warrant to purchase an additional 0.75 shares of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.75 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 6,744,127 shares of common stock, 2,309,428 of Series A non-voting convertible preferred stock and stock purchase warrants to acquire an additional 6,790,169 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 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 \$1.3125 per share beginning 90 days after closing for five years, expiring on May 18, 2021. The warrants are classified as permanent equity at March 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 2,309,428 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 Company adopted the 2008 Stock Option and Restricted Stock Plan (the "2008 Plan"), pursuant to which the Company's Board of Directors could grant either incentive or non-qualified stock options or shares of restricted stock to directors, key employees, consultants and advisors.

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

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 1,355,000 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 March 31, 2017, 1,145,402 shares remain available for issuance under the 2015 Plan, which includes 1,012,171 shares automatically added to the 2015 Plan on January 1, 2017.

On April 28, 2016, the Board of Directors of the Company made a stock option award to Evan Jones, the Company's Chief Executive Officer ("CEO") and Chairman of the Board. The non-qualified stock option award to acquire 766,500 shares of common stock represented approximately 6% of outstanding shares of common stock as of the date of the award. The stock option grant has an exercise price of \$1.35 per share, a ten-year term and a vesting schedule of 25% vesting of the award on the first annual anniversary of the date of grant and then 6.25% vesting each quarter thereafter over three additional years. The plan under which the award was made incorporates by reference the provisions of the Company's 2015 Plan applicable to stock option awards. The stock option award was contingent on receipt of stockholder approval, as the award was made outside of the Company's stockholder-approved incentive plans. The stockholders approved the stock option award at the Company's Annual Meeting of Stockholders held on June 22, 2016.

For the three months ended March 31, 2017 and 2016, the Company recognized stock compensation expense as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
Cost of services	\$ 1,823	\$ 4,312
Research and development	57,778	62,218
General and administrative	152,476	172,103
Sales and marketing	33,328	22,864
	<u>\$ 245,405</u>	<u>\$ 261,497</u>

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

During the three months ended March 31, 2017, the Company granted stock options to acquire 723,600 shares of common stock at a weighted average exercise price of \$1.03 per share and a weighted average grant date fair value of \$0.54 per share. 4,863 options were forfeited during the three months ended March 31, 2017 at a weighted average exercise price of \$1.82 per share. The Company had total stock options to acquire 3,514,071 shares of common stock outstanding at March 31, 2017.

#### **Restricted stock units**

In the fourth quarter of 2015, the Company granted restricted stock units to acquire 75,000 shares of common stock, with a weighted average grant date fair value of \$1.70 per share, 18,750 shares of which remain outstanding as of March 31, 2017. No restricted stock units vested and no restricted stock units were forfeited during the three months ended March 31, 2017.



## Stock purchase warrants

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

Issuance	Exercise Price	Expiration	Outstanding at	
			March 31, 2017	December 31, 2016
August 2007	\$ 7.91	August 2017	8,921	8,921
March 2008	\$ 790.54	March 2018	46	46
November 2009	\$ 7.91	November 2019	6,674	6,674
January 2010	\$ 7.91	January 2020	6,674	6,674
March 2010	\$ 7.91	March 2020	1,277	1,277
November 2011	\$ 7.91	November 2021	5,213	5,213
December 2011	\$ 7.91	December 2021	664	664
March 2012	\$ 109.90	March 2019	4,125	4,125
February 2015	\$ 6.60	February 2025	225,011	225,011
May 2015	\$ 6.60	May 2020	3,457,750	3,457,750
May 2016	\$ 1.31	May 2021	4,739,348	4,739,348
June 2016	\$ 1.31	May 2021	2,050,821	2,050,821
			<u>10,506,524</u>	<u>10,506,524</u>

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

## Note 8 - Commitments

### Operating leases

The Company leases a facility in Woburn, Massachusetts under an operating lease that expires January 30, 2022. The Company also leases a facility in Gaithersburg, Maryland under an operating lease that expires January 31, 2021, with one additional five-year renewal at the Company's election. 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 three months ended March 31, 2017 and 2016 was \$232,836 and \$254,044, 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.

### 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.

## Note 9 - License agreements, research collaborations and development agreements

The Company is a party to five license agreements to acquire certain patent rights and technologies; two related to the FISH product line and three related to the Argus and MapIt product lines. 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 \$69,245 and \$69,854 for the three months ended March 31, 2017 and 2016, respectively. Annual future minimum royalty fees are \$250,000 under these agreements.

In June 2016, the Company entered into a license agreement with Hitachi High-Technologies Corporation ("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 three months ended March 31, 2017, the Company recognized \$6,164 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 \$44,721 and \$93,224 related to these agreements in the three months ended March 31, 2017 and 2016, respectively.

Under the Supply Agreement with Fluidigm, the Company had inventory purchases of \$44,721 and \$67,775 in the three months ended March 31, 2017 and 2016, respectively.

In addition, the Company has several capital lease arrangements for laboratory equipment manufactured by Fluidigm. The Company paid \$30,254 and \$45,106 related to the leased equipment in the three months ended March 31, 2017 and 2016, respectively.

In October 2016, the Company entered into an agreement with Merck Sharp & Dohme Corp., a wholly-owned subsidiary of Merck Co. & Inc. ("Merck"), an affiliate of Merck GHI, a principal stockholder of the Company and a related party to the Company. Under the agreement, Merck will provide access to its archive of over 200,000 bacterial pathogens. OpGen will initially perform 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 OpGen's rapid diagnostic products. Merck will gain access to the high-resolution genotype data for the isolates as well as access to OpGen's 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 \$91,403 of procurement costs which have been recognized as research and development expense, including \$59,133 in the three months ended March 31, 2017.



**Up to 20,000,000 Units (each Unit contains 1 Share of Common Stock and 1 Common Warrant to purchase 1 Share of Common Stock)**  
**or**  
**Up to 20,000,000 Pre-funded Units (each Pre-funded Unit contains 1 Pre-funded Warrant to Purchase 1 Share of Common Stock and 1 Common Warrant to purchase 1 Share of Common Stock)**  
**(Shares of Common Stock Underlying the Pre-funded Warrants) and**  
**(Shares of Common Stock Underlying the Common Warrants)**

**PROSPECTUS**

**H.C. Wainwright & Co.**

, 2017

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## Information Not Required in Prospectus

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the fees and expenses, other than placement agent's fees and expenses, payable in connection with the registration of the common stock hereunder. All amounts are estimates except the SEC registration fee and the FINRA filing fee.

SEC registration fee	\$ 3,904.38
Legal fees and expenses	\$ 350,000.00
Accounting fees and expenses	\$ 250,000.00
FINRA filing fee	\$ 3,903.13
Printer costs and expenses	\$ 4,692.49
Total	<u>\$ 612,500.00</u>

**Item 14. Indemnification of Directors and Officers.**

The Registrant maintains insurance providing for indemnification of its officers and directors and certain other persons against liabilities and expenses incurred by any of them in certain stated proceedings and under certain stated conditions.

**Delaware Corporations**

Section 145 of the Delaware General Corporation Law, or DGCL, provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. Section 145 further provides that a corporation similarly may indemnify any such person serving in any such capacity who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or such other court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper.

## *Certificate of Incorporation and Bylaws*

The Registrant's certificate of incorporation, as amended, provides that a director of the Registrant shall not be personally liable to the Registrant or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Registrant or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit. If the DGCL is hereafter amended to authorize the further elimination or limitation of the liability of directors, then the liability of the directors of the Registrant, in addition to the limitation on personal liability provided herein, shall be limited to the fullest extent permitted by the amended DGCL. Any repeal or modification of this paragraph by the stockholders of the Registrant shall be prospective only, and shall not adversely affect any limitation on the personal liability of a director of the corporation at the time of such repeal or modification. The Registrant's certificate of incorporation further provides that the Registrant's officers and directors shall be indemnified by the Registrant as provided in the Registrant's bylaws.

Under the provisions of the Registrant's bylaws, as amended, any person who is or was a party or is threatened to be made a party of any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Registrant) by reason of the fact that he or she is or was a director, officer, employee or agent of the Registrant or is or was serving at the Registrant's request as a director, officer, employee or agent of another company or other entity shall be indemnified by the Registrant against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action, suit or proceeding if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the Registrant's best interests, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The Registrant shall further indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Registrant to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of the Registrant or is or was serving at the request of the Registrant as a director, officer, employee or agent of another corporation or other entity against expenses (including attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Registrant. Notwithstanding the foregoing, no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Registrant unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper.

The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he or she reasonably believed to be in, or not opposed to, the Registrant's best interests and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

In addition, to the extent that such a person is successful on the merits or otherwise in defense of any action, suit, or proceeding brought against him or her by reason of the fact that he or she is the Registrant's director, officer, employee or agent, he or she shall be indemnified against expenses, including attorneys' fees, actually and reasonably incurred in connection therewith.

The Registrant's bylaws, as amended, provide that expenses (including attorneys' fees) incurred by a director or officer in defending a civil, criminal, administrative, or investigative action, suit or proceeding may be paid by the Registrant in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of the director or officer to repay such amount if it shall ultimately be determined that he or she is not entitled to be indemnified by the Registrant. Such expenses, including attorneys' fees, incurred by other employees and agents may be paid upon such terms and conditions as the Board of Directors deems appropriate.

Any indemnification under the provisions summarized above (unless ordered by a court) shall be made by the Registrant only as authorized in each specific case upon a determination that indemnification of such person is proper under the circumstances because he or she has met the applicable standard of conduct set forth in the applicable provision. Such determination shall be made (1) by a majority vote of the Registrant's directors who are not parties to the action, suit or proceeding (even though less than a quorum), (2) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (3) by the stockholders.

The Registrant maintains director and officer insurance with respect to those claims described above in customary amounts.

The above discussion of the certificate of incorporation and bylaws of the Registrant and the DGCL is not intended to be exhaustive and is qualified in its entirety by such certificates of incorporation, bylaws and the DGCL.

The Registrant has entered into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors, such executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us and/or in furtherance of our rights. Additionally, each of our directors may have certain rights to indemnification, advancement of expenses and/or insurance provided by their affiliates, which indemnification relates to and might apply to the same proceedings arising out of such director's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors are primary and any obligation of the affiliates of those directors to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

**Item 15. Recent Sales of Unregistered Securities.**

The following list sets forth information as to all securities we have sold since May 1, 2014, which were not registered under the Securities Act.

(1) From July 11, 2014 through September 23, 2014, the Company issued convertible notes in an aggregate principal amount of \$2,000,000 to existing investors. The notes were convertible, in whole, at any time upon the approval of the requisite note holders, into Series A Convertible Preferred Stock. The notes were convertible into either (i) one share of Series A Convertible Preferred Stock for each \$1.00 of principal of the note or (ii) shares of a new series of preferred stock of the Company with the rights, privileges, preferences and restrictions determined by the Board of Directors, if issued in the next financing then conducted by the Company at a conversion price equal to the price per share of new preferred stock issued in such next financing of the Company, less twenty-five percent.

(2) In October 2014, the Board of Directors authorized the Company to raise bridge funding up to an aggregate of \$2,000,000 pursuant to the issuance and sale of secured demand notes to existing investors. The secured demand notes each have a term of up to four months. The Company drew down an aggregate of \$1,800,000 of such bridge funding between October 2014 and January 2015.

(3) In February 2015, the Company issued to existing investors \$1.2 million principal amount of convertible notes, or 2015 convertible notes, that are convertible into shares of either common stock or Series A Preferred Stock, depending on whether the public offering contemplated by this prospectus is consummated by June 30, 2015. The 2015 convertible notes were issued pursuant to a Notes Purchase Agreement, dated as of February 11, 2015. Following the initial closing, the Company offered an additional \$0.3 million principal of 2015 convertible notes, on the same terms, as a participation offering to existing investors in the Company who are party to the Company's Third Amended and Restated Investors' Rights Agreement, as amended. The 2015 convertible note holders were, or will, also be issued an aggregate of 225,013 warrants, exercisable for shares of common stock at 110% of the initial public offering price and exercisable only if the offering contemplated by this prospectus is consummated. There was no firm commitment on the part of any investor to participate in the 2015 convertible notes offering.

(4) 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 Merck Global Health Innovation Fund and jVen Capital, each unit consisting of either (i) one share of common stock and a detachable stock purchase warrant to purchase an additional 0.75 of one share of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.75 of one share of common stock, at a price of \$1.14 per unit. The total net proceeds to the Company, after deducting offering commissions and expenses was \$9.5 million.

(5) As of March 31, 2017, 0 warrants issued since May 1, 2014 had been exercised or forfeited.

(6) On May 31, 2017, the Company entered into a Note Purchase Agreement with jVen Capital, which Note Purchase Agreement was amended and restated on July 10, 2017, under which jVen Capital agreed to lend bridge financing in an aggregate principal amount of up to \$1,500,000 to the Company in the form of three \$500,000 secured convertible promissory notes. Pursuant to the terms of the amended and restated Note Purchase Agreement and the underlying bridge financing notes, if a “qualified financing” (offering of debt or equity securities with net proceeds of \$5 million or more to the Company) occurs, the Company has the obligation to repay the outstanding bridge financing notes within five business days after the closing of the qualified financing. If a qualified financing does not occur, and an event of default occurs (the Company fails to pay any outstanding bridge financing notes when due, seeks to liquidate the Company, enters into a bankruptcy proceeding, or fails to pay other indebtedness when due), the then-outstanding bridge financing notes would acquire a two times liquidation preference for unpaid principal and interest. Alternatively, jVen Capital may forego the two times liquidation preference and elect to convert the bridge financing notes to Series B Convertible Preferred Stock, or Preferred Stock, at a ratio of one share of non-voting preferred stock per \$1.00 of principal and interest, which non-voting Preferred Stock would be convertible into 10 shares of voting common stock, otherwise no further preferences are provided to the Preferred Stock. The bridge financing notes contain, and the Certificate of Designation for the Preferred Stock will contain, a blocker provision that prevents any issuance of securities as repayment of the bridge financing notes, or any conversion of the Preferred Stock into common stock if such conversion would violate NASDAQ Listing Rule 5635.

(7) In connection with the bridge financing transaction described in (6) above, the Company issued warrants to purchase 299,575 shares of common stock to jVen Capital, and warrants to purchase 327,995 shares of common stock the MGHIF.

We deemed the offers, sales and issuances of the securities described in paragraphs (1), (2), (3), (4), (6) and (7) above to be exempt from registration under the Securities Act, in reliance on Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, regarding transactions by an issuer not involving a public offering. All purchasers of securities in transactions exempt from registration pursuant to Regulation D represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

All certificates representing the securities issued in the transactions described in this Item 15 included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth in this Item 15.

**Item 16. Exhibits and Financial Statement Schedules.**

(a) Exhibits:

The exhibits to the registration statement are listed in the Exhibit Index to this registration statement and are incorporated herein by reference.

(b) Financial Statements Schedules:

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

**Item 17. Undertakings.**

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of this registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high and of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission (the "Commission") pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement;

*provided, however*, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or date of the first sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which the prospectus forms a part, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of this registration statement or made in a document incorporated or deemed incorporated by reference into this registration statement or prospectus that is a part of this registration statement will, as to a purchaser with a time of contract sale prior to such effective date, supersede or modify any statement that was made in this registration statement or prospectus that was a part of this registration statement or made in any such document immediately prior to such effective date.



(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.

For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Gaithersburg, State of Maryland, on July 11, 2017.

### OPGEN, INC.

By: /s/ Evan Jones

Evan Jones  
Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 2 to the Registration Statement has been signed by the following person in the capacities and on the date indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Evan Jones</u> Evan Jones	Chief Executive Officer and Director (principal executive officer)	July 11, 2017
<u>/s/ Timothy C. Dec</u> Timothy C. Dec	Chief Financial Officer (principal financial officer and principal accounting officer)	July 11, 2017
<u>*</u> Harry J. D'Andrea	Director	July 11, 2017
<u>*</u> Timothy J.R. Harris	Director	July 11, 2017
<u></u> Tina S. Nova	Director	
<u>*</u> David M. Rubin	Director	July 11, 2017
<u>*</u> Misti Ushio	Director	July 11, 2017
<u>* /s/ Timothy C. Dec</u> Timothy C. Dec, as attorney in fact		

EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Identification of Exhibit</b>
<a href="#"><u>1.1 *</u></a>	<a href="#"><u>Form of Securities Purchase Agreement</u></a>
<a href="#"><u>1.2 *</u></a>	<a href="#"><u>Engagement Letter, dated June 12, 2017, between the Registrant and H.C. Wainwright &amp; Co., LLC</u></a>
3.1	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 May 13, 2015)
3.2	Certificate of Correction to Amended and Restated Certificate of Incorporation of OpGen, Inc., filed June 6, 2016 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on June 6, 2016)
3.3	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 of Form S-1, filed on March 3, 2015)
3.4	Form of Certificate of Designation of Series B Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report of Form 8-K/A, filed on June 28, 2017)
4.1	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Form S-1/A, File No. 333-202478, filed on April 28, 2015)
4.2	Form of Common Stock Warrant (to be 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/A, filed on July 10, 2017)
<a href="#"><u>4.3 *</u></a>	<a href="#"><u>Form of Pre-Funded Warrant for 2017 offering</u></a>
<a href="#"><u>4.4 *</u></a>	<a href="#"><u>Form of Common Warrant for 2017 offering</u></a>
<a href="#"><u>4.5 *</u></a>	<a href="#"><u>Form of Placement Agent Warrant for 2017 offering</u></a>
<a href="#"><u>5.1 *</u></a>	<a href="#"><u>Opinion of Ballard Spahr LLP</u></a>
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 to the Registrant's Form S-1/A, File No. 333-202478, filed on 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 to the Registrant's Form S-1, File No. 333-202478, filed on March 3, 2015)
10.1.2	Second Amendment to Lease, dated as of August 15, 2012, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1.2 to the Registrant's Form S-1, File No. 333-202478, filed on March 3, 2015)
10.1.3	Third Amendment to Lease, dated as of December 30, 2013, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1.3 to the Registrant's Form S-1, File No. 333-202478, filed on March 3, 2015)
10.1.4	Fourth Amendment to Lease, dated as of March 21, 2014, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1.4 to the Registrant's Form S-1, File No. 333-202478, filed on 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 to the Registrant's Form S-1/A, File No. 333-202478, filed on March 20, 2015)
10.1.6	Sixth Amendment to Lease Agreement, dated as of April 30, 2015, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1.6 to the Registrant's Form S-1/A, 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 to the Registrant's Current Report on Form 8-K, filed on July 7, 2015)

<b>Exhibit Number</b>	<b>Identification of Exhibit</b>
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 to the Registrant's 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 to the Registrant's Quarterly Report on Form 10-Q, filed on 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 to the Registrant's Form S-1, File No. 333-202478, filed on March 3, 2015)
10.4	2015 Equity Incentive Plan, as amended and restated on February 22, 2017 (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K, filed on March 24, 2017)
10.5 !	Employment Agreement, dated April 17, 2015, by and between the Registrant and Timothy C. Dec (incorporated by reference to Exhibit 10.18 to the Registrant's Form S-1/A, File No. 333- 202478, filed on April 17, 2015)
10.6 !	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.16 to the Registrant's Form S-1/A, File No. 333-202478, filed on April 6, 2015)
10.7	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)
10.8.1 !	Form of Stock Option Agreement under the 2015 Equity Incentive Plan for employees and consultants (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K, filed on March 24, 2017)
10.8.2 !	Form of Stock Option Agreement under the 2015 Equity Incentive Plan for non-employee directors (initial grant) (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K, filed on March 24, 2017)
10.8.3 !	Form of Stock Option Agreement under the 2015 Equity Incentive Plan for non-employee directors (annual grant) (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K, filed on March 24, 2017)
10.9 !	Form of RSU Award Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K, filed March 24, 2017)
10.10	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)
10.11	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 of Current Report on Form 8-K, filed on July 16, 2015)
10.12	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)
10.13	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 10.1 to the Registrant's Current Report on Form 8-K, filed on July 16, 2015)
10.14	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)
10.15	Securities Purchase Agreement, dated 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)
10.16	Amended and Restated Securities Purchase Agreement, dated 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)

<b>Exhibit Number</b>	<b>Identification of Exhibit</b>
10.17 !	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)
10.18 !	Confidential Separation Agreement and General Release, dated September 1, 2016, by and between the Registrant and Kevin Krenitsky, M.D. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 9, 2016)
10.19	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)
10.20	Amended & Restated Note Purchase Agreement, dated 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/A, filed on July 10, 2017)
10.21	Form of Secured Convertible Promissory Note #1 to be issued to jVen Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A, filed on July 10, 2017)
10.22	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)
10.23	Amended and Restated Registration Rights Agreement, dated 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)
10.24	Second Amended and Restated Senior Secured Convertible 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/A, filed on June 28, 2017)
10.24 ±	Supply Agreement, dated 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)
21.1 **	Subsidiaries of the Registrant
<a href="#">23.1 *</a>	<a href="#">Consent of CohnReznick LLP</a>
<a href="#">23.2 *</a>	<a href="#">Consent of Ballard Spahr LLP (included in Exhibit 5.1)</a>
24.1 **	Power of Attorney (on signature page)
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 (Deficit), (iv) Statements of Cash Flows and (v) the Notes to the Financial Statements

\* Filed herewith.

\*\* Previously filed

! 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.

**SECURITIES PURCHASE AGREEMENT**

This Securities Purchase Agreement (this "Agreement") dated as of [\_\_\_], 2017, is between OpGen, Inc., a Delaware corporation (the "Company"), and each purchaser identified on the signature pages hereto (each, including its successors and assigns, a "Purchaser" and collectively the "Purchasers").

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Securities Act"), the Company desires to issue and sell to each Purchaser, and each Purchaser, severally and not jointly, desires to purchase from the Company, securities of the Company as more fully described in this Agreement.

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

**ARTICLE I.  
DEFINITIONS**

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

"Acquiring Person" shall have the meaning ascribed to such term in Section 4.5.

"Action" shall have the meaning ascribed to such term in Section 3.1(j).

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person as such terms are used in and construed under Rule 405 under the Securities Act.

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Closing" means the closing of the purchase and sale of the Securities pursuant to Section 2.1.

"Closing Date" means the Trading Day on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto, and all conditions precedent to (i) the Purchasers' obligations to pay the Subscription Amount and (ii) the Company's obligations to deliver the Securities, in each case, have been satisfied or waived, but in no event later than the third Trading Day following the date hereof.

"Commission" means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.01 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Common Stock Equivalents” means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Company Counsel” means Ballard Spahr LLP, with offices located at 1735 Market Street, 51<sup>st</sup> Floor, Philadelphia, PA 19103.

“Disclosure Schedules” means the Disclosure Schedules of the Company delivered concurrently herewith.

“Evaluation Date” shall have the meaning ascribed to such term in Section 3.1(s).

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Exempt Issuance” means the issuance of (a) shares of Common Stock, options or other equity awards to employees, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company, (b) securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (other than in connection with stock splits or combinations) or to extend the term of such securities, and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that any such issuance shall only be to a Person (or to the equityholders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

“FCPA” means the Foreign Corrupt Practices Act of 1977, as amended.

“FDA” shall have the meaning ascribed to such term in Section 3.1(hh).

“FDCA” shall have the meaning ascribed to such term in Section 3.1(hh).

“GAAP” shall have the meaning ascribed to such term in Section 3.1(h).

“Indebtedness” shall have the meaning ascribed to such term in Section 3.1(aa).

“Intellectual Property Rights” shall have the meaning ascribed to such term in Section 3.1(p).

“Liens” means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

“Material Adverse Effect” shall have the meaning assigned to such term in Section 3.1(b).

“Material Permits” shall have the meaning ascribed to such term in Section 3.1(n).

“Per Share Purchase Price” equals \$\_\_\_, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Placement Agent” means Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.

“Preliminary Prospectus” means any preliminary prospectus relating to the Securities included in the Registration Statement.

“Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

“Product” shall have the meaning ascribed to such term in Section 3.1(hh).

“Prospectus” means the final prospectus filed for the Registration Statement.

“Purchaser Party” shall have the meaning ascribed to such term in Section 4.8.

“Registration Statement” means the effective registration statement on Form S-1 filed with Commission (File No. 333-218392) which registers the sale of the Securities, and all documents and exhibits filed with or incorporated by reference into such registration statement.

“Required Approvals” shall have the meaning ascribed to such term in Section 3.1(e).

“Rule 144” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

“Rule 424” means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.



“SEC Reports” shall have the meaning ascribed to such term in Section 3.1(h).

“Securities” means the Shares, the Warrants and the Warrant Shares.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Series A Warrants” means, collectively, the Common Stock purchase warrants delivered to the Purchasers at the Closing in accordance with Section 2.2(a) hereof, which Warrants shall be exercisable immediately from the Closing Date and have a term of exercise equal to five (5) years, in the form of Exhibit A attached hereto.

“Series B Warrants” means, collectively, the pre-funded Common Stock purchase warrants delivered to certain Purchasers at the Closing in accordance with Sections 2.1 and Section 2.2(a) hereof, which warrants shall be exercisable immediately following their issuance, in the form of Exhibit B attached hereto.

“Shares” means the shares of Common Stock issued or issuable to each Purchaser pursuant to this Agreement.

“Short Sales” means all “short sales” as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include the location and/or reservation of borrowable shares of Common Stock).

“Subscription Amount” means, as to each Purchaser, the aggregate amount to be paid for the Shares and Warrants purchased hereunder as specified below such Purchaser’s name on the signature page of this Agreement and next to the heading “Subscription Amount,” in United States dollars and in immediately available funds (other than, if applicable, a Purchaser’s aggregate exercise price of Series B Warrants, which amounts shall be paid as and when such Warrants are exercised for cash).

“Subsidiary” means any subsidiary of the Company as set forth on Schedule 3.1(a), and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the shares of Common Stock are listed or quoted for trading on the date in question: the NYSE MKT, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange, OTCQB or OTCQX (or any successors to any of the foregoing).

“Transaction Documents” means this Agreement, the Warrants and any other documents or agreements executed in connection with the transactions contemplated hereunder.

“Transfer Agent” means Philadelphia Stock Transfer, Inc., the current transfer agent of the Company, with a mailing address of 2320 Haverford Road, Suite 230, Ardmore, PA 19003 and a facsimile number of (484) 416-3597, and any successor transfer agent of the Company.

“Variable Rate Transaction” shall have the meaning ascribed to such term in Section 4.12(b).

“Warrants” means, collectively, Series A Warrants and Series B Warrants.

“Warrant Shares” means the shares of Common Stock issuable upon exercise of the Warrants.

## ARTICLE II. PURCHASE AND SALE

2.1 Closing. On the Closing Date, upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties hereto, the Company agrees to sell, and the Purchasers, severally and not jointly, agree to purchase, up to an aggregate of up to \$[ ] million of Shares (or Series B Warrants) and Series A Warrants as calculated pursuant to Section 2.2(a). Notwithstanding anything herein to the contrary, to the extent that a Purchaser determines, in its sole discretion, that such Purchaser’s Subscription Amount (together with such Purchaser’s Affiliates and any Person acting as a group together with such Purchaser or any of such Purchaser’s Affiliates) would cause such Purchaser’s beneficial ownership of the shares of Common Stock to exceed 4.99% (or, at the election of the Purchaser, 9.99%) of the outstanding shares of Common Stock, such Purchaser may elect to purchase Series B Warrants in lieu of the Shares as determined pursuant to Section 2.2(a); provided, however, that, in the event that a Purchaser’s Subscription Amount (together with such Purchaser’s Affiliates and any Person acting as a group together with such Purchaser or any of such Purchaser’s Affiliates) would cause such Purchaser’s beneficial ownership of the shares of Common Stock to exceed 19.99% of the outstanding shares of Common Stock, in lieu of shares of Common Stock in excess of such amount, such Purchaser may be entitled to purchase Series B Warrants as determined pursuant to Section 2.2(a). In each case, it appears that the election to receive pre-funded warrants is solely at the option of the Purchaser. Each Purchaser’s Subscription Amount as set forth on the signature page hereto executed by such Purchaser shall be made available for “Delivery Versus Payment” settlement with the Company. The Company shall deliver to each Purchaser its respective Shares (or Series B Warrants) and Series A Warrants as determined pursuant to Section 2.2(a), and the Company and each Purchaser shall deliver the other items set forth in Section 2.2 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.2 and 2.3, the Closing shall occur at the offices of the Placement Agent or such other location as the parties shall mutually agree. Unless otherwise directed by the Placement Agent, settlement of the Shares shall occur via “Delivery Versus Payment” (“DVP”) (i.e., on the Closing Date, the Company shall issue the Shares registered in the Purchasers’ names and addresses and released by the Transfer Agent directly to the account(s) at the Placement Agent identified by each Purchaser; upon receipt of such Shares, the Placement Agent shall promptly electronically deliver such Shares and the Warrants in physical form to the applicable Purchaser, and payment therefor shall be made by the Placement Agent (or its clearing firm) by wire transfer to the Company). The Company covenants that, if the Purchaser delivers a Notice of Exercise (as defined in the Series B Warrants) at least one (1) Trading Day prior to the Closing Date to exercise any Series B Warrants between the date hereof and the Closing Date, the Company shall deliver shares of Common Stock with respect to the Series B Warrants to the Purchaser on the Closing Date in connection with such Notice of Exercise.

2.2 Deliveries.

(a) On or prior to the Closing Date, the Company shall deliver or cause to be delivered to each Purchaser the following:

(i) this Agreement duly executed by the Company;

(ii) legal opinion and negative assurance letter of Company Counsel in form reasonably acceptable to the Placement Agent and

the Purchasers;

(iii) the Company shall have provided each Purchaser with the Company's wire instructions, on Company letterhead and executed by the Chief Executive Officer or Chief Financial Officer;

(iv) subject to the penultimate sentence of Section 2.1, if such Purchaser is acquiring Shares, a copy of the irrevocable instructions to the Transfer Agent instructing the Transfer Agent to deliver on an expedited basis via The Depository Trust Company Deposit or Withdrawal at Custodian system ("DWAC") Shares equal to such Purchaser's Subscription Amount divided by the Per Share Purchase Price, registered in the name of such Purchaser;

(v) to each Purchaser that will receive any Series B Warrants in lieu of Shares pursuant to Section 2.1, Series B Warrants, each registered in the name of such Purchaser to purchase one (1) Common Stock, with an exercise price equal to \$0.01 per Common Stock, such Series B Warrants exercisable in the aggregate for a total number of shares of Common Stock equal to the number of Series B Warrants set forth on such Purchaser's signature page (such Series B Warrant shall be delivered on the Closing Date);

(vi) such number of Series A Warrants equal to \_\_\_ of the number of shares of Common Stock to be delivered in accordance with sub-Section (iv) above (plus the number of Series A Warrants equal to \_\_\_\_ of the number of shares of Common Stock underlying Series B Warrants to be delivered in accordance with sub-Section (v) above);

(vii) on the Closing Date, the duly executed and delivered Secretary's Certificate, in form and substance reasonably satisfactory in all respects to the Placement Agent;

(viii) a 90-day lock-up agreement (the "Lock-Up Agreements") from each of the Company's directors and officers, in a form reasonably acceptable to the Placement Agent and the Purchasers; and

(ix) the Preliminary Prospectus.

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company the following:

(i) this Agreement duly executed by such Purchaser; and

(ii) such Purchaser's Subscription Amount (less, if applicable, the aggregate \$0.01 exercise price per Common Stock of the Series B Warrants issuable to such Purchaser hereunder), which shall be made available for "Delivery Versus Payment" settlement with the Company.

### 2.3 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Purchasers contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of each Purchaser required to be performed at or prior to the Closing Date shall have been performed; and

(iii) the delivery by each Purchaser of the items set forth in Section 2.2(b) of this Agreement.

(b) The respective obligations of the Purchasers hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;

(iii) the delivery by the Company of the items set forth in Section 2.2(a) of this Agreement;

(iv) there shall have been no Material Adverse Effect with respect to the Company since the date hereof; and

(v) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market, and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of such Purchaser, makes it impracticable or inadvisable to purchase the Securities at the Closing.

**ARTICLE III.**  
**REPRESENTATIONS AND WARRANTIES**

3.1 Representations and Warranties of the Company. Except as set forth in the Disclosure Schedules, which Disclosure Schedules shall be deemed a part hereof and shall qualify any representation or otherwise made herein to the extent of the disclosure contained in the corresponding section of the Disclosure Schedules, the Company hereby makes the following representations and warranties to each Purchaser:

(a) Subsidiaries. All of the direct and indirect subsidiaries of the Company are set forth on Schedule 3.1(a). The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If the Company has no subsidiaries, all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing (or its foreign equivalent) under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing (or its foreign equivalent) as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a "Material Adverse Effect") and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary corporate action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution or similar adjustments, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to Section 4.4 of this Agreement, (ii) the filing with the Commission of the Prospectus, (iii) application(s) to each applicable Trading Market for the listing of the Shares and Warrant Shares for trading thereon in the time and manner required thereby, (iv) such filings as are required to be made under applicable state securities laws and (v) such consents, waivers and authorizations that shall be obtained prior to Closing (collectively, the "Required Approvals").

(f) Issuance of the Securities; Registration. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Warrant Shares, when issued in accordance with the terms of the Warrants, will be validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement and the Warrants. The Company has prepared and filed the Registration Statement in conformity with the requirements of the Securities Act, which became effective on \_\_\_\_, 2017 (the "Effective Date"), including the Prospectus, and such amendments and supplements thereto as may have been required to the date of this Agreement. The Company was at the time of the filing of the Registration Statement eligible to use Form S-1. The Registration Statement is effective under the Securities Act and no stop order preventing or suspending the effectiveness of the Registration Statement or suspending or preventing the use of the Prospectus has been issued by the Commission and no proceedings for that purpose have been instituted or, to the knowledge of the Company, are threatened by the Commission. The Company, if required by the rules and regulations of the Commission, shall file the Prospectus with the Commission pursuant to Rule 424(b). At the time the Registration Statement and any amendments thereto became effective, at the date of this Agreement and at the Closing Date, the Registration Statement and any amendments thereto conformed and will conform in all material respects to the requirements of the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading; and the Preliminary Prospectus and the Prospectus and any amendments or supplements thereto, at time the Preliminary Prospectus or the Prospectus, as applicable, or any amendment or supplement thereto was issued and at the Closing Date, conformed and will conform in all material respects to the requirements of the Securities Act and did not and will not contain an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(g) Capitalization. The capitalization of the Company is as set forth on Schedule 3.1(g). The Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than (i) pursuant to the exercise of employee stock options under the Company's stock option plans, (ii) the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans, (iii) pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act, and (iv) pursuant to the Sales Agreement, dated as of September 13, 2016, between the Company and Cowen and Company, LLC, in connection with the Company's "at the market" offering program (the "ATM"). No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents that has not been waived. Except as disclosed in the SEC Reports and as a result of the purchase and sale of the Securities, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock or Common Stock Equivalents or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents or capital stock of any Subsidiary. The issuance and sale of the Securities will not obligate the Company or any Subsidiary to issue shares of Common Stock or Common Stock Equivalents or other securities to any Person (other than the Purchasers) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities. There are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. The Company does not have any stock appreciation rights or "phantom stock" plans or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state or foreign securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(h) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Preliminary Prospectus and the Prospectus, being collectively referred to herein as the “SEC Reports”) on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (“GAAP”), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(i) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in a subsequent SEC Report filed prior to the date hereof, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company’s financial statements pursuant to GAAP or disclosed in the SEC Reports, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans. Except for the issuance of the Securities contemplated by this Agreement or as set forth on Schedule 3.1(i), no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least 1 Trading Day prior to the date that this representation is made.



(j) Litigation. There is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an “Action”) which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(k) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company’s or its Subsidiaries’ employees is a member of a union that relates to such employee’s relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all applicable U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(l) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(m) Environmental Laws. The Company and its Subsidiaries (i) are in compliance with all federal, state, local and foreign laws relating to pollution or protection of human health or the environment (including ambient air, surface water, groundwater, land surface or subsurface strata), including laws relating to emissions, discharges, releases or threatened releases of chemicals, pollutants, contaminants, or toxic or hazardous substances or wastes (collectively, "Hazardous Materials") into the environment, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, as well as all authorizations, codes, decrees, demands, or demand letters, injunctions, judgments, licenses, notices or notice letters, orders, permits, plans or regulations, issued, entered, promulgated or approved thereunder ("Environmental Laws"); (ii) have received all permits licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (iii) are in compliance with all terms and conditions of any such permit, license or approval where in each clause (i), (ii) and (iii), the failure to so comply could be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect.

(n) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(o) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries, (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and, the payment of which is neither delinquent nor subject to penalties, and (iii) Liens disclosed in the Company's SEC Reports. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance.

(p) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights as necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). None of, and neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe (and will not infringe) upon the rights of any Person, except as could not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company has no knowledge of any facts that would preclude it from having valid license rights or clear title to the Intellectual Property Rights. The Company has no knowledge that it lacks or will be unable to obtain any rights or licenses to use all Intellectual Property Rights that are necessary to conduct its business.

(q) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage at least equal to the aggregate Subscription Amount. Neither the Company nor any Subsidiary has been notified that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(r) Transactions With Affiliates and Employees. Except as set forth in the SEC Reports, none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of \$120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

(s) Sarbanes-Oxley; Internal Accounting Controls. The Company and the Subsidiaries are in compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof and as of the Closing and are applicable to the Company and the Subsidiaries, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(t) Certain Fees. Except as set forth in the Preliminary Prospectus or the Prospectus, no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiary to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchasers shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(u) Investment Company. The Company is not, and immediately after receipt of payment for the Securities, will not be required to register as an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not be required to register as an "investment company" under the Investment Company Act of 1940, as amended.

(v) Registration Rights. No Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary, which have not been satisfied or waived or which the Company believes in good faith to have lapsed.

(w) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as disclosed in the SEC Reports, the Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Common Stock is currently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees to the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(x) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control stock acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable to the Purchasers as a result of the Purchasers and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company's issuance of the Securities and the Purchasers' ownership of the Securities.

(y) Disclosure. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, the Company confirms that neither it nor any other Person acting on its behalf has provided any of the Purchasers or their agents or counsel with any information that it believes constitutes or might constitute material, non-public information which is not otherwise disclosed in the Preliminary Prospectus or Prospectus. The Company understands and confirms that the Purchasers will rely on the foregoing representation in effecting transactions in securities of the Company. All of the disclosure furnished by or on behalf of the Company to the Purchasers regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby, including the Disclosure Schedules to this Agreement, is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(z) No Integrated Offering. Assuming the accuracy of the Purchasers' representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of any applicable stockholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(aa) Solvency. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii), the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. Schedule 3.1(aa) sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. For the purposes of this Agreement, "Indebtedness" means (x) any liabilities for borrowed money or amounts owed in excess of \$50,000 (other than trade accounts payable incurred in the ordinary course of business), (y) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (z) the present value of any lease payments in excess of \$50,000 due under leases required to be capitalized in accordance with GAAP. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(bb) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

(cc) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of FCPA.

(dd) Accountants. The Company's independent registered public firm is set forth on Schedule 3.1(dd) of the Disclosure Schedules. To the knowledge and belief of the Company, such accounting firm (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending December 31, 2017.

(ee) Acknowledgment Regarding Purchasers' Purchase of Securities. The Company acknowledges and agrees that each Purchaser is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated hereby and thereby and that no Purchaser is (i) an officer or director of the Company or any of its Subsidiaries, (ii) an "affiliate" of the Company or any of its Subsidiaries (as defined in Rule 144) or (iii) to the knowledge of the Company, a "beneficial owner" of more than 10% of the Common Shares (as defined for purposes of Rule 13d-3 of the Exchange Act. The Company further acknowledges that no Purchaser is acting as a financial advisor or fiduciary of the Company or any of its Subsidiaries (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated hereby and thereby, and any advice given by a Purchaser or any of its representatives or agents in connection with the Transaction Documents and the transactions contemplated hereby and thereby is merely incidental to such Purchaser's purchase of the Securities. The Company further represents to each Purchaser that the Company's decision to enter into the Transaction Documents has been based solely on the independent evaluation by the Company and its representatives.

(ff) Acknowledgement Regarding Purchaser's Trading Activity. Anything in this Agreement or elsewhere herein to the contrary notwithstanding (except for Sections 3.2(e) and 4.14 hereof), it is understood and acknowledged by the Company that: (i) none of the Purchasers has been asked by the Company to agree, nor has any Purchaser agreed, to desist from purchasing or selling, long and/or short, securities of the Company, or "derivative" securities based on securities issued by the Company or to hold the Securities for any specified term; (ii) past or future open market or other transactions by any Purchaser, specifically including, without limitation, Short Sales or "derivative" transactions, before or after the closing of this or future private placement transactions, may negatively impact the market price of the Company's publicly-traded securities; (iii) any Purchaser, and counter-parties in "derivative" transactions to which any such Purchaser is a party, directly or indirectly, presently may have a "short" position in the Common Stock, and (iv) each Purchaser shall not be deemed to have any affiliation with or control over any arm's length counter-party in any "derivative" transaction. The Company further understands and acknowledges that (y) one or more Purchasers may engage in hedging activities at various times during the period that the Securities are outstanding, including, without limitation, during the periods that the value of the Warrant Shares deliverable with respect to Securities are being determined, and (z) such hedging activities (if any) could reduce the value of the existing stockholders' equity interests in the Company at and after the time that the hedging activities are being conducted. The Company acknowledges that such aforementioned hedging activities do not constitute a breach of any of the Transaction Documents.

(gg) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Company's placement agent in connection with the placement of the Securities.

(hh) FDA. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration (“FDA”) or any non-U.S. counterpart, or laboratory-developed service offered under FDA enforcement discretion, that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its Subsidiaries (each such product, a “Product”), such Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company or its Subsidiaries in compliance with all applicable Health Care Laws (as defined below) relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not have a Material Adverse Effect. For services offered under FDA enforcement discretion, they have been developed, verified and offered as a service consistent with all applicable Health Care Laws, except where the failure to be in compliance would not have a Material Adverse Effect. There is no pending, completed or, to the Company’s knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its Subsidiaries, and none of the Company or any of its Subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any of its Subsidiaries, (iv) enjoins production at any facility of the Company or any of its Subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its Subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its Subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable Health Care Laws. The Company has not been informed by the FDA, CMS, or any non-U.S. counterpart that the FDA or any non-U.S. counterpart will prohibit the marketing, sale, license or use in the United States or in any other territory any product proposed to be developed, produced or marketed by the Company or any Subsidiary nor has the FDA or any non-U.S. counterpart expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company or any Subsidiary. To the Company’s knowledge, there are no legal or governmental proceedings relating to any Health Care Law pending or threatened to which the Company is a party, nor is it aware of any material violations of such acts or regulations by the Company, which would have a Material Adverse Effect. For purposes of this Agreement, “Health Care Laws” means: (i) the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder; (ii) all applicable federal, state, local and all applicable foreign health care related fraud and abuse laws, including, without limitation, the Clinical Laboratories Improvement Amendments of 1988 (42 U.S.C. § 263a, et seq., “CLIA”), the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the U.S. Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) (42 U.S.C. Section 1320d et seq.), the exclusion laws (42 U.S.C. § 1320a-7), the civil monetary penalties law (42 U.S.C. § 1320a-7a), the statutes, regulations and directives of applicable government funded or sponsored healthcare programs, and the regulations promulgated pursuant to such statutes; (iii) the Standards for Privacy of Individually Identifiable Health Information (the “Privacy Rule”), the Security Standards, and the Standards for Electronic Transactions and Code Sets promulgated under HIPAA, the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), and the regulations promulgated thereunder and any state or non-U.S. counterpart thereof or other law or regulation the purpose of which is to protect the privacy of individuals or prescribers; (iv) Medicare (Title XVIII of the Social Security Act); (v) Medicaid (Title XIX of the Social Security Act); and (vi) any and all other applicable health care laws and regulations.



(ii) Research Studies and Trials. The research studies and trials conducted by or on behalf of, or sponsored by, the Company or its Subsidiaries, or in which the Company or its Subsidiaries has participated, that are described in the Preliminary Prospectus or the Prospectus, or the results of which are referred to in the Preliminary Prospectus or the Prospectus, as applicable, were and, if still pending, are being, conducted in all material respects in accordance with applicable experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards for products or product candidates comparable to those being developed by the Company or its Subsidiaries and all applicable statutes, rules and regulations of the FDA and other comparable drug and medical device regulatory agencies to which they are subject; the descriptions of the results of such studies and trials contained in the Preliminary Prospectus or the Prospectus do not contain any misstatement of a material fact or omit to state a material fact necessary to make such statements not misleading; neither the Company nor any Subsidiary has knowledge of any research studies or trials not described in the Preliminary Prospectus or the Prospectus the results of which reasonably call into question in any material respect the results of the research studies and trials described in the Preliminary Prospectus or the Prospectus; and neither the Company nor any Subsidiary has received any written notices or correspondence from the FDA or any other foreign, state or local governmental body exercising comparable authority or any institutional review board or comparable authority requiring or threatening the premature termination, suspension, material modification or clinical hold of any research studies or trials conducted by or on behalf of, or sponsored by, the Company or any Subsidiary or in which the Company or any Subsidiary has participated that are described in the Preliminary Prospectus or the Prospectus, and, to the Company's knowledge, there are no reasonable grounds for the same. There has not been any violation of applicable law or regulation by the Company in its product development efforts, submissions or reports to any regulatory authority that could reasonably be expected to require investigation, corrective action or enforcement action, except where such violation would not, singly or in the aggregate, result in a Material Adverse Effect.

(jj) Research Studies and Trials. The research studies and trials conducted by or on behalf of, or sponsored by, the Company or its Subsidiaries, or in which the Company or its Subsidiaries has participated, that are described in the Preliminary Prospectus or the Prospectus, or the results of which are referred to in the Preliminary Prospectus or the Prospectus, as applicable, were and, if still pending, are being, conducted in all material respects in accordance with applicable experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards for products or product candidates comparable to those being developed by the Company or its Subsidiaries and all applicable statutes, rules and regulations of the U.S. Food and Drug Administration (the "FDA") and other comparable drug and medical device regulatory agencies to which they are subject; the descriptions of the results of such studies and trials contained in the Preliminary Prospectus or the Prospectus do not contain any misstatement of a material fact or omit to state a material fact necessary to make such statements not misleading; neither the Company nor any Subsidiary has knowledge of any research studies or trials not described in the Preliminary Prospectus or the Prospectus the results of which reasonably call into question in any material respect the results of the research studies and trials described in the Preliminary Prospectus or the Prospectus; and neither the Company nor any Subsidiary has received any written notices or correspondence from the FDA or any other foreign, state or local governmental body exercising comparable authority or any institutional review board or comparable authority requiring or threatening the premature termination, suspension, material modification or clinical hold of any research studies or trials conducted by or on behalf of, or sponsored by, the Company or any Subsidiary or in which the Company or any Subsidiary has participated that are described in the Preliminary Prospectus or the Prospectus, and, to the Company's knowledge, there are no reasonable grounds for the same. There has not been any violation of applicable law or regulation by the Company in its product development efforts, submissions or reports to any regulatory authority that could reasonably be expected to require investigation, corrective action or enforcement action, except where such violation would not, singly or in the aggregate, result in a Material Adverse Effect.

(kk) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC").

(ll) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

(mm) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(nn) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, and the applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no Action or Proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(oo) Reserved.

3.2 Representations and Warranties of the Purchasers. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein, in which case they shall be accurate as of such date):

(a) Organization; Authority. Such Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by such Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of such Purchaser. Each Transaction Document to which it is a party has been duly executed by such Purchaser, and when delivered by such Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of such Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Understandings or Arrangements. Such Purchaser is acquiring the Securities as principal for its own account and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Securities (this representation and warranty not limiting such Purchaser's right to sell the Securities pursuant to the Registration Statement or otherwise in compliance with applicable federal and state securities laws). Such Purchaser is acquiring the Securities hereunder in the ordinary course of its business.

(c) Purchaser Status. At the time such Purchaser was offered the Securities, it was, and as of the date hereof it is, and on each date which it exercises any Warrants, it will be either: (i) an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act or (ii) a "qualified institutional buyer" as defined in Rule 144A(a) under the Securities Act.

(d) Experience of Such Purchaser. Such Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. Such Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(e) Access to Information. Such Purchaser acknowledges that it has had the opportunity to review the Transaction Documents (including all exhibits and schedules thereto) and the SEC Reports and has been afforded, (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Securities and the merits and risks of investing in the Securities; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment. Such Purchaser acknowledges and agrees that neither the Placement Agent nor any Affiliate of the Placement Agent has provided such Purchaser with any information or advice with respect to the Securities nor is such information or advice necessary or desired. Neither the Placement Agent nor any Affiliate has made or makes any representation as to the Company or the quality of the Securities and the Placement Agent and any Affiliate may have acquired non-public information with respect to the Company which such Purchaser agrees need not be provided to it. In connection with the issuance of the Securities to such Purchaser, neither the Placement Agent nor any of its Affiliates has acted as a financial advisor or fiduciary to such Purchaser.

(f) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any Person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that such Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement or to such Purchaser's representatives, including, without limitation, its officers, directors, partners, legal and other advisors, employees, agents and Affiliates, such Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty against, or a prohibition of, any actions with respect to the borrowing of, arrangement to borrow, identification of the availability of, and/or securing of, securities of the Company in order for such Purchaser (or its broker or other financial representative) to effect Short Sales or similar transactions in the future.

The Company acknowledges and agrees that the representations contained in this Section 3.2 shall not modify, amend or affect such Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transactions contemplated hereby.

**ARTICLE IV.**  
**OTHER AGREEMENTS OF THE PARTIES**

4.1 Warrant Shares. If all or any portion of a Warrant is exercised at a time when there is an effective registration statement to cover the issuance or resale of the Warrant Shares or if the Warrant is exercised via cashless exercise, the Warrant Shares issued pursuant to any such exercise shall be issued free of all legends. If at any time following the date hereof the Registration Statement (or any subsequent registration statement registering the issuance of the Warrant Shares) is not effective or is not otherwise available for the issuance of the Warrant Shares, the Company shall immediately notify the holders of the Warrants in writing that such registration statement is not then effective and thereafter shall promptly notify such holders when the registration statement is effective again and available issuance of the Warrant Shares (it being understood and agreed that the foregoing shall not limit the ability of the Company to issue, or any Purchaser to sell, any of the Warrant Shares in compliance with applicable federal and state securities laws). The Company shall use its commercially reasonable efforts to keep a registration statement (including the Registration Statement) registering the issuance or resale of the Warrant Shares effective during the term of the Warrants.

4.2 Furnishing of Information. Until the earliest of the time that (i) no Purchaser owns Securities or (ii) the Warrants have expired, the Company covenants to timely file (or obtain extensions in respect thereof and file within the applicable grace period) all reports required to be filed by the Company after the date hereof pursuant to the Exchange Act.

4.3 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require stockholder approval prior to the closing of such other transaction unless stockholder approval is obtained before the closing of such subsequent transaction.

4.4 Securities Laws Disclosure; Publicity. The Company shall by 8:00 a.m. (New York City time) on the Trading Day immediately following the date hereof, issue a press release disclosing the material terms of the transactions contemplated hereby. From and after the issuance of such press release, the Company represents to the Purchasers that it shall have publicly disclosed all material, non-public information delivered to any of the Purchasers by the Company or any of its Subsidiaries, or any of their respective officers, directors, employees or agents in connection with the transactions contemplated by the Transaction Documents. In addition, effective upon the issuance of such press release, the Company acknowledges and agrees that any and all confidentiality or similar obligations under any agreement, whether written or oral, between the Company, any of its Subsidiaries or any of their respective officers, directors, agents, employees or Affiliates on the one hand, and any of the Purchasers or any of their Affiliates on the other hand, shall terminate. The Company and each Purchaser shall consult with each other in issuing any other press releases with respect to the transactions contemplated hereby, and neither the Company nor any Purchaser shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of any Purchaser, or without the prior consent of each Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. Notwithstanding the foregoing, the Company shall not publicly disclose the name of any Purchaser, or include the name of any Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of such Purchaser, except (a) as required by federal securities law in connection with the filing of final Transaction Documents with the Commission and (b) to the extent such disclosure is required by law or Trading Market regulations, in which case the Company shall provide the Purchasers with prior notice of such disclosure permitted under this clause (b).

4.5 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that any Purchaser is an “Acquiring Person” under any control stock acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that any Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities under the Transaction Documents or under any other agreement between the Company and the Purchasers.

4.6 Non-Public Information. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, which shall be disclosed pursuant to Section 4.4, the Company covenants and agrees that neither it, nor any other Person acting on its behalf will provide any Purchaser or its agents or counsel with any information that constitutes, or the Company reasonably believes constitutes, material non-public information, unless prior thereto such Purchaser shall have consented to the receipt of such information and agreed with the Company to keep such information confidential. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company. To the extent that the Company delivers any material, non-public information to a Purchaser without such Purchaser’s consent, the Company hereby covenants and agrees that such Purchaser shall not have any duty of confidentiality to the Company, any of its Subsidiaries, or any of their respective officers, directors, agents, employees or Affiliates, or a duty to the Company, any of its Subsidiaries or any of their respective officers, directors, agents, employees or Affiliates not to trade on the basis of, such material, non-public information, provided that the Purchaser shall remain subject to applicable law; provided, that any Purchaser that shall have entered into a confidentiality agreement with the Company shall be deemed to have consented to delivery of material, non-public information and such Purchaser’s trading in the Company’s securities shall be subject to the terms of such confidentiality agreement. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company.

4.7 Use of Proceeds. Except as set forth on Schedule 4.7 attached hereto, the Company shall use the net proceeds from the sale of the Securities hereunder for working capital purposes and shall not use such proceeds: (a) for the satisfaction of any portion of the Company’s debt (other than (i) payment of trade payables in the ordinary course of the Company’s business and prior practices and (ii) the repayment of the Secured Convertible Promissory Notes issued to jVen Capital, LLC), (b) for the redemption of any shares of Common Stock or Common Stock Equivalents, (c) for the settlement of any outstanding litigation or (d) in violation of FCPA or OFAC regulations.

4.8 Indemnification of Purchasers. Subject to the provisions of this Section 4.8, the Company will indemnify and hold each Purchaser and its directors, officers, stockholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls such Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, stockholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "Purchaser Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of such Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is based upon a breach of such Purchaser Party's representations, warranties or covenants under the Transaction Documents or any agreements or understandings such Purchaser Party may have with any such stockholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by such Purchaser Party which constitutes fraud, gross negligence, willful misconduct or malfeasance). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, such Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of such Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (y) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (z) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by such Purchaser Party in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.8 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.9 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue Shares pursuant to this Agreement and Warrant Shares pursuant to any exercise of the Warrants.

4.10 Listing of Common Stock. The Company hereby agrees to use reasonable best efforts to maintain the listing or quotation of the Common Stock on the Trading Market on which it is currently listed, and concurrently with the Closing, the Company shall apply to list or quote all of the Shares and Warrant Shares on such Trading Market and promptly secure the listing of all of the Shares and Warrant Shares on such Trading Market. The Company further agrees, if the Company applies to have the Common Stock traded on any other Trading Market, it will then include in such application all of the Shares and Warrant Shares, and will take such other action as is necessary to cause all of the Shares and Warrant Shares to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of its Common Stock on a Trading Market and will comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of the Trading Market. The Company agrees to maintain the eligibility of the Common Stock for electronic transfer through the Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to the Depository Trust Company or such other established clearing corporation in connection with such electronic transfer.

4.11 Lock-Up. The Company shall not amend, modify, waive or terminate any provision of any of the Lock-Up Agreements except to extend the term of the lock-up period and shall enforce the provisions of each Lock-Up Agreement in accordance with its terms. If any officer or director that is a party to a Lock-Up Agreement breaches any provision of a Lock-Up Agreement, the Company shall promptly use its best efforts to seek specific performance of the terms of such Lock-Up Agreement.

4.12 Subsequent Equity Sales.

(a) From the date hereof until 60 days after the Closing Date, neither the Company nor any Subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents.

(b) From the date hereof until 12 months after the Closing Date, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. "Variable Rate Transaction" means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon and/or varies with the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price. Any Purchaser shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages.



(c) Notwithstanding the foregoing, this Section 4.12 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.13 Equal Treatment of Purchasers. No consideration (including any modification of any Transaction Document) shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of the Transaction Documents unless the same consideration is also offered to all of the parties to such Transaction Documents. For clarification purposes, this provision constitutes a separate right granted to each Purchaser by the Company and negotiated separately by each Purchaser, and is intended for the Company to treat the Purchasers as a class and shall not in any way be construed as the Purchasers acting in concert or as a group with respect to the purchase, disposition or voting of Securities or otherwise.

4.14 Certain Transactions and Confidentiality. Each Purchaser, severally and not jointly with the other Purchasers, covenants that neither it nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any purchases or sales, including Short Sales of any of the Company's securities during the period commencing with the execution of this Agreement and ending at such time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4. Each Purchaser, severally and not jointly with the other Purchasers, covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company pursuant to the initial press release as described in Section 4.4, such Purchaser will maintain the confidentiality of the existence and terms of this transaction and the information included in the Disclosure Schedules. Notwithstanding the foregoing, and notwithstanding anything contained in this Agreement to the contrary, the Company expressly acknowledges and agrees that (i) no Purchaser makes any representation, warranty or covenant hereby that it will not engage in effecting transactions in any securities of the Company after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4, (ii) no Purchaser shall be restricted or prohibited from effecting any transactions in any securities of the Company in accordance with applicable securities laws from and after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4 and (iii) no Purchaser shall have any duty of confidentiality or duty not to trade in the securities of the Company to the Company or its Subsidiaries after the issuance of the initial press release as described in Section 4.4. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the covenant set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement.

4.16 Exercise Procedures. The form of Notice of Exercise included in the Warrants set forth the totality of the procedures required of the Purchasers in order to exercise the Warrants. No additional legal opinion, other information or instructions shall be required of the Purchasers to exercise their Warrants. Without limiting the preceding sentences, no ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required in order to exercise the Warrants. The Company shall honor exercises of the Warrants and shall deliver Warrant Shares in accordance with the terms, conditions and time periods set forth in the Transaction Documents.

**ARTICLE V.**  
**MISCELLANEOUS**

5.1 Termination. This Agreement may be terminated by any Purchaser, as to such Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before \_\_, 2017; provided, however, that no such termination will affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. Except as expressly set forth in the Transaction Documents to the contrary, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement. The Company shall pay all Transfer Agent fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company and any exercise notice delivered by a Purchaser), stamp taxes and other taxes and duties levied in connection with the delivery of any Securities to the Purchasers.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, the Preliminary Prospectus and the Prospectus, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

5.4 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or email attachment at the email address as set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or email attachment at the email address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2<sup>nd</sup>) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers which purchased at least 50.1% in interest of the Shares based on the initial Subscription Amounts hereunder or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought, provided that if any amendment, modification or waiver disproportionately and adversely impacts a Purchaser (or group of Purchasers), the consent of such disproportionately impacted Purchaser (or group of Purchasers) shall also be required. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of each Purchaser (other than by merger). Any Purchaser may assign any or all of its rights under this Agreement to any Person to whom such Purchaser assigns or transfers any Securities, provided that such transferee agrees in writing to be bound, with respect to the transferred Securities, by the provisions of the Transaction Documents that apply to the "Purchasers."

5.8 No Third-Party Beneficiaries. The Placement Agent shall be the third party beneficiary of the representations and warranties of the Company in Section 3.1 and the representations and warranties of the Purchasers in Section 3.2. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Section 4.8 and this Section 5.8.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal Proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, stockholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any Action or Proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such Action or Proceeding is improper or is an inconvenient venue for such Proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such Action or Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If any party shall commence an Action or Proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.8, the prevailing party in such Action or Proceeding shall be reimbursed by the non-prevailing party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Action or Proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a “.pdf” format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or “.pdf” signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever any Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then such Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights; provided, however, that in the case of a rescission of an exercise of a Warrant, the applicable Purchaser shall be required to return any shares of Common Stock subject to any such rescinded exercise notice concurrently with the return to such Purchaser of the aggregate exercise price paid to the Company for such shares and the restoration of such Purchaser’s right to acquire such shares pursuant to such Purchaser’s Warrant (including, issuance of a replacement warrant certificate evidencing such restored right).

5.14 Replacement of Securities. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.

5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Purchasers and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any Action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to any Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under any Transaction Document are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance or non-performance of the obligations of any other Purchaser under any Transaction Document. Nothing contained herein or in any other Transaction Document, and no action taken by any Purchaser pursuant hereto or thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by the Transaction Documents. Each Purchaser shall be entitled to independently protect and enforce its rights including, without limitation, the rights arising out of this Agreement or out of the other Transaction Documents, and it shall not be necessary for any other Purchaser to be joined as an additional party in any Proceeding for such purpose. Each Purchaser has been represented by its own separate legal counsel in its review and negotiation of the Transaction Documents. For reasons of administrative convenience only, each Purchaser and its respective counsel have chosen to communicate with the Company through the legal counsel of the Placement Agent. The legal counsel of the Placement Agent does not represent any of the Purchasers and only represents the Placement Agent. The Company has elected to provide all Purchasers with the same terms and Transaction Documents for the convenience of the Company and not because it was required or requested to do so by any of the Purchasers. It is expressly understood and agreed that each provision contained in this Agreement and in each other Transaction Document is between the Company and a Purchaser, solely, and not between the Company and the Purchasers collectively and not between and among the Purchasers.

5.18 Reserved.

5.19 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.20 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

5.21 **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.**

*(Signature Pages Follow)*

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

**OPGEN, INC.**

Address for Notice:

By: \_\_\_\_\_  
Name:  
Title:

Fax:  
E-mail:

With a copy to (which shall not constitute notice):

Ballard Spahr LLP  
1735 Market Street, 51<sup>st</sup> Floor  
Philadelphia, PA 19103  
Attn: Mary J. Mullany

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK  
SIGNATURE PAGE FOR PURCHASER FOLLOWS]

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IN WITNESS WHEREOF, the undersigned have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser: \_\_\_\_\_

Signature of Authorized Signatory of Purchaser: \_\_\_\_\_

Name of Authorized Signatory: \_\_\_\_\_

Title of Authorized Signatory: \_\_\_\_\_

Email Address of Authorized Signatory: \_\_\_\_\_

Facsimile Number of Authorized Signatory: \_\_\_\_\_

Address for Notice to Purchaser:

Address for Delivery of Securities to Purchaser (if not same as address for notice):

DTC Participant name and number: \_\_\_\_\_

Contact of DTC Participant: \_\_\_\_\_

Telephone Number of Participant Contact: \_\_\_\_\_

Subscription Amount: \$ \_\_\_\_\_

Shares: \_\_\_\_\_

Series B Pre-Funded Warrants: \_\_\_\_\_

Series A Warrants: \_\_\_\_\_

EIN Number: \_\_\_\_\_

Notwithstanding anything contained in this Agreement to the contrary, by checking this box (i) the obligations of the above-signed to purchase the securities set forth in this Agreement to be purchased from the Company by the above-signed, and the obligations of the Company to sell such securities to the above-signed, shall be unconditional and all conditions to Closing shall be disregarded, (ii) the Closing shall occur on the third (3<sup>rd</sup>) Trading Day following the date of this Agreement and (iii) any condition to Closing contemplated by this Agreement (but prior to being disregarded by clause (i) above) that required delivery by the Company or the above-signed of any agreement, instrument, certificate or the like or purchase price (as applicable) shall no longer be a condition and shall instead be an unconditional obligation of the Company or the above-signed (as applicable) to deliver such agreement, instrument, certificate or the like or purchase price (as applicable) to such other party on the Closing Date.

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[SIGNATURE PAGES CONTINUE]

H.C. WAINWRIGHT & CO.

June 12, 2017

STRICTLY CONFIDENTIAL

OpGen, Inc.  
708 Quince Orchard Road, Suite 205  
Gaithersburg, MD 20878

Attention: Evan Jones, Chief Executive Officer

Dear Mr. Jones:

This letter agreement (this "Agreement") constitutes the agreement between OpGen, Inc. (the "Company") and H.C. Wainwright & Co., LLC ("Wainwright"), that Wainwright shall serve as the exclusive agent or underwriter in a registered offering (the "Offering") of securities of the Company (the "Securities") during the Term (as hereinafter defined) of this Agreement (except as provided below with respect to sales under the Company's existing "at the market" offering program). The terms of the Offering and the Securities issued in connection therewith shall be mutually agreed upon by the Company and Wainwright and nothing herein implies that Wainwright would have the power or authority to bind the Company and nothing herein implies that the Company shall have an obligation to issue any Securities. It is understood that Wainwright's assistance in the Offering will be subject to the satisfactory completion of such investigation and inquiry into the affairs of the Company as Wainwright deems appropriate under the circumstances and to the receipt of all internal approvals of Wainwright in connection with the transaction. The Company expressly acknowledges and agrees that Wainwright's involvement in the Offering is strictly on a reasonable best efforts basis and that the consummation of the Offering will be subject to, among other things, market conditions. The execution of this Agreement does not constitute a commitment by Wainwright to purchase the Securities and does not ensure a successful Offering of the Securities or the success of Wainwright with respect to securing any other financing on behalf of the Company. Wainwright may retain other brokers, dealers, agents or underwriters on its behalf in connection with an Offering.

- A. Compensation; Reimbursement. At the closing of the Offering (each, a "Closing"), the Company shall compensate Wainwright as follows:
1. Cash Fee. The Company shall pay to Wainwright a cash fee, or as to an underwritten Offering an underwriter discount, equal to 6.5% of the aggregate gross proceeds raised in the Offering; provided, that, in no event shall any cash fee be paid to Wainwright in connection with sales of Securities to jVen Capital, LLC, Merck & Co., Inc., any Chinese party introduced to the Company by M.S.Q. Ventures Inc., International Finance Corporation, or any of their respective affiliates.
  2. Warrant Coverage. The Company shall issue to Wainwright or its designees at each Closing, warrants (the "Wainwright Warrants") to purchase that number of shares of common stock of the Company equal to 5.0% of the aggregate number of shares of common stock placed in the Offering (and if the Offering includes a "greenshoe" or "additional investment" option component, such number of shares of common stock underlying such additional option component, with the Wainwright Warrants issuable upon the exercise of such option). If the Securities included in the Offering are convertible, the Wainwright Warrants shall be determined by dividing the gross proceeds raised in such Offering divided by the Offering Price (as defined hereunder). The Wainwright Warrants shall have the same terms as the warrants issued to investors in the applicable Offering, except that such Wainwright Warrants shall have an exercise price equal to 125% of the offering price per share (or unit, if applicable) in the applicable Offering and if such offering price is not available, the market price of the common stock on the date the Offering is commenced (such price, the "Offering Price"). If no warrants are issued to investors in the Offering, the Wainwright Warrants shall be in a customary form reasonably acceptable to Wainwright, have a term of five (5) years and an exercise price equal to 125% of the Offering Price.

3. *Expense Allowance.* Out of the proceeds of each Closing, the Company also agrees to pay Wainwright (a) a management fee equal to 1.0% of the gross proceeds raised in the Offering provided, that, in no event shall any management fee be paid to Wainwright in connection with sales of Securities to jVen Capital, LLC, Merck & Co., Inc., any Chinese party introduced to the Company by M.S.Q. Ventures Inc., International Finance Corporation, or any of their respective affiliates; (b) \$50,000 for non-accountable expenses; (c) up to \$100,000 for fees and expenses of legal counsel; plus the additional reimbursable amount payable by the Company pursuant to Paragraph D.3 hereunder; provided, however, that such reimbursement amount in no way limits or impairs the indemnification and contribution provisions of this Agreement.
4. *[Reserved.]*
5. *Right of First Refusal.* If, from the date hereof until the 12-month anniversary following consummation of the Offering, the Company or any of its subsidiaries (a) decides to finance or refinance any indebtedness using a manager or agent, Wainwright (or any affiliate designated by Wainwright) shall have the right to act as a joint book-runner, a manager, a placement agent or an agent with respect to such financing or refinancing for the same economics as the other joint book-runner, manager, placement agents or agent; provided, that Wainwright shall be entitled to at least 33% of the economics of such financing (to be increased to 50% of the economics of such financing if neither Cowen nor Leerink participates in such financings); or (b) decides to raise funds by means of a public offering or a private placement of equity or debt securities using an underwriter or placement agent in each case other than through (i) its existing “at the market” program; (ii) any transaction with a Chinese party introduced to the Company by M.S.Q. Ventures Inc.; or (iii) any transaction with the International Finance Corporation, Wainwright (or any affiliate designated by Wainwright) shall have the right to act as a joint book-running manager or a placement agent for such financing, for the same economics as the other joint bookrunning manager or placement agents; provided, that Wainwright shall be entitled to at least 33% of the economics of such financing (to be increased to 50% of the economics of such financing if neither Cowen nor Leerink participates in such financings). The Company and Wainwright will enter into a new engagement letter with respect to such financing having terms customary for transactions of similar type and size. For the avoidance of doubt, in no event shall Wainwright be entitled to any right of first refusal under the terms of this Agreement in the event that the Offering is not consummated during the Term (as defined below). If Wainwright or one of its affiliates decides to accept any such engagement, the agreement governing such engagement will contain, among other things, provisions for customary fees for transactions of similar size and nature and the provisions of this Agreement, including indemnification, which are appropriate to such a transaction. Wainwright hereby acknowledges that (i) the Company has a pre-existing obligation pursuant to (i) a letter agreement, dated February 26, 2016 as amended by letter dated May 10, 2016 (the “Cowen Engagement Letter”), between the Company and Cowen, and (ii) letter agreement, dated as of March 3, 2016, as amended by letter dated May 10, 2016 (the “Leerink Engagement Letter”), by and between Leerink Partners LLC (“Leerink”) and the Company, to provide each of Cowen and Leerink with a right of first refusal to serve as the Company’s joint bookrunning managing underwriter underwriter in connection with any public offering conducted by the Company (other than an “at the market” offering) until February 26, 2018 in the case of Cowen and March 3, 2018 in the case of Leerink and (ii) the Company will seek a waiver of the right of first refusal from each of Cowen and Leerink pursuant to each respective engagement letter, prior to filing of a registration statement on Form S-1 in connection with the Offering. Notwithstanding anything in this Section to the contrary, the Company’s obligation to offer a right of first refusal to Wainwright is in addition to the Company’s obligation to offer each of Cowen and Leerink the right of first refusal provided in the Cowen Engagement Letter and the Leerink Engagement Letter, respectively. Notwithstanding anything herein to the contrary, Wainwright shall not be entitled to receive a tail fee as provided under clause (4) above with respect to any investor that participates in an offering in connection with which Wainwright serves as a joint book-running manager or placement agent pursuant to the right of first refusal provided in this clause (5).

B. Term and Termination of Engagement; Exclusivity. The term of Wainwright's exclusive engagement will begin on the date hereof and end at the earlier of (i) consummation of the Offering and (ii) three (3) months following the date hereof (the "Term"). Notwithstanding the exclusive nature of Wainwright's engagement, the selling group for the Offering shall include such other agents as shall be mutually agreed upon by the Company and Wainwright. Notwithstanding anything to the contrary contained herein, the Company agrees that the provisions relating to the payment of fees, reimbursement of expenses, right of first refusal, tail, indemnification and contribution, confidentiality, conflicts, independent contractor and waiver of the right to trial by jury will survive any termination of this Agreement. Notwithstanding anything to the contrary contained in this Agreement, in the event that this Agreement shall not be carried out for any reason whatsoever during the Term, the Company shall be obligated to pay to Wainwright its actual and accountable out-of-pocket expenses related to the Offering (including the fees and disbursements of Wainwright's legal counsel) incurred from the date of this Agreement to the date that it shall be determined that this Agreement shall not be carried out. During Wainwright's engagement hereunder: (i) the Company will not, and will not permit its representatives to, other than in coordination with Wainwright, contact or solicit institutions, corporations or other entities or individuals as potential purchasers of the Securities and (ii) the Company will not pursue any financing transaction which would be in lieu of the Offering; provided, that nothing in this Agreement shall prohibit the Company from continuing to sell securities under its existing "at the market" offering program until such date as shall be mutually agreed upon by the Company and Wainwright. Furthermore, the Company agrees that during Wainwright's engagement hereunder, all inquiries, whether direct or indirect, from prospective investors will be referred to Wainwright other than in connection with the Company's existing "at the market" offering program. Additionally, except as set forth hereunder, the Company represents, warrants and covenants that no brokerage or finder's fees or commissions are or will be payable by the Company or any subsidiary of the Company to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other third-party with respect to any Offering.

C. Information; Reliance. The Company shall furnish, or cause to be furnished, to Wainwright all information requested by Wainwright for the purpose of rendering services hereunder and conducting due diligence (all such information being the "Information"). In addition, the Company agrees to make available to Wainwright upon request from time to time the officers, directors, accountants, counsel and other advisors of the Company. The Company recognizes and confirms that Wainwright (a) will use and rely on the Information, including any documents provided to investors in the Offering (the "Offering Documents") which shall include any Purchase Agreement (as defined hereunder), and on information available from generally recognized public sources in performing the services contemplated by this Agreement without having independently verified the same; (b) does not assume responsibility for the accuracy or completeness of the Offering Documents or the Information and such other information; and (c) will not make an appraisal of any of the assets or liabilities of the Company. Upon reasonable request, the Company will meet with Wainwright or its representatives to discuss all information relevant for disclosure in the Offering Documents and will cooperate in any investigation undertaken by Wainwright thereof, including any document included or incorporated by reference therein. In connection with the Offering, at the request of Wainwright, the Company shall deliver such legal letters (including, without limitation, negative assurance letters), opinions, comfort letters, officers' and secretary certificates and good standing certificates, all in form and substance satisfactory to Wainwright and its counsel as is customary for such Offering. Wainwright shall be a third party beneficiary of any representations, warranties, covenants and closing conditions made by the Company in any Offering Documents, including representations, warranties, covenants and closing conditions made to any investor in the Offering.

D. Related Agreements. In connection with the Offering, the Company shall enter into the following additional agreements:

1. *Underwritten Offering*. If an Offering is an underwritten Offering, the Company and Wainwright shall enter into a customary underwriting agreement in form and substance satisfactory to Wainwright and its counsel.
2. *Best Efforts Offering*. If the Offering is on a best efforts basis, the sale of Securities to the investors in the Offering will be evidenced by a purchase agreement ("Purchase Agreement") between the Company and such investors in a form reasonably satisfactory to the Company and Wainwright. Wainwright shall be a third party beneficiary with respect to the representations and warranties included in the Purchase Agreement. Prior to the signing of any Purchase Agreement, officers of the Company with responsibility for financial affairs will be available to answer inquiries from prospective investors.

3. *Escrow and Settlement.* In respect of the Offering, the Company and Wainwright shall enter into an escrow agreement with a third party escrow agent, which may also be Wainwright's clearing agent, pursuant to which Wainwright's compensation and expenses shall be paid from the gross proceeds of the Securities sold. If the Offering is settled in whole or in part via delivery versus payment ("DVP"), Wainwright shall arrange for its clearing agent to provide the funds to facilitate such settlement. The Company shall bear the cost of the escrow agent and shall reimburse Wainwright for the actual out-of-pocket cost of such clearing agent settlement and financing, if any, which cost shall not exceed \$10,000.
4. *FINRA Amendments.* Notwithstanding anything herein to the contrary, in the event that Wainwright determines that any of the terms provided for hereunder shall not comply with a FINRA rule, including but not limited to FINRA Rule 5110, then the Company shall agree to amend this Agreement (or include such revisions in the final underwriting agreement) in writing upon the request of Wainwright to comply with any such rules; provided that any such amendments shall not provide for terms that are less favorable to the Company than are reflected in this Agreement.

E. Confidentiality. In the event of the consummation or public announcement of any Offering, Wainwright shall have the right to disclose its participation in such Offering, including, without limitation, the Offering at its own cost, through "tombstone" advertisements in financial and other newspapers and journals.

F. Indemnity.

1. In connection with the Company's engagement of Wainwright as Offering agent, the Company hereby agrees to indemnify and hold harmless Wainwright and its affiliates, and the respective controlling persons, directors, officers, members, shareholders, agents and employees of any of the foregoing (collectively the "Indemnified Persons"), from and against any and all claims, actions, suits, proceedings (including those of shareholders), damages, liabilities and expenses incurred by any of them (including the reasonable fees and expenses of counsel), as incurred, (collectively a "Claim"), that are (A) related to or arise out of (i) any actions taken or omitted to be taken (including any untrue statements made or any statements omitted to be made) by the Company, or (ii) any actions taken or omitted to be taken by any Indemnified Person in connection with the Company's engagement of Wainwright, or (B) otherwise relate to or arise out of Wainwright's activities on the Company's behalf under Wainwright's engagement, and the Company shall reimburse any Indemnified Person for all expenses (including the reasonable fees and expenses of counsel) as incurred by such Indemnified Person in connection with investigating, preparing or defending any such claim, action, suit or proceeding, whether or not in connection with pending or threatened litigation in which any Indemnified Person is a party; provided, that the Company has received a written undertaking of such Indemnified Person to repay to the Company the amount so advanced if it shall be determined by a court of competent jurisdiction in a final judgment that has become non-appealable that such Indemnified Person was not entitled to indemnification hereunder. The Company will not, however, be responsible for any Claim that is finally judicially determined to have resulted from the fraud, gross negligence or willful misconduct by any person seeking indemnification for such Claim. The Company further agrees that no Indemnified Person shall have any liability to the Company for or in connection with the Company's engagement of Wainwright except for any Claim incurred by the Company as a result of such Indemnified Person's fraud, gross negligence or willful misconduct.

2. The Company further agrees that it will not, without the prior written consent of Wainwright, settle, compromise or consent to the entry of any judgment in any pending or threatened Claim in respect of which indemnification may be sought hereunder (whether or not any Indemnified Person is an actual or potential party to such Claim), unless such settlement, compromise or consent includes an unconditional, irrevocable release of each Indemnified Person from any and all liability arising out of such Claim.
3. Promptly upon receipt by an Indemnified Person of notice of any complaint or the assertion or institution of any Claim with respect to which indemnification is being sought hereunder, such Indemnified Person shall notify the Company in writing of such complaint or of such assertion or institution but failure to so notify the Company shall not relieve the Company from any obligation it may have hereunder, except and only to the extent such failure results in the forfeiture by the Company of substantial rights and defenses. If the Company so elects or is requested by such Indemnified Person, the Company will assume the defense of such Claim, including the employment of counsel reasonably satisfactory to such Indemnified Person and the payment of the fees and expenses of such counsel. In the event, however, that legal counsel to such Indemnified Person reasonably determines that having common counsel would present such counsel with a conflict of interest or if the defendant in, or target of, any such Claim, includes an Indemnified Person and the Company, and legal counsel to such Indemnified Person reasonably concludes that there may be legal defenses available to it or other Indemnified Persons different from or in addition to those available to the Company, then such Indemnified Person may employ its own separate counsel to represent or defend him, her or it in any such Claim and the Company shall pay the reasonable fees and expenses of such counsel. Notwithstanding anything herein to the contrary, if the Company fails timely or diligently to defend, contest, or otherwise protect against any Claim, the relevant Indemnified Party shall have the right, but not the obligation, to defend, contest, compromise, settle, assert crossclaims, or counterclaims or otherwise protect against the same, and shall be fully indemnified by the Company therefor, including without limitation, for the reasonable fees and expenses of its counsel and all amounts paid as a result of such Claim or the compromise or settlement thereof. In addition, with respect to any Claim in which the Company assumes the defense, the Indemnified Person shall have the right to participate in such Claim and to retain his, her or its own counsel therefor at his, her or its own expense.



4. The Company agrees that if any indemnity sought by an Indemnified Person hereunder is held by a court to be unavailable for any reason then (whether or not Wainwright is the Indemnified Person), the Company and Wainwright shall contribute to the Claim for which such indemnity is held unavailable in such proportion as is appropriate to reflect the relative benefits to the Company, on the one hand, and Wainwright on the other, in connection with Wainwright's engagement referred to above, subject to the limitation that in no event shall the amount of Wainwright's contribution to such Claim exceed the amount of fees actually received by Wainwright from the Company pursuant to Wainwright's engagement. The Company hereby agrees that the relative benefits to the Company, on the one hand, and Wainwright on the other, with respect to Wainwright's engagement shall be deemed to be in the same proportion as (a) the total value paid or proposed to be paid or received by the Company pursuant to the applicable Offering (whether or not consummated) for which Wainwright is engaged to render services bears to (b) the fee paid or proposed to be paid to Wainwright in connection with such engagement. Notwithstanding the provisions of this paragraph F.4., no person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) if the Securities Act of 1933, as amended) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.
5. The Company's indemnity, reimbursement and contribution obligations under this Agreement (a) shall be in addition to, and shall in no way limit or otherwise adversely affect any rights that any Indemnified Party may have at law or at equity and (b) shall be effective whether or not the Company is at fault in any way.

G. Limitation of Engagement to the Company. The Company acknowledges that Wainwright has been retained only by the Company, that Wainwright is providing services hereunder as an independent contractor (and not in any fiduciary or agency capacity) and that the Company's engagement of Wainwright is not deemed to be on behalf of, and is not intended to confer rights upon, any shareholder, owner or partner of the Company or any other person not a party hereto as against Wainwright or any of its affiliates, or any of its or their respective officers, directors, controlling persons (within the meaning of Section 15 of the Securities Act or Section 20 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), employees or agents. Unless otherwise expressly agreed in writing by Wainwright, no one other than the Company is authorized to rely upon this Agreement or any other statements or conduct of Wainwright, and no one other than the Company is intended to be a beneficiary of this Agreement. The Company acknowledges that any recommendation or advice, written or oral, given by Wainwright to the Company in connection with Wainwright's engagement is intended solely for the benefit and use of the Company's management and directors in considering a possible Offering, and any such recommendation or advice is not on behalf of, and shall not confer any rights or remedies upon, any other person or be used or relied upon for any other purpose. Wainwright shall not have the authority to make any commitment binding on the Company. The Company, in its sole discretion, shall have the right to reject any investor introduced to it by Wainwright.

H. Limitation of Wainwright's Liability to the Company. Wainwright and the Company further agree that neither Wainwright nor any of its affiliates or any of its their respective officers, directors, controlling persons (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act), employees or agents shall have any liability to the Company, its security holders or creditors, or any person asserting claims on behalf of or in the right of the Company (whether direct or indirect, in contract, tort, for an act of negligence or otherwise) for any losses, fees, damages, liabilities, costs, expenses or equitable relief arising out of or relating to this Agreement or the services rendered hereunder, except for losses, fees, damages, liabilities, costs or expenses that arise out of or are based on any action of or failure to act by Wainwright and that are finally judicially determined to have resulted solely from the, fraud, gross negligence, or willful misconduct by Wainwright.

I. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York applicable to agreements made and to be fully performed therein. Any disputes that arise under this Agreement, even after the termination of this Agreement, will be heard only in the state or federal courts located in the City of New York, State of New York. The parties hereto expressly agree to submit themselves to the jurisdiction of the foregoing courts in the City of New York, State of New York. The parties hereto expressly waive any rights they may have to contest the jurisdiction, venue or authority of any court sitting in the City and State of New York. In the event any party to this Agreement is successful in any action, or suit arising out of or relating to this Agreement, such party shall be entitled, upon entry of the final judgment or award in connection with such action to have and recover from such other party the costs and expenses incurred in connection therewith, including its reasonable attorneys' fees. Any rights to trial by jury with respect to any such action, proceeding or suit are hereby waived by Wainwright and the Company.

J. Notices. All notices hereunder will be in writing and sent by certified mail, hand delivery, overnight delivery or fax, if sent to Wainwright, at the address set forth on the first page hereof, e-mail: notices@hcwco.com, Attention: Head of Investment Banking, and if sent to the Company, to the address set forth on the first page hereof, e-mail: ejones@opgen.com Attention: Chief Executive Officer. Notices sent by certified mail shall be deemed received five days thereafter, notices sent by hand delivery or overnight delivery shall be deemed received on the date of the relevant written record of receipt, notices delivered by fax shall be deemed received as of the date and time printed thereon by the fax machine and notices sent by e-mail shall be deemed received as of the date and time they were sent.

K. Conflicts. The Company acknowledges that Wainwright and its affiliates may have and may continue to have investment banking and other relationships with parties other than the Company pursuant to which Wainwright may acquire information of interest to the Company. Wainwright shall have no obligation to disclose such information to the Company or to use such information in connection with any contemplated transaction.

L. Anti-Money Laundering. To help the United States government fight the funding of terrorism and money laundering, the federal laws of the United States require all financial institutions to obtain, verify and record information that identifies each person with whom they do business. This means we must ask you for certain identifying information, including a government-issued identification number (e.g., a U.S. taxpayer identification number) and such other information or documents that we consider appropriate to verify your identity, such as certified articles of incorporation, a government-issued business license, a partnership agreement or a trust instrument.

M. Miscellaneous. The Company represents and warrants that it has all requisite power and authority to enter into and carry out the terms and provisions of this Agreement and the execution, delivery and performance of this Agreement does not breach or conflict with any agreement, document or instrument to which it is a party or bound. This Agreement shall not be modified or amended except in writing signed by Wainwright and the Company. This Agreement shall be binding upon and inure to the benefit of both Wainwright and the Company and their respective assigns, successors, and legal representatives. This Agreement constitutes the entire agreement of Wainwright and the Company with respect to the subject matter hereof and supersedes any prior agreements with respect to the subject matter hereof. It is hereby understood that (i) the Company shall not be obligated to pay any expenses of Wainwright under paragraph A.3. of that certain letter agreement, dated May 14, 2017 (the "Prior Engagement Letter"), entered into between the Company and Wainwright with respect to a proposed private placement offering of Securities, and (ii) Wainwright shall be entitled to payment of a tail fee under paragraph A.4. of the Prior Engagement Letter only with respect to investors who are listed on Schedule A hereto; provided that such investors have not participated in the Offering. If any provision of this Agreement is determined to be invalid or unenforceable in any respect, such determination will not affect such provision in any other respect, and the remainder of the Agreement shall remain in full force and effect. This Agreement may be executed in counterparts (including facsimile or electronic counterparts), each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

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In acknowledgment that the foregoing correctly sets forth the understanding reached by Wainwright and the Company, please sign in the space provided below, whereupon this letter shall constitute a binding Agreement as of the date indicated above.

Very truly yours,

**H.C. WAINWRIGHT & CO., LLC**

By: /s/ Edward D. Silvera

Name: Edward D. Silvera

Title: COO

Accepted and Agreed:

**OPGEN, INC.**

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer

**Schedule A**

**Tail Investor under Prior Engagement**

AIGH  
Ayrton  
Bigger  
Crossover HC Fund  
DAFNA  
Dolphin  
Empery  
Glen Capital  
Heights  
Hudson Bay  
Intracoastal  
Iroquois  
L1  
LH Financial  
Lincoln Park  
Pura Vida  
RA CAP  
Tavistock  
Tekla

or any of each respective affiliates

**PRE-FUNDED COMMON STOCK PURCHASE WARRANT**

**OPGEN, INC.**

Warrant Shares: \_\_\_\_\_

Issue Date: \_\_\_\_\_, 2017

THIS PRE-FUNDED COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, \_\_\_\_\_ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "Initial Exercise Date") until this Warrant is exercised in full (the "Termination Date") but not thereafter, to subscribe for and purchase from OpGen, Inc., a Delaware corporation (the "Company"), up to \_\_\_\_\_ shares of common stock, par value \$0.01 per share (the "Common Stock") (as subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

**Section 1. Definitions.** In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time shares of Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Trading Day" means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE MKT, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange, OTCQB or OTCQX (or any successors to any of the foregoing).

“Transfer Agent” means \_\_\_\_\_, the current transfer agent of the Company, with a mailing address of \_\_\_\_\_ and a facsimile number of \_\_\_\_\_, and any successor transfer agent of the Company.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy (or .pdf copy via e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) three (3) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the unpaid portion of the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The aggregate Exercise Price of this Warrant, except for a nominal exercise price of \$0.01 per Warrant Share, was pre-funded to the Company on or prior to the Initial Exercise Date and, consequently, no additional consideration (other than the nominal exercise price of \$0.01 per Warrant Share) shall be required to be paid by the Holder to any Person to effect any exercise of this Warrant. The Holder shall not be entitled to the return or refund of all, or any portion, of such pre-paid aggregate Exercise Price under any circumstance or for any reason whatsoever, including in the event this Warrant shall not have been exercised prior to the Termination Date. The exercise price per Ordinary Share under this Warrant shall be \$[ ] [PURCHASE PRICE PER PRE-FUNDED WARRANT PLUS \$0.01], subject to adjustment hereunder (the “Exercise Price”). The remaining unpaid exercise price per Warrant Share shall be \$0.01, subject to adjustment hereunder.

c) Cashless Exercise. If at any time after the Initial Exercise Date, there is no effective registration statement registering, or no current prospectus available for, the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of “regular trading hours” (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder’s execution of the applicable Notice of Exercise if such Notice of Exercise is executed during “regular trading hours” on a Trading Day and is delivered within two (2) hours thereafter pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of “regular trading hours” on such Trading Day;

(B) = \$0.01, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

“Bid Price” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the “Pink Sheets” published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.



“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the “Pink Sheets” published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

- i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder’s or its designee’s balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system (“DWAC”) if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company’s share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earlier of (i) three (3) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the “Warrant Share Delivery Date”). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) three Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10 per Trading Day (increasing to \$20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, “Standard Settlement Period” means the standard settlement period, expressed in a number of Trading Days, on the Company’s primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise delivered by 12:00 p.m. (New York City time) on the Initial Exercise Date, the Company agrees to deliver the Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Initial Exercise Date.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within two Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be [9.99%/4.99%] of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of the shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61<sup>st</sup> day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares or (iv) issues by reclassification of shares of Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) [RESERVED]

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a “Distribution”), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of shares of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding shares of Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the shares of Common Stock or any compulsory share exchange pursuant to which the shares of Common Stock are effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a “Fundamental Transaction”), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the “Alternate Consideration”) receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of shares of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the “Successor Entity”) to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the “Company” shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein.

f) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the shares of Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the shares of Common Stock, (C) the Company shall authorize the granting to all holders of the shares of Common Stock rights or warrants to subscribe for or purchase any capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the shares of Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the shares of Common Stock are converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the shares of Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or stock exchange is expected to become effective or close, and the date as of which it is expected that holders of the shares of Common Stock of record shall be entitled to exchange their shares of Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or stock exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the Issue Date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued shares of Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the shares of Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).



Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, stockholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies, notwithstanding the fact that the Holder's right to exercise this Warrant terminates on the Termination Date. If the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any notices, consents, waivers or other document or communications required or permitted to be given or delivered under the terms of this Warrant must be in writing and will be deemed to have been delivered: (i) upon receipt, if delivered personally; (ii) when sent, if sent by facsimile (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party); (iii) when sent, if sent by e-mail (provided that such sent e-mail is kept on file (whether electronically or otherwise) by the sending party and the sending party does not receive an automatically generated message from the recipient's e-mail server that such e-mail could not be delivered to such recipient) and (iv) if sent by overnight courier service, one (1) Trading Day after deposit with an overnight courier service with next day delivery specified, in each case, properly addressed to the party to receive the same. The addresses, facsimile numbers and e-mail addresses for such communications shall be:

If to the Company:

OpGen, Inc.  
[ADDRESS]  
Facsimile:  
E-mail:  
Attention:

With a copy (for informational purposes only) to:

[ADD]  
[ADDRESS]  
Facsimile:  
E-mail:  
Attention:

If to a Holder, to its address, facsimile number or e-mail address set forth herein or on the books and records of the Company.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any shares of Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

\*\*\*\*\*

*(Signature Page Follows)*

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

**OPGEN, INC.**

By: \_\_\_\_\_  
Name:  
Title:

**NOTICE OF EXERCISE**

TO: OPGEN, INC.

(1) The undersigned hereby elects to purchase \_\_\_\_\_ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

in lawful money of the United States; or

if permitted, the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

\_\_\_\_\_

The Warrant Shares shall be delivered to the following DWAC Account Number:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

[SIGNATURE OF HOLDER]

Name of Investing Entity: \_\_\_\_\_

*Signature of Authorized Signatory of Investing Entity:* \_\_\_\_\_

Name of Authorized Signatory: \_\_\_\_\_

Title of Authorized Signatory: \_\_\_\_\_

Date: \_\_\_\_\_

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ASSIGNMENT FORM

*(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)*

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: \_\_\_\_\_  
(Please Print)

Address: \_\_\_\_\_  
(Please Print)

Phone Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

Dated: \_\_\_\_\_, \_\_\_\_\_

Holder's Signature: \_\_\_\_\_

Holder's Address: \_\_\_\_\_

**COMMON STOCK PURCHASE WARRANT**

**OPGEN, INC.**

Warrant Shares: \_\_\_\_\_

Issue Date: \_\_\_\_\_, 2017

THIS COMMON STOCK PURCHASE WARRANT` (the "Warrant") certifies that, for value received, \_\_\_\_\_ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "Initial Exercise Date") and on or prior to 5:00 PM New York City time on \_\_\_, 202\_, or if the final day of such period falls on a date that is not a Trading Day, the next succeeding Trading Day (the "Termination Date") but not thereafter, to subscribe for and purchase from OpGen, Inc., a Delaware corporation (the "Company"), up to \_\_\_\_\_ shares of common stock, par value \$0.01 per share (the "Common Stock") (as subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time shares of Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE MKT, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange, OTCQB or OTCQX (or any successors to any of the foregoing).

“Transfer Agent” means \_\_\_\_\_, the current transfer agent of the Company, with a mailing address of \_\_\_\_\_ and a facsimile number of \_\_\_\_\_, and any successor transfer agent of the Company.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy (or .pdf copy via e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) three (3) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of the Common Stock under this Warrant shall be \$\_\_\_\_, subject to adjustment hereunder (the “Exercise Price”).



c) Cashless Exercise. If at any time after the Initial Exercise Date, there is no effective registration statement registering, or no current prospectus available for, the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of “regular trading hours” (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder’s execution of the applicable Notice of Exercise if such Notice of Exercise is executed during “regular trading hours” on a Trading Day and is delivered within two (2) hours thereafter pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of “regular trading hours” on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

“Bid Price” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the “Pink Sheets” published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the “Pink Sheets” published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder’s or its designee’s balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system (“DWAC”) if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company’s share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earlier of (i) three (3) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the “Warrant Share Delivery Date”). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) three Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10 per Trading Day (increasing to \$20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, “Standard Settlement Period” means the standard settlement period, expressed in a number of Trading Days, on the Company’s primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within two Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be [9.99%/4.99%] of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of the shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61<sup>st</sup> day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

### Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares or (iv) issues by reclassification of shares of Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) [RESERVED]

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a “Distribution”), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of shares of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding shares of Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the shares of Common Stock or any compulsory share exchange pursuant to which the shares of Common Stock are effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a “Fundamental Transaction”), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the “Alternate Consideration”) receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of shares of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction (other than a Fundamental Transaction which was not approved by the Company’s Board of Directors, as to which this right shall not apply), the Company or any Successor Entity (as defined below) shall, at the Holder’s option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction. Notwithstanding anything to the contrary contained herein, if a Fundamental Transaction has not been approved by the Board of Directors, Holder shall have the option to require the Company or any Successor Entity to purchase its Warrant for the Black Scholes Value of the unexercised portion of this Warrant as of the date of consummation of such Fundamental Transaction using the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction. “Black Scholes Value” means the value of this Warrant based on the Black and Scholes Option Pricing Model obtained from the “OV” function on Bloomberg, L.P. (“Bloomberg”) determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds within five Business Days of the Holder’s election (or, if later, on the effective date of the Fundamental Transaction). The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the “Successor Entity”) to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the “Company” shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein.



f) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the shares of Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the shares of Common Stock, (C) the Company shall authorize the granting to all holders of the shares of Common Stock rights or warrants to subscribe for or purchase any capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the shares of Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the shares of Common Stock are converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the shares of Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or stock exchange is expected to become effective or close, and the date as of which it is expected that holders of the shares of Common Stock of record shall be entitled to exchange their shares of Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or stock exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.



Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the Issue Date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued shares of Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the shares of Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, stockholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies, notwithstanding the fact that the Holder's right to exercise this Warrant terminates on the Termination Date. If the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any notices, consents, waivers or other document or communications required or permitted to be given or delivered under the terms of this Warrant must be in writing and will be deemed to have been delivered: (i) upon receipt, if delivered personally; (ii) when sent, if sent by facsimile (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party); (iii) when sent, if sent by e-mail (provided that such sent e-mail is kept on file (whether electronically or otherwise) by the sending party and the sending party does not receive an automatically generated message from the recipient's e-mail server that such e-mail could not be delivered to such recipient) and (iv) if sent by overnight courier service, one (1) Trading Day after deposit with an overnight courier service with next day delivery specified, in each case, properly addressed to the party to receive the same. The addresses, facsimile numbers and e-mail addresses for such communications shall be:

If to the Company:

OpGen, Inc.  
[ADDRESS]  
Facsimile:  
E-mail:  
Attention:

With a copy (for informational purposes only) to:

[ADD]  
[ADDRESS]  
Facsimile:  
E-mail:  
Attention:

If to a Holder, to its address, facsimile number or e-mail address set forth herein or on the books and records of the Company.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any shares of Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

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*(Signature Page Follows)*

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

**OPGEN, INC.**

By: \_\_\_\_\_  
Name:  
Title:

**NOTICE OF EXERCISE**

TO: OPGEN, INC.

(1) The undersigned hereby elects to purchase \_\_\_\_\_ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

in lawful money of the United States; or

if permitted, the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

\_\_\_\_\_

The Warrant Shares shall be delivered to the following DWAC Account Number:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

[SIGNATURE OF HOLDER]

Name of Investing Entity: \_\_\_\_\_

*Signature of Authorized Signatory of Investing Entity:* \_\_\_\_\_

Name of Authorized Signatory: \_\_\_\_\_

Title of Authorized Signatory: \_\_\_\_\_

Date: \_\_\_\_\_

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ASSIGNMENT FORM

*(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)*

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: \_\_\_\_\_  
(Please Print)

Address: \_\_\_\_\_  
(Please Print)

Phone Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

Dated: \_\_\_\_\_, \_\_\_\_\_

Holder's Signature: \_\_\_\_\_

Holder's Address: \_\_\_\_\_



## PLACEMENT AGENT COMMON STOCK PURCHASE WARRANT

OPGEN, INC.

Warrant Shares: \_\_\_\_\_

Issue Date: \_\_\_\_\_, 2017

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, \_\_\_\_\_ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after [THE EFFECTIVE DATE OF THE REGISTRATION STATEMENT] (the "Initial Exercise Date") and on or prior to 5:00 PM New York City time on \_\_\_, 202\_ [THE FIFTH YEAR ANNIVERSARY OF THE EFFECTIVE DATE OF THE REGISTRATION STATEMENT] (the "Termination Date") but not thereafter, to subscribe for and purchase from OpGen, Inc., a Delaware corporation (the "Company"), up to \_\_\_\_\_ shares of common stock, par value \$0.01 per share (the "Common Stock") (as subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant is issued pursuant to the Engagement Agreement, dated June 12, 2017, between the Company and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time shares of Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE MKT, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange, OTCQB or OTCQX (or any successors to any of the foregoing).

“Transfer Agent” means \_\_\_\_\_, the current transfer agent of the Company, with a mailing address of \_\_\_\_\_ and a facsimile number of \_\_\_\_\_, and any successor transfer agent of the Company.

## Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy (or .pdf copy via e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) three (3) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of the Common Stock under this Warrant shall be \$\_\_\_\_, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at any time after the Initial Exercise Date, there is no effective registration statement registering, or no current prospectus available for, the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the characteristics of the Warrants being exercised, and the holding period of the Warrants being exercised may be tacked on to the holding period of the Warrant Shares. The Company agrees not to take any position contrary to this Section 2(c).

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the “Pink Sheets” published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

- i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder’s or its designee’s balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system (“DWAC”) if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) the Warrant Shares are eligible for resale by the Holder without volume or manner of sale limitations pursuant to Rule 144, or (C) if applicable and permitted under 2(c), this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company’s share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earlier of (i) three (3) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the “Warrant Share Delivery Date”). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) three Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10 per Trading Day (increasing to \$20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, “Standard Settlement Period” means the standard settlement period, expressed in a number of Trading Days, on the Company’s primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within two Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be [9.99%/4.99%] of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of the shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61<sup>st</sup> day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

### Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares or (iv) issues by reclassification of shares of Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) [RESERVED]

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend (other than cash) or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of shares of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding shares of Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the shares of Common Stock or any compulsory share exchange pursuant to which the shares of Common Stock are effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of shares of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction (other than a Fundamental Transaction which was not approved by the Company's Board of Directors, as to which this right shall not apply), the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction. Notwithstanding anything to the contrary contained herein, if a Fundamental Transaction has not been approved by the Board of Directors, Holder shall have the option to require the Company or any Successor Entity to purchase its Warrant for the Black Scholes Value of the unexercised portion of this Warrant as of the date of consummation of such Fundamental Transaction using the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black and Scholes Option Pricing Model obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds within five Business Days of the Holder's election (or, if later, on the effective date of the Fundamental Transaction). The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein.



f) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the shares of Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the shares of Common Stock, (C) the Company shall authorize the granting to all holders of the shares of Common Stock rights or warrants to subscribe for or purchase any capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the shares of Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the shares of Common Stock are converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the shares of Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or stock exchange is expected to become effective or close, and the date as of which it is expected that holders of the shares of Common Stock of record shall be entitled to exchange their shares of Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or stock exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. Pursuant to FINRA Rule 5110(g)(1), neither this Warrant nor any Warrant Shares issued upon exercise of this Warrant shall be sold, transferred, assigned, pledged or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of the offering pursuant to which this Warrant is being issued, except the transfer of any security:

- i. by operation of law or by reason of reorganization of the Company;
- ii. to any FINRA member firm participating in the offering and the officers and partners thereof, if all securities so transferred remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period;
- iii. if the aggregate amount of securities of the Company held by the underwriter and related persons do not exceed 1% of the securities being offered;
- iv. that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or
- v. the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period.

Subject to the foregoing restriction, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the Issue Date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued shares of Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the shares of Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, stockholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies, notwithstanding the fact that the Holder's right to exercise this Warrant terminates on the Termination Date. If the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any notices, consents, waivers or other document or communications required or permitted to be given or delivered under the terms of this Warrant must be in writing and will be deemed to have been delivered: (i) upon receipt, if delivered personally; (ii) when sent, if sent by facsimile (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party); (iii) when sent, if sent by e-mail (provided that such sent e-mail is kept on file (whether electronically or otherwise) by the sending party and the sending party does not receive an automatically generated message from the recipient's e-mail server that such e-mail could not be delivered to such recipient) and (iv) if sent by overnight courier service, one (1) Trading Day after deposit with an overnight courier service with next day delivery specified, in each case, properly addressed to the party to receive the same. The addresses, facsimile numbers and e-mail addresses for such communications shall be:

If to the Company:

OpGen, Inc.  
[ADDRESS]  
Facsimile:  
E-mail:  
Attention:

With a copy (for informational purposes only) to:

[ADD]  
[ADDRESS]  
Facsimile:  
E-mail:  
Attention:

If to a Holder, to its address, facsimile number or e-mail address set forth herein or on the books and records of the Company.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any shares of Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

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*(Signature Page Follows)*

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

**OPGEN, INC.**

By: \_\_\_\_\_

Name:

Title:



**NOTICE OF EXERCISE**

TO: OPGEN, INC.

(1) The undersigned hereby elects to purchase \_\_\_\_\_ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

in lawful money of the United States; or

if permitted, the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

\_\_\_\_\_

The Warrant Shares shall be delivered to the following DWAC Account Number:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

[SIGNATURE OF HOLDER]

Name of Investing Entity: \_\_\_\_\_

*Signature of Authorized Signatory of Investing Entity:* \_\_\_\_\_

Name of Authorized Signatory: \_\_\_\_\_

Title of Authorized Signatory: \_\_\_\_\_

Date: \_\_\_\_\_

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ASSIGNMENT FORM

*(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)*

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: \_\_\_\_\_  
(Please Print)

Address: \_\_\_\_\_  
(Please Print)

Phone Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

Dated: \_\_\_\_\_, \_\_\_\_\_

Holder's Signature: \_\_\_\_\_

Holder's Address: \_\_\_\_\_

Ballard Spahr LLP  
1735 Market Street, 51<sup>st</sup> Floor  
Philadelphia, PA 19103-7599  
TEL 215.665.8500  
FAX: 215.864.8999  
www.ballardspahr.com

July 11, 2017

OpGen, Inc.  
708 Quince Orchard Road  
Suite 205  
Gaithersburg, Maryland 20878

RE: OpGen, Inc.

Ladies and Gentlemen:

We have acted as counsel to OpGen, Inc., a Delaware corporation (the "Company"), in connection with the preparation of a Registration Statement on Form S-1 (Registration No. 333-218392) (the "Registration Statement") filed by the Company with the U.S. Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), on May 31, 2017, as amended on June 28, 2017 and on July 11, 2017, with respect to the offer and sale of (i) up to 20,000,000 units (the "Units"), each Unit consisting of one share of Common Stock of the Company, \$0.01 par value per share (the "Common Stock") and one warrant to purchase one share of Common Stock (each, a "Common Warrant" and collectively, the "Common Warrants"), (ii) up to 20,000,000 pre-funded units (the "Pre-Funded Units"), each Pre-Funded Unit consisting of one pre-funded warrant to purchase one share of Common Stock (each a "Pre-Funded Warrant" and collectively, the "Pre-Funded Warrants") and one Common Warrant, and (iii) warrants to purchase up to 1,000,000 shares of Common Stock (the "HCW Warrants") to be issued to H.C. Wainwright & Co., LLC (the "Placement Agent") as compensation for its services pursuant to an engagement letter entered into by and between the Company and the Placement Agent, dated as of June 12, 2017 (the "Engagement Letter"), the form of which has been filed as Exhibit 1.2 to the Registration Statement. The HCW Warrants, the Common Warrants and the Pre-Funded Warrants are collectively referred to herein as the "Warrants," and the Units, the Pre-Funded Units, the Warrants, and the shares of Common Stock underlying the Warrants are collectively referred to herein as the "Securities."

The Securities are to be sold by the Company pursuant to a prospectus to be filed with the Registration Statement (the "Prospectus"), the Warrants, and a securities purchase agreement pursuant to which certain of the Securities are to be sold (the "Purchase Agreement"). As noted in the Prospectus, for each Pre-Funded Unit sold, the number of Units sold will be decreased on a one-for-one basis.

We have examined originals or copies (certified or otherwise identified to our satisfaction) of (i) the Amended and Restated Certificate of Incorporation of the Company together with all amendments thereto; (ii) the Certificate of Correction to the Amended and Restated Certificate of Incorporation; (iii) the form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock; (iv) the Amended and Restated Bylaws of the Company; (v) the Registration Statement and the exhibits thereto; (vi) the Prospectus; (vii) the Purchase Agreement; (viii) such other corporate records, agreements, documents and instruments; and (ix) such certificates or comparable documents of public officials and other sources, believed by us to be reliable, and of officers and representatives of the Company, and have made such inquiries of such officers and representatives, as we have deemed relevant and necessary as a basis for the opinions hereinafter set forth.

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In such examination, we have assumed the genuineness of all signatures, the legal capacity of all natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified, conformed or photostatic copies and the authenticity of the originals of such latter documents. As to all questions of fact material to this opinion that have not been independently established, we have relied upon certificates or comparable documents of officers and representatives of the Company.

Based upon the foregoing, as subject to the qualifications, assumptions and limitations set forth herein, we are of the opinion that (i) the Securities are or will be, upon issuance, duly authorized, and, when issued and sold in accordance with the terms and conditions of the Purchase Agreement, the Warrants and the Prospectus, as applicable, will be validly issued, fully paid and non-assessable and (ii) provided that the Warrants have been duly executed and delivered by the Company and duly delivered to the purchasers thereof, the Warrants, when issued and sold as contemplated in the Purchase Agreement, the Registration Statement and the Prospectus in exchange for the requisite payment therefor, will be valid and legally binding obligations of the Company.

Our opinion is limited to the laws of the State of Delaware, the laws of the State of New York and the United States federal laws, and we express no opinion with respect to the laws of any other jurisdiction. No opinion is expressed herein with respect to the qualification of the Securities under the securities or blue sky laws of any state or any foreign jurisdiction.

We hereby consent to the filing of this opinion with the Commission as an exhibit to the Registration Statement in accordance with the requirements of Item 601(b)(5) of Regulation S-K promulgated under the Securities Act, and to the use of this firm's name therein and in the Prospectus under the caption "Legal Matters." In giving this consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Securities Act and the rules and regulations promulgated

Sincerely yours,

/s/ Ballard Spahr LLP

**Consent of Independent Registered Public Accounting Firm**

We consent to the inclusion in this Amendment No. 2 to the Registration Statement on Form S-1 (No. 333-218392) of OpGen, Inc. of our report dated March 23, 2017, which includes an explanatory paragraph related to OpGen, Inc.'s ability to continue as a going concern, on our audits of the consolidated financial statements of OpGen, Inc. as of December 31, 2016 and 2015 and for the years then ended. We also consent to the reference to our firm in the caption "Experts."

/s/ CohnReznick LLP

Vienna, Virginia  
July 10, 2017

**Ballard Spahr**  
LLP

1735 Market Street, 51st Floor  
Philadelphia, PA 19103-7599  
TEL 215.665.8500  
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Mary J. Mullany  
Tel: 215.864.8631  
Fax: 215.864.8999  
mullany@ballardspahr.com

July 11, 2017

*By Electronic Filing*

United States Securities and Exchange Commission  
100 F Street N.E.  
Washington D.C. 20549  
Attention: John Reynolds

Re: OpGen, Inc.  
Amendment No. 1 to Registration Statement on Form S-1  
Filed June 29, 2017  
Response dated June 23, 2017  
File No. 333-218392

Ladies and Gentlemen:

We are providing this response letter on behalf of OpGen, Inc. (the "Company") with respect to the Staff's comment letter dated July 7, 2017, regarding the above-referenced Amendment No. 1 to the Registration Statement on Form S-1 (the "Registration Statement"). For your convenience, the Staff's comments have been reproduced below, followed by the Company's response.

General

1. We note your statements in response to prior comment 2 that you consider the bridge financing to have been completed. Given your disclosure on page 61 of the registration statement that you "could issue secured promissory notes of up to \$1,500,000" and your statements in your response regarding the status of the issuance of the notes, it is unclear how you determined that the issuance of promissory notes was completed at the time you filed the registration statement. We further note that the issuance of the notes is subject to various conditions set forth in section 4 of the Note Purchase Agreement filed as Exhibit 10.21. It continues to appear that you commenced the offering of these securities privately and are now attempting to complete the offering through a public offering. Please provide us with a detailed legal analysis, as previously requested, as to how you concluded that you may complete the private placement of the convertible notes and underlying common stock through your public offering on the Form S-1 filed on June 1, 2017, consistent with Section 5 of the Securities Act 1933. Refer to Securities Act Release No. 8828 (August 10, 2007). For additional guidance, please see Securities Act Sections Question 134.02 in the Division of Corporation Finance's Compliance and Disclosure Interpretations (April 24, 2009) available on our website at <http://www.sec.gov/divisions/corpfin/guidance/sasinterp.htm>.

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RESPONSE:

As we discussed during telephone conversations today with the staff, the Company has amended the bridge financing documents with jVen Capital, LLC to remove the provisions that provided the potential for any issuance of shares like those sold in the proposed public offering as repayment of the outstanding bridge financing notes. We believe such amendment decouples the private placement transaction between the Company and jVen Capital, LLC, from the proposed public offering under the Registration Statement.

Facing Page

2. Please disclose the amount or value of each class of securities being registered, not just the aggregate for all classes being registered. Also, please explain how the total registration fee reflects each class being registered.

RESPONSE: We have disclosed the value of each class of securities being registered and the registration fee for each class being registered in the fee table on the Facing Page. We have also revised the fee table in accordance with our telephone conversation.

The Company is filing Amendment No. 2 to the Registration Statement to reflect changes responsive to these comments.

Please contact Timothy C. Dec, the Chief Financial Officer of the Company, at (240) 813-1273, or me, at (215) 864-8631, if you have any questions about our response.

Very truly yours,

/s/ Mary J. Mullany  
Mary J. Mullany

MJM/seh

cc: Evan Jones  
Timothy C. Dec  
Ruairi Regan  
David Link