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

AMENDMENT NO. 1
TO
FORM S-1
REGISTRATION STATEMENT
Under
The Securities Act of 1933

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 201
Gaithersburg, MD 20878
(240) 813-1260**

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

Evan Jones
President and 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)

Copies to:

Mary J. Mullany, Esq.
Ballard Spahr LLP
1735 Market Street
51st Floor
Philadelphia, PA 19103
(215) 665-8500

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" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer
Non-Accelerated Filer

Accelerated Filer
Smaller Reporting Company

CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)(2)	Amount of Registration Fee
Common Stock, par value \$0.01 per share	\$	\$

- (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) Includes the aggregate offering price of additional shares that the underwriters have the option to purchase to cover over-allotments, if any.

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 December __, 2014.

Prospectus



Shares
Common Stock

OpGen, Inc. is offering _____ shares of its common stock. This is our initial public offering and no public market currently exists for our shares.

We intend to apply to list our common stock on The NASDAQ Capital Market prior to the offering contemplated by this prospectus.

We are an “emerging growth company” under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements.

Investing in our common stock involves risks. See “Risk Factors” beginning on page 12.

PRICE \$ _____ PER SHARE

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.

	Per Share	Total
Public offering price	\$ _____	\$ _____
Underwriting discounts and commission	\$ _____	\$ _____
Proceeds, before expenses, to OpGen, Inc. ⁽¹⁾	\$ _____	\$ _____

⁽¹⁾ See “Underwriting” for additional information regarding underwriter compensation.

We will grant the underwriters an option to purchase up to an additional _____ shares of common stock at the public offering price less the underwriting discount.

The underwriters expect to deliver the shares of common stock to purchasers on _____, 2015.

Prospectus dated _____, 2015

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We have not authorized anyone to provide you with any information or to make any representation, other than those contained in this prospectus, any free writing prospectus we have prepared or any document incorporated by reference herein. We take no responsibility for, and provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only in circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus, any free writing prospectus we have prepared or any document incorporated by reference herein, is accurate only as of its date, regardless of the time of delivery of this prospectus or of any sale of our common stock. To the extent there is a conflict between the information contained in this prospectus and the information contained in any document incorporated by reference herein filed prior to the date of this prospectus, you should rely on the information in this prospectus; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in the prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourself about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

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.

Please refer to the Glossary on page 73 of this prospectus for definitions of scientific, health care, regulatory and OpGen-specific terms used in this prospectus.

Overview

We are a commercial stage company using molecular testing and bioinformatics to combat multi-drug resistant bacterial infections. Our products and services are designed to enable healthcare providers to rapidly identify hospital patients who are colonized or infected with life threatening, multi-drug resistant organisms, or MDROs. Our Acuitas™ MDRO Gene Test products, currently available for sale, can be enabled by our Lighthouse™ bioinformatics platform in development, which can provide detailed MDRO molecular information about an individual patient’s resistance profile and integrate this information with data from other patients and hospital-wide aggregate results to help improve overall patient outcomes and to reduce hospital costs. We believe we have an important first-mover advantage in developing and bringing to market the combined package of Acuitas-enabled molecular information about drug resistant genes associated with MDRO infections that are commonly found to cause significant infections in hospitalized patients, and specific genetic information about an acute care hospital’s MDRO gene profile, including antibiotic resistance.

Our lead product, the Acuitas MDRO Gene Test, is, to our knowledge, the first CLIA lab-based test to provide a comprehensive profile of MDRO resistance genes from patients screened for colonization or infection. We first introduced the test in the first half of 2014. To date we have achieved de minimis revenues from the test, but it is in clinical evaluations or in the implementation process at a number of acute care hospitals. In 2015, we expect to expand our customer base and to introduce a number of new products based on our molecular testing and bioinformatics platforms.

We also provide our Argus® Whole Genome Mapping System, MapIt® Services, and MapSolver™ bioinformatics products and services to academic, public health and corporate customers to perform Whole Genome Mapping and analysis of microbial, plant, animal and human genomes for life sciences applications. For information regarding the revenues associated with our Whole Genome Mapping products and services, please refer to “Management’s Discussion and Analysis of Financial Condition and Results of Operations” later in this prospectus.

Antimicrobial Resistance – An Urgent Global Issue

Antimicrobial resistance is one of the most serious health threats in health care today. MDROs have been prioritized as an urgent national and global threat by the Centers for Disease Control and Prevention, or CDC, the President of the United States, and the World Health Organization, or WHO. In September 2014, The White House issued a National Strategy for combating antibiotic-resistant bacteria. The 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 avoidable costs to the U.S. healthcare system. In most cases, these infections require prolonged and/or costlier treatments, extended hospital stays, necessitate 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 range between \$20 and \$35 billion annually.

An emerging U.S. and global threat are CREs - carbapenem-resistant Enterobacteriaceae bacteria - that are either difficult to treat or wholly untreatable. According to CDC Director, Dr. Tom Frieden, CREs are a nightmare bacteria. Our strongest antibiotics do not work and patients are left with potentially untreatable infections with mortality rates ranging between 40% and 80%. CRE strains are transmitted easily in healthcare settings from patients with asymptomatic intestinal colonization and the CRE strains have the potential to spread antibiotic resistance through plasmid transfer to other bacterial species, including common human flora and potential pathogens such as Escherichia coli. The CDC has called for urgent action to combat the growing threat of CRE bacteria. Core prevention measures recommended by the CDC for all acute and long-term care facilities include: contact precautions for all patients who are colonized or infected with CRE, single patient room housing or cohorting, laboratory notification procedures, antibiotic stewardship and screening to identify unrecognized CRE colonization in patients admitted to high risk settings such as ICUs, long term acute care units or facilities, or epidemiological linked contacts.

Culture based screening methods for CRE can take up to five or more days for identification and subsequent characterization of suspected CRE bacteria. The OpGen Acuitas MDRO Gene Test provides accurate test results for CRE genes and other MDRO genes back to the healthcare provider in less than one day. These test results provide actionable information to healthcare providers so that positive patients (both colonized and symptomatic) receive appropriate isolation precautions and patients with negative results can be removed from isolation precautions if applicable.

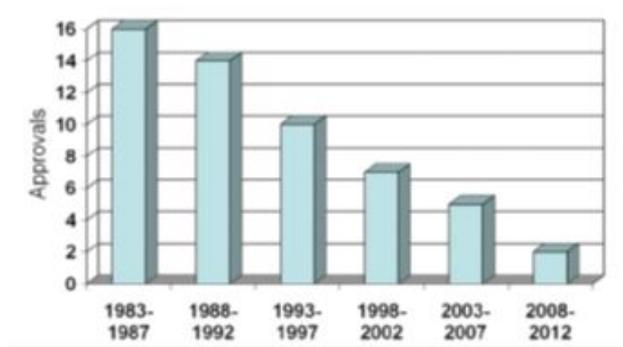
Our Acuitas MDRO Gene Test detects the presence of CRE resistance genes with higher sensitivity than conventional screening methods. In the summer of 2014, we conducted a comparison on samples of patients known to have CRE infections. We conducted a comparison using both the Acuitas MDRO Gene Test and a standard microbial culture testing method, and had the microbial culture results confirmed by a national reference lab. In such comparison, the Acuitas test was 100% sensitive and specific while the standard culture method was just 72% sensitive. Such standard culture method also creates many false positive results which potentially result in patients receiving unnecessary and costly contact precautions. For example, we conducted a recent in-house pilot study of the Acuitas MDRO Gene Test using samples from an acute care hospital, and 32% of initial culture screen results were false positives while the Acuitas test had 100% agreement with the confirmed clinical results.

Emergence of Superbugs and Lack of Treatment Options

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

Exacerbating the problems associated with the emergence of these highly resistant strains leading to Klebsiella pneumonia, or K. pneumonia, 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 that makes spread difficult to control and outbreaks difficult to stop. In addition, K. pneumoniae can survive for several hours on the hands of hospital personnel, which likely facilitates nosocomial spread. Effective control of K. pneumoniae outbreaks requires a detailed understanding of how transmission occurs, but current technologies do not allow healthcare providers to routinely perform these investigations.

The lack of currently available treatment options and scarcity of new treatment options in development are compounding the emerging Superbug problem. Since the 1980s and 1990s there has been a dramatic drop off in the number of new antibiotics developed and approved by the FDA. With few treatment options available, screening, infection control, and antibiotic stewardship have become our most powerful weapons in the fight to contain this building epidemic.



New systemic antibacterial agents approved by the U.S. Food and Drug Administration per 5-year period, through 2012.

Current surveillance methods for MDROs can take up to five days to provide complete results. The turn-around time for these test results needs to be improved for them to impact infection control programs and antibiotic stewardship.

The Opportunity

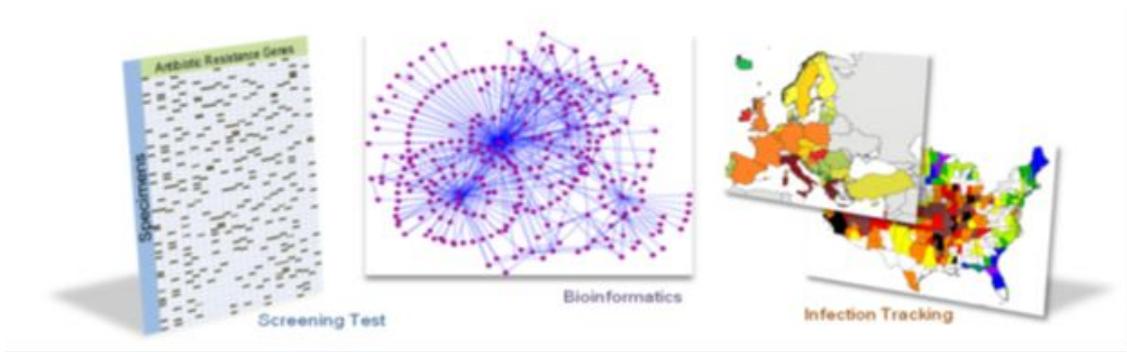
The discovery of antibiotics in the early 20th century fundamentally transformed human and veterinary medicine. Antibiotics save millions of lives each year in the U.S. and around the world. The rise of antibiotic resistant bacteria represents a growing and serious threat to public health and the economy, and now has been raised to the national security threat level. With the rising urgency of this issue and outbreaks of other difficult to treat infectious diseases, such as Ebola, dealing with infectious diseases and combating antibiotic resistant bacteria has become a global priority. Investment in new diagnostic technologies, comprehensive antibiotic stewardship programs, antibiotic development, vaccines and information technology advances are seen as critical elements in the fight against antimicrobial resistance.

Culture based microbiologic methods have been evolving for centuries and are important components of the diagnostic approach to detecting infectious disease. The potential for improvements based on cell culture alone have reached a plateau while the opportunities for improved detection and organism typing with DNA testing are expanding exponentially. Genomic diagnostics using DNA probe analysis, DNA sequencing and advanced bioinformatics are transforming clinical and public health microbiology practice. Using technologies developed for production genetics applications and high resolution genome sequencing it is now possible to envision rapid, cost effective, and highly accurate methods for characterizing bacterial colonization and infections in patients and more broadly in hospitals and other areas of human healthcare. Researchers have shown the ability to predict antibiotic resistance with up to 99% accuracy using DNA testing. This breakthrough combined with the speed, reliability and increased information content available with evolving DNA detection methods is leading to a fundamental transformation of the field of microbiology and the opportunity to dramatically improve patient outcomes.

Our Solution

OpGen intends to transform infectious disease management through innovation in molecular diagnostics, information technology, and microbiology to aid healthcare providers in reducing the burden of drug resistant infections. Our vision is that no patient should suffer from a life threatening, drug resistant infection. We are developing complete solutions for screening patients to determine underlying colonization with antibiotic resistant organisms such as CREs and for the development of early warning antibiotic stewardship programs for colonized patients who become infected. With our Acuitas™ family of products, we anticipate making it possible to rapidly detect and molecularly characterize targeted microorganisms in a hospital or other healthcare setting, including both patients with active infections, and patients or healthcare providers who may be colonized but not currently symptomatic. With this information we believe it will be possible to provide customized diagnostic information for newly diagnosed patients to allow targeted antibiotic therapy earlier and more effectively.

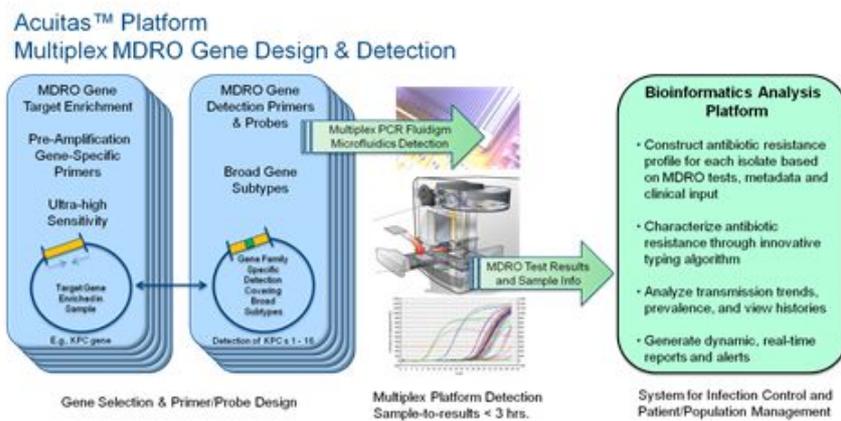
We have developed a comprehensive approach for screening for MDROs in hospitals using DNA testing. Our Acuitas Gene Tests are integrated with our Lighthouse MDRO Management System and laboratory information products to provide real-time information on the MDRO colonization status for patients, acute care ICUs, and hospitals. We combine our molecular test information and microbiology test results from our customized CLIA based tests to create Lighthouse MDRO profiles for hospitals. Lighthouse MDRO profiling facilitates MDRO tracking and results are easily aggregated with hospital data to provide customized reports including alerts, prevalence, trend analysis and transmission information. We anticipate providing this information on a local, regional, and national basis, to help reduce overall disease rates and to strengthen the national capacity to detect and manage treatment of drug resistant bacterial strains.



The OpGen complete solution includes the Acuitas MDRO Gene Test for hospital surveillance programs, the Lighthouse MDRO Management System for in-hospital MDRO patient management and tracking, and integrated reporting capabilities for public health organizations to track MDROs on a local, regional and national basis.

Acuitas MDRO Gene Test

Our Acuitas MDRO Gene Test directly detects seven critical MDRO genes from one patient swab. The test provides fast, accurate molecular results for genes associated with CRE, ESBL (extended spectrum beta lactamase) and VRE (vancomycin resistance enterobacteria) resistant genes. The test identifies patients at risk for being colonized. In our CLIA evaluation studies and customer pilot studies, the test has been proven to be highly accurate when compared to established reference methods, demonstrating nearly 100% correlation in identifying patients carrying MDROs and those free of MDRO bacteria.

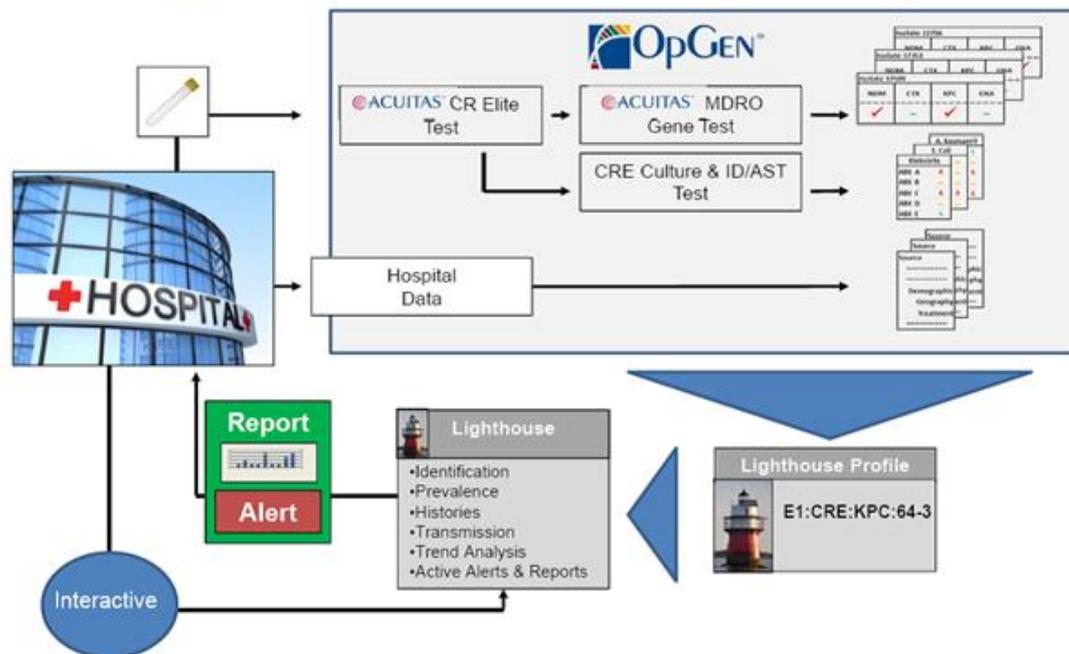


Acuitas gene tests combine Fluidigm’s microfluidic-based production genomics technology with DNA probe reagents designed and manufactured to power our CLIA Lab-based Acuitas gene tests.

Lighthouse MDRO

Our Lighthouse MDRO Management System solution, currently in development and undergoing analytical and clinical validation, enables proactive MDRO management to prevent in-hospital transmission events and to help improve patient outcomes. Trend analysis of patient specific data, data specific to individual hospital facilities and health systems is provided safely and confidentially to healthcare providers. Lighthouse MDRO dynamic profiling incorporates identity, phenotype and MDRO gene presence and assigns unique microbe identifiers, Lighthouse MDRO profiles, based on MDRO gene composition and antibiotic susceptibility, or AST, data. Lighthouse MDRO profiling provides the first diagnostic tracking tool for MDRO infection in the hospital setting. Our Lighthouse MDRO solution is based on our CLIA and HIPAA compliant LIMS database system. We are developing unique web-based portal for access to LIMS based lab reports and Lighthouse MDRO data reports. We anticipate commercializing our Lighthouse MDRO solution with our Acuitas MDRO Gene Tests in the first quarter of 2015.

Lighthouse™ MDRO Management System



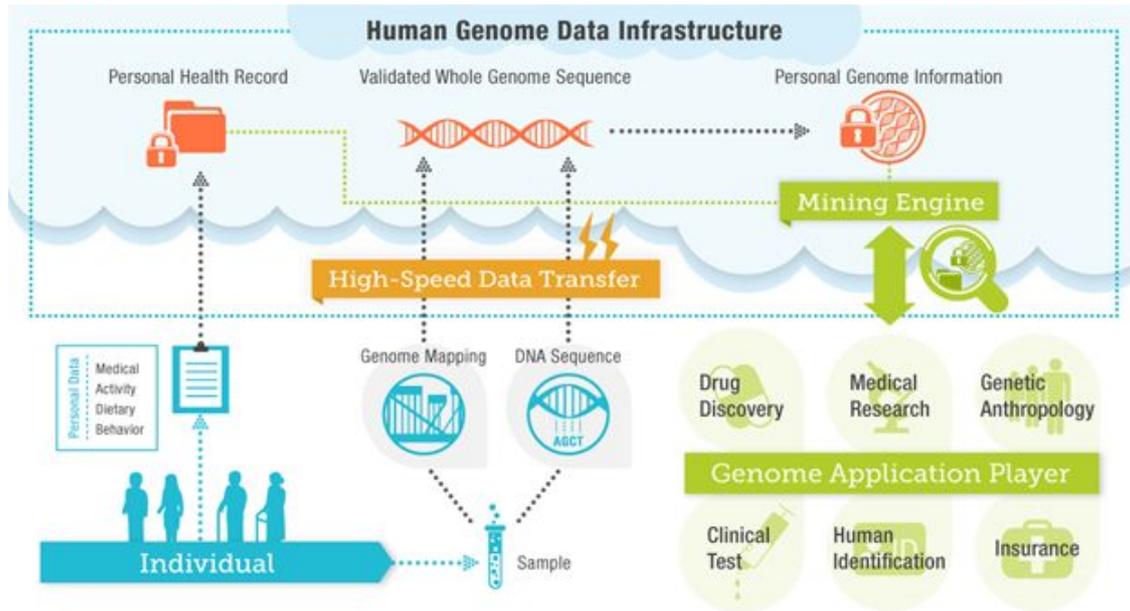
Microbial and human genome mapping and sequencing

Infectious disease testing is undergoing a transformation where DNA testing is replacing classical methods because of its accuracy and speed. DNA tests make it possible to simultaneously detect drug resistance genes, identify the presence of bacteria, viruses and fungi, and perform high resolution genotyping. These tests are generally more sensitive and provide more information than individual cultures. In addition, DNA tests can detect organisms that were undetectable by culture because the target organism was dead or would not grow in the culture medium. High resolution DNA analysis methods such as whole genome DNA sequencing offer the ability to accurately track hospital acquired infections and potentially improve patient diagnosis.

We have developed and commercialized the Argus® Whole Genome Mapping System, MapIt® Services, and MapSolver™ bioinformatics products and services for mapping and analysis of microbial, plant, animal and human genomes for life sciences applications. We have more than ten years of experience mapping microbial genomes. Our customers for these products include government public health agencies such as the CDC, FDA, USDA and biodefense organizations, and use the Argus and MapSolver products in research and development, food safety and public health settings.

In September 2013, we entered into a strategic collaboration with Hitachi High-Technologies Corporation, or Hitachi, to commercialize our Whole Genome Mapping technology for mapping, assembly and analysis of human genomes. In conjunction with Hitachi, we are developing cloud-based genome assembly capabilities for both human and microbial genomes. We intend to continue commercializing microbial configurations of these products through our direct sales efforts. DNA tests and bioinformatics for analysis of whole human genomes will be commercialized through our collaboration with Hitachi.

The following schematic provides a summary of the potential outcome of this collaboration:



© 2014 Hitachi High-Technologies Corporation

Our Strategy

- Commercialize our Lighthouse MDRO Management System to healthcare providers, governments, and diagnostic companies.
- Develop and commercialize proprietary molecular diagnostic products with companion data offerings that provide the ability to efficiently analyze data about MDROs present in a patient sample.
- Capitalize on our first-mover advantage through our CLIA Lab-based test offerings. We are working to integrate hospital-wide infectious organism molecular diagnostic information with antibiotic susceptibility data and combining this information with patient specific data for healthcare providers. These complete infection control, antibiotic stewardship and patient management data product capabilities will be difficult for future market entrants to replicate.
- Expand our lab service offerings and capabilities through supply of kits for use on our DNA probe assay platform and commercially available rapid diagnostic test systems, develop MDRO DNA sequencing tests and informatics, and partner these offerings with our Grow on the Go™ technology.
- Partner with reference laboratories, government agencies, diagnostic companies and information technology providers to offer our Lighthouse MDRO solution on a global basis.
- Build on our established market-leading position in Whole Genome Mapping through our relationship with Hitachi for human genome assembly and analysis and expanded research programs directed at complete DNA sequence assembly and bioinformatics.
- Accelerate growth through strategic partnerships, sponsored research programs with governments and industry, and strategic acquisitions.

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 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. For the years ended December 31, 2013 and 2012 and the nine months ended September 30, 2014, we had a net loss of \$10.1 million, \$9.3 million and \$4.3 million, respectively. From our inception through September 30, 2014, we had an accumulated deficit of \$95.4 million. Our monthly cash burn rate is approximately \$500,000, and we expect to require additional bridge funding on a monthly basis to maintain our cash position until consummation of the offering contemplated in this prospectus.
- We may not be able to generate sufficient revenue from the Acuitas MDRO Gene Test and Lighthouse MDRO Management System or our relationships with hospitals to achieve or maintain profitability.
- Our success depends on the achievement of greater market acceptance of the Acuitas MDRO Gene Test and Lighthouse MDRO Management System. If physicians do not believe the Acuitas MDRO Gene Test and our Lighthouse MDRO Management System consistently generate actionable information about MDROs present at their facilities, they may be less likely to order our products and services in the future, and our business could suffer.
- If we are unable to scale our operations to support increased demand for the Acuitas MDRO Gene Test and Lighthouse MDRO Management System, our business could suffer.
- Our information technology systems and assets are vital to the development and commercialization of our Lighthouse MDRO Management System, and the Human Chromosome Explorer we are developing with Hitachi, and any failure of these systems could harm our business.
- In order to successfully commercialize our Acuitas MDRO Gene Test, Lighthouse MDRO Management System and future products, we need to expand our sales and marketing capabilities and will require substantial additional capital to fund such expansion.
- 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.
- If our sole laboratory facility becomes damaged or inoperable, our ability to conduct our business may be jeopardized.
- We rely on a limited number of suppliers or, in some cases, a sole supplier, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers.
- If the FDA were to begin regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval.
- Our patent and intellectual property rights may not adequately protect our technologies and tests.

Company and Other Information

We were incorporated under the laws of the State of Delaware in January 2001. Our principal executive office is located at 708 Quince Orchard Road, Gaithersburg, Maryland, 20878, and our telephone number is (301) 869-9683. Our website address is 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.

On December 18, 2013, we effected a 1 for 790.5407 reverse stock split of our common stock. All references to shares, stock options and warrants outstanding, and the exercise price of outstanding derivative securities have been adjusted to reflect such reverse stock split.

We own various U.S. federal trademark registrations and applications, and unregistered trademarks and servicemarks, including OpGen®, Acuitas™, Lighthouse™, Argus®, MapSolver™ and Genome-Builder™. BioMark™ is a trademark of Fluidigm Corporation and Human Chromosome ExplorerSM is a servicemark of Hitachi High-Technologies Corporation. 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.

Implications of Being an Emerging Growth Company

As a company with less than \$1.0 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 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 this offering. 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 \$1.0 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.

THE OFFERING

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares (shares if the underwriters exercise their option to purchase additional shares in full)
Underwriters' option to purchase additional shares	We will grant a 30-day option to the underwriters to purchase up to an aggregate of additional shares of common stock.
Use of proceeds	We estimate that we will receive net proceeds from this offering of approximately \$ million, or approximately \$ million if the underwriters exercise their option to purchase additional shares in full, at an assumed public offering price of \$ per share, after deducting underwriting discounts and commissions and estimated offering expenses. We expect to use the net proceeds from this offering to fund increased sales and marketing, and research and development activities, and for working capital and general corporate purposes. See "Use of Proceeds" for additional information.
Risk factors	You should carefully read "Risk Factors" in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
NASDAQ Capital Market trading symbol	To be applied for.

The number of shares of our common stock to be outstanding after this offering is based on 5,862,401 shares of our common stock outstanding as of September 30, 2014, on an as-converted basis assuming conversion of our Series A Convertible Preferred Stock, or Series A Preferred Stock, and our convertible notes, convertible into Series A Preferred Stock, or convertible notes, and excludes:

- 410,870 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2014 at a weighted-average exercise price of \$1.13 per share;
- 130,640 restricted stock units issued to our Chief Executive Officer in March 2014;
- 51,227 shares of common stock reserved for future issuance under our 2008 Stock Option and Restricted Stock Plan, as amended, or the 2008 Plan; and
- 37,078 shares of common stock issuable upon the exercise of outstanding warrants to purchase our common stock.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- no issuance or exercise of stock options on or after September 30, 2014; and
- no exercise by the underwriters of their option to purchase additional shares of common stock in this offering.

SUMMARY FINANCIAL DATA

The following summary financial data should be read together with our financial statements and related notes, “Selected Financial Data” 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, 2013 and 2012 and the nine months ended September 30, 2014 and 2013, and the balance sheet data as of September 30, 2014 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.

	<u>Year Ended December 31,</u>		<u>Nine Months Ended</u>	
	<u>2013</u>	<u>2012</u>	<u>2014</u>	<u>September 30,</u> <u>2013</u>
	(In thousands, except share and per share data)			
	(Unaudited)			
Statements of Operations Data:				
Revenue	\$ 2,411	\$ 5,802	\$ 3,004	\$ 1,795
Operating expenses:				
Cost of sales	1,823	3,211	691	1,307
Research and development ⁽¹⁾	4,152	4,782	3,300	3,303
General and administrative ⁽¹⁾	2,762	2,473	1,652	2,189
Sales and marketing ⁽¹⁾	3,053	4,274	1,583	2,310
Argus Whole Genome obsolescence	951	--	--	--
Total operating expenses ⁽¹⁾	<u>12,741</u>	<u>14,740</u>	<u>7,227</u>	<u>9,109</u>
Loss from operations	(10,330)	(8,938)	(4,223)	(7,314)
Interest income	1	4	--	1
Interest expense	(32)	(119)	(47)	(9)
Change in fair value of warrant liability	135	--	--	--
Other income (expense), net	91	(231)	4	99
Net loss	<u>\$ (10,135)</u>	<u>\$ (9,284)</u>	<u>\$ (4,266)</u>	<u>\$ (7,223)</u>
Net loss applicable to common stockholders	<u>\$ (15,508)</u>	<u>\$ (14,209)</u>	<u>\$ (4,271)</u>	<u>\$ (11,403)</u>
Net loss per common share, basic and diluted	<u>\$ (896.09)</u>	<u>\$ (4,042.38)</u>	<u>\$ (11.78)</u>	<u>\$ (3,232.04)</u>
Shares used in computing net loss per common share, basic and diluted	<u>17,306</u>	<u>3,515</u>	<u>362,536</u>	<u>3,528</u>
Pro forma net loss per common share, basic and diluted (unaudited) (2)	<u>\$ (23.06)</u>		<u>\$ (0.97)</u>	
Pro forma shares used in computing net loss per common share, basic and diluted (unaudited)	<u>439,217</u>		<u>4,359,800</u>	

(1) Includes stock-based compensation as follows:

	<u>Year Ended</u> <u>December 31,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2013</u>	<u>2012</u>	<u>2014</u>	<u>2013</u>
	(In thousands)			
	(Unaudited)			
Research and development	\$ 8	\$ 24	\$ 18	\$ 7
General and administrative	143	177	59	133
Sales and marketing	<u>2</u>	<u>14</u>	<u>3</u>	<u>2</u>
Total stock-based compensation	<u>\$ 153</u>	<u>\$ 215</u>	<u>\$ 80</u>	<u>\$ 142</u>

(2) Pro forma basic and diluted net loss per share is calculated assuming the conversion of all of our outstanding shares of Series A redeemable convertible preferred stock and our convertible notes into common stock at the beginning of the period or at the original date of issuance, if later.

As of September 30, 2014

	<u>Actual</u>	<u>Pro Forma</u>	<u>Pro Forma</u>
		(In thousands)	As Adjusted
		(Unaudited)	
Balance Sheet Data:			
Cash and cash equivalents	\$ 782	\$ 782	\$
Working capital deficiency	(2,693)	(1,193)	
Total assets	2,209	2,209	
Redeemable convertible preferred stock	3,943	-	
Accumulated deficit	(95,367)	(95,367)	
Total stockholders' deficit	(6,022)	(579)	

The preceding table presents a summary of our unaudited balance sheet data as of September 30, 2014:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock and convertible notes into an aggregate of 5,499,864 shares of our common stock upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to the receipt of the estimated net proceeds from the sale of _____ shares of common stock in this offering at the initial public offering price of \$ _____ per share, and after deducting the underwriting discounts and commissions and estimated expenses payable by us.

RISK FACTORS

Investing in our common stock 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 Our Business

We are an early, commercial stage company and our Acuitas MDRO Gene Test and Lighthouse MDRO Management System may never achieve significant commercial market acceptance.

Currently, we rely principally on the commercialization of our Acuitas MDRO Gene Test and Lighthouse MDRO Management System products and services to generate future revenue growth. To date such products have delivered only de minimis 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 are using our products. We achieved our first commercial sales of these products and services in the third quarter of 2014, and experienced very limited revenue and customer adoption during 2014. In addition, demand for our Acuitas and Lighthouse MDRO products may not increase as quickly as planned and 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 MDRO assay solution by our target inpatient health care 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.

Our products may never achieve significant commercial market acceptance.

Our Acuitas MDRO Gene Test and Lighthouse MDRO Management System products 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 microbiology and molecular tests;
- our ability to convince the medical community of the accuracy and speed of our products and services, as contrasted with current methods available;
- the willingness of hospitals and physicians to utilize our products and services; and
- the agreement by inpatient health care facilities to recognize the patient safety, improved outcome and cost-effectiveness benefits of using our products and budgeting to pay for them without reimbursement.

We have a history of losses, and we expect to incur net losses for the next several years.

We have incurred substantial net losses since our inception, and we expect to continue to incur additional losses for the next several years. For the years ended December 31, 2013 and 2012 and the nine months ended September 30, 2014, we had a net loss of \$10.1 million, \$9.3 million and \$4.3 million, respectively. From our inception through September 30, 2014, we had an accumulated deficit of \$95.4 million. The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2013 and 2102 contains explanatory language that substantial doubt exists about our ability to continue as a going concern, without raising additional capital. Our monthly cash burn rate is approximately \$500,000, and we expect to require additional bridge funding on a monthly basis to maintain our cash position until consummation of the offering contemplated in this prospectus. We expect to continue to incur significant operating expenses and anticipate that our expenses will increase due to costs relating to, among other things:

- researching, developing, validating and commercializing potential future diagnostic and screening solutions, including our Acuitas MDRO Gene Test and Lighthouse MDRO Management System;
- developing, presenting and publishing additional clinical and economic utility data intended to increase clinician adoption of our current and future solutions;
- expansion of our operating capabilities;
- maintenance, expansion and protection of our intellectual property portfolio and trade secrets;
- future clinical trials;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize potential future solutions;
- employment of additional clinical, quality control, scientific, customer service, laboratory, billing and reimbursement and management personnel; and
- employment of operational, financial, accounting and information systems personnel, consistent with expanding our operations and our status as a newly public company following this offering.

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. For a detailed discussion of our financial condition and results of operations, see “*Management’s Discussion and Analysis of Financial Condition and Results of Operations.*”

The further development and commercialization of our Acuitas MDRO Gene Test and Lighthouse MDRO Management System products are key to our business. If we fail to take advantage of our first mover position, we may not be able to grow our revenue and additional product offerings.

Our ability to generate revenue is currently principally dependent on sales of our whole genome mapping products, Acuitas MDRO Gene Test and Lighthouse MDRO Management System products. If we are not able to take advantage of our first mover position in the MDRO testing market to increase our customer base quickly, we may find that our competitors, who are better capitalized and larger than us, can access inpatient health care settings more quickly with competing assay and information system products. If that happens our business could suffer.

New test development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize additional diagnostic and screening solutions. The further development and commercialization of additional diagnostic and screening solutions are key to our growth strategy. New test development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize such solutions.

A key element of our strategy is to discover, develop, validate and commercialize a portfolio of new diagnostic and screening solutions to combat MDRO outbreaks and the associated costs to patients, inpatient facilities and the health care industry. We cannot assure you that we will be able to successfully complete development of or commercialize any of our planned future solutions, or that they will prove to be capable of reliably being used for screening and outbreak management services in inpatient healthcare settings. Before we can successfully develop and commercialize any of our currently planned or other new products, we will need to:

- conduct substantial research and development;
- conduct clinical validation studies;
- expend significant funds;

- expand and scale-up our laboratory processes;
- expand and train our sales force; and
- seek and obtain regulatory clearance or approvals of our new solutions, as required by applicable regulations.

This process involves a high degree of risk and may take up to several years or more. Our test development and commercialization 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 clearances or approvals to market the test; or
- lack of commercial acceptance by inpatient health care 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 future success is dependent upon our ability to expand our customer base and introduce new products.

The current customers we are targeting for our Acuitas MDRO Gene Test are acute care hospitals, particularly those with advanced care units, such as intensive care units. We believe it is these types of acute care facilities where the risk of colonization and the presence of active MDRO infections are most likely to occur. Our success will depend, in part, upon our ability to increase our market penetration to other inpatient facilities, such as nursing homes, rehabilitation centers and other acute and long-term care facilities where the presence of patients colonized with MDROs can significantly increase the facility's risk of outbreak infections. We need to provide a compelling case for the savings, in patient safety and recovery, reduced length of stay and reduced costs that come from adopting our MDRO diagnosis and management solutions. 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 solutions requires substantial time and expense. Any failure to expand our existing customer base, or launch new solutions, would adversely affect our ability to improve our operating results.

We have seen declining revenues from our current customers for our Whole Genome Mapping products and services over the past few years, as DNA sequencing techniques and products have grown in popularity. While we continue to provide products and services to our existing customer base, including federal and state agencies, including the CDC and public health agencies, universities, and global research organizations, we anticipate that such revenues will be replaced by revenue from our Hitachi collaboration-based products or continue to decline, particularly in view of our focus on our MDRO products and services.

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

The sales cycle for our Acuitas MDRO Gene Test and Lighthouse MDRO Management System products is lengthy, which makes it difficult for us to accurately forecast revenues in a given period, and may cause revenue and operating results to vary significantly from period to period. Potential customers for our products typically need to commit significant time and resources to evaluate our products and their decision to purchase our products may be further limited by budgetary constraints and numerous layers of internal review and approval, which are beyond our control. We spend substantial time and effort assisting potential customers in evaluating our products. Even after initial approval by appropriate decision makers, the negotiation and documentation processes for the actual adoption of our product 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 utilization of our products, has varied and could be 12 months or longer, which has made it difficult for us to accurately project revenues and other 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 financial results may fluctuate on a quarterly basis which may adversely affect the price of our common stock.

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 Acuitas MDRO Gene Test and Lighthouse MDRO Management System products through our own direct sales force. We have limited experience in marketing and selling these products, which had their formal commercial launch in late 2013. In addition, our assays and information management system represent a new technology to the inpatient healthcare facility market. Our future sales will depend in large part on our ability to increase our marketing efforts and adequately address our customers' needs. The inpatient health care facility 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 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 be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.

We commenced the formal commercial launch of our CLIA Lab in late 2013 and launched the Acuitas MDRO Gene Test in the second quarter of 2014. During 2015, if we are unable to meet test turn-around time expectations, quality targets, retain and hire personnel, scale our LIMS data solution or if we have other failures in our commercial operations we could face significant setbacks in our ability to execute our business strategy.

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 solutions by clinicians and healthcare facilities and the rate of reimbursement of our current and future solutions by payors may be negatively affected.

The results of our clinical and economic validation studies involving our Acuitas MDRO assay have been presented at major infectious disease and infection control society meetings. We anticipate publishing results in peer-reviewed publications in leading medical journals in the near future. 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 solutions and adoption by key opinion leaders in the infectious disease market are very important to the commercial success of our current and any future products. 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 the clinical benefits of these solutions. Clinicians may not adopt our current and future solutions 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.

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 solutions would suffer and our business would be harmed. If our current and future solutions or the technology underlying Acuitas MDRO Gene Test or Lighthouse MDRO Management System products or our future solutions 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.

If we cannot enter into and maintain new clinical collaborations, our efforts to commercialize our existing products and our development of new products could be delayed.

Our collaboration with Hitachi is important to the development of new products using our Whole Genome Mapping technology in human chromosome applications, our collaborations with other industry participants, and our partnering with acute care hospitals in conducting initial evaluations of our Acuitas MDRO Gene Test are all important to us. In the future, we may work with a clinical collaborator to further develop, gain FDA approval for, and commercialize our tests. If any of our collaborators decides not to work with us in the future, or, if hospitals do not convert to customers, it could materially adversely impact our business.

If our sole laboratory facility becomes inoperable, we will be unable to perform Acuitas MDRO Gene Test assays and future solutions, if any, and our business will be harmed.

We perform all of our diagnostic services in our CLIA 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 the Clinical Laboratory Improvement Amendments of 1988, or 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. We would also be required to secure and maintain state licenses required by several states, including 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. If we failed to secure any such licenses, we would not be able to process samples from recipients in such states. 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.

In order to meet the turn-around time required for our Acuitas MDRO Gene Test assays, 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 are located near to our sole laboratory facility in Gaithersburg, Maryland. As we expand our customer base, 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. 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, including Fluidigm, for certain laboratory reagents, supplies and substances which we use in our laboratory operations and products. An interruption in our laboratory operations could occur if we encounter delays or difficulties in securing these reagents, sequencers, or other laboratory materials, and if we cannot then obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. In particular, we rely on Fluidigm as the sole supplier of the microfluidic test platform used in our Acuitas MDRO Gene Test, and as the sole provider of maintenance and repair services for its BioMark HD system. Any disruption in Fluidigm's operations could impact our supply chain and laboratory operations of our molecular information platform and our ability to conduct our business and generate revenue.

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. In the case of an alternative supplier for Fluidigm, there can be no assurance that replacement equipment will be available or will meet our quality control and performance requirements for our laboratory operations. 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.

We face competition from companies that offer products or have conducted research to diagnose or screen for MDROs. Our principal competition comes from Cepheid, Becton-Dickinson, bioMerieux and Nanosphere. Our competitors also include laboratory companies such as Bio-Reference Laboratories, Inc., Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated. Many hospitals and academic medical centers may also seek to perform the type of molecular testing we perform at their own facilities. Most of these competitors are better capitalized or have access to more resources than we do. We may not be able to effectively compete in the MDRO testing or screening market despite our first mover advantage.

If we are unable to raise additional capital on acceptable terms in the future, it may limit our ability to develop and commercialize new diagnostic and screening solutions and technologies, and we may have to curtail or cease operations.

We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. Specifically, we may need to raise additional capital to, among other things:

- complete development of our Acuitas MDRO Gene Test assays and Lighthouse MDRO Management System products and develop future products and services;
- increase our selling and marketing efforts to drive market adoption and address competitive developments;
- expand our clinical laboratory operations;
- fund our clinical validation study activities;
- expand our research and development activities;
- sustain or achieve broader commercialization of our products;
- acquire or license products or technologies; and
- finance our capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- the level of research and development investment required to develop our current and future product and service offerings;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our need or decision to acquire or license complementary technologies or acquire complementary businesses;
- changes in test development plans needed to address any difficulties in commercialization;
- competing technological and market developments;
- whether our diagnostic solutions become subject to additional U.S. Food and Drug Administration, or FDA, or other regulation; and
- changes in regulatory policies or laws that affect our operations.

Additional capital, if needed, may not be available on satisfactory terms, or at all. Furthermore, if we raise additional funds by issuing equity securities, dilution to our existing stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or our products under development, or grant licenses on terms that are not favorable to us, which could lower the economic value of those programs to us. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities, which may cause us to grow at a slower pace, or not at all, and our business could be adversely affected.

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. 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.

If we lose the support of key opinion leaders, it may be difficult to establish our products as a standard of care for infectious disease diagnosis and screening, which may limit our revenue growth and ability to achieve profitability.

We have established relationships with leading opinion leaders at premier institutions. If these key opinion leaders determine that our products or services are not clinically effective or that alternative technologies are more effective, or if they elect to use internally developed products, we would encounter significant difficulty establishing our product offerings as a standard of care, which would limit our revenue growth and our ability to achieve profitability.

We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.

We anticipate growth in our business operations. This future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales force management. We may not be able to maintain the quality or expected turnaround times of our diagnostic or screening results, or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and management controls, as well as our reporting systems and procedures. The time and resources required to implement the systems to handle such growth is uncertain, and failure to complete this in a timely and efficient manner could adversely affect our operations.

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

Clinical laboratory tests like the 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. FDA defines the term laboratory developed test as an *in vitro* diagnostic test that is intended for clinical use and designed, manufactured and used within a single laboratory. We believe that the Acuitas MDRO Gene Test is an LDT. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug and Cosmetic Act, or 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 guidance that, when finalized, would adopt a risk-based framework that would increase FDA oversight of LDTs. As part of this developing framework, 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, 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.

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 approval, is required for the Acuitas MDRO Gene Test or any of our future tests, products or services we may develop, or we decide to voluntarily pursue FDA approval, we may be forced to stop selling our tests while we work to obtain FDA approval. Our business would be negatively affected until such review is completed and clearance to market or approval is 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 the 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 for 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 unable to develop products to keep pace with rapid technological, medical and scientific change, our operating results and competitive position could be harmed.

In recent years, there have been numerous advances in technologies relating to diagnostics, particularly diagnostics that are based on genomic information. These advances require us to continuously develop our technology and work to develop new solutions to keep pace with evolving standards of care. Our products and services could become obsolete unless we continually innovate and expand our product offerings. If we are unable to develop new products or to demonstrate the applicability of our products, our sales could decline and our competitive position could be harmed.

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, 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 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 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 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 were unable to secure a license from New York or from other states where we are required to hold licenses, we would not be able to test specimens from those states.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, enacted in March 2010, made changes that significantly affect the pharmaceutical and medical device industries and clinical laboratories. As begun in 2013, each medical device manufacturer must pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its FDA-listed medical devices. The FDA has asserted that clinical laboratory tests such as the Acuitas MDRO Gene Test are medical devices. The Acuitas MDRO Gene Test is not currently listed as a medical device with the FDA, but we cannot assure you that the tax will not be extended to LDTs such as ours in the future if they were to be regulated as a device.

Other significant measures contained in the PPACA include coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The PPACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the PPACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce healthcare expenditures, which may have a negative impact on payment rates for services, including our tests. The IPAB proposals may impact payments for clinical laboratory services for our customers beginning in 2016, and for hospital services beginning in 2020, and may indirectly reduce demand for our product candidates.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2014 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The full impact on our business of the PPACA and the other new laws is uncertain. Nor is it clear whether other legislative changes will be adopted or how such changes would affect our industry generally or our ability to successfully commercialize our product candidates, if approved. Changes in healthcare policy, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management's attention from our business. Such copayments by Medicare beneficiaries for laboratory services were discussed as possible cost savings for the Medicare program as part of the debt ceiling budget discussions in mid-2011 and may be enacted in the future. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

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.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to other regulation by both the federal government and the states in which we conduct our business, including:

- billing and payment regulations applicable to clinical laboratories;
- the Federal anti-kickback law and state anti-kickback prohibitions;
- the Federal physician self-referral prohibition, commonly known as the Stark Law, and state equivalents;
- the Federal Health Insurance Portability and Accountability Act of 1996;
- the Medicare civil money penalty and exclusion requirements;

- the Federal False Claims Act civil and criminal penalties and state equivalents; and
- the Foreign Corrupt Practices Act of 1977, which will apply to our future international activities.

We have adopted policies and procedures designed to comply with these laws and regulations. Our compliance is subject to governmental review. The growth of our business and sales organization may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalties associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

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 Health Insurance Portability and Accountability Act of 1996, or HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill facilities or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our current and future solutions and other patient and clinician education and outreach efforts through our website, and manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the U.S. and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

If we 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.

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. As of September 30, 2014, we had license or ownership rights to 68 patents, including 19 pending United States non-provisional patent applications, and 15 issued United States patents. 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.

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, workers' compensation, products liability 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 may use third party collaborators to help us develop, validate or commercialize any new diagnostic solutions, and our ability to commercialize such solutions could be impaired or delayed if these collaborations are unsuccessful.

We may in the future selectively pursue strategic collaborations for the development, validation and commercialization of any new products and services we may develop. In any future third party collaboration, we may be dependent upon the success of the collaborators in performing their responsibilities and their continued cooperation. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development, validation and commercialization of our potential solutions may be delayed if collaborators fail to fulfill their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. Disputes with our collaborators could also impair our reputation or result in development delays, decreased revenues and litigation expenses.

Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting changes or require us to change our compensation policies.

Accounting methods and policies for diagnostic companies, including policies governing revenue recognition, research and development and related expenses and accounting for stock-based compensation, are subject to further review, interpretation and guidance from relevant accounting authorities, including the SEC. Changes to, or interpretations of, accounting methods or policies may require us to reclassify, restate or otherwise change or revise our financial statements, including those contained in this filing.

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 the Acuitas MDRO Gene Test could lead to product liability claims if someone were to allege that Acuitas MDRO Gene Test 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 solutions. 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 2015 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 losses to offset income before such unused losses expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, or 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 net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be further limited. We do not believe that we will experience an ownership change as a result of this initial public offering. However, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2013, we had federal net operating loss carryforwards of \$26.1 million and research and development tax credits of \$1.8 million that could be limited if we experience an ownership change, which could have an adverse effect on our results of operations. These federal net operating loss carryforwards will expire commencing in 2021 if not utilized.

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, or IT, 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 Lighthouse MDRO Management System, we are substantially dependent on our IT systems. IT 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 IT 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 IT 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.

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.

Health insurers and other third party payors may decide not to cover, or may reduce or discontinue reimbursing for, our tests or any other diagnostic tests we may develop in the future, or may provide inadequate reimbursement, which could jeopardize our ability to expand our business and achieve profitability.

Neither we or our customers currently receive reimbursement from Medicare, Medicaid, other governmental payors or commercial third party payors for our tests. If we decide to pursue reimbursement, we will need to apply for coverage determinations from a number of payors. The Centers for Medicare and Medicaid Services, or CMS, under the U.S. Department of Health and Human Services, or HHS, establishes reimbursement payment levels and coverage rules for Medicare and Medicaid. State Medicaid plans and commercial third party payors establish rates and coverage rules independently. As a result, the coverage determination process is often a time-consuming and costly process that requires us to provide scientific and clinical support for the use of our tests to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained.

Even if one or more third party payors decides to reimburse for our tests, that payor may reduce utilization or stop or lower payment at any time, which could reduce our revenues. For example, payment for clinical laboratory tests furnished to Medicare fee-for-service beneficiaries is made based on a fee schedule established from time to time by CMS. In recent years, payments under these fee schedules have decreased and may decrease more. Some commercial third party payors are guided by Medicare clinical laboratory fee schedules in establishing their reimbursement rates. We cannot predict whether or when third party payors will cover our tests or offer adequate reimbursement to make them commercially attractive. Furthermore, if we enter into contracts with commercial third party payors, we may be reimbursed at an amount lower than the contracted test price. Clinicians may decide not to order our tests if third party payments are inadequate, especially if ordering the test could result in financial liability for the patient.

Billing complexities associated with obtaining payment or reimbursement for our tests may negatively affect our revenues, cash flow and profitability.

Billing for laboratory testing services is complex. We generally perform tests in advance of payment and without certainty as to the outcome of the billing process. In cases where we receive a fixed fee per test, we may still have disputes over pricing and billing. We currently receive payment directly from hospitals and healthcare facilities, but in the future we may receive payment from a variety of payors, such as commercial insurance carriers, including managed care organizations and governmental programs, primarily Medicare and Medicaid. Each payor typically has different billing requirements, and the billing requirements of many payors have become increasingly stringent. In addition, part of the focus on healthcare cost containment activities and healthcare reform is on reimbursement and/or payment for healthcare services, including laboratory tests. Such focus includes ongoing assessment of reimbursement regulations, including balance billing, collection of copays and deductibles and other reimbursement matters, particularly in the setting of high deductible insurance plans, managed care and other healthcare reform initiatives.

Among the factors that could complicate our billing of third party payors are:

- disparity in coverage among various payors;
- disparity in information and billing requirements among payors;
- changing reimbursement laws, regulations and payor policies; and
- incorrect or missing billing information, which is required to be provided by the prescribing physician.

These billing complexities, and the related uncertainty in obtaining payment for our tests, could negatively affect our revenues, cash flow and profitability.

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, individual hospitals and health systems may be less willing to invest in our MDRO surveillance and prevention programs. 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 we accept payment from federal and state healthcare programs, we will be subject to 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 and loss of reimbursement, 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. In the event we begin accepting reimbursement from federal or state healthcare programs for our tests, we would be subject to 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, or a contracted sales agent, 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 HHS 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 Being a Public Company

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 will 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 Securities and Exchange Commission, or 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 will need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, these rules and regulations will increase our legal, accounting and financial compliance costs and will make some activities more time-consuming and costly. We also expect that it will be more expensive for us to obtain director and officer liability insurance.

If we are unable to implement and 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 will be 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, beginning with our annual report for the year ending December 31, 2015, provide a management report on the 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. We are in the process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, our management will be unable to conclude that our internal control over financial reporting is effective. Moreover, when we are no longer an emerging growth 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.

If we are unable to conclude that our internal control over financial reporting is effective, or when we are no longer an emerging growth 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 may elect 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 of 1933, or the Securities Act. We will remain an emerging growth company for up to five years, although if our revenue exceeds \$1 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 the end of that five-year period, we would cease to be an emerging growth company as of December 31 of that year. As an emerging growth company, we may choose to 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 of 2002, 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 this Offering and Our Common Stock

Our stock price may be volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

Prior to this offering, there has been no public market for our common stock, and an active public market for our stock may not develop or be sustained after this offering. We and the representatives of the underwriters have determined the initial public offering price of our common stock through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our stock following this offering. In addition, the trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated variations in our and our competitors' results of operations;
- announcements by us or our competitors of new products, commercial relationships or capital commitments;
- issuance of new securities analysts' reports or changed recommendations for our stock;
- periodic fluctuations in our revenue, due in part to the way in which we recognize revenue;
- actual or anticipated changes in regulatory oversight of our products;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- announced or completed acquisitions of businesses or technologies by us or our competitors;

- any major change in our management; and
- general economic conditions and slow or negative growth of our markets.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company after the closing of this offering, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on shares outstanding as of September 30, 2014, on an as-converted basis, assuming the conversion of our outstanding Series A Preferred Stock and convertible notes, upon the closing of this offering, we will have outstanding a total of 5,862,401 shares of common stock. Of these shares, 144,694 will be freely tradable, without restriction, in the public market immediately after the offering. Each of our directors and officers and substantially all of our other stockholders has entered into a lock-up agreement with the underwriters that restricts their ability to sell or transfer their shares. The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. The underwriters, however, may, in their sole discretion, waive the contractual lock-up prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of September 30, 2014, up to an additional 5,717,707 shares of common stock will be eligible for sale in the public market, of which 5,027,627 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act, and various vesting agreements. In addition, 410,870 shares of common stock that are subject to outstanding options, 37,078 shares of common stock that are subject to outstanding warrants and 130,640 shares underlie restricted stock units as of September 30, 2014 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act. We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to options outstanding and reserved for issuance under our stock plans. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will be eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates and any lock-up agreements described above. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Insiders have substantial control over us and will be able to influence corporate matters.

As of September 30, 2014, directors and executive officers and their affiliates beneficially owned, in the aggregate, approximately 82% of our outstanding capital stock. As a result, these stockholders will be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or its assets. This concentration of ownership could limit stockholders' ability to influence corporate matters and may have the effect of delaying or preventing a third party from acquiring control over us.

Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.

Provisions in our restated certificate of incorporation and our amended and restated bylaws to become effective upon the closing of this offering may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 5,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our chairman of the board or our chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors; and
- require a super-majority of votes to amend certain of the above-mentioned provisions.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

Our management will have discretion in the use of the net proceeds from this offering and may not use them in a way which increases the value of your investment.

We currently intend to use the net proceeds of the offering for selling and marketing activities, including expansion of our sales force to support the ongoing commercialization of our current products and future products, for research and development activities, including medical and clinical costs, related to the continued support of the Acuitas MDRO Gene Test and Lighthouse MDRO Management System, as well as the development of our product pipeline, and for general and administrative expenses (including compensation of our officers and directors and other personnel-related costs and the costs of operating as a public company), and for working capital and other general corporate purposes. However, our management will have discretion in the application of the net proceeds from this offering and investors will be relying on the judgment of our management regarding the application of those proceeds. The amounts and timing of our actual expenditures depend on numerous factors, including the timing and amount of our cash receipts from the sale of products; the timing and amount of our expenses related to the sale of our products and costs related to geographical expansion of our sales efforts; the ongoing status of and results from our clinical trials and other studies; changes in regulatory requirements or other regulatory or compliance matters applicable to our current or future products and services; identification of opportunities to acquire businesses or assets or license technologies that we believe are in the best interests of our stockholders; and any unforeseen cash needs. Depending on the outcome of these factors, our plans and priorities may change and we may apply the net proceeds of this offering differently than we currently anticipate. Our management may spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock, and you will not have the opportunity to influence management's decisions on how to use the proceeds from this offering. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of new tests and cause the price of our common stock to decline.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock immediately after this offering. Therefore, if you purchase our common stock in this offering, you will incur an immediate dilution of \$ in net tangible book value per share from the price you paid, based on the initial public offering price of \$ per share. In addition, new investors who purchase shares in this offering will contribute approximately % of the total amount of equity capital raised by us through the date of this offering, but will only own approximately % of the outstanding equity capital. The exercise of outstanding options and warrants will result in further dilution. For a detailed description of the dilution that you will experience immediately after this offering, see “**Dilution**”.

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, our loan and security agreement restricts 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.

If an active, liquid trading market for our common stock does not develop, you may not be able to sell your shares quickly or at or above the initial offering price.

There has not been a public market for our common stock. An active and liquid trading market for our common stock may not develop or be sustained following this offering. You may not be able to sell your shares quickly or at or above the initial offering price. The initial public offering price has been determined by negotiations with the representatives of the underwriters. This price may not be indicative of the price at which our common stock will trade after this offering, and our common stock could trade below the initial public offering price.

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:

- the development and commercialization of our Acuitas MDRO Gene Test and Lighthouse MDRO Management System products;
- 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;
- changes in laws or regulations applicable to our business, including potential regulation by the FDA;
- our ability to develop and commercialize new products and the timing of commercialization;
- our liquidity and working capital requirements, including our long-term future cash requirements beyond the next 12 months;
- our expectations regarding future revenue and expenses; and
- our expectations regarding the use of proceeds from this offering.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statement made by us in this prospectus speaks only as of the date on which it is made. We disclaim any duty to update any of these forward-looking statements after the date of this prospectus to confirm these statements to actual results or revised expectations.

You may rely only on the information contained in this prospectus. You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This prospectus contains statistical data and estimates that we obtained from industry publications and reports. These publications typically indicate that they have obtained their information from sources they believe to be reliable, but do not guarantee the accuracy and completeness of their information. Some data contained in this prospectus is also based on our internal estimates. We are responsible for the information contained in the prospectus and believe it to be reasonable.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of shares of our common stock in this offering will be approximately \$ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' over-allotment option to purchase additional shares from us is exercised in full, we estimate that our net proceeds will be approximately \$ million.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our common stock and to facilitate our future access to the public capital markets. We currently intend to use the net proceeds from this offering as follows:

- approximately \$ million for selling and marketing activities, including expansion of our sales force to support the ongoing commercialization of our current products and future products;
- approximately \$ million for research and development related to the continued support of our Acuitas and Lighthouse products, as well as the further development of our product pipeline; and
- the remainder for general and administrative expenses (including compensation of our officers and directors and other personnel-related costs and costs of operating as a public company), and for working capital and other general corporate purposes.

The expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. 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 closing of this offering. We will have discretion in the way that we use the net proceeds and investors will be relying on our judgment regarding the application of the net proceeds of this offering. The amounts and timing of our actual expenditures depend on numerous factors, including the success of our product development pipeline activities and acceptance of our products by key opinion leaders, hospitals, long-term care facilities and other healthcare providers.

Depending on the outcome of these factors, our plans and priorities may change, and we may be required to apply the net proceeds of this offering differently than we currently anticipate, and it may be necessary to allocate more or less of the net proceeds to the categories described above. We do not expect that we will decrease our estimated allocations to research and development or selling and marketing to fund potential acquisitions or for general and administrative expenses if doing so would have an adverse effect on the financial resources we believe will be necessary for us to pursue our business goals.

DIVIDEND POLICY

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors. In addition, the terms of our outstanding indebtedness restrict our ability to pay dividends, and any future indebtedness that we may incur could preclude us from paying dividends. Investors should not purchase our common stock with the expectation of receiving cash dividends.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2014, as follows:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our convertible preferred stock and convertible notes into an aggregate of 5,499,864 shares of common stock upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to the receipt of the estimated net proceeds from the sale of _____ shares of common stock in this offering at the initial public offering price of \$ _____ per share, after deducting the underwriting discounts and commissions and estimated expenses payable by us.

You should read this table in conjunction with “Selected Financial Data” and “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 September 30, 2014		
	<u>Actual</u> (In thousands,	<u>Pro Forma</u> except share and per	<u>Pro Forma as</u> Adjusted
	(In thousands,	except share and per	share data)
	(Unaudited)	(Unaudited)	(Unaudited)
Cash and cash equivalents	\$ 782	\$ 782	\$
Convertible notes	\$ 1,500	\$ -	\$
Long-term debt, net of discount	266	266	
Redeemable convertible preferred stock, par value \$0.01 per share:			
6,000,000 shares authorized, 3,999,864 issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted.	3,943	--	
Stockholder’s (deficit) equity:			
Common stock, par value \$0.01 per share: 7,500,000 shares authorized, 362,536 shares issued and outstanding, actual; 7,500,000 shares authorized, 5,862,401 shares issued and outstanding, pro forma; and _____ shares authorized and _____ shares issued and outstanding, pro forma as adjusted	4	59	
Preferred stock, par value \$0.01 per share; no shares authorized, issued or outstanding, actual and pro forma; 5,000,000 shares authorized, no shares issued or outstanding, pro forma as adjusted	--	--	
Additional paid-in capital	89,341	94,729	
Accumulated deficit	(95,367)	(95,367)	
Total stockholders’ (deficit) equity	(6,022)	(579)	
Total capitalization	\$ (313)	\$ (313)	\$

If the underwriters’ over-allotment option were exercised in full, pro forma as adjusted cash and cash equivalents, common stock, additional paid-in capital, total stockholders’ equity and shares issued and outstanding as of September 30, 2014 would be \$____, \$____, \$____, \$____, \$____ and _____, respectively.

The number of shares of common stock in the table above excludes:

- 410,870 shares of common stock issuable upon the exercise of options outstanding at September 30, 2014 at a weighted average exercise price of \$1.13 per share;
- 130,640 restricted stock units issued to our Chief Executive Officer in March 2014;
- 51,227 shares of common stock reserved for future issuance under our 2008 Plan; and
- 37,078 shares of common stock issuable upon the exercise of warrants to purchase our common stock.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Net tangible book value per share is determined by dividing our total tangible assets less our total liabilities by the number of shares of common stock outstanding. Our historical net tangible book value (deficit) as of September 30, 2014, was (\$2.1) million, or (\$0.36) per share of common stock, including conversion of all outstanding shares of Series A Preferred Stock and all convertible notes. Our pro forma net tangible book value as of September 30, 2014, was \$_____ million, or \$_____ per share of common stock, based on the total number of shares of our common stock outstanding as of September 30, 2014, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock and convertible notes into common stock upon the closing of this offering.

After giving effect to the sale of shares of common stock in this offering at the initial public offering price of \$_____ per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2014 would have been \$_____ million, or \$_____ per share. This represents an immediate increase in pro forma net tangible book value of \$_____ per share to existing stockholders and an immediate dilution in net tangible book value of \$_____ per share to purchasers of common stock in this offering, as illustrated in the following table:

Initial public offering price per share		\$
Pro forma net tangible book value per share as of September 30, 2014	\$	(0.36)
Increase in pro forma net tangible book value per share attributable to new investors		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to investors participating in this offering		\$

If the underwriters' over-allotment option to purchase additional shares is exercised in full, the pro forma as adjusted net tangible book value per share after this offering would be \$_____ per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be \$_____ per share and the dilution to new investors purchasing shares in this offering would be \$_____ per share.

The following table presents, on a pro forma as adjusted basis as of September 30, 2014, the differences between existing stockholders and purchasers of shares in this offering with respect to the number of shares purchased from us, the total consideration paid and the average price paid per share, which with respect to the purchasers of shares in this offering, is based on the initial public offering price of \$_____ per share, before deducting underwriting discounts and commissions and estimated expenses payable by us:

	Total Shares		Total Consideration		Average Price per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering					
Investors participating in this offering					
Total		100.0%	\$	100.0%	

If the underwriters' over-allotment option to purchase additional shares is exercised in full, existing stockholders would own _____ % and new investors would own _____ % of the total number of shares of our common stock outstanding immediately after this offering.

The calculations above are based on shares outstanding as of September 30, 2014 after giving effect to the automatic conversion of all outstanding shares of convertible preferred stock and convertible notes into common stock upon the closing of this offering and exclude:

- 410,870 shares of common stock issuable upon the exercise of options outstanding at September 30, 2014, at a weighted average exercise price of \$1.13 per share;
- 130,640 restricted stock units issued to our Chief Executive Officer in March 2014;
- 51,277 shares of common stock reserved for future issuance under our 2008 Plan; and
- 37,078 shares of common stock issuable upon the exercise of warrants to purchase our common stock.

To the extent that any outstanding options or warrants are exercised or new options are issued under our incentive plans, there will be further dilution to investors participating in this offering.

SELECTED FINANCIAL DATA

We derived the selected statements of operations data for the years ended December 31, 2013 and 2012 and the selected balance sheets data as of December 31, 2013 and 2012 from our audited financial statements included elsewhere in this prospectus. We derived the selected statements of operations data for the nine months ended September 30, 2014 and 2013 and the selected balance sheets data as of September 30, 2014 from our unaudited interim condensed financial statements and related notes included elsewhere in this prospectus. Our unaudited interim condensed financial statements were prepared on the same basis as our audited financial statements and include, in our opinion, all adjustments, consisting of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those financial statements. Historical results are not necessarily indicative of the results that may be expected in the future. You should read the selected financial data together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements, related notes and other financial information included elsewhere in this prospectus. The selected financial data is qualified in its entirety by the financial statements, related notes and related notes included elsewhere in this prospectus.

	Year Ended December 31,		Nine Months Ended September 30,	
	2013	2012	2014	2013
	(In thousands, except share and per share data)			
	(Unaudited)			
Statements of Operations Data:				
Revenue	\$ 2,411	\$ 5,802	\$ 3,004	\$ 1,795
Operating expenses:				
Cost of sales	1,823	3,211	691	1,307
Research and development ⁽¹⁾	4,152	4,782	3,300	3,303
General and administrative ⁽¹⁾	2,762	2,473	1,652	2,189
Sales and marketing ⁽¹⁾	3,053	4,274	1,583	2,310
Argus Whole Genome obsolescence	951	--	--	--
Total operating expenses ⁽¹⁾	<u>12,741</u>	<u>14,740</u>	<u>7,227</u>	<u>9,109</u>
Loss from operations	(10,330)	(8,938)	(4,223)	(7,314)
Interest income	1	4	--	1
Interest expense	(32)	(119)	(47)	(9)
Change in fair value of warrant liability	135	--	--	--
Other income (expense), net	91	(231)	4	99
Net loss	<u>\$ (10,135)</u>	<u>\$ (9,284)</u>	<u>\$ (4,266)</u>	<u>\$ (7,223)</u>
Net loss applicable to common stockholders	<u>\$ (15,508)</u>	<u>\$ (14,209)</u>	<u>\$ (4,271)</u>	<u>\$ (11,403)</u>
Net loss per common share, basic and diluted	<u>\$ (896.09)</u>	<u>\$ (4,042.38)</u>	<u>\$ (11.78)</u>	<u>\$ (3,232.04)</u>
Shares used in computing net loss per common share, basic and diluted	<u>17,306</u>	<u>3,515</u>	<u>362,536</u>	<u>3,528</u>
Pro forma net loss per common share, basic and diluted (unaudited) ⁽²⁾	<u>\$ (23.06)</u>		<u>\$ (0.97)</u>	
Pro forma shares used in computing net loss per common share, basic and diluted (unaudited)	<u>439,217</u>		<u>4,359,800</u>	

(1) Includes stock-based compensation as follows:

	Year Ended December 31,		Nine Months Ended September 30,	
	2013	2012	2014	2013
	(In thousands)		(Unaudited)	
Research and development	\$ 8	\$ 24	\$ 18	\$ 7
General and administrative	143	177	59	133
Sales and marketing	2	14	3	2
Total stock-based compensation	<u>\$ 153</u>	<u>\$ 215</u>	<u>\$ 80</u>	<u>\$ 142</u>

- (2) Pro forma basic and diluted net loss per share is calculated assuming the conversion of all of our outstanding shares of Series A redeemable convertible preferred stock and our convertible notes into common stock at the beginning of the period or at the original date of issuance, if later.

	September 30, 2014	December 31, 2013	December 31, 2012
	(In thousands)		
	(Unaudited)		
Balance Sheets Data:			
Cash and cash equivalents	\$ 782	\$ 1,400	\$ 7,118
Working capital deficiency	(2,693)	(791)	(7,185)
Total assets	2,209	3,159	10,600
Redeemable convertible preferred stock	3,943	2,000	83,745
Accumulated deficit	(95,367)	(91,101)	(75,593)
Total stockholders' deficit	(6,022)	(1,833)	(75,593)

	As of September 30, 2014		Pro Forma As Adjusted
	Actual	Pro Forma (In thousands) (Unaudited)	
Balance Sheets Data:			
Cash and cash equivalents	\$ 782	\$ 782	\$
Working capital deficiency	(2,693)	(1,193)	
Total assets	2,209	2,209	
Redeemable convertible preferred stock	3,943	-	
Accumulated deficit	(95,367)	(95,367)	
Total stockholders' (deficit) equity	(6,022)	(579)	

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, Inc. was incorporated in Delaware on January 22, 2001. OpGen is a commercial-stage company using rapid molecular testing and bioinformatics to combat multi-drug resistant infections, as well as providing products and services for Whole Genome Mapping and analysis of microbial, plant, animal and human genomes for life sciences applications. The Company's recently developed clinical products and services enable healthcare providers to rapidly identify hospital patients who are colonized with multi-drug resistant organisms, or MDROs, and other potentially life threatening microbes. Our clinical products are enabled by our Lighthouse™ bioinformatics platform which provides detailed MDRO molecular information about an individual patient's resistance profile and integrates this information with data from other patients and hospital wide aggregate results to help improve overall patient outcomes and to reduce hospital costs. The Company's lead clinical product is the Acuitas™ MDRO Gene Test, a CLIA-lab based test to provide a comprehensive profile of MDRO resistance genes from patients screened for colonization or infection. In addition, we have more than ten years of experience mapping microbial and other genomes using our proprietary Whole Genome Mapping technology and providing related products and services to our customers. The Company's headquarters and principal operations are in Gaithersburg, Maryland. The Company had an additional facility in Madison, Wisconsin, which was closed in April 2013. The Company operates in one business segment.

Recent Developments

In February and April 2013, the Company restructured its operations to reduce expenditures and conserve cash while accelerating its planned strategic re-positioning into the clinical diagnostics market. In connection with this restructuring, the Company reduced its workforce by approximately 36%, or 16 employees. Also in April 2013, the Company discontinued development of software related to its Whole Genome Mapping product line and charged \$203,858 of previously capitalized software development costs to research and development.

In September 2013, the Company entered into a technology development agreement with Hitachi High-Technologies Corporation to develop the Company's Whole Genome Mapping technology into applications to analyze human DNA. Prior to this agreement, the focus of the Company's Whole Genome Mapping product offerings were genomes other than human, especially microbial. The Company expects to recognize over \$2 million in revenue related to this agreement in 2014.

In December 2013, management conducted a thorough review of its inventory position and intellectual property portfolio for its Whole Genome Mapping product line based on actual and projected sales levels. As a result, a provision for inventory losses of \$950,881 was charged against operations to write down inventory to its expected net realizable value. In addition, one technology license agreement was terminated and the remaining licensed technology costs related to that terminated license of \$35,518 were amortized in full. A change in the estimated useful lives of the other Whole Genome Mapping technology assets was made such that the amortization period for all licensed technology would end no later than December 31, 2014. The inventory and technology charges in December 2013 were for assets that were primarily focused on non-human Whole Genome Mapping applications where sales had been declining. Management believes it is likely that revenues will continue to decline for these applications.

In late 2013 and throughout 2014, the Company has continued to seek to raise capital to further its business. We raised \$4.0 million in a convertible notes offering, which converted to Series A Convertible Preferred Stock, and two Series A Convertible Preferred Stock offerings during the fourth quarter of 2013 and early 2014, raised \$1.5 million through the issuance of convertible debt in the third quarter of 2014 and raised \$1.0 million through the issuance of promissory notes in October and November 2014. Management remains actively engaged in efforts to raise additional capital. Our current operating assumptions, which include our best estimate of future revenue and operating expenses, indicate that our current cash on hand as of September 30, 2014 of approximately \$0.8 million will not be sufficient to fund operations through the end of 2014.

In the event the Company is unable to successfully raise additional capital, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to 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.

Results of Operations for the Years Ended December 31, 2013 and 2012

Revenues

	Year ended December 31,	
	2013	2012
Product sales	\$ 1,735,517	\$ 3,767,968
Laboratory services	630,851	770,600
Collaboration revenue	44,239	1,263,159
Total revenue	\$ 2,410,607	\$ 5,801,727

The Company's total revenue decreased 58% in 2013, from \$5.8 million to \$2.4 million. This decrease is primarily attributable to:

- A decrease of 54% in products sales. Unit sales of Whole Genome Mapping systems fell from ten in 2012 to three in 2013, accounting for \$1.7 million of the decline in product sales. The balance of the decrease was related to lower unit sales of Whole Genome Mapping reagents.
- A decrease of 18% in laboratory services revenue.
- A decrease of 96% in revenue generated under collaborative arrangements. The Company earned \$1.3 million in 2012 under a collaboration contract that was completed in early 2013. In late 2013, the Company entered into a new collaboration contract with a different customer. Revenue in 2013 represented only a small amount of revenue for each of those contracts.

Management believes that product and laboratory service revenues for non-human Whole Genome Mapping applications have declined in recent periods as improvements in DNA sequencing technologies have reduced the demand for mapping, especially in microbial applications.

The Company expects revenues to increase in 2014 over 2013. Collaboration revenue in 2014 is expected to exceed \$2.0 million related to the Hitachi contract signed in late 2013. Whole Genome mapping revenues are projected to decline in 2014, primarily related to lower sales of Argus systems.

Operating Expenses

	Year ended December 31,	
	2013	2012
Cost of product sales	\$ 1,501,648	\$ 2,903,652
Cost of services	320,938	307,539
Research and development	4,151,936	4,782,414
General and administrative	2,762,205	2,472,454
Sales and marketing	3,053,394	4,274,180
Argus™ Whole Genome obsolescence	950,881	-
Total operating expenses	\$ 12,741,002	\$ 14,740,239

The Company's total operating expenses decreased 14% in 2013 as contrasted with 2012, from \$14.7 million to \$12.7 million. This decrease is primarily attributable to:

- a decrease of 48% in cost of product sales related to lower unit sales and cost reductions in the Company's Whole Genome Mapping manufacturing operations;
- a decrease of 29% in sales and marketing expenses as cost reductions implemented in early 2013 reduced payroll, consulting and travel expenses by \$0.8 million and outside marketing expenses by \$0.4 million;
- a decrease of 13% in research and development expenses primarily related to staffing reductions made in early 2013;
- an increase of 4% in cost of services revenues, mostly related to higher operating supplies costs;
- a decrease of 29% in sales and marketing expenses as cost reductions implemented in early 2013 reduced payroll, consulting and travel expenses by \$0.8 million and outside marketing expenses by \$0.4 million;
- offset by a 12% increase in general and administrative expenses, mostly related to higher legal expenses; and
- an increase in operating expenses due to a write-down of the Company's Whole Genome Mapping inventory of approximately \$1.0 million in 2013.

The Company expects that operating expenses will decline in 2014 compared with 2013 as costs savings from the February and April 2013 workforce and expense reductions continued into 2014. In addition, 2014 projected operating expenses are lower compared with 2013 as 2013 included a \$1.0 million inventory write-down and \$0.3 of restructuring costs.

Other Income (Expense)

	Year ended December 31,	
	2013	2012
Interest income	\$ 1,222	\$ 4,489
Interest expense	(31,598)	(118,666)
Change in fair value of derivative financial instruments	134,560	-
Other income (expense)	91,390	(231,023)
Total other income (expense)	\$ 195,574	\$ (345,200)

Total net other income was \$0.2 million in 2013, as compared to total net other expense of \$0.3 million in 2012. Significant changes from year to year consist of:

- Our interest expense was lower in 2013 as convertible loan amounts from our investors were lower and outstanding for shorter periods of time.
- The fair value of our warrant liabilities decreased to zero in 2013 as all derivative securities that gave rise to these obligations were eliminated in our December 2013 recapitalization. As a result, we recognized a gain on the elimination of this obligation.
- Other income (expense) in 2012 included \$0.1 million of bad debt expense and \$0.1 million for the cost of a Series C warrant granted to our collaboration partner while other income (expense) in 2013 included income for loan forgiveness, a reversal of bad debt expense and gains on the sale of excess equipment.

Results of Operations for the Nine Months Ended September 30, 2014 and 2013

Revenues

	Nine Months ended September 30,	
	2014	2013
Product sales	\$ 841,567	\$ 1,221,220
Laboratory services	379,339	556,902
Collaboration revenue	1,783,340	16,461
Total revenue	\$ 3,004,246	\$ 1,794,583

The Company's total revenue increased 67% from the 2013 period to the 2014 period, from \$1.8 million to \$3.0 million. This increase is primarily attributable to:

- A decrease of 31% in products sales as Whole Genome Mapping system sales declined \$0.5 million, partially offset by an increase of \$0.1 million in Argus System service revenues.
- A decrease of 32% in MapIt laboratory services revenue.
- Collaboration revenue of \$1.8 million in 2014 reflecting a full nine months of development efforts compared with almost no revenue in 2013.

Operating Expenses

	Nine Months ended September 30,	
	2014	2013
Cost of product sales	\$ 292,116	\$ 1,012,396
Cost of services	398,628	293,149
Research and development	3,300,124	3,303,000
General and administrative	1,652,599	2,190,595
Sales and marketing	1,583,718	2,309,673
Total operating expenses	\$ 7,227,185	\$ 9,108,813

In 2014, the Company's total operating expenses decreased 21% from the 2013 period, from \$9.1 million to \$7.2 million. This decrease is primarily attributable to:

- A decrease of 71% in cost of products sales. This decrease resulted from lower manufacturing costs, lower unit volumes and lower royalty expense.
- An increase of 36% in cost of services revenues mostly related to complex large genome projects.
- A decrease of 31% in sales and marketing expenses. Payroll, consulting and travel expenses for sales and marketing activities were \$0.7 million lower in the 2014 period.
- A decrease of 25% in general and administrative expenses. Lower payroll and legal expenses were the principal reason general and administrative expenses declined.

Other Income (Expense)

	Nine Months ended September 30,	
	2014	2013
Interest income	\$ 120	\$ 1,176
Interest expense	(47,468)	(9,127)
Other income (expense)	4,400	98,991
Total other income (expense)	\$ (42,948)	\$ 91,040

Total net other expense was \$43 thousand in the 2014 period, as compared to total net other income of \$0.1 million in the 2013 period. Significant changes from period to period consist of:

- our interest expense was higher in 2014 due to our outstanding convertible loans principal in 2014; and
- other income (expense) in the first nine months of 2013 included loan forgiveness and the reversal of bad debt expense.

Liquidity and Capital Resources

At December 31, 2013, the Company had approximately \$1.4 million in cash and cash equivalents, compared to \$7.1 million at December 31, 2012. During 2014, the Company has raised gross proceeds of approximately \$4.0 million through the issuance of redeemable convertible preferred stock, convertible promissory notes and promissory notes. Management remains actively engaged in efforts to raise additional capital. We have cash on hand of \$0.8 million as of September 30, 2014. Our current operating assumptions, which include our best estimate of future revenue and operating expenses, indicate that our current cash on hand as of September 30, 2014 will not be sufficient to fund operations through the end of 2014.

The Company does not currently have any bank credit lines. If in the future the Company does not turn profitable or generate cash from operations as anticipated and additional capital is needed to support operations, management may be unable to obtain such financing, or obtain it on favorable terms. In the event the Company is unable to successfully raise additional capital, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to 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.

The Company's primary cash requirements are to fund operations, including operations as well as research and development programs and collaborations, and to support general and administrative activities, and to fund acquisitions of products or businesses. The Company has never generated positive cash flows from operations. To bridge the gap between revenues and operating and capital needs, the Company has, in the past, relied on a variety of financing sources, including the issuance of equity and equity-linked securities. The Company's financial statements have been prepared on a basis that assumes that it will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. These statements do not include any adjustments that might result if the carrying amount of recorded assets and liabilities are not realized.

Sources and Uses of Cash

During 2014, the Company has raised gross proceeds of approximately \$4.0 million through the issuance of redeemable convertible preferred stock, convertible promissory notes and promissory notes. The Company does not currently have any bank credit lines. Management remains actively engaged in efforts to raise additional capital.

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

	Year ended December 31,		Nine Months ended September 30,	
	2013	2012	2014	2013
Net cash used in operating activities	\$ (7,487,822)	\$ (7,961,001)	\$ (3,905,198)	\$ (6,184,949)
Net cash used in investing activities	\$ (109,871)	\$ (210,528)	\$ (39,537)	\$ (38,459)
Net cash provided by (used) in financing activities	\$ 1,880,324	\$ 14,773,718	\$ 3,325,963	\$ (106,921)

Net Cash Used In Operations

Net cash used in operating activities was \$7.5 million for the year ended December 31, 2013, compared to \$8.0 million for 2012. The slight decrease was primarily due to a \$0.9 million increase in net loss in 2013, offset by a \$1.0 million net increase in working capital and a \$0.3 million increase in noncash expenses (such as stock-based compensation expense, and inventory obsolescence reserves).

Net cash used in operating activities was \$3.9 million for the nine months ended September 30, 2014, compared to \$6.2 million for the comparable 2013 interim period. The decrease was primarily due to a \$3.0 million decrease in net loss in 2014, offset by a \$0.8 million net decrease in working capital.

Net Cash Used In Investing Activities

Net cash used in investing activities for all periods consisted solely of purchases of property and equipment used in our business. The amount of capital expenditures varies from period to period based on operating needs and cash availability.

Net Cash Provided By (Used In) Financing Activities

Net cash provided by financing activities was \$1.9 million during 2013, as compared to \$14.8 million during 2012. Net cash provided by financing activities was \$3.3 million during the nine months ended September 30, 2014, as compared to a use of funds of \$0.1 million during the nine months ended September 30, 2013. The primary sources and uses of financing activities in both periods were capital raised from the sale of preferred stock and from the issuance of debt instruments, offset in part by principal payments on debt instruments and capital lease obligations.

Critical Accounting Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on the Company's financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires management 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 financial statements, estimates are used for, but not limited to, stock-based compensation, allowances for doubtful accounts and inventories, valuation of derivative financial instruments, 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.

Please refer to the next page, under the subheading "Stock-Based Compensation" for a discussion of our common stock valuation methodology for purposes of estimating stock-based compensation on our share-based compensation.

Revenue Recognition

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

When the 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 the 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 (considered multiple elements) 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 is recognized for Genome Builder software and for consumables, when sold on a stand-alone basis, upon delivery to the customer.

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.

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

Impairment of Long-Lived Assets

The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. An impairment loss would be measured as the amount by which the carrying value of the asset exceeds the estimated fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less costs to sell.

Stock-Based Compensation

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

For all time-vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. Share-based compensation expense recognized is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period.

The fair value of stock-based payments is estimated, on the date of grant, using the Black-Scholes model. Option valuation models, including the Black-Scholes model, require the input of highly subjective estimates and assumptions, and changes in those estimates and assumptions can materially affect the grant-date fair value of an award. These assumptions include the fair value of the underlying common stock at the grant date, risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

In estimating the fair value of the underlying common stock at the grant date for employee grants (or the performance commitment date or complete date for non-employee grants) given the lack of an active public market for the common stock, the Company's board of directors determined the fair value of the underlying common stock after considering contemporaneous third-party valuations, which valuations were made using highly complex and subjective judgments and estimates. In the absence of a public market, and as an emerging growth company with significant operating losses, the contemporaneous valuations were performed in accordance with applicable methodologies, approaches and assumptions as discussed in the technical practice-aid issued by the American Institute of Certified Public Accountants Practice Aid entitled "Valuation of Privately-Held Company Equity Securities Issued as Compensation," and considered many objective and subjective factors to determine the common stock fair market value at each valuation date, including:

1. the most recent sales of the Company's preferred stock;
2. the preferential rights of the outstanding preferred stock.
3. the achievement of clinical and operational milestones by the Company;
4. the status of strategic relationships with collaborators;
5. the significant risks associated with the Company's stage of development;
6. capital market conditions for life science and medical diagnostic companies, particularly similarly situated, privately held, early-stage companies; and
7. the Company's available cash, financial condition and results of operations.

See additional discussion of the use of estimates relating to stock-based compensation, and a discussion of management's methodology for developing each of the assumptions used in such estimates, in Notes 1 and 8 to the financial statements as of and for the years ended December 31, 2013 and 2012, and Notes 1, 4 and 10 to the unaudited interim condensed financial statements for the periods ended September 30, 2014 and 2013, included elsewhere in this prospectus.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recently Issued Accounting Standards

In July 2012, the Financial Accounting Standards Board, or FASB, issued accounting guidance to simplify the evaluation for impairment of indefinite-lived intangible assets. Under the updated guidance, an entity has the option of first performing a qualitative assessment to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired before proceeding to the quantitative impairment test under which it would calculate the asset's fair value. When performing the qualitative assessment, the entity must evaluate events and circumstances that may affect the significant inputs used to determine the fair value of the indefinite-lived intangible asset. The adoption of this standard in 2013 did not have a material impact on the Company's consolidated results of operations, cash flows or financial position.

In July 2013, the FASB issued guidance for the presentation of an unrecognized tax benefit when a net operating loss, or NOL, carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance requires an entity to present in the financial statements an unrecognized tax benefit, or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for an NOL carryforward, a similar tax loss, or a tax credit carryforward. If the NOL carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the jurisdiction or the tax law of the jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit will be presented in the financial statements as a liability and will not be combined with deferred tax assets. This guidance does not require any additional recurring disclosures and is effective for fiscal years beginning after December 15, 2013. The adoption of this guidance did not have a material impact on our financial statements.

In May 2014, the 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. The standard is effective for our reporting year beginning January 1, 2017 and early adoption is not permitted. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our 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. The standard is effective for our reporting year beginning January 1, 2017 and early adoption is not permitted. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

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

Overview

We are a commercial stage company using molecular testing and bioinformatics to combat multi-drug resistant bacterial infections. Our products and services are designed to enable healthcare providers to rapidly identify hospital patients who are colonized or infected with life threatening, multi-drug resistant organisms, or MDROs. Our Acuitas™ MDRO Gene Test products, currently available for sale, can be enabled by our Lighthouse™ bioinformatics platform in development, which can provide detailed MDRO molecular information about an individual patient's resistance profile and integrate this information with data from other patients and hospital-wide aggregate results to help improve overall patient outcomes and to reduce hospital costs. We believe we have an important first-mover advantage in developing and bringing to market the combined package of Acuitas-enabled molecular information about drug resistant genes associated with MDRO infections that are commonly found to cause significant infections in hospitalized patients, and specific genetic information about an acute care hospital's MDRO gene profile, including antibiotic resistance.

Our lead product, the Acuitas MDRO Gene Test, is, to our knowledge, the first CLIA lab-based test to provide a comprehensive profile of MDRO resistance genes from patients screened for colonization or infection. We first introduced the test in the first half of 2014. To date we have achieved de minimis revenues from the test, but it is in clinical evaluations or in the implementation process at a number of acute care hospitals. In 2015, we expect to expand our customer base and to introduce a number of new products based on our molecular testing and bioinformatics platforms.

We also provide our Argus® Whole Genome Mapping System, MapIt® Services, and MapSolver™ bioinformatics products and services to academic, public health and corporate customers to perform Whole Genome Mapping and analysis of microbial, plant, animal and human genomes for life sciences applications. For information regarding the revenues associated with our Whole Genome Mapping products and services, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations" earlier in this prospectus.

Please refer to the Glossary on page 73 of this prospectus for definitions of scientific, diagnostic, health care and regulatory terms used in this prospectus.

Antimicrobial Resistance – An Urgent Global Issue

Antimicrobial resistance is one of the most serious health threats in health care today. 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. The 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 avoidable costs to the U.S. healthcare system. In most cases, these infections require prolonged and/or costlier treatments, extended hospital stays, necessitate 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 range between \$20 and \$35 billion annually.

An emerging U.S. and global threat are CREs - carbapenem-resistant Enterobacteriaceae bacteria - that are either difficult to treat or wholly untreatable. According to CDC Director, Dr. Tom Frieden, CREs are a nightmare bacteria. Our strongest antibiotics do not work and patients are left with potentially untreatable infections with mortality rates ranging between 40% and 80%. CRE strains are transmitted easily in healthcare settings from patients with asymptomatic intestinal colonization and the CRE strains have the potential to spread antibiotic resistance through plasmid transfer to other bacterial species, including common human flora and potential pathogens such as Escherichia coli. The CDC has called for urgent action to combat the growing threat of CRE bacteria. Core prevention measures recommended by the CDC for all acute and long-term care facilities include: contact precautions for all patients who are colonized or infected with CRE, single patient room housing or cohorting, laboratory notification procedures, antibiotic stewardship and screening to identify unrecognized CRE colonization in patients admitted to high risk settings such as ICUs, long term acute care units or facilities, or epidemiological linked contacts.

Culture based screening methods for CRE can take up to five or more days for identification and subsequent characterization of suspected CRE bacteria. The OpGen Acuitas MDRO Gene Test provides accurate test results for CRE genes and other MDRO genes back to the healthcare provider in less than one day. These test results provide actionable information to healthcare providers so that positive patients (both colonized and symptomatic) can receive appropriate isolation precautions and patients with negative results can be removed from isolation precautions if applicable.

Our Acuitas MDRO Gene Test detects the presence of CRE resistance genes with higher sensitivity than conventional screening methods. In the summer of 2014, we conducted a comparison on samples of patients known to have CRE infections. We conducted a comparison using both the Acuitas MDRO Gene Test and a standard microbial culture testing method, and had the microbial culture results confirmed by a national reference lab. In such comparison, the Acuitas test was 100% sensitive and specific while the standard culture method was just 72% sensitive. Such standard culture method also creates many false positive results which potentially result in patients receiving unnecessary and costly contact precautions. For example, we conducted a recent in-house pilot study of the Acuitas MDRO Gene Test using samples from an acute care hospital, and 32% of initial culture screen results were false positives while the Acuitas test had 100% agreement with the confirmed clinical results.

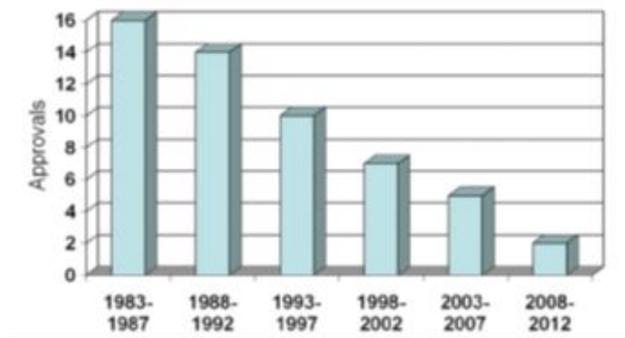
Active surveillance for antibiotic-resistant microbial colonization has been shown to reduce overall infection rates and to help reduce hospital costs by avoiding unnecessary hospital days per patient. For example, Israel had a country-wide outbreak of *Klebsiella pneumoniae* carbapenemase, or KPC, from 2005 to 2008. In late 2005 one patient with a KPC-positive infection was diagnosed. Within months, CRE infections spread through the hospital and then through the Israeli health care system. By March 2007, there were 1,275 cases nationwide. As a result of this national healthcare crisis, Israel implemented mandatory guidelines, including CRE surveillance, along with coordinated infection control interventions. The benefits of MDRO surveillance and coordinated infection control procedures were clearly documented in this broad-based, country wide screening initiative. Infections per 100,000 patient days were reduced thirty fold and unnecessary patient days in the hospital were reduced from 24 days to 4.5 days.

Emergence of Superbugs and Lack of Treatment Options

Over the last decade, multi drug resistant gram-negative bacteria, or MDR-GNB, frequently referred to as Superbugs, have been implicated in severe hospital acquired infections, or HAIs, and their occurrence has increased steadily. For example, *Klebsiella 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 mortality rate upwards of 50%.

Exacerbating the problems associated with the emergence of these highly resistant strains of pneumonia *K. pneumoniae* is their propensity to cause outbreaks in health care 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 that makes spread difficult to control and outbreaks difficult to stop. In addition, *K. pneumoniae* can survive for several hours on the hands of hospital personnel, which likely facilitates nosocomial spread. Effective control of *K. pneumoniae* outbreaks requires a detailed understanding of how transmission occurs, but current technologies do not allow healthcare providers to routinely perform these investigations.

The lack of currently available treatment options and scarcity of new treatment options in development are compounding the emerging Superbug problem. Since the 1980s and 1990s there has been a dramatic drop off in the number of new antibiotics developed and approved by the FDA. With few treatment options available, screening, infection control, and antibiotic stewardship have become our most powerful weapons in the fight to contain this building epidemic.



New systemic antibacterial agents approved by the U.S. Food and Drug Administration per 5-year period, through 2012.

Carbapenem and ESBL Resistant Gram-negative Bacteria

When gram-negative ESBL resistant bacteria become carbapenem resistant a Superbug resistant to virtually all antibiotics is created. Enterobacteriaceae are a large family of gram-negative bacteria that represent many of the emerging Superbugs. Many of these bacteria are a normal part of the gut flora and frequently cause urinary tract, bloodstream and intra-abdominal community-acquired and healthcare-associated infections. β -lactamases are enzymes produced by some of these bacteria that, depending on the type of enzyme, can make them resistant to various classes of β -lactam antibiotics, the main treatment for these infections. In the mid-1980's, a new group of these enzymes was detected, the extended-spectrum β -lactamases, ESBLs, which confer resistance to expanded-spectrum cephalosporins but not to carbapenems. Carbapenems are used as last resort drugs. Because of their side-effects they are primarily used for treating infections due to ESBL producing Enterobacteriaceae. Over the past decade carbapenemases, a group of clinically important β -lactamases have emerged and spread among Enterobacteriaceae. Carbapenemases are enzymes that can efficiently hydrolyse most β -lactams, including carbapenems. Some prevalent and emerging types of carbapenemases are KPC, Verona integron-encoded metallo- β -lactamases, or VIM, OXA type 48 β -lactamase, or OXA-48, and recently New Delhi metallo- β -lactamase, or NDM. Many carbapenemase producing Enterobacteriaceae strains frequently carry additional resistance determinants to other non β -lactam antibiotics, making them highly antibiotic-resistant. The most common are colistin (in general, the polymyxins), tigecycline (although less consistently) and fosfomycin.

Current surveillance methods for MDROs can take up to five days to provide complete results. The turn-around time for these test results needs to be improved for them to impact infection control programs and antibiotic stewardship.

The Opportunity

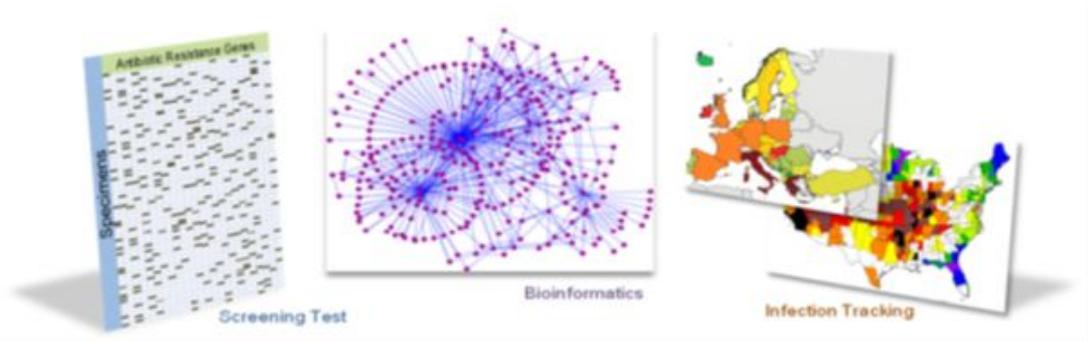
The discovery of antibiotics in the early 20th century fundamentally transformed human and veterinary medicine. Antibiotics save millions of lives each year in the U.S. and around the world. The rise of antibiotic resistant bacteria represents a growing and serious threat to public health and the economy, and now has been raised to the national security threat level. With the rising urgency of this issue and outbreaks of other difficult to treat infectious diseases, such as Ebola, dealing with infectious diseases and combating antibiotic resistant bacteria has become a global priority. Investment in new diagnostic technologies, comprehensive antibiotic stewardship programs, antibiotic development, vaccines and information technology advances are seen as critical elements in the fight against antimicrobial resistance.

Culture-based microbiologic methods have been evolving for centuries and are important components of the diagnostic approach to detecting infectious disease. The potential for improvements based on cell culture alone have reached a plateau while the opportunities for improved detection and organism typing with DNA testing are expanding exponentially. Genomic diagnostics using DNA probe analysis, DNA sequencing, and advanced bioinformatics are transforming clinical and public health microbiology practice. Using technologies developed for production genetics applications and high resolution genome sequencing it is now possible to envision rapid, cost effective, and highly accurate methods for characterizing bacterial colonization and infections in patients and more broadly in hospitals and other areas of human healthcare. Researchers have shown the ability to predict antibiotic resistance with up to 99% accuracy using DNA testing. This breakthrough combined with the speed, reliability and increased information content available with evolving DNA detection methods is leading to a fundamental transformation of the field of microbiology and the opportunity to dramatically improve patient outcomes.

Our Solution

OpGen intends to transform infectious disease management through innovation in molecular diagnostics, information technology, and microbiology to aid healthcare providers in reducing the burden of drug resistant infections. Our vision is that no patient should suffer from a life threatening, drug resistant infection. We are developing complete solutions for screening patients to determine underlying colonization with antibiotic resistant organisms such as CREs and for the development of early warning antibiotic stewardship programs for colonized patients who become infected. With our Acuitas™ family of products we anticipate making it possible to determine the genetic characteristics of targeted infectious organisms in a hospital or other healthcare setting, including both patients with active infections, and patients or healthcare providers who may be colonized but not currently symptomatic. With this information we believe it will be possible to provide customized diagnostic information for newly diagnosed patients to allow targeted antibiotic therapy earlier and more effectively.

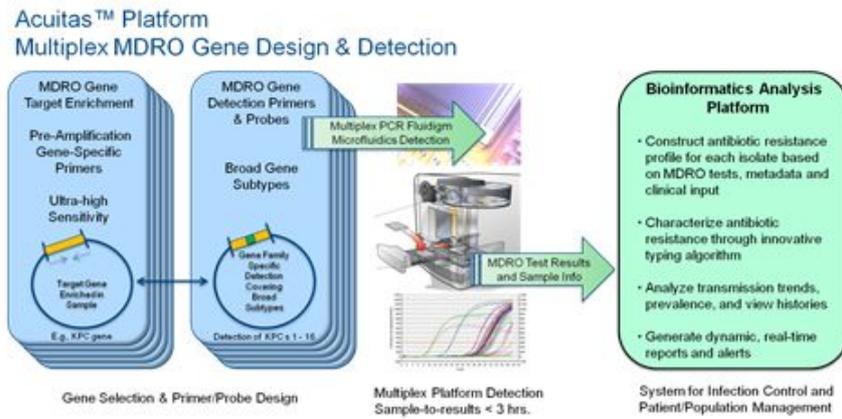
We have developed a comprehensive approach for screening for MDROs in hospitals using DNA testing. Our Acuitas Genet Tests are integrated with our Lighthouse MDRO Management System and laboratory information products to provide real-time information on the MDRO colonization status for patients, acute care ICUs, and hospitals. We combine our molecular test information and microbiology test results from our customized CLIA based tests to create Lighthouse MDRO profiles. Lighthouse MDRO profiling facilitates MDRO tracking and results are easily aggregated with hospital data to provide customized reports including alerts, prevalence, trend analysis and transmission information. We anticipate providing this information on a local, regional, and national basis, to help reduce overall disease rates and to strengthen the national capacity to detect and manage treatment of drug resistant bacterial strains.



The OpGen complete solution includes the Acuitas MDRO Gene Test for hospital surveillance programs, the Lighthouse MDRO Management System for in-hospital MDRO patient management and tracking, and integrated reporting capabilities for public health organizations to track MDROs on a local, regional and national basis.

Acuitas MDRO Gene Test

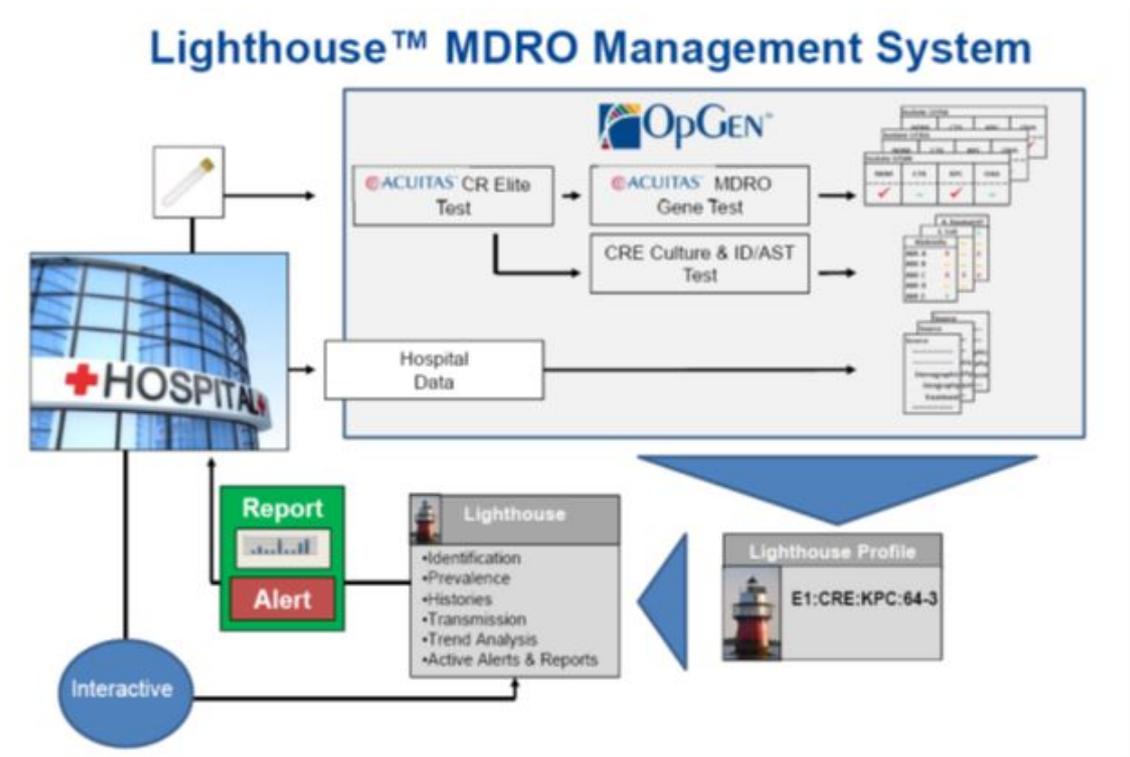
Our Acuitas MDRO Gene Test directly detects seven critical MDRO genes from one patient swab. The test provides fast, accurate molecular results for genes associated with CRE, ESBL (extended spectrum beta lactamase) and VRE (vancomycin resistance enterobacteria) resistance genes. The test identifies patients at risk for being colonized. In our CLIA evaluation studies and customer pilot studies, the test has been proven to be highly accurate when compared to established reference methods, demonstrating nearly 100% correlation in identifying patients carrying MDROs and those free of MDRO bacteria.



Acuitas gene tests combine Fluidigm's microfluidic-based production genomics technology with DNA probe reagents designed and manufactured to power our CLIA lab-based Acuitas gene tests.

Lighthouse MDRO

Our Lighthouse MDRO Management System solution, currently in development and undergoing analytical and clinical validation, enables proactive MDRO management to prevent in-hospital transmission events and to help improve patient outcomes. Trend analysis of patient specific data, data specific to individual hospital facilities and health systems is provided safely and confidentially to healthcare providers. Lighthouse MDRO dynamic profiling incorporates identity, phenotype and MDRO gene presence and assigns unique microbe identifiers, Lighthouse MDRO profiles, based on MDRO gene composition and antibiotic susceptibility, or AST, data. Lighthouse MDRO profiling provides the first diagnostic tracking tool for MDRO infection in the hospital setting. Our Lighthouse MDRO solution is based on our CLIA and HIPAA compliant LIMS database system. We are developing unique web-based portal for access to LIMS based lab reports and Lighthouse MDRO data reports. We anticipate commercializing our Lighthouse MDRO solution with our Acuitas MDRO Gene Tests in the first quarter of 2015.



Acuitas CR Elite, Resistome and Grow on the Go

Our CR Elite culture test is designed for culture-based confirmation of CRE resistance with the Acuitas MDRO Gene test. Positive MDRO gene tests are reflex tested to determine organism ID and AST profiles. We are also developing companion culture for ESBL and our proprietary Grow on the Go technology. With Grow on the Go, specimens are cultured during transport to allow for overnight shipping and immediate analysis on receipt at the OpGen CLIA Lab.

Acuitas Resistome Gene Test

We are using our production genomics capabilities to develop the Acuitas Resistome Gene test. The test is anticipated to include resistant genes for carbapenems, ESBLs, ampicillin-resistant genes and other key MDRO genes. We anticipate using the Resistome Gene test for Lighthouse MDRO profiling of specimens collected in hospitals for MDRO surveillance and clinical isolates from infected patients. The Lighthouse MDRO profiles will enable improved infection control procedures, antibiotic stewardship and individualized patient care. We also anticipate combining tests for important infectious diseases such as *C. difficile*, MRSA, and others to provide comprehensive MDRO screening and patient management solutions.

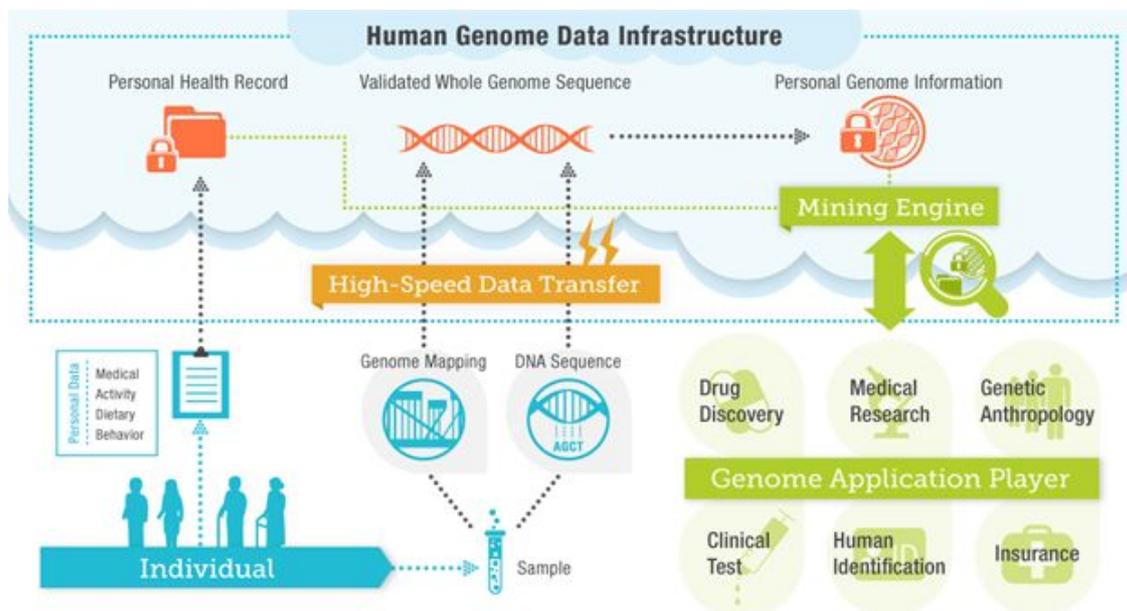
Microbial and human genome mapping and sequencing

Infectious disease testing is undergoing a transformation where DNA testing is replacing classical methods because of its accuracy and speed. DNA tests make it possible to simultaneously detect drug resistance genes, identify the presence of bacteria, viruses and fungi, and perform high resolution genotyping. These tests are generally more sensitive and provide more information than individual cultures. In addition, DNA tests can detect organisms that were undetectable by culture because the target organism was dead or would not grow in the culture medium. High resolution DNA analysis methods such as whole genome DNA sequencing offer the ability to accurately track hospital acquired infections and potentially improve patient diagnosis.

We have developed and commercialized the Argus® Whole Genome Mapping System, MapIt® Services, and MapSolver™ bioinformatics products and services for mapping and analysis of microbial, plant, animal and human genomes. We have more than ten years of experience mapping microbial genomes. Our customers include government public health agencies such as the CDC, FDA, USDA and biodefense organizations.

In September 2013, we entered into a strategic partnership with Hitachi High-Technologies Corporation to commercialize our technology for mapping, assembly, and analysis of human genomes. In conjunction with Hitachi, we are developing cloud-based genome assembly capabilities for both human and microbial genomes. We intend to continue commercializing microbial configurations of these products through our direct sales efforts. DNA tests and bioinformatics for analysis of whole human genomes will be commercialized through our partnership with Hitachi.

The following schematic provides a summary of the potential outcome of this collaboration:



During 2013, four customers of our Whole Genome Mapping and MapIt Services offerings each represented more than 10% of our revenue during the year, BGI-Hongkong, Co., Ltd (12%), VA Medical Center, Cleveland, OH (12%), Sciencewerke Pte Ltd (10%), and University of Antwerpen (10%). The revenues from a single customer have varied significantly from year to year, depending on the projects and external events causing them to increase or decrease the use of our products. For the nine months ended September 30, 2014, Hitachi represented our most significant source of revenue under the collaboration described above (64% of our revenue) and no other customer represented more than 10% of our revenues in that period. We believe the collaboration with Hitachi is important to our business, and loss of such relationship could have a material effect on our business.

Our Strategy

- Commercialize our Lighthouse MDRO Management System to healthcare providers, governments, and diagnostic companies.
- Develop and commercialize proprietary molecular diagnostic products with companion data offerings that provide the ability to efficiently analyze data about MDROs present in a patient sample.
- Capitalize on our first-mover advantage through our CLIA Lab-based test offerings. We are working to integrate hospital-wide infectious organism molecular diagnostic information with antibiotic susceptibility data and combining this information with patient specific data for healthcare providers. These complete infection control, antibiotic stewardship and patient management data product capabilities will be difficult for future market entrants to replicate.
- Expand our lab service offerings and capabilities through supply of kits for use on our DNA probe assay platform and commercially available rapid diagnostic test systems, develop MDRO DNA sequencing tests and informatics, and partner these offerings with our Grow on the Go™ technology.
- Partner with reference laboratories, government agencies, diagnostic companies and information technology providers to offer our Lighthouse MDRO solution on a global basis.
- Build on our established market-leading position in Whole Genome Mapping through our relationship with Hitachi for human genome assembly and analysis and expanded research programs directed at complete DNA sequence assembly and bioinformatics.
- Accelerate growth through strategic partnerships, sponsored research programs with governments and industry, and strategic acquisitions.

Market Opportunities

We operate in the approximately \$800 million annual U.S. market for screening and testing for hospital acquired infections. Our initial focus is the U.S. hospital market where there are approximately 6,000 hospitals and a potential market opportunity of 7 million tests annually for our Acuitas MDRO Gene Test. We estimate that approximately 25% of patients are high risk and candidates for our test in the 500 hospitals with more than 350 beds and approximately 20% of patients are high risk in the 1,000 hospitals with between 150 and 350 beds are candidates for our products and services. The trend towards consolidated health systems is combining these two segments into large health systems that are the initial targets for our test and informatics solutions. A typical large health system could have more than \$4 billion in annual revenue, a central hospital with more than 400 beds and 6-8 smaller hospitals and long term care facilities. These large health systems have started to centralize their microbiology lab testing making an attractive target market for OpGen.

The trend towards forming accountable care organizations, or ACOs, is expected to increase the focus on length of stay and the overall cost of hospital procedures. Since HAIs result in increased costs of approximately \$24,000 per patient, we anticipate ACOs will be particularly receptive to our MDRO management solutions.

Over the last several years we have developed extensive experience in DNA analysis of human microbial pathogen outbreaks. Our Whole Genome Mapping technology played a key role in helping rapidly identify the source of a number of major disease outbreaks such as the E. coli 0104 outbreak in Germany in 2011, a recent cholera outbreak in Haiti, and outbreaks from contaminated spinach in the U.S. We have 40 of our Argus Whole Genome Mapping Systems at leading public health, biodefense, academic and industrial laboratories worldwide. Eight of our systems are in use at public health laboratories such as the CDC and the FDA.

We intend to market our comprehensive solutions to state public health organizations and federal government agencies for tracking of MDRO infections and internationally in the hospital market and to sovereign governments for surveillance and outbreak management.

Commercialization Strategy & Plans

Our strategy is optimized to help establish our Lighthouse MDRO Management System and our Acuitas tests as the standard of care in the U.S. We are capitalizing on our first-mover advantage by partnering with leading healthcare systems to evaluate the improved clinical outcomes that can be obtained using our products and services. Initially we work to demonstrate that screening with our Acuitas MDRO Gene Test and the Lighthouse MDRO Management System will improve clinical outcomes and reduce hospital HAI rates and costs. Our clinical evaluations with healthcare providers are designed to demonstrate the performance of our products and that implementation will result in more accurate and timely patient isolation, the isolation decisions and infection control procedures. A second goal is to demonstrate the potential for improved antibiotic stewardship by appropriate antibiotic selection. During 2014, we have refined and implemented our Partner-Pilot-Program selling process described below.

- **Partner.** Through our consulting process and development of a client services agreement, we establish OpGen as a trusted and professional partner to provide the information necessary so that healthcare providers can manage infection control on an institution-wide basis.
- **Pilot.** A detailed plan is prepared within the client institution to conduct point prevalence surveys, culture isolate characterization and comparison to internal methods currently in use. During the pilot phase and at completion, a detailed formal report is prepared and provided. Our reports highlight overall test performance including the detection of colonization or infection missed by conventional methods.
- **Program.** The customized program for each institution includes implementation of MDRO screening, ongoing testing of clinical isolates, and the integration of this data into our Lighthouse MDRO Management System.

We may also enter into Performance Based Risk Sharing Agreements with healthcare institutions to introduce our diagnostic and screening products and services to them.

To date, approximately ten acute care hospitals and long term care facilities have participated in our Partner-Pilot-Program process, one of which initiated modest product purchases in 2014. During 2015, we expect these hospitals and facilities to become long-term customers supporting our growth projections. We anticipate expanding these programs to capture cost-benefit and clinical outcomes data for use by such facilities in addressing MDRO diagnosis and surveillance, antibiotic resistance and antibiotic stewardship concerns.

Achieving Standard of Care

We anticipate using our early adopter accounts as references as we replicate our Partner-Pilot-Program approach. A second major initiative is to develop institution-wide Lighthouse MDRO Management System surveillance programs. We intend to establish and brand our Lighthouse MDRO surveillance and control management systems. Our capitated surveillance testing programs will bring the following benefits to participating institutions:

- Platinum status as a proactive MDRO surveillance and “best practices” institution;
- Patient safety and enhanced hospital reputation benefits;
- Compliance with CDC and public health guidelines and reporting requirements;
- Reduced length of stay, improved antibiotic stewardship and overall cost savings;
- Insurance against potential negative headline risk from undetected MDRO hospital wide outbreaks.

Establishing MDRO surveillance screening as the standard of care in the U.S. is an important corporate objective. Recent experience with the Ebola outbreak in West Africa is expected to help reinforce the view that early and aggressive action is important to prevent uncontrollable infectious disease outbreaks in future years. Capitalizing on the President’s National Strategy for Combating Antibiotic Resistance we intend to help establish additional clinical practice guidelines and legislative requirements. At the healthcare system level our plan is to:

- Close early adopter institutions;
- Demonstrate the value of our complete solutions in clinical practice;
- Document and educate healthcare providers regarding the clinical validation, clinical utility and improved outcomes that can be obtained with our comprehensive solution;
- Demonstrate the cost effectiveness of MDRO surveillance to hospital administrators;
- Build consumer and public awareness regarding the benefits of MDRO surveillance and best practices in infection control.

Opportunity for single comprehensive solution

Our products and services are integrated into a single comprehensive solution for healthcare providers. By completely addressing institutional needs for informatics, genetic analysis and microbiologic testing we are establishing a market leadership position as a trusted expert in MDRO testing. The OpGen solution is optimized to help hospitals reduce hospital acquired disease rates by helping rapidly identify patients colonized with MDROs who should receive contact precautions and to help guide antibiotic therapy. Additional products in development are outlined below.

R&D

Our current focus is on the development of our Acuitas and Lighthouse MDRO products and service offerings. For the years ended December 31, 2013 and 2012, our research and development expenditures were \$4,151,936 and \$4,782,414, respectively, and were \$3,300,124 for the nine months ended September 30, 2014.

We intend to build on our market leading position and first-mover advantage by continuing to invest in the development of our Acuitas and Lighthouse MDRO product offerings. Our ongoing research and development efforts include:

- Further development of our Acuitas gene tests;
- Investments in information technology including our Lighthouse MDRO portal database interpretation capabilities, and next generation sequencing assembly and bioinformatics;
- Improved microbiology methods for MDRO culture screening such as our Grow on the Go technology, ESBL culture and additional culture methods to help improve test workflows;
- Combined testing methods from new sample types; and
- Multiplex tests addressing newly identified clinical needs.

Acuitas Resistome

We are developing the Acuitas Resistome test for rapid, high resolution, low cost testing of microbial isolates. The Resistome test will enable higher resolution Lighthouse MDRO profiling for patients with positive Acuitas MDRO Gene tests and for positive samples from infected patients and repositories of specimens at public health labs.

Lighthouse MDRO Portal

We are developing the Lighthouse MDRO portal to provide infection control personnel and physicians access to data from our CLIA Lab LIMS database and to allow users to generate customized tracking reports for MDROs in the hospital.

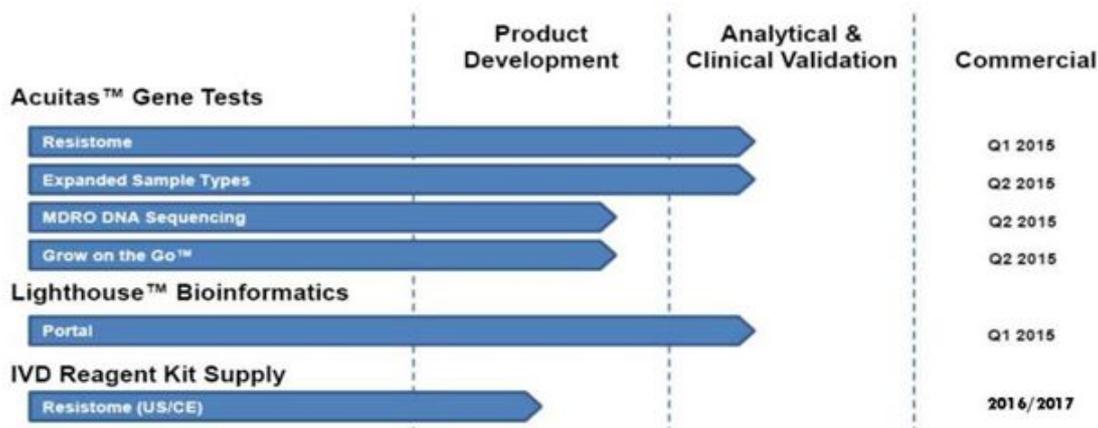
Acuitas MDRO sequencing

The Acuitas MDRO sequencing tests under development will allow healthcare providers to do high resolution typing of MDRO isolates with the same Lighthouse MDRO profile to determine if these patients are infected with the same organism or different ones. We anticipate healthcare providers will use this information to help resolve overall infectious rates, track outbreaks, and adjudicate claims with payors to prove if an infection is hospital acquired or was with the patient on arrival.

Expanded Sample Types

The Acuitas MDRO Gene Test is CLIA validated for perianal swabs. We anticipate expanding the sample types for the test to include stool, nasal swabs, skin, urine and groin swabs and environmental specimens. The expanded sample types will open new market opportunities for the company including the ability to offer combined C. difficile/MDRO testing, MRSA/MDRO testing and to expand our environment testing service offerings.

The following table highlights our key MDRO tests development programs and their anticipated commercial launch dates:



Clinical Studies and Publications

Documenting the performance of our products and their clinical utility through rigorous clinical and economic outcome studies is an important element of our business strategy.

We have developed an extensive clinical studies plan designed to demonstrate the utility of our products and services to stakeholders in the healthcare system. The objective of these studies is to demonstrate that our Acuitas gene tests combined with the Lighthouse MDRO Management System will enable clinical decisions that favorably improve patient outcomes reducing length of stay, hospital costs, and help to reduce the overall level of disease in hospital systems.

Successful Beta studies have been completed with the Children’s National Medical Center, the University of Maryland Medical System, and the University of Louisville Medical School. These studies compare the performance of our Acuitas MDRO Gene test with expert culture and third-party molecular testing methods.

CLIA validation studies are complete for our MRSA, C. difficile, and MDRO gene tests and for our CR Elite CRE culture test. Results for the Acuitas MDRO Gene test showing the excellent performance of the test are highlighted below.

Results of CLIA Laboratory analytical sensitivity study for Acuitas MDRO Gene Test:

MDRO Gene	Organism	LOD (CFU/mL) ¹
KPC	E. cloacae	84
NDM	K. pneumoniae	93
VIM	S. marcescens, P. aeruginosa, E. cloacae	37-154
IMP	K. pneumoniae	13-66
OXA-48	K. pneumoniae	79
OXA-23	A. baumannii	109
OXA-51	A. baumannii	125
CTX-M	K. pneumoniae	79-151
VanA	E. faecium	250

Results of CLIA Laboratory analytical specificity for Acuitas MDRO Gene Test:

Acuitas	MDRO Gene Presence ²	MDRO Gene Absence ²
+	100	0
-	0	143

Results of CLIA Laboratory reproducibility study for Acuitas MDRO Gene Test:

Inter and Intra-Assay Reproducibility										
Assay	Day One			Day Two			Day Three			Level (Ct)
	High Target	Mid Target	Low Target	High Target	Mid Target	Low Target	High Target	Mid Target	Low Target	
Kpc	6	9	13	5	9	12	5	9	12	12
Ndm	7	10	13	6	8	12	6	9	12	12
Vim(A)	7	12	15	7	10	14	7	10	14	14
Vim(B)	7	11	14	7	10	14	7	10	14	14
Vim(C)	5	7	10	4	6	10	4	6	9	9
Imp(A)	6	9	13	6	9	13	6	9	12	12
Imp(B)	9	13	16	9	12	15	9	11	15	15
Oxa(A)	6	10	13	6	9	12	6	9	13	13
Oxa(B)	5	7	10	5	7	10	5	7	9	9
Oxa(C)	7	10	13	6	9	13	7	10	13	13
Ctx-M(A)	7	10	14	7	10	13	7	10	13	13
Ctx-M(B)	5	9	12	6	8	12	5	8	12	12
VanA	11	14	18	10	13	16	11	14	17	17

Three spiked e-swab at i) low (1-fold above the LOD), ii) medium (2-fold above the LOD) and iii) high (3-fold above the LOD) concentrations of target for each reaction were extracted and tested in duplicate. Each data point on the table represents the average of six results (three extracted tested in duplicate).

Results of CLIA Laboratory accuracy study for Acuitas MDRO Gene Test: ⁽³⁾

Reaction Level Accuracy		
	MDRO Pos	MDRO Neg
Acuitas Positive	42	2
Acuitas Negative	0	1596
Sensitivity =	100%	
Specificity =	99.87%	

- (1) Acuitas MDRO Gene Test CLIA Validation test results. Limit of Detection, or LOD, determined in serial dilution studies with negative peri anal swabs spiked with organism containing the target.
- (2) Analytical specificity determined against 100 clinical isolates with known MDRO genes and 143 without MDRO genes that are detected by the Acuitas test. Average within day %CV for low target levels across all targets was 3.7%.
- (3) Accuracy study included 118 peri-anal swabs tested in a blinded manner with multiple operators. Included 108 swabs containing 42 known MDRO genes covering all Acuitas MDRO gene targets and 10 clinical isolates without known MDRO genes.

Payments and Reimbursement

Our tests, test kits, and informatics services are sold to hospitals and public health organizations on a fee for service and direct basis. We envision selling our Lighthouse MDRO Management System to health systems and hospitals under capitated, flat-rate contracts. Health systems absorb the costs of extended stay from hospital acquired infections, HAIs, and from 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 6 days or more for patients infected with MDROs resulting in increased costs of \$14,000 to \$33,000 per 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 will help adjudicate payment favorably for hospitals. Isolation procedures are also costly to hospitals, so it is critical that isolation/deisolation 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. In addition to costs to individual hospitals, 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 Gene test results and the comprehensive panel of results available from one patient sample. We believe the combination of the efficient Acuitas MDRO Gene Test and the Lighthouse MDRO Management System 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:

- Reduced length of stays;
- Cost savings and improved patient outcomes; and
- Avoidance of penalties by third-party payors for hospital acquired infections.

We employ diverse marketing programs to inform key stakeholders of the value of our solution in order to drive adoption. As part of our marketing strategy, we educate hospitals, other health care institutions, and healthcare professionals about our unique 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 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.

Dependence on Third Party Payors

We do not currently rely on any third party payors for payment for or reimbursement of our Acuitas MDRO Gene Test.

Reimbursement Strategy

In the event we seek reimbursement from federal healthcare programs and third party payors, to employ this strategy we will:

- Meet the evidence standards necessary to be consistent with leading clinical guidelines. We believe inclusion in leading clinical practice guidelines plays a critical role in payors' coverage decisions.

- We will employ a team of reimbursement specialists to ensure our payor outreach strategy reacts and anticipates the changing needs of our customer base and who will work with payors to obtain maximum reimbursement. A customer service team will 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 will 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 payors.
- Compile a growing library of peer-reviewed studies that demonstrate the Acuitas MDRO test is effective, accurate and faster than current methods.

Third Party Relationships

Building and fostering relationships with third party companies who provide instrument reagent systems, hospital and DNA analysis software, and expanded distribution is an important business strategy for the Company.

Fluidigm Corporation

In December 2013, we purchased a BioMark HD DNA detection system and related instruments from Fluidigm to use in our Acuitas test development. In March 2014, we entered into a Supply Agreement with Fluidigm with respect to our purchases of Fluidigm's microfluidic chips, reagents, and other consumables used on the instrument. As we move towards kit-based configurations of our products we intend to negotiate with Fluidigm to allow OpGen to distribute Fluidigm microfluidic chips as part of our integrated Acuitas test kits for use on Fluidigm instrument systems. We believe that as of mid-2014, more than 600 BioMark systems are in use worldwide, providing potential customers for our Acuitas tests and services. The Supply Agreement currently has a one-year term, but we intend to request that Fluidigm enter into a new supply agreement. We cannot provide assurances that we will reach agreement with Fluidigm with respect to a new supply agreement or any agreement relating to the distribution of Fluidigm's products with our Acuitas test kits.

Hitachi High-Technologies Collaboration

Our collaboration with Hitachi High-Technologies Corporation is strategically important to the Company. Since September 2013, we have been working with Hitachi to develop the Human Chromosome Explorer, a cloud-based service for human chromosome mapping, analysis and structural variation detection that will be commercialized by Hitachi with OpGen-supported Whole Genome Mapping and sequencing services and bioinformatics. Under contract from Hitachi, we are jointly developing a suite of bioinformatics and data management applications in a cloud-based environment for comprehensive and efficient automated analysis of structural variations of entire human genomes. Collaborations under an early access program are currently underway, and we expect Hitachi to launch their full service in 2015. OpGen is a service provider to Hitachi for their Human Chromosome Explorer and we anticipate jointly developing additional genome assembly and analysis capabilities. In addition to generating revenue for OpGen, the Hitachi relationship is strategically important because it serves as a way for the company to leverage its expertise and technologies in the human genetics market and simultaneously to strengthen our core technology position in DNA sequence assembly and analysis for microbial genomes.

Laboratory Operations

Our laboratory operations are headquartered at our CLIA-certified laboratory in Gaithersburg, MD, where we perform all Acuitas MDRO testing. Once received, samples are processed through our automated accessioning system, prepared for review and analyzed at our laboratory. Specimens that are received by courier by 6 p.m. are analyzed during the night shift and the results are provided the following morning. When culture results are requested, the tests are performed over the next 48 hours. Our Gaithersburg, Maryland facility is responsible for quality assurance oversight, licensing and regulation compliance and maintenance for both of our laboratories to ensure data integrity and consistent, validated processes.

We believe we have sufficient laboratory capacity to process Acuitas MDRO tests for at least the next 24 months.

Quality Assurance

Our quality assurance function oversees the quality of our laboratories as well as the quality systems used in research and development, client services, billing operations and sales and marketing. We have established a quality system, including implementation and maintenance, document control, supplier qualification, corrective or preventive actions oversight, and employee training processes that we believe achieves excellence in operations across the entire business. We continuously monitor and improve our quality over time and believe our implementation of these processes has supported our achievement of product performance, customer satisfaction and retention and a philosophy of continuous improvement.

Competition

We believe the principal competitive factors in our target market include:

- quality and strength of clinical and analytical validation data;
- confidence in diagnostic results;
- cost-effectiveness; and
- ease of use.

We believe we compete favorably on the factors described above.

Our principal competition comes from traditional methods used by healthcare providers to diagnose and screen for MDROs.

We also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated, with strong infrastructure to support the commercialization of diagnostic services. We face potential competition from companies, such as Cepheid, bioMerieux and Nanosphere.

In addition, competitors may develop their own versions of our solution in countries where we do not have patents or where our intellectual property rights are not recognized and compete with us in those countries.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical and research and development resources and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by physicians and payors as functionally equivalent to our solution, or offer solutions at prices designed to promote market penetration, which could force us to lower the list price of our solutions 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.

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.

As of September 30, 2014, we had license or ownership rights to 68 patents, including 25 pending United States non-provisional patent applications, and 15 issued United States patents. Our issued patents begin to expire in April 2015 and are fully expired by December 2023.

We intend to file additional patent applications in the United States and abroad to strengthen our intellectual property rights; however, our patent applications (including the patent applications listed above) may not result in issued patents in a timely fashion or at all, and we cannot assure investors that any patents that have issued or might issue will protect our technology. We may receive notices of claims of potential infringement from third parties in the future. For additional information, see the section of this prospectus captioned “Risk Factors—Risks Related to Intellectual Property”.

We hold registered trademarks in the United States for OpGen®, Argus® and MapIt® and Canadian and European Community registered trademarks for OpGen. We have filed U.S. trademark applications for Acuitas™, Genome-Builder™, Lighthouse™, MapCard™, MapCode™, MapSolver™, Secure™, Secure Elite™ Map Type™ and Whole Genome Mapping™.

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.

Near-Term Plan of Operation

We anticipate that our expenditures will increase over the next 18 months in connection with the implementation of our strategy. Specifically, we expect our research and development expenses will increase as we invest in activities related to developing additional products, such as Acuitas Resistome, as well as the continued development and support of Acuitas MDRO Gene Testing and the Lighthouse MDRO Management System. Our key strategic initiatives are set forth in “Business—Our Strategy” and our plans for developing additional products can be found in “Business—Commercialization Strategy and Plans”. We also expect our selling and marketing expenses will increase as a result of the costs associated with hiring additional internal sales personnel in connection with our planned expansion, and additional marketing and education efforts in order to promote our Acuitas MDRO Gene Testing and the Lighthouse MDRO Management System and to educate health care organizations about our tests. Additionally, we also expect that our general and administrative expenses will increase as we incur additional expenses related to operating as a public company and expand our billing and client services functions to support anticipated increased demand for our test. We believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents, will exceed those additional expenditures and our current cash usage rates and will be sufficient to meet our anticipated cash requirements for at least the next 12 months, and as such, we do not expect it will be necessary to raise additional capital during that period.

Our expectations with respect to our near term operating plan and ability to effectively execute on this plan are subject to a number of risks, and many of these risks are outside of our control. If one or more of these events were to occur in the near term, it may be necessary for us to shift our priorities and our plans, abandon or delay one or more of our planned activities, or otherwise adjust our proposed near- and long-term business plans. Please see “Risk Factors” for a discussion of these risks and events, and their potential effects on our business.

Regulation

Clinical Laboratory Improvement Amendments of 1988, or CLIA

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 under CLIA to perform 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 CLIA certificate expires on October 1, 2015.

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 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 be eligible to bill for diagnostic services provided to Medicare beneficiaries. 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 the Acuitas MDRO Gene Test are regulated under the Clinical Laboratory Improvement Amendments of 1988, or 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. FDA defines the term laboratory developed test (LDT) as an in vitro diagnostic test that is intended for clinical use and designed, manufactured and used within a single laboratory. We believe that the Acuitas MDRO Gene Test is an LDT. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug and Cosmetic 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 guidance that, when finalized, would adopt a risk-based framework that would increase FDA oversight of LDTs. As part of this developing framework, 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, 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.

Some products are for research use only, or 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 diagnostic utility or that it is intended for human clinical 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 in vitro diagnostic product does not render the device exempt from otherwise applicable clearance, approval, or other requirements. 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 FDA's current and forthcoming guidance on LDTs and IUOs/RUOs on our solutions 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 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. Legislative proposals addressing oversight of LDTs were introduced in recent years and 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.

If premarket review, including approval, is required, our business could be negatively affected until such review is completed and clearance to market or approval is obtained, and the FDA could require that we stop selling our diagnostic services pending premarket clearance or approval. If our diagnostic services are allowed to remain on the market but there is uncertainty about the legal status of our services, if we are required by the FDA to label them investigational, or if labeling claims the FDA allows us to make are limited, order levels may decline and reimbursement may be adversely affected. The regulatory process may involve, among other things, successfully completing additional clinical studies and submitting a premarket notification or filing a PMA application with the FDA. If premarket review is required by the FDA, there can be no assurance that our diagnostic services will be cleared or approved on a timely basis, if at all, nor can there any be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our solution. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to heightened requirements of the FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA premarket review of our diagnostic services if we determine that doing so would be appropriate.

U.S. Food and Drug Administration: Diagnostic Kits

Diagnostic kits, including collection systems, like the Copan Eswab used to provide our test specimens, and our Resistome product under development, that are sold and distributed through interstate commerce are regulated as medical devices by the FDA. Devices subject to FDA regulation must undergo premarket review prior to commercialization unless the device is of a type exempted from such review. In addition, manufacturers of medical devices must comply with various regulatory requirements under the Federal Food, Drug, and Cosmetic Act, or FDC Act, and implementing regulations promulgated under that Act. Entities that fail to comply with FDA requirements may be subject to issuance of notice of observations, untitled or warning letters, and can be liable for criminal or civil penalties, such as recalls, import detentions, seizures, or injunctions, including orders to cease manufacturing.

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Many Class I devices are exempt from FDA premarket review requirements. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices must typically be approved by the FDA before they are marketed. For Class II devices, the FDA generally requires clearance through the premarket notification, or 510(k) clearance, process.

Generally, establishments that manufacture or distribute devices, including manufacturers, repackagers and relabelers, specification developers, and initial importers, are required to register their establishments with the FDA and provide the FDA a list of the devices that they handle at their facilities.

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

The FDA has issued a regulation outlining specific requirements for "specimen transport and storage containers." "Specimen transport and storage containers" are medical devices "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. A specimen transport and storage container is a Class I device. It is subject to MDR requirements, the reporting of corrections and removals, registration and listing. It is exempt from premarket review, and from QSR labeling requirements except for recordkeeping and complaint handling requirements, so long as no sterility claims are made. Our facility is registered with the FDA as a specification developer, which means that we can sell the collection system under our own name and outline the specifications used to make the collection system, but a third party assembles the collection system for us. The container we provide for collection and transport of our samples from a hospital to our clinical reference laboratory is listed with the FDA as a Class I medical device and is subject to regulation by the FDA. If the FDA were to determine that our sample collection container is a Class II medical device, the manufacturer would be required to obtain FDA clearance to use the container.

The FDA enforces the requirements described above by various means, including inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an Untitled Letter or Warning Letter to more severe sanctions such as:

- fines, injunctions, and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production; and
- criminal prosecution.

Health Insurance Portability and Accountability Act

Under the federal Health Insurance Portability and Accountability Act of 1996, or 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 health care 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 health care 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.

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, 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 speaking engagements and consulting activities. We have structured these arrangements with terms intended to comply with the requirements of the personal services exception to Stark and Maryland Physician Self-Referral Law.

However, we cannot be certain that regulators would find these arrangements to be in compliance with Stark, 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.

Further, if we submit claims in violation of the Maryland Physician Self-Referral Law, we can be held liable to the payor 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 health care 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 health care 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 health care programs for a minimum of five years. In addition, HHS has the authority to impose civil assessments and fines and to exclude health care providers and others engaged in prohibited activities from Medicare, Medicaid and other federal health care programs. Actions which violate the Anti-Kickback Law also incur 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.

Although the Anti-Kickback Law applies only to federal health care 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 payors. 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 health care 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 health care 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 specifies 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 health care 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 health care 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 is due to be renewed in June 2016.

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, or will obtain, licenses from 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.

Employees

As of October 15, 2014, we had 31 employees, of which 10 work in laboratory operations, 8 in research and development and clinical development, 6 in selling and marketing, and 7 in general and administrative. None of our employees are the subject of collective bargaining arrangements, and our management considers its relationships with employees to be good.

Facilities

We lease 20,713 square feet of office and laboratory space at our headquarters in Gaithersburg, Maryland under a lease that expires in the second quarter of 2015. In 2015, we anticipate renewing our lease or entering into a new lease for office and laboratory space in the Gaithersburg, Maryland area. We believe that our existing facilities, or any such new facilities are 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.

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.

Raw Materials and Suppliers

We procure reagents, equipment, chips and other materials we use to perform the Acuitas MDRO Gene Test from sole suppliers such as Fluidigm. 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 alternate 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 the Acuitas MDRO Gene Test, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, our business would be negatively affected.

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 legal proceedings.

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 health care providers and other health care system participants, including insurers, formed under the PPACA, to provide coordinated health care to patients.

“Acuitas MDRO Gene Test” means our internally developed test that detects seven critical MDRO genes, including CRE, ESBL and VRE resistant organisms, from one patient swab.

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

“Argus Whole Genome Mapping” means OpGen’s commercially available technology that provides a high resolution, complete visual map of a whole genome and individual chromosomes, which is based on OpGen’s unique single molecule analysis technology. 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.

“bioinformatics” 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 bioinformatics” we mean bioinformatics combined with higher levels of complexity, sophistication and subject matter expertise related to MDROs, diagnostics, antibiotics stewardship, and development of associated analysis tools, or novel application of existing bioinformatics in future products or services. In this prospectus we also sometimes use the phrase “bioinformatics products and services,” often interchangeably with “bioinformatics platform,” to describe the Company’s focus on the use of bioinformatics and advanced bioinformatics in its current and future product and service offerings.

“bioinformatics platform” means a combination of software tools and analytical processes that streamline the production and analysis of bioinformatics data. When we use the term “bioinformatics platform,” we are primarily referring to our Lighthouse MDRO Management System.

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

“*C. difficile*” means clostridium difficile, a serious MDRO that causes intestinal tract infections that can lead to sepsis.

“CLIA Lab” means our clinical or reference laboratory meeting the requirements of the Commercial Laboratory Improvements Act of 1988, as amended.

“CRE” means Carbapenem-resistant Enterobacteraceae.

“CR Elite” is our culture test is designed for culture-based confirmation of CRE resistance with the Acuitas MDRO Gene test.

“DNA probe analysis” is a test where an agent binds directly to a predefined or labeled sequence of nucleotides in a DNA molecule in order to detect unique nucleotide sequences within the DNA of a microorganism.

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

“ESBL” means extended spectrum beta lactamase organisms.

“FDA” means the U.S. Food and Drug Administration.

“Grow on the Go” is our proprietary specimen transport solution that allows a specimen to be cultured during transport to allow for overnight shipping and immediate analysis on receipt at the OpGen CLIA Lab.

“HAIs” means hospital acquired infections. Such infections could arise first in the hospital or other healthcare setting, or could result from a colonized patient developing an active infection in 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 are federal laws mandating security and privacy of protected personal health information of patients.

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

“KPC” means Klebsiella pneumonia carbapenemase infection.

“Lighthouse MDRO Management System” is our product being internally developed to provide real-time information on the MDRO colonization status for patients, acute care ICUs, and hospitals. We combine our molecular test information and microbiology test results from our customized CLIA based tests to create Lighthouse MDRO profiles for hospitals. Lighthouse MDRO profiling facilitates MDRO tracking and results are easily aggregated with hospital data to provide customized reports including alerts, prevalence, trend analysis and transmission information.

“LIMS” means a laboratory information management system.

“MDR” means multi-drug resistant.

“MDR-GNB” means gram negative bacteria that are resistant to multi antibiotic treatment alternatives. MDR-GNBs include the following organisms – MDR Klebsiella pneumonia, MDR-Pseudomonas aeruginosa, MDR-Acinetobacter baumannii and Enterobacterceae producing extended-spectrum β -lactamases (ESBL) and carbapenemases.

“MDRO” means multi-drug resistant organisms.

“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.

“PPACA” means the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act.

“production genomics” is the market application of technologies that apply DNA testing methodologies and bioinformatics to sequence, assemble and analyze the function and structure of genomes. Specifically, these technologies are used in settings that demand high throughput and high accuracy.

“Resistome” means our rapid, high resolution, low cost test in development, that is anticipated to include resistant genes for carbapenems, ESBLs, ampicillin-resistant genes and other key MDRO genes.

“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.

MANAGEMENT

Directors and Executive Officers

Our executive officers and directors and their respective ages and positions as of October 31, 2014:

Name	Age	Position
<i>Executive officers:</i>		
Evan Jones.	57	President, Chief Executive Officer and Chair of the Board
C. Eric Winzer	57	Senior Vice President, Finance and Chief Financial Officer
G. Terrance Walker, Ph.D.	55	Senior Vice President, Research and Development
Vadim Sapiro	43	Chief Information Officer
David Hoekzema	51	Vice President, Business Development and Operations
<i>Consultant:</i>		
Robert McG. Lilley	69	Chief Commercial Officer
<i>Non-management directors:</i>		
Brian G. Atwood (2)	61	Director
Timothy Howe (1)(2)	56	Director
Laurence R. McCarthy Ph.D.(1)	70	Director
Misti Ushio, Ph.D.(1)	42	Director

(1) Member of the Compensation Committee.

(2) Member of the Audit Committee.

Executive Officers

Evan Jones has served as our President and Chief Executive Officer since October 2013 and as Executive Chairman of our board of directors since September 2010. Since 2007, Mr. Jones has served as managing member of jVen Capital, LLC (jVen), a life sciences investment company. Previously, he co-founded Digene Corporation, or Digene, a publicly traded biotechnology company focused on women's health and molecular diagnostic testing that was sold to QIAGEN NV (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 served as a member of the board of directors of CAS Medical Systems, Inc. (NASDAQ: CASM), a developer of patient vital signs monitoring products and technologies, from June 2008 to October 2013. Mr. Jones has served on the boards of directors of Fluidigm Corporation (NASDAQ: FLDM), a provider of life science analytical and preparatory systems for markets such as single cell biology and production genomics, since March 2011, Foundation Medicine, Inc. (NASDAQ: FMI), a cancer testing molecular informatics company since 2013, and Veracyte, Inc. (NASDAQ: VCYT), a molecular cytology 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 President and Chief Executive Officer and as Executive Chairman of our board of directors 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. The Board believes that Mr. Jones' more than 30 years' leadership experience in the life science and healthcare industries, his extensive board experience at both privately held and publicly traded companies and his investment expertise, coupled with his deep understanding of our technologies, product candidates, market and history make him an essential contributor to our Board, including his service as Chairman of the Board.

C. Eric Winzer joined OpGen as Chief Financial Officer in June 2009. Mr. Winzer brings almost thirty years of experience in addressing diverse financial issues including raising capital, financial reporting, investor relations, banking, taxation, mergers and acquisitions, financial planning and analysis, and accounting operations. Prior to joining OpGen, Mr. Winzer served as Executive Vice President and Chief Financial Officer for Avalon Pharmaceuticals, Inc. (Avalon), a biotechnology company developing targeted therapeutics for oncology. Prior to Avalon, Mr. Winzer was with Life Technologies (formerly Invitrogen Corporation), a provider of life science technologies for disease research and drug discovery, where he served as Senior VP and Chief Financial Officer, Executive Sponsor for their ERP implementation, and as the VP of Finance. Previously held positions also include Mr. Winzer's various financial positions at Genex Corporation. Currently, Mr. Winzer serves as director and audit committee chair at Cytomedix, Inc. (OTCQX: CMXI). Mr. Winzer received his B.A. in Economics and Business Administration from McDaniel College and an M.B.A. from Mount Saint Mary's University.

G. Terrance Walker, Ph.D. joined OpGen in June 2013 as Vice President, Research and Development and was promoted to Senior Vice President, Research and Development in October 2014. Dr. Walker's responsibilities include leading the development of genomic technologies and new products supporting molecular diagnostics for infectious diseases. Prior to OpGen, Dr. Walker previously led drug target validation, biomarker discovery and clinical diagnostic development at Pfizer Inc. (NYSE: PFE), GlaxoSmithKline plc (NYSE: GSK), Becton, Dickinson and Company (NYSE: BDX) (Becton), Duke University and The Biomarker Factory across most disease areas and stages of development from discovery through late clinical trials. Dr. Walker received his Ph.D. in Biophysical Chemistry from the University of Rochester with postdoctoral training in Biophysical Chemistry at the University of California, Berkeley.

Vadim Sapiro joined OpGen in December 2011 as Chief Information Officer. Mr. Sapiro is responsible for leading the development of the Company's bioinformatics applications, software, databases and information technology operations. Prior to OpGen, Mr. Sapiro was senior vice president at SAIC-Frederick (SAIC) overseeing the Information Systems Program for the National Cancer Institute at Frederick with responsibility for information technology, scientific computing and bioinformatics. Among Mr. Sapiro's projects were technical program management and operations for the cancer Biomedical Informatics Grid (caBIG™), the cancer Human Biobank (caHUB) and The Cancer Genome Atlas (TCGA). Prior to SAIC, Mr. Sapiro was Vice President for Information Technology with the J. Craig Venter Institute. Mr. Sapiro is active in the regional and national technology and research communities, having served on many life sciences and biotech focused advisory boards and review committees. Mr. Sapiro holds a B.S. in Mathematics and Computer Science from the University of Maryland.

David Hoekzema joined OpGen in July 2012 as Vice President, Business Development and Operations. Mr. Hoekzema's responsibilities include the expansion of technology and assay development partnerships in clinical diagnostics and life sciences. Mr. Hoekzema is also responsible for OpGen's production and service operations. He has over twenty-five years of experience in global biotechnology markets, with leadership and management roles spanning business development, sales and marketing, and commercial and technical operations at QIAGEN NV (NASDAQ: QGEN), Cambrex Corporation (NYSE: CBM), Life Technologies, and Advanced Biotechnologies Inc. Prior to joining OpGen, Mr. Hoekzema was Vice President, Business Development at SAIC, leading the formation of technology partnerships for Frederick National Laboratory for Cancer Research. Mr. Hoekzema holds a B.S. in Biology from Frostburg State University and an M.B.A. from the University of Maryland, Robert H. Smith School of Business.

Consultant

Robert McG. Lilley was retained by OpGen in October 2014 as our Chief Commercial Officer. Mr. Lilley is currently non-executive Chairman of the Board of Directors of Immunexpress, Inc., a Seattle-based molecular diagnostic company focused on developing diagnostic tests for patients at risk of sepsis. Mr. Lilley previously served as Senior Vice President, Global Sales and Marketing for Digene Corporation, from June 1999 until its sale to QIAGEN NV in 2007. He had held prior sales executive positions with Digene March 1997 to June 1999. Mr. Lilley worked for QIAGEN NV as Senior Advisor, Molecular Diagnostics from August 2007 until September 2009. Mr. Lilley previously served as Head of Europe, Middle East, and Africa (EMEA) Sales and Marketing for TDS Healthcare Information Systems, as well as Senior Vice President and General Manager EMEA of Alltel Healthcare Systems.

Non-Management Directors

Brian G. Atwood has been a member of our board of directors since July 2007 and is currently chair of our audit committee. Mr. Atwood specializes in biotechnology investing at Versant Ventures. He is a co-founder of Versant Ventures and before this spent four years at Brentwood Venture Capital where, as a general partner, he led investments in biotechnology, pharmaceuticals, and bioinformatics. He also has more than fifteen years of operating experience in the biotechnology industry, with emphasis on therapeutic products, devices, diagnostics, and research instrumentation. Prior to launching his career in venture capital, Mr. Atwood was founder, President, and CEO of Glycomed Incorporated (Glycomed), a publicly traded biotechnology company. At Glycomed, Mr. Atwood concentrated on business development and strategic alliances, closing deals with Eli Lilly & Company, Millipore, Genentech and Sankyo, before leading the sale of Glycomed to Ligand Pharmaceuticals Incorporated. Prior to Glycomed, he co-founded and served as director of Perkin Elmer/Cetus Instruments, a joint venture for robotics automation and genomics research instruments and products later acquired by Perkin Elmer. Under Mr. Atwood's management, the venture developed and launched the GeneAmp® Polymerase Chain Reaction (PCR) system, the fundamental DNA amplification innovation responsible for fueling the explosive growth of genomics research. He currently serves as a board member at the private companies PhaseRx, Inc., Groove BioPharma, Inc., Acumen Diagnostics, and Atreca, Inc., as well as the public companies, Clovis Oncology, Inc. (NASDAQ: CLVS), FivePrime Therapeutics, Inc. (NASDAQ: FPRX), Veracyte, Inc. (NASDAQ: VCYT), and Immune Design Corp. (NASDAQ: IMDZ). Mr. Atwood had previously served on the board of Pharmion Corporation (sold to Celgene Corporation in 2008); Cadence Pharmaceuticals (acquired), Trius Therapeutics (acquired). Mr. Atwood received a B.S. in Biological Sciences from the University of California, Irvine; an M.S. from the University of California, Davis, and an M.B.A. from Harvard Business School. Mr. Atwood's extensive biotechnology, bioinformatics and investing experience, and his familiarity with privately held companies in our industry position him to provide valuable insight and make substantial contributions to our Board and to our Audit Committee.

Timothy Howe has been a director of OpGen since July 2013. Mr. Howe is a co-founder of Collinson Howe Venture Partners, Inc. (CHVP), the predecessor firm to CHL Medical Partners, which manages \$340 million in committed capital focused on early stage investing across the entire spectrum of healthcare. Prior to co-founding CHVP in 1990, Mr. Howe was a Partner at Schroder Ventures in the United States, responsible for co-managing several venture capital and private equity funds since joining Schroder Ventures in 1984. Mr. Howe has been an active investor and board member responsible for numerous private investments in the biotechnology, diagnostics, medical device and services areas, including Innotech, Inc. (sold to Johnson & Johnson), Camitro Corporation (sold to ArQule, Inc.), Medicus Insurance Holdings (sold to NORCAL Mutual), RxCentric, Inc. (sold to Allscripts, Inc.), Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN), and still private companies Care Management Technologies, Inc., and Medmark Services, Inc. Mr. Howe is a graduate of Columbia College and the Columbia Graduate School of Business, where he has also been an Adjunct Assistant Professor since 1995, teaching venture capital management. The Board believes that Mr. Howe's qualifications, attributes and skills for service on our Board include his experience with venture-backed companies, his corporate governance experience and venture capital management experience.

Laurence R. McCarthy, Ph.D. has been a director of OpGen since July 2013. Dr. McCarthy joined Ampersand Capital Partners in 2007 as an Operating Partner and serves as Executive Chairman of Bako Pathology Services, and as a Director of Dynex and Magellan. He has served as Executive Chairman of Viracor-IBT, Executive Chairman of PrimeraDx, and as a member of the Board of Directors of Genoptix and ATS. As the President and CEO through 2004, and later as Chairman and Chief Technology Officer of Focus Diagnostics, Inc. (Focus), he built Focus from a \$2 million business to a leading esoteric lab with over \$80 million in revenues by the time of its acquisition by Quest Diagnostics Incorporated in 2006. Prior to Focus, Dr. McCarthy served in various positions at Boehringer Mannheim GmbH and Becton Dickinson & Co. He holds a Ph.D. in Microbiology from the University of New Hampshire and served on the faculties of Johns Hopkins, the University of North Carolina and Cornell University. Dr. McCarthy's greater than 40 years' experience in healthcare, his background in building and growing companies in biotechnology, microbiology, laboratory services and healthcare industries, his strong technical expertise in infectious disease, as well as his senior management experience, faculty positions and extensive board service at diagnostic and infectious disease-focused companies and academic institutions allow him to play an integral role as a member of our Board. His broad experience in many biotechnology and life science companies gives him a keen understanding and appreciation of the many regulatory and developmental issues confronting diagnostic laboratory and biotechnology companies. Dr. McCarthy is also not affiliated with any of our significant investors; he was elected to fill the independent director position on our Board.

Misti Ushio, Ph.D. has been a director of OpGen since March 2012. Dr. Ushio is a Managing Director at Harris & Harris Group, Inc. (Harris & Harris) Prior to joining Harris & Harris in 2007, Dr. Ushio worked at Merck & Co. (NYSE: MRK) for over ten years in bioprocess research & development focused on vaccines and biologics, and was a Technology Licensing Officer at Columbia University. Dr. Ushio currently serves on the board of Accelerator-NYC, TARA Biosystems, AgBiome, Senova Systems, SynGlyco, and ProMuc. Her past investments include BioVex Group, Inc. (acquired by Amgen Inc. (NASDAQ: AMGN), TetraVita (acquired by Eastman) and Ancora Pharmaceutrial (acquired by Corden Pharma). She also serves as founding CEO of TARA Biosystems. 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. Dr. Ushio's extensive board, management and operational leadership experience, her familiarity with both private and publicly traded companies in our industry and her scientific background make Dr. Ushio a vital and valuable contributor to our Board and to our Compensation Committee of which she is Chair.

The Company and the Company's preferred stock investors are parties to a Third Amended and Restated Voting Agreement, dated as of December 18, 2013, as amended, or the Voting Agreement, pursuant to which such preferred stock investors have agreed to vote their shares to elect to the board of directors one individual designated by each of Versant Ventures, CHL Medical Partners, Harris & Harris and jVen. Versant Ventures has designated Mr. Atwood, CHL Medical Partners has designated Mr. Howe, and Harris & Harris has designated Dr. Ushio. The Voting Agreement further provides that the preferred stock investors shall vote their shares to elect the Company's Chief Executive Officer to the board of directors.

No director, executive officer or control person of the Company has been involved in any legal proceeding listed in Item 401(f) of Regulation S-K in the past 10 years.

Clinical and Scientific Advisory Board

We leverage the expertise of our Clinical and Scientific Advisory Board to assist us in evaluation and strategic planning regarding the development and commercialization of our products and products in development. We also harness the clinical experience of our Clinical and Scientific Advisory Board members in the areas of MDROs, diagnosis, treatment and surveillance of antibiotic resistant organisms, and strategies for gaining acceptance among healthcare providers for our products.

Timothy J.R. Harris, Ph.D. is a science and business leader with over thirty-two years of experience guiding and leading laboratory work and scientists in a range of research areas. He is a molecular biologist and biochemist, and currently serves as the Senior Vice President for Translational Medicine and Technology at Biogen Idec Inc. (NASDAQ: BIIB). He was the Chief Technology Officer and Director of the Advanced Technology Program at SAIC-Frederick, Inc. in Maryland, which operates the National Cancer Institute's leading center for cancer and AIDS research (now Frederick National Laboratory operated by Leidos Biomedical Research, Inc.). He has served as President and Chief Executive Officer of Novasite Pharmaceuticals, Inc., and founded SGX Pharmaceuticals, Inc. (formerly Structural GenomiX Inc.) (SGX) in 1999, 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 Axyx Pharmaceuticals Inc. (formerly Sequana Therapeutics Inc.). He began his career working on animal viruses such as that causing foot-and-mouth disease and was one of the first molecular biologists at Celltech Ltd. (now UCB Pharma S.A.) in the United Kingdom. He subsequently spent five years at Glaxo Group Research Ltd. 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.

Attila Lorincz, Ph.D. is Director of the Molecular Epidemiology Laboratory at the Wolfson Institute of Preventive Medicine where his research interests include the epigenomics of prostate, breast and cervical cancers. Recently his team has developed a set of new diagnostic and prognostic cancer biomarkers based on DNA methylation assays. He is leading a new discovery initiative in next-generation deep sequencing and in elucidating the comparative epigenomic systems of human cancers. While a research fellow at the University of California, Santa Barbara, he was the first to report that yeast cdc28 is a protein kinase and the prototype of the human cell cycle cdk genes. His human papillomavirus studies began in collaboration with Nobel Laureate Harald zurHausen and this work produced clones of many novel carcinogenic HPV types. In 1990, Dr. Lorincz co-founded Digene Corp. (now QIAGEN Inc.) as Chief Scientific Officer. His research led to the Hybrid Capture (HC) series of tests. HC2 was the first HPV test to be FDA-approved for cervical pre-cancer screening and is widely regarded as the international reference standard. His subsequent research work includes the development of a simple robust HPV test for resource-limited regions and a randomized clinical trial to validate self-sampling as an efficient screening approach to prevent cervical cancer. Dr. Lorincz has written more than 240 peer-reviewed papers and is an inventor on 45 patents related to diagnostic and prognostic testing. He was the recipient of several prestigious prizes including the 1994 American Venereal Disease Association Achievement Award and THE TIMES Award 2012 for UK research project of the year. Currently he serves as the Editor-in-Chief of Expert Reviews in Molecular Diagnostics. Dr. Lorincz received a doctorate in genetics from Trinity College, University of Dublin, Ireland.

James W. Snyder, Ph.D., D(ABMM), F(AAM) is the Chief of Microbiology at the University of Louisville Hospital, and Professor of Pathology, Department of Pathology, Division of Laboratory Medicine at the University of Louisville School of Medicine. He is the recipient of the 2009 American Society for Microbiology (ASM) TREK Diagnostic ABMM/ABMLI Professional Recognition Award, for outstanding contributions to the professional recognition of clinical microbiologists and/or immunologists. He authored the ASM Cumitech publication, “Laboratory Safety, Management, and Diagnosis of Biological Agents Associated with Bioterrorism,” in 2000, and the American Academy of Microbiology colloquium report, “Bioterrorism Threats to our Future.” He is a charter member of the Laboratory Response Network (LRN) that was created by the Centers for Disease Control and Prevention (CDC), the Association of Public Health Laboratories (APHL), and the Federal Bureau of Investigation (FBI), to prepare the laboratory for bioterrorism events and emerging infectious diseases. His research interests include product and instrument evaluation, in vitro activity of new antibiotics, fungal physiology, molecular diagnostics, and ophthalmic infections and effectiveness of antibiotics. Dr. Snyder received his Ph.D. from the University of Dayton. He is a Fellow of the American Academy of Microbiology and a Colonel in the U.S. Army Reserves.

Richard P. Wenzel, M.D., M.Sc. is a professor and former chairman of the Department of Internal Medicine at Virginia Commonwealth University School of Medicine. In 2014, he received the International Federation of Infection Control’s Martin S. Favero Award for lifetime achievements and significant contributions made to the field of infection prevention and control worldwide. Considered to be one of the founders of hospital epidemiology, his writings and the individuals who trained under him have had a profound impact on infection control and prevention across the globe. He has authored more than 500 scientific publications and six textbooks. He is also the first editor-at-large of *The New England Journal of Medicine* and the founding editor of the journals *Infection Control and Hospital Epidemiology* and *Clinical Performance and Quality Health Care*. He is a member of the American Society of Clinical Investigation (ASCI), the Association of American Physicians (AAP) and a charter member of the Surgical Infections Society. Dr. Wenzel is a former president of the Society of Healthcare Epidemiology of America (SHEA) and former councilor of the Infectious Diseases Society of America (IDSA). In March 2004, he was named President-Elect (2004-06) of the International Society for Infectious Diseases, and in 2006-08 he was the President. From 2003 to 2008, he served as President of MCV Physicians, the clinical practice plan for more than 600 physicians. Dr. Wenzel was educated at Jefferson Medical College (Thomas Jefferson University) in Philadelphia and at London University, London School of Hygiene and Tropical Medicine (Epidemiology).

Board Leadership Structure and Board’s Role in Risk Oversight

Our board of directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our board of directors performs this oversight role by using several different levels of review. In connection with its reviews of the operations and corporate functions of our company, our board of directors addresses the primary risks associated with those operations and corporate functions. In addition, our board of directors reviews the risks associated with our company’s business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.

Each of our board committees also oversees the management of our risk that falls within the committee’s areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Financial Officer is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks and reporting the same to the audit committee. In connection with its risk management role, our audit committee meets privately with representatives from our independent registered public accounting firm, and privately with our Chief Financial Officer. The audit committee oversees the operation of our risk management program, including the identification of the primary risks associated with our business and periodic updates to such risks, and reports to our board of directors regarding these activities.

Board Committees

Our board of directors has established an audit committee and a compensation committee, each of which operates pursuant to a separate charter adopted by our board of directors. The composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, the NASDAQ Stock Market and the Securities and Exchange Commission, or SEC, rules and regulations.

Audit Committee

Brian Atwood, Timothy Howe and Evan Jones currently serve on the audit committee, which is chaired by Brian Atwood. Our board of directors has determined that each member of the audit committee is “independent” for audit committee purposes as that term is defined in the rules of the SEC and the applicable NASDAQ Stock Market rules, except for Mr. Jones, who is our Chief Executive Officer. The audit committee’s responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the audit plan with the independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- reviewing the Company’s periodic reports to be filed with the SEC;
- recommending, based upon the audit committee’s review and discussions with management and the independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- overseeing our compliance with applicable legal and regulatory requirements;
- reviewing all related party transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

Compensation Committee

Misti Ushio, Timothy Howe and Lawrence McCarty currently serve on the compensation committee, which is chaired by Misti Ushio. Under NASDAQ Stock Market rules, we are permitted to phase in our compliance with the independent compensation committee requirements set forth in NASDAQ Marketplace Rule 5605(d). Our board of directors has determined that each of its members is “independent” as that term is defined in the applicable NASDAQ Stock Market rules. The compensation committee’s responsibilities include:

- annually reviewing and recommending to our board of directors corporate goals and objectives, and determination of the achievement thereof, relevant to the compensation of our Chief Executive Officer and other executive officers;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and recommending to our board of directors the compensation of our Chief Executive Officer;
- determining, or reviewing and recommending to our board of directors for approval, the compensation of our other executive officers;
- reviewing and establishing our overall management compensation philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential current compensation advisors in accordance with the independence standards identified in the applicable NASDAQ Stock Market rules;
- retaining and approving the compensation of any compensation advisors;
- reviewing and approving, or reviewing and recommending to our board of directors for approval, our policies and procedures for the grant of equity-based awards;
- determining or reviewing and making recommendations to our board of directors with respect to director compensation;
- preparing the compensation committee report required by SEC rules to be included in our annual proxy statement;
- reviewing and discussing with management the compensation discussion and analysis to be included in our annual proxy statement or Annual Report on Form 10-K; and
- reviewing and discussing with our board of directors corporate succession plans for the Chief Executive Officer and other key officers.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Corporate Governance

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

Limitation of Liability

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, or controlling persons, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

EXECUTIVE COMPENSATION

Compensation Tables

Summary Compensation Table—2013 and 2012 Fiscal Years

The following table presents information regarding the total compensation awarded to, earned by, and paid during the fiscal years ended December 31, 2013 and December 31, 2012 to our chief executive officer and the two most highly-compensated executive officers (other than the chief executive officer) who were serving as executive officers at the end of the year ended December 31, 2013, and to one individual who served as our chief executive officer until October 25, 2013. These individuals are our named executive officers for 2013.

Name and Principal Position	Year	Salary	Bonus	Stock Awards (1)	Option Awards (2)	NonEquity Incentive Plan Compensation	All Other Compensation	Total
Evan Jones President and Chief Executive Officer (3)	2013	\$ 12,500	-	-	-	-	-	12,500
	2012	\$ 100,000	-	-	-	-	-	100,000
C. Eric Winzer, Executive Vice President, Chief Financial Officer	2013	\$ 260,000	-	21,667	6,235	-	1,600 (4)	289,502
	2012	\$ 256,923	-	-	1,853	-	5,000 (4)	263,776
Thomas M. Ross, Senior Vice President, Commercial Operations (5)	2013	\$ 255,000	-	21,250	2,545	-	1,177 (4)	279,972
	2012	\$ 29,423	-	-	4,340	-	-	33,763
C. Douglas White, former President and Chief Executive Officer (6)	2013	\$ 262,299	-	-	-	-	16,946 (7)	279,245
	2012	\$ 335,385	-	-	17,972	-	5,000 (4)	358,357

- (1) Represents restricted preferred stock units awarded to each of Mr. Winzer and Mr. Ross as compensation for revising their change in control and severance arrangements in November 2013.
- (2) Reflects the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. Assumptions made in the calculation of these amounts are described in Note 8 to the Company's audited consolidated financial statements, included in this prospectus.
- (3) Mr. Jones has served as our Executive Chairman of the Board since January 2011, and as our President, Chief Executive Officer and Chairman of the Board since October 25, 2013. During 2012 and the first quarter of 2013, he received compensation for serving as our Executive Chairman. When he assumed the role of Chief Executive Officer, he agreed to receive compensation through the issuance of restricted stock units, from October 25, 2013 to June 30, 2014. The restricted stock units were issued to him in March 2014.
- (4) Represents a 401(k) match for the periods indicated.
- (5) Mr. Ross left the Company in September 2014.
- (6) Mr. White was President and Chief Executive Officer from June 2010 until October 25, 2013.
- (7) Represents a 401(k) plan match (\$2,014) and payment of accrued and unused paid time off at the time of departure (\$14,932).

Employment Agreements with Our Named Executive Officers

We have entered into an employment agreement with each of the named executive officers. These employment agreements provide for “at will” employment.

Evan Jones - On March 3, 2014, we entered into an amended and restated employment agreement with Evan Jones, our President and Chief Executive Officer. The agreement provides Mr. Jones to serve as our President and Chief Executive Officer at the equivalent of seventy percent (70%) of a full-time commitment, with an initial base salary at an annual adjusted rate of \$190,000 and annual bonus opportunities based on performance goals determined by our board, with a maximum target of thirty-five percent (35%) of annual base salary. Mr. Jones agreed to accept, in lieu of payment of his base salary in cash, shares of the Company’s common stock as compensation for his services from October 25, 2013 until June 30, 2014. In addition, Mr. Jones received an award of stock options to acquire 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. Under the 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.

C. Eric Winzer – On January 19, 2011, we entered into an executive change in control and severance benefits agreement with Eric Winzer, our Chief Financial Officer. The agreement was amended on November 1, 2013. Under such agreement, upon any termination of Mr. Winzer’s employment without “cause” that constitutes a “separation from service” under Section 409A of the Internal Revenue Code, Mr. Winzer will receive severance compensation equal to his base salary at the time of termination for six (6) months. In addition, if a change in control of the Company occurs, and Mr. Winzer is an employee on the date of such change in control, 50% of the then-unvested portion of any outstanding stock options made under the 2008 Plan on or prior to December 31, 2011 will vest and become exercisable. In addition, if such outstanding unvested stock options granted prior to December 31, 2011, or the 2011 Awards, are not continued, assumed or substituted in such change of control transaction, or if Mr. Winzer’s employment is terminated without cause in the six months after the effective date of the change in control, 100% of such 2011 Awards will become vested and exercisable. In addition, Mr. Winzer can terminate his agreement for “good reason” within twelve (12) months after a change in control and be entitled to his severance payments and acceleration of his 2011 Awards, to the extent not vested. The agreement continues in full force and effect unless and until the Company terminates the Agreement by providing Mr. Winzer with sixty (60) days prior written notice. The agreement includes standard confidentiality, general release and other provisions.

Thomas M. Ross – On November 1, 2013, we entered into an executive change in control and severance benefits agreement with Tom Ross, our Senior Vice President, Commercial Operations. Under such agreement, upon any termination of Mr. Ross’ employment without “cause” that constituted a “separation from service” under Section 409A of the Internal Revenue Code, Mr. Ross would have received severance compensation equal to his base salary at the time of termination for six (6) months. In addition, if a change in control of the Company occurred, and Mr. Ross had been an employee on the date of such change in control, 100% of the then-unvested portion of any outstanding stock options made under the 2008 Plan would have vested and become exercisable. Mr. Ross voluntarily terminated his employment with the Company in September 2014 and his agreement terminated at that time.

C. Douglas White – On June 2, 2010, we entered into an employment agreement with Doug White to serve as our President and Chief Executive Officer, and we entered into an executive change in control and severance agreement, or severance agreement, with Mr. White. Under the employment agreement, Mr. White was entitled to receive a base salary of \$325,000 per year, an annual incentive bonus opportunity up to thirty-five percent (35%) of his base salary, and stock options, granted under the 2008 Plan, to acquire four percent (4%) of the fully diluted shares following the closing of the Company’s Series B Convertible Preferred Stock in 2011, or the 2011 Award. Under the severance agreement, upon a change in control, fifty percent (50%) of the unvested portion of the 2011 Award would have vested and become exercisable. In addition, any termination of Mr. White’s employment without “cause” or for “good reason” would have entitled Mr. White to receive severance compensation equal to his base salary at the time of termination for twelve (12) months, and the remainder of the 2011 Award would have vested and become exercisable. Mr. White resigned effective October 25, 2013, and his employment agreement and severance agreement terminated at that time.

Definitions

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

- “cause” means mean: (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 executive’s consent: (i) a 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—2013

The following table summarizes, for each of the named executive officers, the number of shares of common stock underlying outstanding stock options held as of December 31, 2013. On December 18, 2013, we effected a 1 for 790.5407 reverse stock split of our common stock. All references in this table have been adjusted to reflect such reverse stock split.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2013										
OPTION AWARDS						STOCK AWARDS				
Name	(1) Number of Securities Underlying Unexercised Options Exercisable	(1) Number of Securities Underlying Unexercised Options	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options	Option Exercise Price (\$)	Option Expiration Date	(2) Number of Shares of Stock that have not Vested	(3) 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	89	—	—	79.05	07/23/2018	—	—	—	—	
(4)	1,495	352	—	110.68	09/21/2020	—	—	—	—	
C. Eric Winzer	253	—	—	79.05	06/15/2019	21,667	21,667	—	—	
(5)	157	33	—	79.05	04/15/2020	—	—	—	—	
	137	—	—	110.68	02/15/2021	—	—	—	—	
	234	114	—	110.68	02/15/2021	—	—	—	—	
	178	234	—	7.91	03/23/2022	—	—	—	—	
		443	—	7.91	02/12/2023	—	—	—	—	
		949	—	7.91	07/25/2023	—	—	—	—	
Thomas M. Ross	20	44	—	7.91	07/19/2022	21,250	21,250	—	—	
(6)	229	689	—	7.91	10/25/2022	—	—	—	—	
	—	253	—	7.91	02/12/2023	—	—	—	—	
	—	317	—	7.91	07/25/2023	—	—	—	—	
C. Douglas White	2,485	—	—	110.68	02/15/2021	—	—	—	—	
(7)	3,518	—	—	110.68	02/15/2021	—	—	—	—	
	199	—	—	110.68	02/15/2021	—	—	—	—	
	1,496	—	—	7.91	03/23/2022	—	—	—	—	

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

(2) Represents restricted preferred stock units awarded to each of Mr. Winzer and Mr. Ross as compensation for revising their change in control and severance arrangements in November 2013. The restricted preferred stock units awarded to Mr. Ross were forfeited in September 2014 when he resigned from the Company. The restricted preferred stock units awarded to Mr. Winzer on November 1, 2013 will vest upon the lapse of forfeiture restrictions on December 18, 2014.

(3) Based on fair market value of the Company's common stock on December 31, 2013, of \$0.05 per share, and of the Company's Series A Convertible Preferred Stock on December 31, 2013, of \$1.00 per share.

- (4) 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) and February 15, 2011 (1,847 shares). On April 24, 2014, Mr. Jones was awarded a non-qualified stock option to acquire 174,235 shares of common stock, with the standard vesting schedule, an exercise price of \$0.05 per share (representing the fair market value of the common stock on the date of grant) and expiring on April 24, 2024.
- (5) The stock option awards made to Mr. Winzer have the vesting schedule set forth in footnote (1) and were awarded on June 15, 2009 (253 shares), April 15, 2010 (190 shares), February 15, 2011 (two awards, 137 and 348 shares, respectively), March 23, 2012 (412 shares), February 12, 2013 (443 shares) and July 25, 2013 (949 shares). On April 24, 2014, Mr. Winzer was awarded an incentive stock option to acquire 13,352 shares of common stock, with the standard vesting schedule, an exercise price of \$0.05 per share (representing the fair market value of the common stock on the date of grant) and expiring on April 24, 2024.
- (6) Mr. Ross received stock option awards on July 19, 2012 (64 shares), October 25, 2012 (918 shares), February 12, 2013 (253 shares) and July 25, 2013 (316 shares). The vesting schedule for all stock option awards was as set forth in footnote (1). Mr. Ross left the Company in September 2014 and has not, to date, exercised any vested stock options.
- (7) Mr. White received three stock option awards on February 15, 2011 (for 3,615, 3,774 and 199 shares, respectively), and two stock option awards on March 23, 2012 (for 1,247 and 2,743 shares, respectively), Mr. White was vested in 7,698 stock options on October 25, 2013, upon his departure from the Company. Mr. White did not exercise any vested stock options and all such vested stock options expired and went back into the 2008 Plan in January 2014.

Director Compensation

The following table presents the total compensation for each person who served as a member of our board of directors during 2013, other than Mr. Jones. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2013. Compensation paid to Mr. Jones, who is also our President and Chief Executive Officer, is described above under “Summary Compensation Table—2013 and 2012.” The Board of Directors intends to approve a director compensation policy to be effective following the successful consummation of this offering.

Director Compensation

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards (\$)	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total(\$)
Brian G. Atwood	—	—	—	—	—	—	—
Timothy Howe	—	—	—	—	—	—	—
Lawrence R. McCarthy Ph.D.	\$ 4,647	—	(1)	—	—	—	\$ 4,647
Misti Ushio Ph.D.	—	—	—	—	—	—	—

- (1) In addition to serving on our Board of Directors, Dr. McCarthy serves on our Scientific Advisory Board. Pursuant to his consulting agreement, he receives compensation of \$10,000 per year, and stock option awards sufficient to maintain his ownership of our capital stock at 0.33% on a fully diluted basis. On July 25, 2013, Dr. McCarthy received a stock option to acquire 1,450 shares of common stock. The option value was \$6,530, the exercise price was \$7.91 per share and the options will vest in September 2017. In addition, as of the date of this prospectus, Dr. McCarthy holds stock options to acquire an aggregate of 16,610 shares of our common stock.

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

2008 Plan

Our 2008 Plan was approved by our board of directors and stockholder 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 503,347 shares of our common stock are reserved for issuance under the 2008 Stock Option Plan. As of September 30, 2014, 410,870 shares of our common stock were subject to outstanding option awards and 51,227 shares of our common stock remain available for future issuance under the 2008 Plan.

The Compensation Committee of our Board of Directors administers the 2008 Plan. Subject to the terms of the 2008 Plan, the committee has the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards. Awards under the 2008 Plan may be granted to key employees, and directors of, and consultants to and advisors to the Company or its affiliates. Awards may also be made to members of our Board of Directors.

The 2008 Plan provides for the grant of stock options and restricted stock awards. The committee determines 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 committee determines the conditions and restrictions and purchase price, if any, for grants or sales or restricted stock to plan participants. The committee may also at any time accelerate the vesting or acceleration 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 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.

The committee may amend the 2008 Plan or any outstanding award at any time for any purpose permitted by law, and may at any time terminate the 2008 Plan as to any future grants of awards; provided, that otherwise expressly provided in the 2008 Plan, no amendment may impair the rights of a participant without the affected participant's consent unless the committee expressly reserved the right to do so at the time of an award.

Bonus Plan

The Board of Directors approves a cash-based incentive compensation bonus plan for management within the first 90 days of each fiscal year. The Board, upon the recommendations of management, selects Company-specific performance goals that must be achieved in order for such bonuses to be payable. In 2013, the incentive compensation bonus plan consisted of performance goals related to the sale of Argus Systems and MapIt Services, establishment of a clinical laboratory meeting the CLIA Lab requirements, entry into collaboration arrangements with third parties and initial development of our MDRO assays and bioinformatics capabilities. The board of directors determined that the performance goals for 2013 were not achieved, therefore no named executive officer received a bonus for 2013.

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a tax-advantaged basis. All participants' interests in their contributions are 100% vested when contributed. Pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Until April 2013, the Company matched 50% of an employee's contributions to the 401(k) plan up to 4%. In April 2013, the Company match was discontinued. The retirement plan is intended to qualify under Sections 401(a) and 501(a) of the Code.

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 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. The Supply Agreement terminates in March 2014. Evan Jones, our Chief Executive Officer and Chair of the Board, is a director of Fluidigm. The approximate dollar value of the amount involved in the transaction with Fluidigm under the Supply Agreement during 2014 was \$121,000. 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.

Sales and Purchases of Securities

In February 2011, as part of a continuation of an offering that began in 2010, the Company sold 7,042,253 shares of its Series B Convertible Preferred Stock to existing and new investors at a purchase price of \$0.355 per share. Investors participating in the February 2011 offering included affiliates of Evan Jones and Brian Atwood, who were, at the time, a member of the Company's board of directors.

In November and December 2011, the Company issued convertible notes in an aggregate principal amount of \$2,132,651 and related warrants to purchase common stock to existing investors. Investors participating in the offering included affiliates of Evan Jones and Brian Atwood, each of whom was at the time a member of the Company's board of directors.

In March, April, October and December 2012, the Company sold an aggregate of 126,802,946 shares of its Series C Convertible Preferred Stock to existing and new investors at a purchase price of \$0.138 per share. Investors participating in the offering included affiliates of Evan Jones, Misti Ushio and Brian Atwood, each of whom was at the time a member of the Company's board of directors.

In December 2013, the Company effected a recapitalization whereby all of the then existing preferred stock was converted into common stock, all accrued and unpaid cumulative dividends on the preferred stock were cancelled, and a 1 for 790.5407 reverse stock split was effected on all outstanding shares of common stock. In connection with the recapitalization, the Company issued to existing investors convertible notes in an aggregate principal amount of \$2,000,000 that were convertible into a new Series A Convertible Preferred Stock. Investors participating in the offering included affiliates of Evan Jones, Brian Atwood, Tim Howe and Misti Ushio, each of whom was at the time a member of the Company's board of directors. These convertible notes were converted into shares of Series A Convertible Preferred Stock by all of the investors in December 2013.

In February and April 2014, the Company sold 2,000,000 shares of its Series A Convertible Preferred Stock to existing investors at a purchase price of \$1.00 per share. Investors participating in the offering included affiliates of Evan Jones, Brian Atwood, Misti Ushio and Timothy Howe, each of whom was at the time a member of the Company's board of directors.

In July, August and September 2014, the Company issued to existing investors convertible notes in an aggregate principal amount of \$1,500,000 that were convertible into Series A Convertible Preferred Stock. Investors participating in the offering included affiliates of Evan Jones, Brian Atwood and Misti Ushio, each of whom was at the time a member of the Company's board of directors.

Holders of our convertible preferred stock and convertible notes are entitled to certain registration rights following this offering with respect to the common stock issued or issuable upon conversion of the convertible preferred stock, which conversion will occur automatically upon the closing of this offering. See “Description of Capital Stock–Investor Rights Agreement” for additional information.

Consulting Arrangements

Dr. McCarthy, in addition to serving on our board of directors, provides consulting services as a member of our scientific advisory board. Pursuant to a July 2013 agreement between Dr. McCarthy and the Company, Dr. McCarthy advises the Company in the areas of Whole Genome Mapping, DNA sequence analysis and the Company’s surveillance and diagnostic products for hospital acquired infections. Dr. McCarthy’s term on the scientific advisory board is for one (1) year, commencing on July 1, 2013, and will automatically renew for additional one-year periods unless written notice of termination is provided by either party at least forty-five (45) days prior to the termination date. In consideration for such services, we have agreed to pay Dr. McCarthy an annual fee of \$10,000, payable in equal quarterly installments of \$2,500 on the last day of each calendar quarter. Under this and a predecessor agreement, Dr. McCarthy earned \$11,250 during the fiscal year ended December 31, 2013.

Indemnification Agreements

We have entered into agreements to indemnify our directors and executive officers to the maximum extent allowed under Delaware law. Subject to the provisions of these agreements, these agreements, among other things, provide for indemnification of these individuals for certain expenses (including attorneys’ fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of us or that person’s status as a member of our board of directors.

Policies for Approval of Related Party 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, or each, a related party, must be approved by our Audit Committee.

PRINCIPAL STOCKHOLDERS

The following table and footnotes set forth certain information known to us regarding beneficial ownership of our capital stock as of October 31, 2014, as adjusted to reflect the sale of common stock offered by us in this offering, for :

- each person known by us to be the beneficial owner of more than 5% of our capital stock;
- our named executive officers;
- each of our directors; and
- all executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Except as noted by footnote, and subject to community property laws where applicable, we believe based on the information provided to us that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

On December 18, 2013, we effected a 1 for 790.5407 reverse stock split of our common stock. All references below to shares, stock options and warrants outstanding have been adjusted to reflect such reverse stock split. The table lists applicable percentage ownership based on 5,993,041 shares of common stock outstanding as of October 31, 2014 and also lists applicable percentage ownership based on shares of common stock assumed to be outstanding after the closing of the offering. Options and warrants to purchase shares of common stock that are exercisable within 60 days of October 31, 2014 are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person's ownership percentage.

Name and Address of Beneficial Owner ⁽¹⁾	Number of Shares Beneficially Owned	Percentage of Outstanding Common Stock	
		Before Offering	After Offering
5% Stockholders			
jVen Capital, LLC ⁽²⁾	1,810,132	30.0%	
Entities affiliated with Versant Ventures ⁽³⁾	1,643,764	27.2%	
Harris & Harris Group, Inc. ⁽⁴⁾	848,920	14.1%	
Entities affiliated with CHL Medical Partners ⁽⁵⁾	383,155	6.4%	
Entities affiliated with Mason Wells ⁽⁶⁾	341,069	5.7%	
Directors and Executive Officers			
Evan Jones ⁽⁷⁾	1,961,769	32.5%	
Brian G. Atwood ⁽⁸⁾	1,643,764	27.2%	
Timothy Howe ⁽⁹⁾	383,155	6.4%	
Laurence R. McCarthy, Ph.D. ⁽¹⁰⁾	4,361	*	*
Misti Ushio, Ph.D. ⁽¹¹⁾	848,920	14.1%	
C. Eric Winzer ⁽¹²⁾	26,795	*	
Thomas M. Ross ⁽¹³⁾	528	*	*
C. Douglas White ⁽¹⁴⁾	-	*	*
Directors and Executive Officers as a group (12 persons) ⁽¹⁵⁾	4,903,570	80.8%	

* Less than 1%

- (1) Unless otherwise note, the business address of each beneficial owner is c/o OpGen, Inc., 708 Quince Orchard Road, Suite 160, Gaithersburg, Maryland 20878.
- (2) Includes 130,640 shares of common stock acquired upon the lapse of forfeiture restrictions on a like number restricted stock units, 1,059,213 shares of common stock issuable upon the conversion of 1,059,213 shares of Series A Preferred Stock, 749,366 shares of common stock issuable upon the conversion of convertible promissory notes in the aggregate principal amount of \$749,366 and warrants to purchase 1,553 shares of common stock. As the managing member of jVen Capital, LLC, Evan Jones has voting and investment authority over the shares held by that entity.
- (3) Includes 72,166 shares of common stock, 1,153,229 shares of common stock issuable upon the conversion of 1,153,229 shares of Series A Preferred Stock, 402,348 shares of common stock issuable upon conversion of a convertible promissory note in the principal amount of \$402,348 and warrants to purchase 6,368 shares of common stock owned by Versant Venture Capital III, L.P. Also includes 427 shares of common stock, 6,810 shares of common stock issuable upon the conversion of 6,810 shares of Series A Preferred Stock, 2,377 shares of common stock issuable upon conversion of a convertible promissory note in the principal amount of \$2,377 and warrants to purchase 39 shares of common stock owned by Versant Side Fund III, L.P. The address for the Versant Venture funds is One Sansome Street, Suite 3630, San Francisco, CA 94104. As the managing directors of Versant Ventures III, LLC, Brian G. Atwood; Bradley J. Bolzon, Ph.D.; Samuel D. Colella; Ross A. Jaffe, M.D.; William J. Link, Ph.D.; Barbara N. Lubash; Donald B. Milder; Rebecca B. Robertson; and Charles H. Warden share voting and investment authority over the shares held by both Versant Venture Capital III, L.P. and Versant Side Fund III, L.P.
- (4) Includes 29,883 shares of common stock, 610,017 shares of common stock issuable upon the conversion of 610,017 shares of Series A Preferred Stock and 209,020 shares of common stock issuable upon conversion of a convertible promissory note in the principal amount of \$209,020. The address for Harris & Harris Group, Inc. is 1450 Broadway, 24th Floor, New York, NY 10018. As the managing directors of Harris & Harris Group, Inc., Douglas W. Jamison; Daniel B. Wolfe, Ph.D.; Alexei A. Andreev, Ph.D.; and Misti Ushio, Ph.D. share voting and investment authority over the shares held by Harris & Harris Group, Inc.
- (5) Includes 51,163 shares of common stock, 294,506 shares of common stock issuable upon the conversion of 294,506 shares of Series A Preferred Stock and warrants to purchase 6,713 shares of common stock owned by CHL Medical Partners III, L.P. Also includes 4,654 shares of common stock, 25,505 shares of common stock issuable upon the conversion of 25,505 shares of Series A Preferred Stock and warrants to purchase 614 shares of common stock owned by CHL Medical Partners III Side Fund, L.P. The address for the CHL Medical Partners funds is 1055 Washington Boulevard, 6th Floor, Stamford, CT 06901. Voting and investment authority over the shares held by CHL Medical Partners III, L.P. and CHL Medical Partners III Side Fund, L. P. is exercised by Collinson Howe & Lennox II, LLC in its role as general partner and investment advisor to the limited partnerships. The members of Collinson Howe & Lennox II, LLC are Jeffrey J. Collinson; Myles D. Greenberg, M.D.; Timothy F. Howe; Ronald W. Lennox; and Gregory M. Weinhoff, M.D.
- (6) Includes 17,805 shares of common stock and warrants to purchase 3,264 shares of common stock owned by Mason Wells Biomedical Fund I, Limited Partnership. Also includes 320,000 shares of common stock issuable upon conversion of 320,000 shares of Series A Preferred Stock owned by Mason Wells OpGen Holdings, Inc. The address of Mason Wells is 411 East Wisconsin Avenue, Suite 1280, Milwaukee, WI 53202. As the managing director of the Mason Wells Biomedical Fund I, Limited Partnership and Mason Wells OpGen Holdings, Inc., John Byrnes has voting and investment authority over the shares held by the Mason Wells Biomedical Fund I, Limited Partnership and Mason Wells OpGen Holdings, Inc.
- (7) Includes 130,640 shares of common stock and vested stock options to purchase 1,936 shares of common stock, which are directly owned. Also includes 19,011 shares of common stock issuable upon the conversion of 19,011 shares of Series A Preferred Stock and warrants to purchase 50 shares of common stock owned by his wife. Also includes 1,810,132 shares of common stock, on an as converted and as exercised basis, beneficially owned by jVen Capital, LLC, of which Mr. Jones is managing member (see footnote 2 above).
- (8) Consists of 1,643,764 shares of common stock, on an as converted and as exercised basis, beneficially owned by affiliates of Versant Ventures, of which Mr. Atwood is a Managing Director (see footnote 3 above).
- (9) Consists of 383,155 shares of common stock, on an as converted and as exercised basis, beneficially owned by affiliates of CHL Medical Partners, of which Mr. Howe is a Partner (see footnote 5 above).
- (10) Consists of shares that can be acquired upon the exercise of vested stock options.
- (11) Consists of 848,920 shares of common stock, on an as converted and as exercised basis, beneficially owned by Harris & Harris Group, Inc. of which Dr. Ushio is a Managing Director (see footnote 4 above).
- (12) Includes 127 shares of common stock, 21,667 shares of common stock issuable upon the conversion of 21,667 restricted stock units to acquire shares of Series A Preferred Stock and vested options to purchase 5,001 shares of common stock.
- (13) Consists of vested options to purchase 528 shares of common stock. Mr. Ross left the Company in September 2014, and his outstanding vested stock options will terminate, if not exercised, on December 26, 2014.
- (14) Mr. White left the Company in October 2013.
- (15) In addition to the beneficial ownership described in footnotes (2) through (14), includes vested stock options to purchase 34,278 shares of common stock held by other executive officers.

DESCRIPTION OF CAPITAL STOCK

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.

General

Prior to this offering, there has not been an established public trading market for our common stock.

Currently, our authorized capital stock consists of 7,500,000 shares of common stock, par value \$0.01 per share, and 6,000,000 shares of preferred stock, par value \$0.01 per share, all of which shares of preferred stock are designated as Series A Preferred Stock. As of September 30, 2014, 5,862,401 shares of our common stock (including shares to be acquired on the conversion of outstanding shares of Series A Preferred Stock and the conversion of Convertible Notes), were outstanding and held by 79 stockholders of record. In addition, as of September 30, 2014, we had outstanding options to purchase 410,870 shares of our common stock, at a weighted average exercise price of \$1.13 per share, 7,143 of which were exercisable, and 130,640 restricted stock units issued to our Chief Executive Officer in March 2014.

The following is a summary of the rights of our common stock and preferred stock and certain provisions of our restated certificate of incorporation and amended and restated bylaws, as they will be in effect upon the closing of this offering. For more detailed information, please see our restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is part.

Immediately following the closing of this offering, our authorized capital stock will consist of _____ shares, with a par value of \$0.01 per share, of which:

- _____ shares will be designated as common stock; and
- _____ shares will be designated as preferred stock.

Common Stock

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. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Our certificate of incorporation in effect prior to the closing of this offering provides that, upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act covering the offer and sale of our common stock with gross cash proceeds to us (before underwriting discounts, commissions and fees) of at least \$30.0 million, and a purchase price per share of at least \$4.00, each share of preferred stock shall automatically be converted into shares of common stock at the then-effective conversion price for such series upon the closing of this offering. Accordingly, upon the closing of this offering, each outstanding share of our Series A Preferred Stock will be converted into one share of common stock, or an aggregate of 3,999,864 shares of common stock, and Convertible Notes, if converted into Series A Preferred Stock will be converted into one share of common stock for each \$1.00 principal amount of the Convertible Notes, or 1,500,000 shares of common stock.

Following the conversion of each share of our preferred stock into shares of common stock, our certificate of incorporation will be amended and restated to delete all references to the prior series of preferred stock and our board of directors will have the authority, without further action by our stockholders, to issue from time to time up to 5,000,000 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 shares of preferred stock.

Registration Rights

The holders of our registrable shares, as described in the Third Amended and Restated Investors' Rights Agreement between us and the holders of these shares, or the investors' rights agreement, or their permitted transferees are entitled to rights with respect to the registration of these shares under the Securities Act of 1933, as amended, or the Securities Act. 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.

Demand Registration Rights

As of October 31, 2014, the holders of 5,875,400 shares of our common stock or their permitted transferees, are entitled to demand registration rights. Under the terms of the investors' rights agreement, we will be required, upon the written request of holders of at least 20% of the then outstanding registrable shares, to use our commercially reasonable efforts to effect the registration of all or a portion of these shares for public resale. We are required to effect only two registrations pursuant to this provision of the investors' rights agreement. A demand for registration may not be made until 180 days after the completion of this offering.

Short Form Registration Rights

As of October 31, 2014, the holders of 5,875,400 shares of our common stock or their permitted transferees are also entitled to short form registration rights. If we are eligible to file a registration statement on Form S-3, upon the written request of these holders of our common stock to sell registrable securities at an aggregate price of at least \$2.0 million, we will be required to use our best efforts to effect a registration of such shares. We are required to effect only two registrations in any 12 month period pursuant to this provision of the investors' rights agreement.

Piggyback Registration Rights

As of September 30, 2014, the holders of 5,875,400 shares of our common stock or their permitted transferees are entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions, we and the underwriters may limit the number of shares included in the underwritten offering if the underwriters believe that including these shares would adversely affect the offering.

Indemnification

Our 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.

Expiration of Registration Rights

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.

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.

No Written Consent of Stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only 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 and a majority of the outstanding shares of each class entitled to vote thereon as a class, 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 75% of the outstanding shares entitled to vote on the amendment, and not less than 75% 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 75% 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 certificate of incorporation provides for 5,000,000 authorized shares of preferred stock. 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, 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.

Exchange Listing

We intend to apply to list our common stock on the NASDAQ Capital Market prior to the completion of this offering.

SHARES ELIGIBLE FOR FUTURE SALE

Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, the sale of a portion of our shares will be limited after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of September 30, 2014, upon the completion of this offering, shares of our common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options. Except for approximately shares subject to lock-up agreements, all of our outstanding shares will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below.

Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately shares immediately after this offering assuming no exercise of the underwriters' option to purchase additional shares, based on the number of shares outstanding as of September 30, 2014; or
- the average weekly trading volume of our common stock on The NASDAQ Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Provided, in each case, which we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701.

Lock-up Agreements

In connection with this offering we and our officers, directors, substantially all of our stockholders and option holders have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of our common stock or securities convertible into or exchangeable for shares of common stock, enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock or such other securities, file or cause to be filed a registration statement covering shares of common stock or any securities that are convertible into, exchangeable for, or represent the right to receive, common stock or any substantially similar securities, or publicly disclose the intention to do any of the foregoing, during the period from the date of this prospectus continuing through the date days after the date of this prospectus, except with the prior written consent of the underwriter. This agreement does not apply to the issuance by us of shares under any existing employee benefit plans. These agreements are subject to certain exceptions, as set forth in “Underwriters”.

Registration Rights

As of September 30, 2014, the holders of 5,875,400 shares of common stock or their transferees are entitled to various rights with respect to registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See “Description of Capital Stock—Registration Rights” for additional information.

Stock Option Plans

We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to options outstanding or reserved for issuance under our stock plans. We expect to file this registration statement as soon as practicable after this offering. However, none of the shares registered on Form S-8 will be eligible for resale until the expiration of the lock-up agreements to which they are subject.

CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary of certain material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of shares of our common stock issued pursuant to this offering. This summary deals only with shares of our common stock acquired by a stockholder in this offering and that are held as a capital asset within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or the Code. This summary does not address the U.S. federal income tax considerations applicable to a stockholder that is subject to special treatment under U.S. federal income tax laws, including: a dealer in securities or currencies; a financial institution; a regulated investment company; a real estate investment trust; a tax-exempt organization; an insurance company; a person holding our common stock as part of a hedging, integrated, conversion or straddle transaction or a person deemed to sell our common stock under the constructive sale provisions of the Code; a trader in securities that has elected the mark-to-market method of accounting; an entity that is treated as a partnership for U.S. federal income tax purposes; a person that received our common stock in connection with services provided to the company or any of its affiliates; a U.S. person whose “functional currency” is not the U.S. dollar; a “controlled foreign corporation”; a “passive foreign investment company”; or a U.S. expatriate.

This summary is based upon provisions of the Code, and applicable Treasury regulations promulgated or proposed thereunder, rulings and judicial decisions, all as in effect as of the date hereof. Those authorities may be changed, perhaps with retroactive effect, or may be subject to differing interpretations, which could result in U.S. federal income tax consequences different from those discussed below. This summary does not address all aspects of U.S. federal income tax, does not address all tax considerations that may be relevant to stockholders in light of their personal circumstances and does not address any state, local, foreign, gift, estate or alternative minimum tax considerations.

For purposes of this discussion, a “U.S. holder” is a beneficial holder of our common stock that is: an individual citizen or resident of the United States for U.S. federal income tax purposes; a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia; an estate the income of which is subject to U.S. federal income taxation regardless of its source; or a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (as defined in the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

For purposes of this discussion, a “non-U.S. holder” is a beneficial holder of our common stock that is for U.S. federal income tax purposes an individual, corporation, estate or trust and is not a U.S. holder.

If a partnership (or an entity or arrangement that is treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a person treated as a partner in the partnership for U.S. federal income tax purposes generally will depend upon the status of the partner and the activities of the partnership. Partnerships and other entities that are treated as partnerships for U.S. federal income tax purposes and persons holding our common stock through a partnership or other entity treated as a partnership for U.S. federal income tax purposes are urged to consult their own tax advisors.

This summary is for general information only and is not intended to be tax advice. Holders of our common stock are urged to consult their own tax advisors concerning the tax considerations related to the acquisition, ownership and disposition of our common stock in light of their particular circumstances, as well as any tax considerations arising under the laws of any other jurisdiction, including any state, local and foreign income and other tax laws.

U.S. Holders

The following discussion is a summary of certain U.S. federal income tax considerations relevant to a U.S. holder of our common stock.

Distributions

Distributions with respect to our common stock, if any, generally will be includible in the gross income of a U.S. holder as ordinary dividend income to the extent of our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. Any portion of a distribution in excess of current and accumulated earnings and profits will be treated as a non-taxable return of capital, up to the U.S. holder’s adjusted tax basis in its shares of our common stock with respect to which the distribution was made. Any such distribution in excess of the U.S. holder’s adjusted tax basis in its shares will be treated as capital gain and as long-term capital gain if the U.S. holder’s holding period exceeds one year. If certain requirements are met (including certain holding period requirements), distributions constituting dividends paid to non-corporate U.S. holders generally will qualify for the reduced tax rate on qualified dividend income.

Distributions constituting dividends for U.S. federal income tax purposes that are paid to U.S. holders that are corporations may qualify for the 70% dividends received deduction, or DRD, which is generally available to corporations that own less than 20% of the voting power or value of the outstanding stock of the distributing corporation. A U.S. holder that is a corporation holding 20% or more of the distributing corporation (by vote and value) may be eligible for an 80% DRD with respect to any such dividends. No assurance can be given that we will have sufficient earnings and profits (as determined for U.S. federal income tax purposes) to cause any distributions to be treated as dividends eligible for a DRD. In addition, a DRD is available only if certain other requirements (including certain holding period requirements) are satisfied, and a DRD may be subject to limitations in certain circumstances, which are not discussed herein.

Sale, Exchange, Redemption or Certain Other Taxable Dispositions of Our Common Stock

A U.S. holder of shares of our common stock generally will recognize gain or loss on the taxable sale, exchange, redemption (provided the redemption is treated as a sale or exchange), or other taxable disposition of such shares in an amount equal to the difference between such U.S. holder's amount realized on such disposition and such U.S. holder's adjusted tax basis in its shares of our common stock disposed of. A U.S. holder's amount realized generally will equal the amount of cash and the fair market value of any property received in consideration for the shares of common stock disposed of. Such gain or loss will be capital gain or loss, and will be long-term capital gain or loss if the U.S. holder's holding period for the shares of our common stock disposed of exceeds one year at the time of disposition. The deductibility of capital losses is subject to certain limitations. U.S. holders should consult their tax advisors regarding the treatment of capital gains and capital losses.

Medicare Tax on Net Investment Income

An additional 3.8% Medicare tax will be imposed on certain net investment income of certain U.S. holders that are individuals, estates or trusts. Such tax applies to the lesser of (i) the U.S. holder's net investment income for the relevant taxable year and (ii) the excess of the U.S. holder's adjusted gross income (with certain adjustments) over a specified threshold amount. Net investment income generally includes dividends and net gains from the disposition of shares of our common stock. U.S. holders that are individuals, estates or trusts should consult their tax advisors regarding the effect, if any, of the Medicare tax on their ownership and disposition of our common stock.

Information Reporting and Backup Withholding Tax

In general, information reporting will apply to payments of dividends on shares of our common stock and proceeds of a disposition of shares of our common stock to U.S. holders, other than certain exempt recipients such as corporations. Under U.S. federal income tax law, dividends and proceeds from the sale of shares of our common stock paid to a U.S. holder (other than an exempt recipient) may be subject to "backup" withholding at the then applicable rate. Backup withholding generally applies to a U.S. holder if the holder (i) fails to furnish to us or our paying agent a correct social security number or other taxpayer identification number, or TIN, or fails to furnish a certification of exempt status, (ii) has been notified by the IRS that it is subject to backup withholding as a result of the failure to properly report payments of interest or dividends or (iii) under certain circumstances, fails to provide a certified statement, signed under penalty of perjury, that the TIN provided is its correct number and that it is a U.S. person that is not subject to backup withholding. Backup withholding is not an additional tax. Any amounts withheld from payments to a U.S. holder under the backup withholding rules will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle the holder to a refund, provided that the required information is timely furnished to the IRS. Certain U.S. persons are exempt from backup withholding, including corporations, provided that their exemptions from backup withholding are properly established.

Non-U.S. Holders

The following is a summary of certain U.S. federal tax considerations applicable to a non-U.S. holder of our common stock.

Distributions

Distributions treated as dividends for U.S. federal income tax purposes (as described above under “—U.S. Holders— Distributions”), if any, that are paid to a non-U.S. holder with respect to shares of our common stock will be subject to U.S. federal withholding tax at a 30% rate (or a lower rate prescribed by an applicable income tax treaty) unless the dividends are effectively connected with the non-U.S. holder’s conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained in the U.S.). To claim the exemption from withholding with respect to any such effectively connected income, the non-U.S. holder must furnish to us or our paying agent a properly executed IRS Form W-8ECI (or applicable successor form), certifying under penalties of perjury that a dividend paid on our common stock is not subject to withholding tax. The certification requirement also may require a non-U.S. holder to provide its U.S. taxpayer identification number.

If a non-U.S. holder is engaged in a trade or business in the United States and dividends with respect to our common stock are effectively connected with the conduct of such trade or business and, if required by an applicable income tax treaty, are attributable to a U.S. permanent establishment or fixed base, then the non-U.S. holder generally will be subject to U.S. federal income tax on such dividends on a net income basis in the same manner as if received by a U.S. holder (although the dividends will be exempt from the 30% U.S. federal withholding tax, provided the certification requirements are satisfied). In addition, if the non-U.S. holder is a corporation for U.S. federal income tax purposes, such holder may, under certain circumstances, be subject to an additional branch profits tax equal to 30% (or a lower rate prescribed by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year.

A non-U.S. holder who wishes to claim the benefit of an exemption or reduced rate of U.S. federal withholding tax under an applicable income tax treaty must furnish to us or our paying agent a valid IRS Form W-8BEN (or applicable successor form) certifying, under penalties of perjury, such non-U.S. holder’s qualification for the exemption or reduced rate. If a non-U.S. holder is eligible for an exemption or a reduced rate of U.S. federal withholding tax pursuant to an applicable income tax treaty, it may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the IRS.

If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a non-taxable return of capital, up to the non-U.S. holder’s adjusted tax basis in its shares of our common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “—Sale, exchange, redemption or certain other taxable dispositions of our common stock.” If we are not able to determine whether or not a distribution will exceed current and accumulated earnings and profits at the time a distribution is made, we may withhold tax on the entire amount of such distribution at the same rate as we would withhold on a dividend. However, a non-U.S. holder may obtain a refund of any excess withholding by filing an appropriate claim for refund with the IRS.

Any distribution described in this section would also be subject to the discussion below in “Foreign Account Tax Compliance Act.”

Sale, Exchange, Redemption or Certain Other Taxable Dispositions of Our Common Stock

Subject to the discussions below regarding backup withholding and the Foreign Account Tax Compliance Act, a non-U.S. holder generally will not be subject to U.S. federal income tax or withholding tax on gain realized upon a sale, exchange or other taxable disposition of shares of our common stock unless: (i) the gain is effectively connected with the conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a U.S. permanent establishment or a fixed base), of the non-U.S. holder; (ii) the non-U.S. holder is a non-resident alien individual who is present in the United States for 183 days or more in the taxable year of that disposition, and certain other conditions are met; or (iii) we are or have been a “U.S. real property holding corporation”, or a USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition and the non-U.S. holder’s holding period for our common stock, or the relevant period.

If the first exception applies, the non-U.S. holder generally will be subject to U.S. federal income tax on a net basis with respect to such gain in the same manner as if such holder were a resident of the United States. In addition, if the non-U.S. holder is a corporation for U.S. federal income tax purposes, such gains may, under certain circumstances, also be subject to the branch profits tax at a rate of 30% (or at a lower rate prescribed by an applicable income tax treaty).

If the second exception applies, the non-U.S. holder generally will be subject U.S. federal income tax at a rate of 30% tax on the gain from a disposition of our common stock, which may be offset by capital losses allocable to U.S. sources during the taxable year of disposition (even though the non-U.S. holder is not considered a resident of the United States).

With respect to the third exception above, we believe we currently are not, and we do not anticipate becoming, a USRPHC for U.S. federal income tax purposes. Because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests, there can be no assurances that we will not become a USRPHC in the future. Generally, a corporation is a USRPHC only if the fair market value of its U.S. real property interests (as defined in the Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Even if we are or become a USRPHC, a non-U.S. holder would not be subject to U.S. federal income tax on a sale, exchange or other taxable disposition of our common stock by reason of our status as a USRPHC so long as (i) our common stock continues to be regularly traded on an established securities market (within the meaning of Section 897(c)(3) of the Code) during the calendar year in which such disposition occurs and (ii) such non-U.S. holder does not own and is not deemed to own (directly, indirectly, or constructively) more than 5% of our common stock at any time during the relevant period. If we are a USRPHC and the requirements of (i) or (ii) are not met, gain on the disposition of shares of our common stock generally will be taxed in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax will not apply.

Information Reporting and Backup Withholding Tax

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions, regardless of whether withholding was required. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. A non-U.S. holder will generally be subject to backup withholding at the then applicable rate for dividends paid to such holder unless such holder furnishes a valid IRS Form W-8BEN (or such other applicable form and documentation as required by the Code or the Treasury regulations) certifying under penalties of perjury that it is a non-U.S. holder (and the payor does not have actual knowledge or reason to know that such holder is a United States person as defined under the Code), or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to U.S. federal withholding tax, as described above in "Distributions," generally will be exempt from U.S. backup withholding.

Information reporting and, depending on the circumstances, backup withholding will apply to the payment of the proceeds of a sale or other disposition of shares of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies that it is not a United States person (as defined under the Code) and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the U.S. through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Prospective investors should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of the information returns may be made available to the tax authorities in the country in which the non-U.S. holder resides or is incorporated under the provisions of an applicable treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a credit against a non-U.S. holder's U.S. federal income tax liability, if any, and may entitle such holder to a refund, provided that an appropriate claim is timely filed with the IRS.

Foreign Account Tax Compliance Act

Under the Foreign Account Tax Compliance Act, or FATCA, a 30% withholding tax will apply to dividends on, or gross proceeds from the sale or other disposition of, shares of our common stock paid to certain non-U.S. entities (including financial intermediaries) unless various information reporting and due diligence requirements, which are different from and in addition to the certification requirements described elsewhere in this discussion, have been satisfied (generally relating to ownership of by U.S. persons of interests in or accounts with those entities). The withholding rules applicable to payments of dividends on our common stock will be phased in beginning January 1, 2014. The withholding rules will apply to payments of gross proceeds from dispositions of U.S. common stock beginning January 1, 2017.

Holders of our common stock should consult their tax advisors regarding the possible impact of FATCA on their investment in our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

UNDERWRITING

The company and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. are the representatives of the underwriters.

Name	Number of Shares
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may be increased or the offering may be terminated.

The following tables show the per share and total underwriting discounts and commissions to be paid to the underwriters by the company. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Total		
	Per Share	No Exercise	Full Exercise
Public offering price	\$	\$	\$
Underwriting discounts and commissions to be paid by us	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

Determination of Offering Price

Before this offering, there has been no public market for our shares. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies in the U.S. that the underwriters believe to be comparable to us,

- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for our shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

General

The company estimates that its share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$.

The company has agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Price Stabilization, Short Positions and Penalty Bids

Shares sold by the underwriters to the public will initially be offered at the public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$ per share from the public offering price. After the offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

The company has agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of its common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 60 days, in certain instances, and 90 days, in other instances, after the date of this prospectus, except with the prior written consent of the representatives. This agreement does not apply to any existing employee benefit plans. See "Shares Available for Future Sale" for a discussion of certain transfer restrictions.

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the company’s stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on NASDAQ, in the over-the-counter market or otherwise.

The company may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. In connection with those derivatives, the third parties may sell securities covered by this prospectus, including in short sale transactions. If so, the third party may use securities pledged by the company or borrowed from the company or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from the company in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter or will be identified in a post-effective amendment.

In addition, in connection with this offering certain of the underwriters (and selling group members) may engage in passive market making transactions in our common stock on The NASDAQ Stock Market prior to the pricing and completion of this offering. Passive market making consists of displaying bids on The NASDAQ Stock Market no higher than the bid prices of independent market makers and making purchases at prices no higher than these independent bids and effected in response to order flow. Net purchases by a passive market maker on each day are generally limited to a specified percentage of the passive market maker’s average daily trading volume in the common stock during a specified period and must be discontinued when such limit is reached. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of these transactions. If passive market making is commenced, it may be discontinued at any time.

Selling Restrictions

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”), from and including the date on which the European Union Prospectus Directive (the “EU Prospectus Directive”) was implemented in that Relevant Member State (the “Relevant Implementation Date”) an offer of securities described in this prospectus may not be made to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the EU Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of securities described in this prospectus may be made to the public in that Relevant Member State at any time:

- to any legal entity which is a qualified investor as defined under the EU Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the EU Prospectus Directive); or
- in any other circumstances falling within Article 3(2) of the EU Prospectus Directive, provided that no such offer of securities described in this prospectus shall result in a requirement for the publication by us of a prospectus pursuant to Article 3 of the EU Prospectus Directive.

For the purposes of this provision, the expression an “offer of securities to the public” in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the EU Prospectus Directive in that Member State. The expression “EU Prospectus Directive” means Directive 2003/71/EC (and any amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State, and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

Each underwriter has represented and agreed that:

- it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Ballard Spahr LLP, Philadelphia, Pennsylvania.

EXPERTS

The financial statements as of December 31, 2013 and for the year then ended included in this prospectus have been audited by CohnReznick LLP, an independent registered 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.

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2012 and for the year then ended, as set forth in their report (which contains an explanatory paragraph relating to the Company's experience of recurring operating losses and negative cash flows from operations as described in Note 2 to the financial statements). We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

The Company's financial statements were audited by Ernst & Young LLP as of and for the year ended December 31, 2012. Upon completion of Ernst & Young LLP's audit of our 2012 financial statement, we dismissed Ernst & Young LLP as our independent accountant and engaged CohnReznick LLP as our new independent accountant.

The report of Ernst & Young LLP on the Company's financial statements as of and for the year ended December 31, 2012 did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope, or accounting principle, except for an explanatory paragraph relating to the Company's experience of recurring operating losses and negative cash flows from operations. Further, during the year ended December 31, 2012, and prior to engaging CohnReznick LLP as our independent accountant, there were no disagreements between the Company and Ernst & Young LLP on any matters of accounting principles or practices, financial statement disclosure, or auditing scope and procedures which, if not resolved to the satisfaction of Ernst & Young LLP, would have caused Ernst & Young LLP to make reference to the matter in their report. In addition, there were no "reportable events" as that term is described in Item 304(a)(1)(v) of Regulation S-K.

The Company has requested Ernst & Young LLP to furnish it a letter addressed to the Securities and Exchange Commission stating whether Ernst & Young LLP agrees with the above statements. A copy of that letter, dated December 31, 2014, is filed as Exhibit 16.1 to this Form S-1, Amendment No. 1.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules to the registration statement. Please refer to the registration statement, exhibits and schedules for further information with respect to the common stock offered by this prospectus. Statements contained in this prospectus regarding the contents of any contract or other document are only summaries. With respect to any contract or document that is filed as an exhibit to the registration statement, you should refer to the exhibit for a copy of the contract or document, and each statement in this prospectus regarding that contract or document is qualified by reference to the exhibit. You may read and copy the registration statement and its exhibits and schedules at the SEC's public reference room, located at 100 F Street, N.E., Room 1580, Washington D.C. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding companies, such as ours, that file documents electronically with the SEC. The address of that website is www.sec.gov. The information on the SEC's web site is not part of this prospectus, and any references to this web site or any other web site are inactive textual references only.

Upon the closing of this offering, we will become subject to the information and reporting requirements of the Securities Exchange Act of 1934 and, in accordance with this law, will be required to file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above.

REFERENCES

The following documents are referenced in this prospectus related to our business:

- “*Antibiotic Resistance Threats in the United States, 2013*,” report of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Dr. Tom Frieden, M.D., MPH, Director (Apr 23, 2013).
- “*Containment of a Country-wide Outbreak of Carbapenem-Resistant Klebsiella pneumonia in Israeli Hospitals via a Nationally Implemented Intervention*” by Mitchell J. Schwaber, Boaz Lev, Avi Israeli, Ester Solter, Gill Smollan, Bina Rubinovitch, Itamar Shalit, Yehuda Carmeli and the Israel Carbapenem-Resistant Enterobacteriaceae Working Group, **Clinical Infectious Diseases**, volume 52, pages 848-55 (Apr 1, 2011).
- “*Combating Antibiotic-Resistant Bacteria*,” Executive Order of The White House, issued September 18, 2014.
- “*Global Spread of Carbapenemase-producing Enterobacteriaceae*, by Patrice Nordmann,” Thierry Naas and Laurent Poirel, *Emerging Infectious Diseases*, volume 17, no. 10, www.cdc.gov/eid (Oct 2011).
- “*The Last Resort*” by Maryn McKenna, **Nature**, volume 499, pages 394-96 (Jul 25, 2013).
- “*10 x '20 Progress-Development of New Drugs Active Against Gram-Negative Bacilli: An Update from the Infectious Diseases Society of America*,” by Helen W. Boucher, George H. Talbot, Daniel K. Benjamin Jr., John Bradley, Robert J. Gidos, Ronald N. Jones, Barbara E. Murray, Robert A. Bonomo and David Gilbert, **Clinical Infectious Diseases**, volume 56, pages 1685-94 (Jun 15, 2013).
- “*Updated ECDC risk assessment on the spread of new Delhi metallo-β-lactamase and its variants within Europe*,” Technical Report of the European Centre for Disease Prevention and Control, http://ecdc.europa.eu/en/publications/Publications/Forms/ECDC_DisForm.aspx?ID=740 (Sept 13, 2011).

OPGEN, INC.
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Years Ended December 31, 2013 and 2012

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
OpGen, Inc.

We have audited the accompanying balance sheet of OpGen, Inc. as of December 31, 2013, and the related statements of operations, stockholders' deficit and cash flows for the year then ended. OpGen, Inc.'s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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 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 financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of OpGen, Inc. as of December 31, 2013, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

The 2013 financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in the Note 1 to the 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 its ability to continue as a going concern. The 2013 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ CohnReznick LLP

Vienna, Virginia
November 21, 2014

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
OpGen, Inc.

We have audited the accompanying balance sheet of OpGen, Inc. (the Company), as of December 31, 2012 and the related statements of operations, changes in stockholders' equity and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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 financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's 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 financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of OpGen, Inc. at December 31, 2012 and the results of its operations and its cash flows for each of the year then ended in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

McLean, Virginia
November 21, 2014

OpGen, Inc.
Balance Sheets

	December 31,	
	2013	2012
Assets		
Current assets		
Cash and cash equivalents	\$ 1,400,345	\$ 7,117,714
Accounts receivable, net	241,897	1,138,322
Inventory, net	175,713	914,496
Prepaid expenses and other current assets	146,438	288,138
Total current assets	1,964,393	9,458,670
Property and equipment, net	1,079,423	890,216
Licensed technology and other intangible assets, net	57,594	166,046
Other noncurrent assets	57,459	84,658
Total assets	\$ 3,158,869	\$ 10,599,590
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities		
Accounts payable	\$ 869,172	\$ 597,712
Accrued compensation and benefits	517,250	831,283
Accrued liabilities	743,767	547,213
Deferred revenue	509,728	156,870
Current portion of long term debt	10,000	110,000
Current maturities of long-term capital lease obligation	105,967	30,548
Total current liabilities	2,755,884	2,273,626
Long-term capital lease obligation, less current maturities	234,562	40,963
Derivative financial instruments	-	132,921
Total liabilities	2,990,446	2,447,510
Commitments and contingencies (note 10)		
Redeemable convertible preferred stock		
Series A redeemable convertible preferred stock, \$.01 par value; 2,500,000 shares authorized; 1,999,864 shares issued and outstanding at December 31, 2013; aggregate liquidation preference of \$3,999,728 at December 31, 2013	1,999,864	-
Series A redeemable convertible preferred stock, \$.01 par value; 26,345,800 shares authorized; 25,205,800 shares issued and outstanding at December 31, 2012	-	33,987,502
Series B redeemable convertible preferred stock, \$.01 par value; 64,936,385 shares authorized; 64,936,385 shares issued and outstanding at December 31, 2012	-	27,096,513
Series C redeemable convertible preferred stock, \$.01 par value; 152,869,987 shares authorized; 126,802,946 shares issued and outstanding at December 31, 2012	-	17,736,824
Series A-1 redeemable convertible preferred stock, \$.01 par value; 4,857,621 shares authorized; 4,857,621 shares issued and outstanding at December 31, 2012	-	4,924,230
Total redeemable convertible preferred stock	1,999,864	83,745,069
Stockholders' deficit		
Common stock, \$.01 par value; 3,500,000 shares authorized; 362,536 and 3,517 shares issued and outstanding at December 31, 2013 and 2012, respectively	3,625	35
Additional paid-in capital	89,265,757	-
Accumulated deficit	(91,100,823)	(75,593,024)
Total stockholders' deficit	(1,831,441)	(75,592,989)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	\$ 3,158,869	\$ 10,599,590

See Notes to Financial Statements

OpGen, Inc.
Statements of Operations
Years ended December 31,

	<u>2013</u>	<u>2012</u>
Revenue		
Product sales	\$ 1,735,517	\$ 3,767,968
Laboratory services	630,851	770,600
Collaborations revenue	44,239	1,263,159
Total revenue	2,410,607	5,801,727
Operating expenses		
Cost of products sold	1,501,648	2,903,652
Cost of services	320,938	307,539
Research and development	4,151,936	4,782,414
General and administrative	2,762,205	2,472,454
Sales and marketing	3,053,394	4,274,180
Argus™ Whole Genome obsolescence	950,881	–
Total operating expenses	12,741,002	14,740,239
Operating loss	(10,330,395)	(8,938,512)
Other income (expense)		
Interest income	1,222	4,489
Interest expense	(31,598)	(118,666)
Change in fair value of warranty liability	134,560	–
Other income (expense)	91,390	(231,023)
Total other income (expense)	\$ 195,574	\$ (345,200)
Net loss	\$ (10,134,821)	\$ (9,283,712)
Preferred stock dividends and accretion	(5,372,978)	(4,925,242)
Net loss applicable to common stockholders	\$ (15,507,799)	\$ (14,208,954)
Net loss per common share – basic and diluted	\$ (896.09)	\$ (4,042.38)
Weighted average shares outstanding – basic and diluted	17,306	3,515
Pro forma net loss per common share, basic and diluted (unaudited)	\$ (23.06)	
Pro forma weighted average shares outstanding – basic and diluted (unaudited)	439,217	

See Notes to Financial Statements

OpGen, Inc.
Statements of Stockholder's Deficit
Years ended December 31, 2013 and 2012

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>			
Balances at December 31, 2011	3,470	\$ 35	\$ -	\$ (61,602,790)	\$ (61,602,755)
Stock option exercises	47	-	3,750	-	3,750
Stock compensation expenses	-	-	214,970	-	214,970
Accrued dividends, Series A, B and C preferred stock	-	-	-	(4,630,728)	(4,630,728)
Accretion of Series A, B and C preferred stock	-	-	(218,720)	(75,794)	(294,514)
Net loss	-	-	-	(9,283,712)	(9,283,712)
Balances at December 31, 2012	3,517	35	-	(75,593,024)	(75,592,989)
Stock option exercises	46	-	1,217	-	1,217
Stock compensation expense	-	-	152,753	-	152,753
Accrued dividends, Series A, B and C preferred stock	-	-	-	(5,058,786)	(5,058,786)
Accretion of Series A, B and C preferred stock	-	-	-	(314,192)	(314,192)
Conversion of preferred to common stock	358,973	3,590	89,111,787	-	89,115,377
Net loss	-	-	-	(10,134,821)	(10,134,821)
Balances at December 31, 2013	362,536	\$ 3,625	\$ 89,265,757	\$ (91,100,823)	\$ (1,831,441)

See Notes to Financial Statements

OpGen, Inc.
Statements of Cash Flows
Years ended December 31,

	<u>2013</u>	<u>2012</u>
Cash flows from operating activities		
Net loss	\$ (10,134,821)	\$ (9,283,712)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	661,807	583,717
Amortization of debt discount	5,406	67,789
Non-cash interest expense including beneficial conversion	6,334	20,184
Bad debt expense	7,301	129,846
Recovery of bad debt	(49,050)	–
Loan forgiveness	(36,811)	–
Stock compensation expense	152,753	214,970
Inventory obsolescence	924,285	99,721
Change in fair value of derivative financial instruments	(134,560)	–
Other non-cash items	1,639	112,577
Changes in operating assets and liabilities::		
Accounts receivable	938,174	524,903
Inventory	(506,088)	461,028
All other assets	163,493	(129,104)
Accounts payable	271,460	(384,184)
Accrued compensation and other liabilities	(112,002)	(104,695)
Deferred revenue	352,858	(274,041)
Net cash used in operating activities	(7,487,822)	(7,961,001)
Cash flows from investing activities		
Purchases of property and equipment	(109,871)	(210,528)
Net cash used in investing activities	(109,871)	(210,528)
Cash flows from financing activities		
Proceeds from issuance of preferred stock, net of issuance costs	(2,670)	13,404,082
Proceeds from borrowings on convertible notes, net of issuance costs	969,864	1,389,550
Proceeds from sale of short-term notes	1,030,000	400,000
Proceeds from exercise of stock options and warrants	1,217	3,750
Payments on debt	(75,000)	(400,000)
Payments on capital lease obligations	(43,087)	(23,664)
Net cash provided by financing activities	1,880,324	14,773,718
Net (decrease) increase in cash and cash equivalents	(5,717,369)	6,602,189
Cash and cash equivalents at beginning of year	7,117,714	515,525
Cash and cash equivalents at end of year	\$ 1,400,345	\$ 7,117,714
Supplemental disclosure of cash flow information		
Cash paid during the year for interest	\$ 26,088	\$ 5,789
Supplemental disclosure of noncash investing and financing activities:		
Acquisition of equipment through capital leases	\$ 312,105	\$ 31,846
Conversion of convertible promissory notes to Series C preferred stock	–	\$ 3,532,282
Conversion of convertible promissory notes to Series A preferred stock	\$ 1,999,864	–

See Notes to Financial Statements

OpGen, Inc.
Notes to Financial Statements
December 31, 2013 and 2012

Note 1 - Organization

OpGen, Inc. (OpGen or the Company) was incorporated in Delaware on January 22, 2001. OpGen is a commercial stage company using molecular testing and bioinformatics to combat multi-drug resistant infections. The Company's products and services enable healthcare providers to rapidly identify hospital patients who are colonized with life threatening, multi-drug resistant organisms, or MDROs. The Company's Acuitas™ gene-based testing products are enabled by the Lighthouse™ bioinformatics platform which provides detailed MDRO molecular information about an individual patient's resistance profile and integrates this information with data from other patients and hospital-wide aggregate results to help improve overall patient outcomes and to reduce hospital costs. The Company believes that it has an important first-mover advantage in providing Acuitas-enabled molecular information to healthcare providers on a commercial scale.

The Company's headquarters and principal operations are in Gaithersburg, Maryland. The Company had an additional facility in Madison, Wisconsin, which was closed in April 2013. The Company operates in one business segment.

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 availability of additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop and commercialize its novel technology as well as raise additional capital.

Note 2 - Going concern and management's plans

The accompanying 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, negative operating cash flows and has a deficit in stockholders' equity.

As more fully described in Notes 5 and 13, the Company raised \$4.0 million in two Series A Preferred Stock offerings during the fourth quarter of 2013 and early 2014, raised \$1.5 million through the issuance of convertible debt in the third quarter of 2014, and raised \$1.0 million through the issuance of promissory notes in the fourth quarter of 2014. Management is actively engaged in efforts to raise additional capital. The Company's current operating assumptions, which include management's best estimate of future revenue and operating expenses, indicate that current cash on hand will not be sufficient to fund operations as currently configured through the end of 2014.

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 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.

These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Note 3 - Summary of significant accounting policies

Use of estimates

In preparing financial statements in conformity with accounting principles generally accepted in the United States ("US 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 financial statements, estimates are used for, but not limited to, stock-based compensation, allowances for doubtful accounts and inventories, valuation of derivative financial instruments, 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.

OpGen, Inc.
Notes to Financial Statements
December 31, 2013 and 2012

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.

The Company obtained a certificate of deposit in the amount of \$52,459, which is required as collateral for a letter of credit benefiting the landlord for the Gaithersburg facility lease. The Company obtained an additional certificate of deposit of \$5,000, which is required by its credit card processor. These certificates of deposits are reflected in other long-term assets on the accompanying balance sheets.

Fair value measurements

Included in the financial statements are certain financial instruments carried at fair value, including cash and cash equivalents. US GAAP establishes 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.

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 following tables present the fair value hierarchy for the Company's financial assets and liabilities measured at fair value on a recurring basis at December 31, 2013 and 2012:

	December 31, 2013 Total	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3
Cash and cash equivalents	\$ 1,400,345	\$ 1,248,885	\$ 151,460	\$ –

	December 31, 2012 Total	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3
Cash and cash equivalents	\$ 7,117,714	\$ 362,796	\$ 6,754,918	\$ –
Series A convertible preferred stock warrant	(661)	–	–	(661)
Series C convertible preferred stock warrant	(132,260)	–	–	(132,260)

OpGen, Inc.
Notes to Financial Statements
December 31, 2013 and 2012

The Company's Level 1 securities primarily consist of cash. The Company determines the estimated fair value for its Level 1 securities using quoted (unadjusted) prices for identical assets or liabilities in active markets.

The Company's Level 2 securities primarily consist of money market funds and U.S. Treasury Notes. The Company determines the estimated fair value for its Level 2 securities using the following methods: quoted prices for similar assets/liabilities in active markets, inputs other than quoted prices that are observable for the asset/liability (e.g., interest rates, yield curves volatilities, default rates, etc.) and inputs that are derived principally from or corroborated by other observable market data.

The following table presents information about the Series A convertible preferred stock warrant derivative liability, which was measured at fair value on a recurring basis using significant unobservable inputs (Level 3). This warrant was converted into a common stock warrant in connection with the 2013 recapitalization:

	December 31	
	2013	2012
Balance beginning of year	\$ (661)	\$ (661)
Transfers to (from) Level 3	-	-
Total gains realized/unrealized included in earnings	661	-
Balance end of year	<u>\$ -</u>	<u>\$ (661)</u>

The following table presents information about the Series C convertible preferred stock warrant liability when the Company issued a warrant to purchase 3,260,870 shares of Series C preferred stock as part of an existing development agreement under which the Company is performing work for the development partner. The warrant is measured at fair value on a recurring basis using significant unobservable inputs (Level 3). This warrant was converted into a common stock warrant in the 2013 recapitalization (see note 5).

	December 31	
	2013	2012
Balance beginning of year	\$ (132,260)	\$ (19,683)
Transfers to (from) Level 3	-	-
Total expenses realized included in earnings	(1,639)	(112,577)
Total gains realized/unrealized included in earnings	133,899	-
Balance end of year	<u>\$ -</u>	<u>\$ (132,260)</u>

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 45 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 Company charged \$7,301 and \$129,846 as bad debt expense within other expense in 2013 and 2012, respectively, for accounts it considered uncollectible. The allowance for doubtful accounts was \$88,097 and \$129,846 as of December 31, 2013 and 2012, respectively. Approximately \$49,050 was collected from an international distributor during 2013 on the bad debt written off in 2012 and that amount was reversed in 2013.

At December 31, 2013, the Company had accounts receivable from three customers which individually represent 24%, 20%, and 10% of total accounts receivable. At December 31, 2012, the Company had accounts receivable from three customers which individually represent 33%, 31%, and 10% of total accounts receivable. For the year ended December 31, 2013 four individual customers represented 12%, 12%, 10% and 10% of revenues. For the year ended December 31, 2012 one individual customer represented 22% of revenues.

Inventories

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

	December 31	
	2013	2012
Raw materials and supplies	\$ 51,005	\$ 110,274
Work-in-process	63,917	248,757
Finished goods	60,791	555,465
Total inventories	\$ 175,713	\$ 914,496

Inventories include the Argus™ Whole Genome Mapping Systems, reagents and supplies used for Argus™ consumable kits, and cards used for the Argus™ Whole Genome Mapping System as well as in the sales of the Company's laboratory services. Systems placed at customer sites under the Company's Sales Evaluation Program are included in finished goods inventory and represented \$0 and \$416,266 at December 31, 2013 and 2012, respectively. Inventory reserve for obsolescence and expirations was \$1,024,006 and \$99,721 at December 31, 2013 and 2012, respectively.

Based on actual and anticipated sales levels of Argus™ Whole Genome Mapping Systems, in 2013 management conducted a thorough review of its inventory position for this product line. As a result, a provision for inventory losses of approximately \$950,000 was charged against operations in 2013 to write down inventory to its expected net realizable value.

Software development costs

The cost to produce software that is sold as a separate product is capitalized when the software reaches technical feasibility in the development process. Technical feasibility begins when the product design is completed, which is typically when the final product specifications are determined. Costs incurred prior to technical feasibility are expensed as incurred as research and development. Capitalized costs are included in other assets when deferred and are included in cost of product sales as the software is sold.

In 2012, the Company capitalized \$20,138 in software production costs related to software the Company was developing for its Whole Genome Mapping product offering. An additional \$183,720 of software production costs were incurred in 2013. Development of this software was terminated in April 2013 when the Company restructured its operations and accelerated its planned strategic re-positioning into the clinical diagnostics market. At that time, the Company charged the \$203,858 of costs incurred since inception of the software development to operations as research and development expense. Capitalized software costs included in other assets were \$0 and \$20,138 at December 31, 2013 and 2012, respectively.

Product warranty

A warranty reserve is established upon the sale of any product that is covered by warranty based on the estimated cost of replacement parts during the warranty period. Warranty periods are provided for twelve months. The reserve is adjusted during the warranty period to reflect the remaining estimated costs under the warranty.

OpGen, Inc.
Notes to Financial Statements
December 31, 2013 and 2012

The following table presents the accrued warranty reserve, the warranty expense and cost of replacement parts:

	2013	2012
Balance at beginning of year	\$ 19,750	\$ 70,000
Warranty expense (reversal)	8,298	(33,732)
Cost of replacement parts and related delivery	(21,548)	(16,518)
Balance at end of year	<u>\$ 6,500</u>	<u>\$ 19,750</u>

Licensed technology and other intangible assets

Licensed technology and other intangible assets consist primarily of costs related to patents and licensed technology. These costs were capitalized and amortized over the estimated useful lives of the underlying technology, which ranged from two to 10 years. As part of an analysis of the Argus™ Whole Genome Mapping technology in 2013, a change in the estimated lives was made during 2013 such that the amortization period for all of the licensed technology would end by December 31, 2014. In addition, one license agreement was terminated in December 2013 and the related licensed technology costs were amortized in full. As a result, approximately \$90,000 of capitalized technology costs and associated accumulated amortization were written off upon the termination of the fully amortized license.

Total amortization expense was \$108,452 and \$55,194 for the years ended December 31, 2013 and 2012, respectively. Accumulated amortization was \$641,355 and \$622,904 at December 31, 2013 and 2012, respectively.

Estimated amortization expense for the year ending December 31, 2014 on amortized intangible assets as of December 31, 2013, is \$57,594.

Property and equipment

Property and equipment are 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 \$553,355 and \$528,524 for the years ended December 31, 2013 and 2012, respectively. Property and equipment consisted of the following at December 31, 2013 and 2012:

	2013	2012
Laboratory equipment	\$ 2,265,717	\$ 1,947,442
Office furniture and equipment	792,129	481,607
Computers	1,167,144	1,126,184
Leasehold improvements	250,442	217,287
	<u>4,475,432</u>	<u>3,772,520</u>
Less accumulated depreciation	(3,396,009)	(2,882,304)
Property and equipment, net	<u>\$ 1,079,423</u>	<u>\$ 890,216</u>

In 2012, the Company began to provide Argus™ Whole Genome Systems under its Argus Reagent Rental Program to customers, to 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 selling 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, 2013 and 2012, these costs were approximately \$81,000 and \$38,000, respectively. The costs to maintain these systems are charged to operations as incurred.

Impairment of long-lived assets

The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. An impairment loss would be measured as the amount by which the carrying value of the asset exceeds the estimated fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less costs to sell. As of December 31, 2013 and 2012, the Company determined that there were no impaired long-lived assets.

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. Deferred rent is included in accrued liabilities on the balance sheets.

Revenue recognition

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

Amounts billed to customers for shipping and handlings are included in revenue when the related product or service revenue is recognized. Shipping and handling costs are included in cost of sales. The Company recognized \$35,213 and \$49,467 in 2013 and 2012, respectively, for shipping and handling.

Revenue from sales of the Argus™ System

When the 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 the 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 (considered multiple elements) 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 stand-alone 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.

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.

Fair value of financial instruments

All current assets and liabilities are carried at cost, which approximates fair value, because of the short-term maturities of those instruments. Debt and capital leases are reflective of fair value based on instruments with similar terms available to the Company.

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, fees paid to consultants and outside service partners.

Income taxes

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax basis of assets and liabilities and their financial reporting amounts at each year-end based on the enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. 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.

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.

Loss per share

Basic loss per share is computed by dividing net loss applicable to common shareholders 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 shareholders 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 common stock options, stock purchase warrants, convertible preferred stock and convertible debt exercisable or exchangeable into common stock which have been excluded from the computation of diluted loss per share, were 2.1 million and 0.4 million for the years ended December 31, 2013 and 2012. The Company's convertible preferred stock contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; 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.

Redeemable Convertible Preferred Stock

The carrying value of the Company's redeemable convertible preferred stock is increased by the accretion of related discounts, issuance costs and accrued but unpaid dividends so that the carrying amount will equal the redemption amount at the dates the stock becomes redeemable. The Company's Series A, A-1, B, and C preferred stock is redeemable at the option of the holders of 70% of the outstanding shares of preferred stock, subject to certain additional requirements (Note 6).

Share-based compensation

Share-based payments are recognized at fair value. The fair value of share-based payments 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. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. Share-based compensation expense recognized is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period.

The Company utilizes the Black-Scholes model for estimating fair value of its stock options granted. 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

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. The board of directors made contemporaneous determinations of fair value. In the absence of a public market, and as an emerging company with no significant revenues, the Company believes that it is appropriate to consider a range of factors to determine the fair market value of the common stock at each grant date. The factors include: (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.

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. The Company does not maintain an internal market for its shares and its shares are not traded publicly. The Company has been able to identify several public entities of similar size, complexity and stage of development; accordingly, historical volatility has been calculated using the volatility of these companies.

Expected dividend yield

The Company has never declared or paid dividends 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 estimates of the expected term of the option term so that estimates will approximate actual behavior for similar options.

Expected forfeiture rate

The forfeiture rate is the estimated percentage of options granted that is expected to be forfeited or canceled on an annual basis before becoming fully vested. The Company estimates the forfeiture rate based on turnover data with further consideration given to the class of the employees to whom the options were granted.

The estimated fair value of equity instruments issued to nonemployees are recorded at fair value on the earlier of the performance commitment date or the date the services required are completed.

Research collaborations and development agreements

In August 2011, the Company entered into a collaboration agreement with a university in the United States to collect, produce, and distributes high-quality, annotated genomic sequence and organism phenotype data from clinically relevant microbes and associated patient demographic data. The primary responsibilities of the university were to create a data storage model including whole genome map data, perform genomic sequencing of relevant microbes, and coordinate publications. The Company's primary responsibilities were to provide funding of up to \$250,000 for the hiring of two informatics resources at the university, supply whole genome maps, and supply other clinically relevant data. The collaboration was expected to operate through the end of 2012 and was cancelable by either party on 60 days' notice. The Company accrued \$135,557 in research and development expenses in 2012 related to this project. The Company and the university amended the contract in 2014 to adjust the scope of the work to the \$135,557 already incurred and to adjust the payment schedule such that the \$135,557 is paid over 2014 and 2015.

In 2007, the Company entered into a development agreement with a governmental entity in which the Company would receive fixed milestone payments for meeting development milestones under the agreement. The first phase of this agreement was completed in 2010. The Company also issued a warrant for Series A preferred stock to the governmental entity at the initiation of the agreement. In December 2011, the Company amended the agreement to begin a new phase of development work. Under the contract, the Company was contracted to significantly modify existing software, which changed the functionality of the existing software and other components supplied under the contract. The Company received fixed-fee payments for development work under this amendment and recognized revenue using percentage of completion accounting. The Company recognized revenue of \$16,461 and \$1,263,159 in 2013 and 2012, respectively, under this contract. Expenses incurred for development activities under this amendment are reported as research and development expenses as incurred and were \$4,514 in 2013 and \$565,408 in 2012. Upon signing the amendment in December 2011, the Company agreed to issue the governmental entity warrants to purchase Series C preferred shares upon the successful close of a Series C financing. On March 5, 2012, the Company issued a warrant to purchase 3,260,870 shares of Series C preferred stock as part of an existing development agreement under which the Company performed work for the development partner. The warrant became vested in proportion to the revenue received by the Company under the development agreement and was fully vested in early 2013. The warrant was exercisable at \$0.138 and has a term of seven years. The Company valued the warrant at \$133,899, which was recorded as a liability and expensed proportional to the revenue earned. The Company recognized charges to other expense of \$1,639 and \$112,577 in 2013 and 2012, respectively. The Series C Preferred Stock warrant was converted into a Common Stock warrant to purchase 4,125 shares of common stock in the December 2013 recapitalization (see note 5).

In September 2013, the Company entered into a technology development agreement in which the Company would receive fixed milestone payment for meeting development milestones under the agreement. Since the milestones are substantive, the Company will recognize revenue in the period in which the substantive milestone is achieved. No revenue was recognized under this provision during 2013. In addition, the Company received an upfront payment of \$250,000, which will be recognized on a straight-line basis over the term of the technology development agreement. The Company recognized revenue of \$27,778 during 2013.

Reverse stock split

In connection with the recapitalization of the Company (see note 5), on December 18, 2013, the Company affected a 1-for-790.5407 reverse split of its Common Stock. The reverse stock split affected all of the holders of common stock uniformly. Shares of Common Stock underlying outstanding options and warrants were proportionately reduced and the exercise price of outstanding options and warrants was proportionately increased in accordance with the terms of the agreements governing such securities. All Common Stock share and per share information in the accompanying financial statements and notes thereto included in this report have been retroactively adjusted to reflect retrospective application of the reverse stock split, except for par value per share and the number of authorized shares, which were not affected by the reverse stock split. In addition, corresponding amounts were reclassified from common stock to additional paid-in capital.

Reclassifications

Certain amounts present in the balance sheet, statement of operations, and statement of cash flows for 2012 have been reclassified to conform to current year presentation.

Recent Accounting Pronouncements

In July 2012, the Financial Accounting Standards Board (“FASB”) issued accounting guidance to simplify the evaluation for impairment of indefinite-lived intangible assets. Under the updated guidance, an entity has the option of first performing a qualitative assessment to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired before proceeding to the quantitative impairment test under which it would calculate the asset’s fair value. When performing the qualitative assessment, the entity must evaluate events and circumstances that may affect the significant inputs used to determine the fair value of the indefinite-lived intangible asset. The adoption of this standard in 2013 did not have a material impact on the Company’s consolidated results of operations, cash flows or financial position.

In July 2013, the FASB issued guidance for the presentation of an unrecognized tax benefit when a net operating loss (“NOL”) carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance requires an entity to present in the financial statements an unrecognized tax benefit, or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for an NOL carryforward, a similar tax loss, or a tax credit carryforward. If the NOL carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the jurisdiction or the tax law of the jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit will be presented in the financial statements as a liability and will not be combined with deferred tax assets. The adoption of this standard in 2014 did not have a material impact on the Company’s consolidated results of operations, cash flows or financial position.

In May 2014, the 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. The standard is effective for our reporting year beginning January 1, 2017 and early adoption is not permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its 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. The standard is effective for our reporting year beginning January 1, 2017 and early adoption is not permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

Note 4 - Restructuring costs

In October 2011, the Company restructured its operations to reduce expenditures and conserve cash. In connection with this restructuring, the Company reduced its workforce by approximately 20%, or 10 employees. For the year ended December 31, 2011, the Company recorded restructuring charges of \$197,411, of which \$128,260 was paid by December 31, 2011. The remaining restructuring costs were paid in full during 2012. The restructuring charges were recorded as components of operating expenses based on the function performed by the employees receiving the severance benefits. There were no material adjustments to the recognized restructuring charges.

In February and April 2013, the Company restructured its operations to reduce expenditures and conserve cash while accelerating its planned strategic repositioning into the clinical diagnostics market. In connection with this restructuring, the Company reduced its workforce by approximately 36%, or 16 employees.

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The following table presents the accrued restructuring costs and the amounts paid:

	2013	2012
Balance at beginning of year	\$ —	\$ 69,351
Restructuring expense	329,649	—
Amounts paid	(329,649)	(69,351)
Balance at end of year	<u>\$ —</u>	<u>\$ —</u>

Note 5 - Recapitalization

On November 1, 2013, the Company and various investors entered into a financing commitment agreement whereby the Company sold Demand Notes to the investors in the amount of \$1,030,000 and the Company commenced a rights offering consisting of \$2,000,000 Convertible Promissory Notes. The Convertible Promissory Notes were convertible into Series A Convertible Preferred Stock at \$1.00 per Series A share. On December 18, 2013, the Company issued \$1,999,864 in Convertible Promissory Notes in exchange for \$969,864 in cash and in exchange for the Demand Notes. On December 30, 2013, the Convertible Promissory Notes were converted into 1,999,864 shares of Series A Convertible Preferred Stock.

In conjunction with, and as a condition of, the financing described above, the following actions were taken as of the date of the issuance of the Convertible Promissory Notes. These actions are collectively referred to as the “December 2013 recapitalization.”

1. A mandatory conversion of all outstanding shares of Senior Preferred Stock into Common Stock in accordance with the terms of the Certificate of Incorporation,
2. A mandatory conversion of all outstanding shares of the Series A-1 Preferred Stock into Common Stock on a one-to-one basis,
3. Elimination of all mandatory, accrued, cumulative and unpaid dividends on the Senior Preferred Stock,
4. A 1-for-790.5407 reverse stock split of the Company’s Common Stock as of the financing date, and
5. Conversion of all outstanding options and warrants on the terms above.

The table below sets forth the various stock issuances of the Company that were outstanding immediately before the December 2013 recapitalization, including the anti-dilution rights available to those shares. The Preferred Stock issuances, excluding anti-dilution rights, were convertible into existing common shares on a one for one basis. The shares listed below, including anti-dilution rights, were converted into 362,537 shares of common stock in the 1 for 790.5407 reverse stock split.

	Shares Outstanding
Series A Preferred Stock	25,205,800
Series A Anti-dilution rights	35,915,987
Series B Preferred Stock	64,936,385
Series B Anti-dilution rights	26,036,056
Series C Preferred Stock	126,802,946
Series A-1 Preferred Stock	4,857,621
Common Stock	<u>2,817,182</u>
Equivalent common shares before recap	<u>286,571,977</u>

The table below sets forth the warrants that were outstanding immediately before the December 2013 recapitalization. These warrants were converted into 37,078 shares of common stock warrants in the 1 for 790.5407 reverse stock split.

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	Warrants Outstanding
Series A Preferred Warrants	1,140,000
Series A Anti-dilution rights	1,624,306
Series C Preferred Warrants	3,260,870
Common Stock Warrants	<u>23,254,778</u>
Equivalent common shares before recap	<u>29,279,954</u>

Immediately prior to the December 2013 recapitalization, there were 16,532,569 common stock options outstanding. These options were converted into options to acquire 20,956 shares of common stock in the 1 for 790.5407 reverse stock split.

Note 6 - Redeemable convertible preferred stock

The Company issued 1,999,864 shares of Series A Convertible Preferred Stock in December 2013 at \$1.00 per share in exchange for \$1,999,864 in Convertible Promissory Notes (see note 5). The Series A Preferred Stock has 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 has 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 are at two times the Series A Preferred Stock purchase price. The Series A Preferred stockholders are 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 has broad based anti-dilution rights.

Beginning in December 2020, the Company may be 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 take place in three equal annual installments. Series A preferred stock would be redeemed at two times the original issue price per share plus all accrued and unpaid dividends. The redemptions are subject to certain equity adjustments for specified anti-dilution transactions, as defined.

The holders of Series A preferred stock have 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 is one common share for each preferred share, which may be adjusted for specified dilutive transactions. At December 31, 2013, the Company has reserved 1,999,864 shares of common stock for potential conversion of Series A.

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The following roll-forward tables provide activity related to the Preferred Stock issuances that were outstanding prior to the December 2013 recapitalization:

Series A-1:

Ending balance, December 31, 2011	\$ 4,916,451
Accretion of issuance costs	7,779
Ending balance, December 31, 2012	4,924,230
Accretion of issuance costs	6,011
Balance, December 17, 2013	4,930,241
Recapitalization	(4,930,241)
Ending balance, December 31, 2013	<u>\$ —</u>

Series A:

Ending balance, December 31, 2011	\$ 31,733,883
Accrual related to cumulative dividends	2,021,989
Accretion of issuance costs	231,630
Ending balance, December 31, 2012	33,987,502
Accrual related to cumulative dividends	1,939,120
Accretion of issuance costs	209,512
Balance, December 17, 2013	36,136,134
Recapitalization	(36,136,134)
Ending balance, December 31, 2013	<u>\$ —</u>

Series B:

Ending balance, December 31, 2011	\$ 25,233,129
Accrual related to cumulative dividends	1,849,246
Accretion of issuance costs	14,138
Ending balance, December 31, 2012	27,096,513
Accrual related to cumulative dividends	1,773,457
Accretion of issuance costs	13,121
Balance, December 17, 2013	28,883,091
Recapitalization	(28,883,091)
Ending balance, December 31, 2013	<u>\$ —</u>

Series C:

Ending balance, December 31, 2011	\$ —
Proceeds from issuance, net of issuance costs	16,936,364
Accrual related to cumulative dividends	759,494
Accretion of issuance costs	40,966
Ending balance, December 31, 2012	17,736,824
Accrual related to cumulative dividends	1,346,209
Issuance of Series C - additional costs	(2,670)
Accretion of issuance costs	85,548
Balance, December 17, 2013	19,165,911
Recapitalization	(19,165,911)
Ending balance, December 31, 2013	<u>\$ —</u>

On March 5, 2012, the Company issued 68,336,521 shares of Series C redeemable convertible preferred stock at a per share price of \$0.138 to existing and new investors for gross cash proceeds of \$5,834,382 and in exchange for \$3,596,058 of principal and accrued interest related to convertible promissory notes issued in late 2011 and February 2012. In a subsequent participation rights offering in April 2012, the Company issued an additional 3,615,563 shares of Series C redeemable convertible preferred stock for gross proceeds of \$498,948. On October 26, 2012, the Company issued an additional 54,347,826 Series C shares to several existing investors for gross proceeds of \$7,500,000. In a subsequent participation rights offering in December 2012, the Company issued an additional 503,036 shares of Series C redeemable convertible preferred stock for gross proceeds of \$69,419. The Company incurred issuance costs of \$562,443 related to these Series C preferred stock sales. Holders of the Series A, Series B, and Series C preferred stock (senior preferred) outstanding before the December 2013 recapitalization had a liquidation preference senior to that of the common stock. Upon a liquidation of the Company, the proceeds of the liquidation would have been distributed as follows, unless the senior preferred stock holders would receive a greater amount upon the conversion of their shares to common. First, to the holders of Series C preferred stock, an amount per share equal to two times the Series C Original Issue Price; second, to the holders of Series A and B preferred stock, pari passu, an amount per share equal to the Series A Original Issue Price and the Series B Original Issue Price (as applicable); third, to the holders of Series C preferred stock an amount equal to all unpaid Series C dividends; fourth, to the holders of Series A and Series B preferred stock, pari passu, an amount equal to all unpaid Series A and Series B dividends (as applicable); and the remainder to common stockholders.

The holders of the Series A-1 preferred stock had no voting rights and were not entitled to receive any dividends. Upon the closing of a qualified initial public offering of at least \$30.0 million, all outstanding shares of Series A-1 preferred stock would have automatically converted into common stock at \$1.02 per share or, at the Company's option, could be settled in cash for an amount not to exceed \$4,857,622.

Note 7 - Debt

Debt consists of the following:

	December 31	
	2013	2012
Note payable to State of Maryland	\$ —	\$ 100,000
Note payable to Montgomery County	10,000	10,000
	10,000	110,000
Less current portion	(10,000)	(110,000)
	\$ —	\$ —

In November 2011, the Company entered into a note and warrant purchase agreement with certain holders of the Company's then outstanding Series A and B preferred stock under which the Company could borrow up to \$2,499,250 in exchange for convertible promissory notes (the "Notes") and common stock warrants. The Company borrowed \$2,132,656 under this agreement in exchange for convertible promissory notes and warrants to purchase 4,635,741 shares of common stock at \$0.01 per share. The Notes originally matured on June 30, 2012, and bore interest at 8%. The Company issued additional convertible promissory notes in the amount of \$1,400,000 in February 2012 on terms similar to the November 2011 note and warrant agreement except that no warrants were issued with the February 2012 notes. The November 2011 and February 2012 notes, plus accrued interest, were converted into Series C preferred stock in March 2012 (see Note 6). In January 2012, the Company borrowed \$400,000 from one of its existing shareholders and issued a short-term demand note, which bore interest at 8%. The note, plus accrued interest, was paid in full in February 2012.

In 2009, the Company entered into loan agreements with the Department of Business and Economic Development, a principal department of the State of Maryland, and Montgomery County, Maryland. Under the terms of the agreements, the State of Maryland and Montgomery County loaned the Company \$100,000 and \$10,000, respectively, to assist in the relocation of the Company's operations from Wisconsin to Gaithersburg, Maryland. Interest on the loans accrued at 3%. The interest was deferred and the loans were forgivable under certain conditions, including the Company maintaining operations in Gaithersburg, Maryland, and attaining a specified level of staffing at that site on or before December 31, 2012. The Company did not attain the required level of staffing at December 31, 2012, and, as a result, these notes and accrued interest became due in 2013. The Company negotiated a settlement with the State of Maryland under which it paid \$75,000 in June 2013 in full satisfaction of the \$100,000 loan principal balance and accrued interest of \$11,811. The Company also negotiated a settlement with Montgomery County under which accrued interest due under the loan provisions was forgiven and the loan would be paid in equal quarterly installments over the eight quarters ending December 31, 2015. The Company recorded the loan and interest forgiveness of \$36,811 as Other Income in 2013 for these two loans.

The Company sold \$1,030,000 of Demand Notes in November 2013. The Demand Notes were due on December 31, 2013, accrued interest at 8% and could be prepaid at any time before maturity by the Company. The Company granted a security interest to substantially all of its assets to the Demand Note holders.

On December 18, 2013, the Company sold \$1,999,864 of Convertible Promissory Notes in exchange for the Demand Notes above and \$969,869 in cash. The Convertible Promissory Notes were due on the earlier of December 18, 2014, an event of default, or a change in control as defined in the Convertible Promissory Note. Interest accrued at 8% per annum and the Convertible Promissory Notes were convertible into one share of Series A Convertible Preferred Stock for each \$1.00 principal remaining on the note. The Convertible Promissory Notes were unsecured. The Convertible Promissory Notes were converted into 1,999,864 shares of Series A Preferred Stock on December 30, 2013.

The weighted average interest rate in 2013 on the Company's debt instruments was approximately 8%. Interest in the amount of \$10,691 was accrued and paid in cash on the Demand Notes in 2013. Interest in the amount of \$5,120 was accrued in 2013 on the Convertible Promissory Notes and paid in 2014.

Note 8 - Stockholders' deficit

Stock option plan

In 2002, the Company adopted the 2002 Stock Option and Restricted Stock Plan (the 2002 plan), pursuant to which the Company's Board of Directors could grant either incentive or non-qualified stock options to officers and employees. The 2002 plan authorized a pool of options to purchase a total of 3,036 shares of the Company's common stock. The 2002 plan specified that, in a calendar year, the aggregate fair market value of incentive stock options vested, determined at the date of the grant, could not exceed \$100,000 for any participant. Stock options were granted at fair market value or at 110% of fair market value for those participants who were more than 10% shareholders. Generally, stock options have 10-year contractual terms, vest 25% per year and become fully exercisable after four years from the grant date.

In 2008, the Company amended and restated the 2002 Stock Option and Restricted Stock Plan through the adoption of 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, shares of restricted stock, or other stock-based awards to officers, directors, employees, consultants and advisors. Upon adoption, the 2008 plan authorized grants of options to purchase a total of 7,569 shares of the Company's common stock. Only employees are eligible to have options granted as "incentive stock options." Generally, stock options have 10-year contractual terms, vest 25% per year and become fully exercisable after four years from the grant date. The Company increased the number of shares of common stock available under the 2008 plan to 8,738 shares in 2009, 20,332 shares in 2011, and 36,668 shares in 2012. In conjunction with the December 2013 recapitalization and the associated financing, the number of shares reserved for issuance under the 2008 plan was set at 266,609. At December 31, 2013, there were 183,153 shares available for grant under the 2008 plan.

For the years ended December 31, 2013 and 2012, the Company recorded \$152,753 and \$214,970, respectively, of stock compensation expense. There were no amounts capitalized for the years ended December 31, 2013 and 2012. The allocation of stock compensation expense by operating expenses category is as follows:

	Year Ended December 31	
	2013	2012
Research and development	\$ 7,876	\$ 23,927
General and administrative	142,583	176,695
Sales and marketing	2,294	14,348
	<u>\$ 152,753</u>	<u>\$ 214,970</u>

At December 31, 2013, the Company had unrecognized expense related to its stock options of \$73,443 which will be recognized over a weighted-average period of 1.91 years. A summary of the status of options granted under the plan is presented below as of and for the years ended December 31, 2013 and 2012:

	Number of Stock Options	Weighted- Average Exercise Price	Weighted- Average Contractual Term (in Years)
Outstanding at January 1, 2012	16,305	\$ 103.32	8.34
Granted	7,948	\$ 7.91	
Forfeited	(2,078)	\$ 83.40	
Exercised	(47)	\$ 79.79	
Outstanding at December 31, 2012	22,128	\$ 70.97	7.89
Granted	7,064	\$ 7.91	
Forfeited	(8,190)	\$ 57.86	
Exercised	(46)	\$ 27.17	
Outstanding at December 31, 2013	<u>20,956</u>	<u>\$ 54.93</u>	8.05
Exercisable at end of year	<u>11,975</u>	<u>\$ 85.17</u>	7.28
Vested and expected to vest	<u>20,400</u>	<u>\$ 56.85</u>	8.00

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The weighted-average grant-date fair value for the option awards granted during the years ended December 31, 2013 and 2012 was \$3.56 and \$4.47, respectively. The total fair value of options vested in the years ended December 31, 2013 and 2012, was \$164,248 and \$221,570, respectively.

The fair value of each option grant was estimated at the date of grant using the Black -Scholes option pricing model based on the assumptions below:

	Year Ended December 31	
	2013	2012
Dividend yield	0.00%	0.00%
Expected life (years)	6.25	6.25
Risk-free interest rate	.93-1.69%	.81-1.38%
Volatility	60%	60%

Stock warrants

As of December 31, 2013, the following common stock warrants were outstanding:

Issuance	Type	Number	Exercise Price	Expiration
August 2007	Common	8,921	\$ 7.91	August 2017
September 2007	Common	3,451	\$ 790.54	September 2014
March 2008	Common	46	\$ 790.54	March 2018
April 2009	Common	33	\$ 790.54	April 2014
November 2009	Common	6,674	\$ 7.91	November 2019
January 2010	Common	6,674	\$ 7.91	January 2020
March 2010	Common	1,277	\$ 7.91	March 2020
November 2011	Common	5,213	\$ 7.91	November 2021
December 2011	Common	664	\$ 7.91	December 2021
March 2012	Common	4,125	\$ 109.09	March 2019

As described in Note 5, these warrants were converted into 37,078 common stock warrants in the December 2013 recapitalization.

The warrants listed above were issued in connection with various debt, preferred stock or development contract agreements. The estimated fair value of those warrants issued in connection with debt agreements were recorded as deferred financing costs and amortized to interest expense over the term of the related debt agreement. For the years ended December 31, 2013 and 2012, the Company recorded \$5,406 and \$18,199, respectively, for the amortization of the value of warrants related to debt issued in 2011. The estimated fair values of the warrants issued in connection with the preferred stock agreement were recorded as equity issuance costs and reduced the carrying value of the preferred stock at the issuance dates. The preferred stock is being accreted to its redemption value. The Company recorded \$314,192 and \$294,513, respectively, for the years ended December 31, 2013 and 2012, for the accretion of these equity issuance costs. The warrants exercisable into Series A and Series C preferred stock were required to be classified as a liability and marked to their estimated fair value at each reporting date since the preferred stock is redeemable for cash in certain circumstances outside of the Company's control. For the years ended December 31, 2013 and 2012, the Company recorded \$134,560 and \$0, respectively, as a change in the estimated fair value. The estimated fair value of the warrants for preferred stock issued in connection with the development contract agreement was recorded as warrant liability and expensed to other expense proportional to the revenue earned under the contract. For the years ended December 31, 2013 and 2012, the Company recorded \$1,639 and \$112,577, respectively, as other expense.

Note 9 - Income taxes

At December 31, 2013 and 2012, the Company has net deferred tax assets of \$28,704,670 and \$23,947,196, respectively, consisting of net operating loss (NOL) carry forwards, research and development (R&D) credits, and differences between depreciation and amortization recorded for financial statement and tax purposes. The Company's net deferred tax assets at December 31, 2013 and 2012 have been offset by a valuation allowance of the same amount. The valuation allowance has been recorded due to the uncertainty of realization of the deferred tax asset.

Deferred taxes - tax basis

The Company's deferred tax assets and liabilities as of December 31, 2013 and 2012 are as follows:

	2013	2012
Shared based compensation	\$ 127,429	\$ 81,578
Accrued employee benefits and severance	17,036	102,340
Deferred rent	23,342	48,069
Depreciation and amortization	172,357	260,404
Inventory reserve	377,674	35,614
Accrued bonus	13,640	-
Amortization	80,525	-
R&D credit carryforward	1,759,478	1,609,546
Federal NOL carryforward	26,137,776	21,809,859
Total deferred tax assets	28,709,257	23,947,410
Less: Valuation allowance	(28,704,670)	(23,947,196)
Deferred tax liabilities:		
Fixed assets	\$ (4,587)	\$ (214)
Net deferred tax asset/liability	\$ -	\$ -

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

	2013	2012
US Federal statutory rate	34.0%	34.0%
State income tax, net of Federal benefit	2.9%	1.5%
Change in valuation allowance	(46.7%)	(14.7%)
Changes in state tax rates and other	9.8%	(20.8%)
	0.0%	0.0%

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 \$70,903,156 and \$61,373,248 at December 31, 2013 and 2012, respectively. The NOL carry forwards begin to expire in 2021. 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.

Note 10 - Lease commitments

Operating leases

During 2008, the Company relocated its headquarters to Gaithersburg, Maryland. Under the terms of an operating lease for that facility, the Company was obligated to pay \$26,229 per month beginning in July 2008 with a 3% increase each anniversary date ending in September 2012. In April 2011, this lease was modified and extended until September 2014. The monthly base rent was increased to \$40,218 beginning in July 2011, and includes a 3% increase in August of each year. In addition, the Company leased space in Madison, Wisconsin under an operating lease which was terminated in April 2013.

OpGen, Inc.
Notes to Financial Statements
December 31, 2013 and 2012

For all of the operating leases, the Company is responsible for all utilities, repairs, insurance, and taxes. Expense under the Company's leases for the years ended December 31, 2013 and 2012, was \$885,310 and \$943,049, respectively.

The Company leases computer equipment, office furniture, and equipment under various capital leases. The leases commenced beginning in 2006 and expire at various dates through 2018. Five new leases commenced in 2013. 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, 2013:

Years ending December 31:	<u>Capital Leases</u>	<u>Operating Leases</u>	<u>Total</u>
2014	\$ 132,433	\$ 409,128	\$ 541,561
2015	117,592	-	117,592
2016	89,765	-	89,765
2017	29,622	-	29,622
2018	27,153	-	27,153
	<u>\$ 396,565</u>	<u>\$ 409,128</u>	<u>\$ 805,693</u>
Less amount representing interest	<u>(56,036)</u>		
Present value of minimum lease payments	340,529		
Less current maturities	<u>(105,967)</u>		
Long-term portion of capital lease obligation	<u>\$ 234,562</u>		

Amortization expense associated with equipment under capital leases for the years ended December 31, 2013 and 2012 was \$52,599 and \$26,321, respectively, and is included within depreciation and amortization expense in the statements of operations.

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

	<u>2013</u>	<u>2012</u>
Laboratory equipment	\$ 364,471	\$ 26,860
Computers	153,693	112,734
Less accumulated amortization	<u>(122,619)</u>	<u>(70,220)</u>
Capital lease assets, net	<u>\$ 395,545</u>	<u>\$ 69,374</u>

Note 11 - Employee benefit plan

Substantially all employees are eligible to participate in a retirement Savings Plan, the OpGen 401(k) Plan. The Company made matching contributions up to 2% of eligible compensation (subject to a \$255,000 compensation limit for 2013) until April 2013 when they were suspended. For the years ended December 31, 2013 and 2012, the Company contributed \$27,299 and \$81,911, respectively, to the Savings Plan.

Note 12 - License agreements

The Company was a party to three license agreements to acquire certain patent rights and technologies until December 2013 when one of the agreements was terminated. Royalties are incurred upon the sale of a product or service which utilizes the licensed technology. Certain of the agreements require it to pay minimum royalties or license maintenance fees. The accompanying financial statements reflect \$199,449 and \$238,405 of total royalty expense for the years ended 2013 and 2012, respectively, which are classified as cost of sales in the accompanying statements of operations. In 2014, future minimum royalty fees are \$90,000 under these agreements.

Note 13 - Subsequent events

The Company has performed an evaluation of subsequent events through the date the accompanying financial statements were issued and did not identify any material subsequent transactions that require disclosure, other than those matters discussed below.

Sales of Preferred Stock

In February 2014, the Company sold 1,405,096 shares of Series A Convertible Preferred Stock at \$1.00 per share for gross proceeds of \$1,405,096. In April 2014, the Company sold an additional 594,904 shares of Series A Convertible Preferred Stock for gross proceeds of \$594,904. The terms and provisions of the Series A Convertible Preferred Stock were the same as that issued in December 2013.

In conjunction with the Series A Preferred Stock sold above, the Company increased the number of shares available for grant under the 2008 plan to 503,347.

Issuance of Debt

In July, August and September 2014, the Company raised \$1.5 million through the issuance of convertible debt. The debt is convertible, at the option of the holders or in certain cases at the Company's option, into shares of Series A preferred stock or other potential equity securities. The debt bears interest at 8% and is due in full on July 11, 2015.

In October 2014, the Company raised \$0.5 million in capital through the issuance of 8% secured promissory notes, due in February 2015. In November 2014, the Company raised \$0.5 million of capital through the issuance of 8% secured promissory notes due in March 2015.

Lease Extension

In March 2014, the Company extended the termination date of its Gaithersburg, Maryland facility lease to April 2015 under the terms and provisions of the existing lease except that 50% of the monthly rental fee for October and November 2014 will be abated. The lease extension increased the estimated future minimum payments under this lease by \$271,593.

OpGen, Inc.
Notes to Financial Statements
December 31, 2013 and 2012

Note 14 - Pro Forma Net Loss Per Share Available to Common Stockholders (Unaudited)

The following table sets forth the computation of the Company's unaudited pro forma basic and diluted net loss per common share after giving effect to the conversion into shares of common stock of (i) convertible notes and (ii) redeemable convertible preferred stock using the as-if converted method as though the conversions had occurred as of the earlier of the specific issuance date or at the beginning of the period (in thousands, except share and per share amounts):

	<u>Year ended December 31, 2013</u>
Net loss available for common shareholders	\$ (15,508)
Interest on convertible notes	5
Preferred stock dividends	5,373
	<u> </u>
Pro forma net loss available for common shareholders	<u>\$ (10,130)</u>
Weighted average common shares outstanding - basic and diluted	17,306
Pro forma adjustment to reflect assumed conversion of convertible notes	-
Pro forma adjustment to reflect assumed conversion of redeemable convertible preferred stock	421,911
Pro forma adjustment to reflect assumed conversion of restricted stock units	-
	<u> </u>
Pro forma weighted average common shares outstanding - basic and diluted	<u>439,217</u>
	<u> </u>
Pro forma net loss per common share - basic and diluted	<u>\$ (23.06)</u>

OPGEN, INC.

Index to Unaudited Interim Condensed Financial Statements

Nine Months Ended September 30, 2014 and 2013

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OpGen, Inc.
Condensed Balance Sheet
(Unaudited)

	<u>September 30,</u> <u>2014</u>	<u>December 31,</u> <u>2013</u>	<u>Pro Forma</u> <u>Stockholders'</u> <u>Equity (Deficit)</u> <u>at September 30,</u> <u>2014</u>
Assets			
Current assets			
Cash and cash equivalents	\$ 781,573	\$ 1,400,345	
Accounts receivable, net	184,046	241,897	
Inventory, net	379,482	175,713	
Prepaid expenses and other current assets	90,935	146,438	
Total current assets	1,436,036	1,964,393	
Property and equipment, net	700,720	1,079,423	
Licensed technology and other intangible assets, net	14,398	57,594	
Other noncurrent assets	57,459	57,459	
Total assets	\$ 2,208,613	\$ 3,158,869	
Liabilities, Preferred Stock and Stockholders' Deficit			
Current liabilities			
Accounts payable	\$ 899,025	\$ 869,172	
Accrued liabilities	1,234,318	1,261,017	
Deferred revenue	388,177	509,728	
Convertible notes	1,500,000	--	
Current maturities of long-term debt and capital lease obligation	107,560	115,967	
Total current liabilities	4,129,080	2,755,884	
Capital lease obligation, less current maturities	158,644	234,562	
Total liabilities	4,287,724	2,990,446	
Commitments and contingencies			
Redeemable convertible preferred stock			
Series A redeemable convertible preferred stock, \$.01 par value; 6,000,000 shares authorized; 3,999,864 shares issued and outstanding at September 30, 2014; liquidation preference of \$8 million at September 30, 2014	3,942,585	1,999,864	-
Total redeemable convertible preferred stock	3,942,585	1,999,864	-
Stockholders' deficit			
Common stock, \$.01 par value; 7,500,000 shares authorized; 362,537 shares issued and outstanding at September 30, 2014	3,625	3,625	59,930
Additional paid-in capital	89,341,395	89,265,757	94,727,675
Accumulated deficit	(95,366,716)	(91,100,823)	(95,366,716)
Total stockholders' deficit	(6,021,696)	(1,831,441)	(579,111)
Total liabilities, preferred stock and stockholders' deficit	\$ 2,208,613	\$ 3,158,869	

See notes to unaudited condensed financial statements.

OpGen, Inc.
Condensed Statements of Operations
Nine Months Ended September 30,
(Unaudited)

	2014	2013
Revenue		
Product sales	\$ 841,567	\$ 1,221,220
Laboratory services	379,339	556,902
Collaborations revenue	1,783,340	16,461
Total revenue	3,004,246	1,794,583
Operating expenses		
Cost of products sold	292,116	1,012,396
Cost of services	398,628	293,149
Research and development	3,300,124	3,303,000
General and administrative	1,652,599	2,190,595
Sales and marketing	1,583,718	2,309,673
Total operating expenses	7,227,185	9,108,813
Operating loss	(4,222,939)	(7,314,230)
Other income (expense)		
Interest income	120	1,176
Interest expense	(47,468)	(9,127)
Other income (expense)	4,400	98,991
Total other income (expense)	(42,948)	91,040
Net loss	(4,265,887)	(7,223,190)
Preferred stock dividends and accretion	(4,819)	(4,179,450)
Net loss available to common stockholders	\$ (4,270,706)	\$ (11,402,640)
Net loss per common share - basic and diluted	\$ (11.78)	\$ (3,232.04)
Weighted average shares outstanding - basic and diluted	362,536	3,528
Pro forma net loss per common share – basic and diluted	\$ (0.97)	
Pro forma weighted average shares outstanding – basic and diluted	4,359,800	

See notes to unaudited condensed financial statements.

OpGen, Inc.
Condensed Statements of Cash Flows
Nine Months Ended September 30,

	<u>2014</u>	<u>2013</u>
Cash flows from operating activities		
Net loss	\$ (4,265,887)	\$ (7,223,190)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	461,432	474,149
Amortization of debt discount	4,807	-
Non-cash interest expense	16,076	10,098
Recovery of bad debt	(4,400)	(49,050)
Loan forgiveness	-	(36,811)
Stock compensation expense	80,457	140,860
Inventory obsolescence	(44,595)	(70,144)
Other non-cash items	-	1,339
Changes in operating assets and liabilities:		
Accounts receivable	62,251	789,924
Inventory	(159,174)	(619,172)
All other assets	78,311	187,924
Accounts payable	29,853	210,723
Accrued liabilities	(42,778)	(301,578)
Deferred revenue	(121,551)	299,979
Net cash used in operating activities	(3,905,198)	(6,184,949)
Cash flows from investing activities		
Purchases of property and equipment	(39,537)	(38,459)
Net cash used in investing activities	(39,537)	(38,459)
Cash flows from financing activities		
Proceeds from issuance of preferred stock, net of issuance costs	1,937,902	(2,670)
Proceeds from borrowings on convertible notes, net of issuance costs	1,472,386	-
Proceeds from exercise of stock options and warrants	-	1,061
Payments on debt	(3,750)	(75,000)
Payments on capital lease obligations	(80,575)	(30,312)
Net cash provided by (used in) financing activities	3,325,963	(106,921)
Net (decrease) increase in cash and cash equivalents	(618,772)	(6,330,329)
Cash and cash equivalents at beginning of period	1,400,345	7,117,714
Cash and cash equivalents at end of period	\$ 781,573	\$ 787,385
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	\$ 26,088	\$ 7,624
Supplemental disclosure of noncash investing and financing activities:		
Acquisition of equipment purchased through capital leases	\$	\$ 40,959

See notes to unaudited condensed financial statements.

Notes to Unaudited Condensed Financial Statements
September 30, 2014 and 2013

Note 1 - Organization

OpGen, Inc. (OpGen or the Company) was incorporated in Delaware on January 22, 2001. OpGen is a commercial stage company using molecular testing and bioinformatics to combat multi-drug resistant infections. The Company's products and services enable healthcare providers to rapidly identify hospital patients who are colonized with life threatening, multi-drug resistant organisms, or MDROs. The Company's Acuitas™ gene-based testing products are enabled by the Lighthouse™ bioinformatics platform which provides detailed MDRO molecular information about an individual patient's resistance profile and integrates this information with data from other patients and hospital-wide aggregate results to help improve overall patient outcomes and to reduce hospital costs. The Company believes that it has an important first-mover advantage in providing Acuitas-enabled molecular information to healthcare providers on a commercial scale.

The Company's headquarters and principal operations are in Gaithersburg, Maryland. The Company had an additional facility in Madison, Wisconsin, which was closed in April 2013. The Company operates in one business segment.

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 availability of additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop and commercialize its novel technology as well as raise additional capital.

Note 2 - Going concern and management's plans

The accompanying 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, negative operating cash flows and has a deficit in stockholders' equity.

The Company raised \$4.0 million in two Series A Preferred Stock offerings during the fourth quarter of 2013 and early 2014, raised \$1.5 million through the issuance of convertible debt in the third quarter of 2014, and raised \$1.0 million through the issuance of promissory notes in the fourth quarter of 2014. Management is actively engaged in efforts to raise additional capital. The Company's current operating assumptions, which include management's best estimate of future revenue and operating expenses, indicate that current cash on hand will not be sufficient to fund operations as currently configured through the end of 2014.

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 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. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Note 3 - Summary of significant accounting policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). In our opinion, the accompanying unaudited interim condensed financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The interim condensed results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules and regulations prescribed by the United States Securities and Exchange Commission. We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim condensed financial statements are read in conjunction with the audited financial statements and notes included elsewhere herein.

Use of estimates

In preparing financial statements in conformity with accounting principles generally accepted in the United States, 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 financial statements, estimates are used for, but not limited to, stock-based compensation, allowances for doubtful accounts and inventories, valuation of derivative financial instruments, 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 current assets and liabilities are carried at cost, which approximates fair value, because of the short-term maturities of those instruments. Debt and capital leases are reflective of fair value based on instruments with similar terms available to the Company.

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.

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 45 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 \$79,697 as of September 30, 2014.

At September 30, 2014, the Company had accounts receivable from two customers which individually represent 41%, and 19% of total accounts receivable. For the nine months ended September 30, 2014 one individual customer represented 64% of revenues. For the nine months ended September 30, 2013 four individual customers represented 16%, 16%, 13% and 12% of revenues.

Licensed technology and other intangible assets

Licensed technology and other intangible assets consist primarily of costs related to patents and licensed technology. These costs were capitalized and amortized over the estimated useful lives of the underlying technology, which ranged from two to 10 years. As part of an analysis of the Argus™ Whole Genome Mapping technology in 2013, a change in the estimated lives was made during 2013 such that the amortization period for all of the licensed technology would end by December 31, 2014. In addition, one license agreement was terminated in December 2013 and the related licensed technology costs were amortized in full. As a result, approximately \$90,000 of capitalized technology costs and associated accumulated amortization were written off upon the termination of the fully amortized license.

Total amortization expense was \$43,195 and \$81,521 for the nine months ended September 30, 2014 and 2013, respectively. Accumulated amortization was \$684,551 at September 30, 2014.

Impairment of long-lived assets

The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. An impairment loss would be measured as the amount by which the carrying value of the asset exceeds the estimated fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less costs to sell. During the nine months ended September 30, 2014 and 2013, the Company determined that there were no impaired long-lived assets.

Redeemable convertible preferred stock

The carrying value of the Company's redeemable convertible preferred stock is increased by the accretion of related discounts, issuance costs and accrued but unpaid dividends so that the carrying amount will equal the redemption amount at the dates the stock becomes redeemable. As of September 30, 2014, the Company had 3,999,864 of Series A redeemable convertible preferred stock outstanding. The Series A preferred stock is redeemable at the option of the holders of 70% of the outstanding shares of preferred stock, subject to certain additional requirements.

Revenue recognition

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

Revenue from sales of the Argus™ System

When the 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 the 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 (considered multiple elements) 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 stand-alone 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.

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.

Income taxes

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax basis of assets and liabilities and their financial reporting amounts at each year-end based on the enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. 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.

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.

The Company has federal NOL carryforwards of \$70,903,156 and \$61,373,248 at December 31, 2013 and 2012, respectively. Despite the NOL carryforwards, which begin to expire in 2012, the Company may have future tax liability due to alternative minimum tax or state tax requirements. Also, use 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.

Loss per share

Basic loss per share is computed by dividing net loss available to common shareholders 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 shareholders 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 common stock options, stock purchase warrants, convertible preferred stock and convertible debt exercisable or exchangeable into common stock which have been excluded from the computation of diluted loss per share, were 6.1 million and 0.4 million for the nine months ended September 30, 2014 and 2013, respectively. The Company's convertible preferred stock contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; 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.

Stock-based compensation

Share-based payments to employees are recognized at fair value. The fair value of share-based payments 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. The estimated fair value of equity instruments issued to nonemployees are recorded at fair value on the earlier of the performance commitment date or the date the services required are completed.

For all time-vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. Share-based compensation expense recognized is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period.

Recent accounting pronouncements

In July 2012, the Financial Accounting Standards Board (“FASB”) issued accounting guidance to simplify the evaluation for impairment of indefinite-lived intangible assets. Under the updated guidance, an entity has the option of first performing a qualitative assessment to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired before proceeding to the quantitative impairment test under which it would calculate the asset’s fair value. When performing the qualitative assessment, the entity must evaluate events and circumstances that may affect the significant inputs used to determine the fair value of the indefinite-lived intangible asset. The adoption of this standard in 2013 did not have a material impact on the Company’s consolidated results of operations, cash flows or financial position.

In July 2013, the FASB issued guidance for the presentation of an unrecognized tax benefit when a net operating loss (“NOL”) carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance requires an entity to present in the financial statements an unrecognized tax benefit, or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for an NOL carryforward, a similar tax loss, or a tax credit carryforward. If the NOL carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the jurisdiction or the tax law of the jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit will be presented in the financial statements as a liability and will not be combined with deferred tax assets. The adoption of this guidance in 2014 did not have a material impact on our financial statements.

In May 2014, the 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. The standard is effective for our reporting year beginning January 1, 2017 and early adoption is not permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its 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. The standard is effective for our reporting year beginning January 1, 2017 and early adoption is not permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

Note 4 - Fair value measurements

Included in the financial statements are certain financial instruments carried at fair value, including cash and cash equivalents. 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.

Notes to Unaudited Condensed Financial Statements
September 30, 2014 and 2013

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 following tables present the fair value hierarchy for the Company's financial assets and liabilities measured at fair value on a recurring basis at September 31, 2014:

	September 30, 2014 Total	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3
Cash and cash equivalents	\$ 781,573	\$ 780,104	\$ 1,469	\$ –

The Company's Level 1 securities primarily consist of cash. The Company determines the estimated fair value for its Level 1 securities using quoted (unadjusted) prices for identical assets or liabilities in active markets.

The Company's Level 2 securities primarily consist of money market funds and U.S. Treasury Notes. The Company determines the estimated fair value for its Level 2 securities using the following methods: quoted prices for similar assets/liabilities in active markets, inputs other than quoted prices that are observable for the asset/liability (e.g., interest rates, yield curves volatilities, default rates, etc.) and inputs that are derived principally from or corroborated by other observable market data.

Prior to the December 2013 Recapitalization (see Note 6), the Company had outstanding stock purchase warrants entitling the holders to purchase its Series A redeemable convertible preferred stock. The following table presents information about the Series A convertible preferred stock warrant derivative liability, which was measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

	September 30	
	2014	2013
Balance beginning of year	\$ –	\$ (661)
Transfers to (from) Level 3	–	–
Total gains realized/unrealized included in earnings	–	–
Balance at September 30	<u>\$ –</u>	<u>\$ (661)</u>

The warrant derivative liability was settled in December 2013 when the warrant was converted into a common stock warrant in connection with the December 2013 Recapitalization.

Prior to the December 2013 Recapitalization (see Note 6), the Company had outstanding stock purchase warrants entitling the holders to purchase its Series C redeemable convertible preferred stock. The following table presents information about the Series C convertible preferred stock warrant derivative liability to purchase 3,260,870 shares of Series C preferred stock as part of an existing development agreement under which the Company is performing work for the development partner. The warrant is measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

	September 30	
	2014	2013
Balance beginning of year	\$ –	\$ (132,260)
Transfers to (from) Level 3	–	–
Total gains realized/unrealized included in earnings	–	(1,339)
Balance at September 30	<u>\$ –</u>	<u>\$ (133,599)</u>

The warrant derivative liability was settled in December 2013 when the warrant was converted into a common stock warrant in connection with the December 2013 Recapitalization.

The Company has not nonfinancial assets and liabilities measured at fair value on a recurring basis. The Company measures its long-lived assets (intangible assets and property and equipment) on a nonrecurring basis when impairments are identified; no such impairments were identified during the nine months ended September 30, 2014 and 2013.

Note 5 - Research collaborations and development agreements

In August 2011, the Company entered into a collaboration agreement with a university in the United States to collect, produce, and distribute high-quality, annotated genomic sequence and organism phenotype data from clinically relevant microbes and associated patient demographic data. The primary responsibilities of the university were to create a data storage model including whole genome map data, perform genomic sequencing of relevant microbes, and coordinate publications. The Company's primary responsibilities were to provide funding of up to \$250,000 for the hiring of two informatics resources at the university, supply whole genome maps, and supply other clinically relevant data. The collaboration was expected to operate through the end of 2012 and was cancelable by either party on 60 days' notice. The Company accrued \$135,557 in research and development expenses in 2012 related to this project. The Company and the university amended the contract in 2014 to adjust the scope of the work to the \$135,557 already incurred and to adjust the payment schedule such that the \$135,557 is paid over 2014 and 2015.

In 2007, the Company entered into a development agreement with a governmental entity in which the Company would receive fixed milestone payments for meeting development milestones under the agreement. The first phase of this agreement was completed in 2010. The Company also issued a warrant for Series A preferred stock to the governmental entity at the initiation of the agreement. In December 2011, the Company amended the agreement to begin a new phase of development work. Under the contract, the Company was contracted to significantly modify existing software, which changed the functionality of the existing software and other components supplied under the contract. The Company received fixed-fee payments for development work under this amendment and recognized revenue using percentage of completion accounting. Upon signing the amendment in December 2011, the Company agreed to issue the governmental entity warrants to purchase Series C preferred shares upon the successful close of a Series C financing. On March 5, 2012, the Company issued a warrant to purchase 3,260,870 shares of Series C preferred stock as part of an existing development agreement under which the Company performed work for the development partner. The warrant became vested in proportion to the revenue received by the Company under the development agreement and was fully vested in early 2013. The warrant was exercisable at \$0.138 and has a term of seven years. The Company valued the warrant at \$133,899, which was recorded as a liability and expensed proportional to the revenue earned. The Series C Preferred Stock warrant was converted into a Common Stock warrant to purchase 4,125 shares of common stock in the December 2013 Recapitalization.

In September 2013, the Company entered into a technology development agreement in which the Company would receive fixed milestone payment for meeting development milestones under the agreement. Since the milestones are substantive, the Company will recognize revenue in the period in which the substantive milestone is achieved. In addition, the Company received an upfront payment of \$250,000, which will be recognized on a straight-line basis over the term of the technology development agreement. The Company attained twelve milestones during the first nine months of 2014 and recognized \$1.8 million of revenue under this agreement.

Note 6 - Restructuring costs

In February and April 2013, the Company restructured its operations to reduce expenditures and conserve cash while accelerating its planned strategic repositioning into the clinical diagnostics market. In connection with this restructuring, the Company reduced its workforce by approximately 36%, or 16 employees. The Company incurred and paid approximately \$330,000 of restructuring costs during the nine months ended September 30, 2013 (none in 2014).

Note 7 - December 2013 recapitalization

On November 1, 2013, the Company and various investors entered into a financing commitment agreement whereby the Company sold Demand Notes to the investors in the amount of \$1,030,000 and the Company commenced a rights offering consisting of \$2,000,000 Convertible Promissory Notes. The Convertible Promissory Notes were convertible into Series A redeemable convertible preferred stock at \$1.00 per share. On December 18, 2013, the Company issued \$1,999,864 in Convertible Promissory Notes in exchange for \$969,864 in cash and in exchange for the Demand Notes. On December 30, 2013, the Convertible Promissory Notes were converted into 1,999,864 shares of Series A redeemable convertible preferred stock.

In conjunction with, and as a condition of, the financing described above, the following actions were taken as of the date of the issuance of the Convertible Promissory Notes. These actions are collectively referred to as the "December 2013 Recapitalization."

- A mandatory conversion of all outstanding shares of senior preferred stock into Common Stock in accordance with the terms of the Certificate of Incorporation;
- A mandatory conversion of all outstanding shares of the Series A-1 Preferred Stock into Common Stock on a one-to-one basis;
- Elimination of all mandatory, accrued, cumulative and unpaid dividends on the senior preferred stock;
- A 1-for-790.5407 reverse stock split of the Company's Common Stock as of the financing date; and
- Conversion of all outstanding options and warrants for preferred stock into options and warrants for common stock on the terms above.

As of December 31, 2013, and as a result of the (i) December 31, 2013 Recapitalization and (ii) December 2013 issuance of Convertible Promissory Notes and their subsequent conversion into Series A redeemable convertible preferred stock, the Company had the following equity securities outstanding:

- 362,537 shares of common stock outstanding;
- 1,999,864 shares of Series A redeemable convertible preferred stock outstanding and convertible into 1,999,864 shares of common stock;
- Stock purchase warrants outstanding to purchase 37,078 shares of common stock; and
- Stock options outstanding to purchase 20,956 shares of common stock.

Note 8 - Redeemable convertible preferred stock

The Company's redeemable convertible preferred stock is classified as temporary equity due to redemption provisions outside of the Company's control.

On July 10, 2014, in advance of the issuance of notes convertible into additional shares of the Company's Series A redeemable convertible preferred stock, the Company filed its Ninth Amended and Restated Certificate of Incorporation to increase the number of authorized shares of preferred stock from 2.5 million to 6.0 million, all designated as Series A preferred stock (further convertible into common stock), and to increase the number of authorized shares of common stock from 3.5 million to 7.5 million.

Series A redeemable convertible preferred stock

The Company issued 1,999,864 shares of Series A redeemable convertible 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 redeemable convertible preferred stock for gross proceeds of \$594,904. The Company incurred issuance costs of \$62,098 related to these Series A preferred stock sales. As of September 30, 2014, the Company had a total of 3,999,864 shares of Series A redeemable convertible preferred stock outstanding, convertible into 3,999,864 shares of common stock.

The Series A redeemable convertible preferred stock has 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 redeemable convertible preferred stock has 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 are at two times the Series A redeemable convertible preferred stock purchase price. The Series A redeemable convertible preferred stockholders are 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 redeemable convertible preferred stock has broad based anti-dilution rights.

The holders of Series A redeemable convertible preferred stock have 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 is one common share for each preferred share, which may be adjusted for specified dilutive transactions. Beginning in December 2020, the Company may be obligated to redeem shares of Series A redeemable convertible preferred stock, if requested, by holders of at least 70% of the then-outstanding shares of preferred stock. The redemption, if requested, would take place in three equal annual installments. Series A redeemable convertible preferred stock would be redeemed at two times the original issue price per share plus all accrued and unpaid dividends. The redemptions are subject to certain equity adjustments for specified anti-dilution transactions, as defined.

Senior preferred stock

Holders of the Series A, Series B, and Series C preferred stock (senior preferred) outstanding before the December 2013 Recapitalization had a liquidation preference senior to that of the common stock. Upon a liquidation of the Company, the proceeds of the liquidation would have been distributed as follows, unless the senior preferred stock holders would receive a greater amount upon the conversion of their shares to common. First, to the holders of Series C preferred stock, an amount per share equal to two times the Series C Original Issue Price; second, to the holders of Series A and B preferred stock, *pari passu*, an amount per share equal to the Series A Original Issue Price and the Series B Original Issue Price (as applicable); third, to the holders of Series C preferred stock an amount equal to all unpaid Series C dividends; fourth, to the holders of Series A and Series B preferred stock, *pari passu*, an amount equal to all unpaid Series A and Series B dividends (as applicable); and the remainder to common stockholders. The Company accrued dividends of \$3,934,612 during the nine months ended September 30, 2013; all such dividends were eliminated in connection with the December 2013 Recapitalization. All senior preferred stock was converted to common stock in connection with the December 2013 Recapitalization.

The holders of the Series A-1 preferred stock had no voting rights and were not entitled to receive any dividends. Upon the closing of a qualified initial public offering of at least \$30.0 million, all outstanding shares of Series A-1 preferred stock would have automatically converted into common stock at \$1.02 per share or, at the Company's option, could be settled in cash for an amount not to exceed \$4,857,622. The Series A-1 redeemable convertible preferred stock was converted to common stock in connection with the December 2013 Recapitalization.

Note 9 - Debt

In July, August and September 2014, the Company raised \$1.5 million through the issuance of convertible debt. The debt is convertible, at the option of the holders or in certain cases at the Company's option, into shares of Series A preferred stock or other potential equity securities. The debt bears interest at 8% and is due in full on July 11, 2015. The debt is convertible, at the option of at least 67% of the convertible debt holders, into either (i) one share of Series A Convertible Preferred Stock for each \$1.00 of convertible debt, or (ii) shares of a new preferred stock issued in the next financing at a price per share of the stock issued in the next financing, less 25%.

In 2009, the Company entered into loan agreements with the Department of Business and Economic Development, a principal department of the State of Maryland, and Montgomery County, Maryland. Under the terms of the agreements, the State of Maryland and Montgomery County loaned the Company \$100,000 and \$10,000, respectively, to assist in the relocation of the Company's operations from Wisconsin to Gaithersburg, Maryland. Interest on the loans accrued at 3%. The interest was deferred and the loans were forgivable under certain conditions, including the Company maintaining operations in Gaithersburg, Maryland, and attaining a specified level of staffing at that site on or before December 31, 2012. The Company did not attain the required level of staffing at December 31, 2012, and, as a result, these notes and accrued interest became due in 2013. The Company negotiated a settlement with the State of Maryland under which it paid \$75,000 in June 2013 in full satisfaction of the \$100,000 loan principal balance and accrued interest of \$11,811. The Company also negotiated a settlement with Montgomery County under which accrued interest due under the loan provisions was forgiven and the loan would be paid in equal quarterly installments over the eight quarters ending December 31, 2015. The Company recorded the loan and interest forgiveness of \$38,242 as Other Income in 2013 for these two loans.

The Company sold \$1,030,000 of Demand Notes in November 2013. The Demand Notes were due on December 31, 2013, accrued interest at 8% and could be prepaid at any time before maturity by the Company. The Company granted a security interest to substantially all of its assets to the Demand Note holders.

On December 18, 2013, the Company sold \$1,999,864 of Convertible Promissory Notes in exchange for the Demand Notes above and \$969,869 in cash. The Convertible Promissory Notes were due on the earlier of December 18, 2014, an event of default, or a change in control as defined in the Convertible Promissory Note. Interest accrued at 8% per annum and the Convertible Promissory Notes were convertible into one share of Series A redeemable convertible preferred stock for each \$1.00 principal remaining on the note. The Convertible Promissory Notes were unsecured. The Convertible Promissory Notes were converted into 1,999,864 shares of Series A redeemable convertible preferred stock on December 30, 2013.

The weighted average interest rate for the nine months ended September 30, 2014 on the Company's debt instruments was approximately 8%.

Note 10 - Stockholders' equity (deficit)

On July 10, 2014, in advance of the issuance of notes convertible into additional shares of the Company's Series A redeemable convertible preferred stock, the Company filed its Ninth Amended and Restated Certificate of Incorporation to increase the number of authorized shares of preferred stock from 2.5 million to 6.0 million, all designated as Series A preferred stock (further convertible into common stock), and to increase the number of authorized shares of common stock from 3.5 million to 7.5 million.

Stock options and restricted stock awards

In 2002, the Company adopted the 2002 Stock Option and Restricted Stock Plan (the 2002 plan), pursuant to which the Company's Board of Directors could grant either incentive or non-qualified stock options to officers and employees. The 2002 plan authorized a pool of options to purchase a total of 3,036 shares of the Company's common stock. The 2002 plan specified that, in a calendar year, the aggregate fair market value of incentive stock options vested, determined at the date of the grant, could not exceed \$100,000 for any participant. Stock options were granted at fair market value or at 110% of fair market value for those participants who were more than 10% shareholders. Generally, stock options have 10-year contractual terms, vest 25% per year and become fully exercisable after four years from the grant date.

In 2008, the Company amended and restated the 2002 Stock Option and Restricted Stock Plan through the adoption of 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, shares of restricted stock, or other stock-based awards to officers, directors, employees, consultants and advisors. At September 30, 2014, there were 51,227 shares available for grant under the 2008 plan.

For the nine months ended September 30, 2014 and 2013, the Company recorded \$80,457 and \$140,860, respectively, of stock compensation expense. The allocation of stock compensation expense by operating expenses is as follows:

	Nine Months Ended September	
	30,	
	2014	2013
Research and development	\$ 18,443	\$ 6,544
General and administrative	59,492	132,801
Sales and marketing	2,522	1,515
	\$ 80,457	\$ 140,860

During the nine months ended September 30, 2014, the Company granted stock options to acquire 401,053 shares of common stock at an exercise price of \$0.05 per share and with a weighted average grant date fair value of \$0.03. The Company has total stock options to acquire 410,870 shares of common stock outstanding at September 30, 2014.

In March of 2014 the Company awarded 130,640 restricted stock units to acquire 130,640 shares of common stock to its Chief Executive Officer, Evan Jones. The restricted stock units were compensation to Mr. Jones for his service as Chief Executive Officer from before the grant date through June 2014 and were subject to forfeiture if Mr. Jones did not continue to perform management services through October 24, 2014. The Company reported compensation expense of \$6,532 for these restricted stock units in 2014 which was based on the fair market value of the underlying shares at the date of grant.

Stock purchase warrants

The Company has total stock purchase warrants to acquire 37,078 shares of common stock outstanding at September 30, 2014.

Note 11 - License agreements

The Company was a party to three license agreements to acquire certain patent rights and technologies until December 2013 when one of the agreements was terminated. Royalties are incurred upon the sale of a product or service which utilizes the licensed technology. Certain of the agreements require it to pay minimum royalties or license maintenance fees. The Company incurred \$73,142 and \$150,840 of total royalty expense for the nine months ended September 30, 2014 and 2013, respectively, which are classified as cost of sales in the accompanying statements of operations.

Note 12 - Subsequent events

The Company has performed an evaluation of subsequent events through the date the accompanying financial statements were issued and did not identify any material subsequent transactions that require disclosure, other than those matters discussed below.

In October 2014, the Company raised \$0.5 million of capital through the issuance of 8% secured promissory notes, due in February 2015. In November 2014, the Company raised \$0.5 million of capital through the issuance of 8% secured promissory notes due in March 2015. In December 2014, the Company raised \$0.5 million of capital through the issuance of 8% secured promissory notes due April 2015.

Note 13 - Pro Forma Net Loss Per Share Available to Common Stockholders

The following table sets forth the computation of the Company's unaudited pro forma basic and diluted net loss per common share after giving effect to the conversion into shares of common stock of (i) convertible notes, (ii) redeemable convertible preferred stock, and (iii) unvested restricted stock units using the as-if converted method as though the conversions had occurred as of the earlier of the specific issuance date or at the beginning of the period (in thousands, except share and per share amounts):

	Nine months ended September 30, 2014
Net loss available for common shareholders	\$ (4,271)
Interest on convertible notes	26
Preferred stock dividends	5
Pro forma net loss available for common shareholders	\$ (4,240)
Weighted average common shares outstanding - basic and diluted	362,536
Pro forma adjustment to reflect assumed conversion of convertible notes	354,252
Pro forma adjustment to reflect assumed conversion of redeemable convertible preferred stock	3,542,040
Pro forma adjustment to reflect assumed conversion of restricted stock units	100,972
Pro forma weighted average common shares outstanding - basic and diluted	4,359,800
Pro forma net loss per common share - basic and diluted	\$ (0.97)



Shares
COMMON STOCK

PART II

Information Not Required in Prospectus

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the fees and expenses, other than underwriting discounts and commissions, 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	\$	*
Legal fees and expenses	\$	*
Accounting fees and expenses	\$	*
FINRA filing fee	\$	*
Printer costs and expenses	\$	*
Total	\$	*

* To be included in an amendment.

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have 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.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Exchange Act.

Item 15. Recent Sales of Unregistered Securities.

On December 18, 2013, we effected a 1 for 790.5407 reverse stock split of our common stock. All references to shares, stock options and warrants outstanding, and the exercise price of outstanding derivative securities have been adjusted to reflect such reverse stock split.

The following list sets forth information as to all securities we have sold since January 1, 2011, which were not registered under the Securities Act.

1. On November 8, 2011, the Company issued convertible notes in an aggregate principal amount of \$1,893,752.67 and related warrants to purchase common stock to existing institutional and individual accredited investors. In December 2011, a second closing took place to allow other existing institutional and individual accredited investors to participate in the financing opportunity in order to maintain their percentage-ownership position in the Company. The December 2011 closing resulted in the issuance of additional notes in an aggregate principal amount of \$405,456.09, plus related warrants. The convertible notes matured on June 30, 2012. Warrant holders paid an aggregate purchase price of \$229.93. The warrants expire on November 8, 2021. Upon exercise, warrant holders receive the number of shares purchasable under the warrant multiplied by the difference of the fair market value of one exercise share (to be determined by the Company's Board of Directors, in good faith; or the per share offering price to the public if the warrant is exercised in connection with an initial public offering) minus the exercise price. That product is then divided by the fair market value of one exercise share.

2. From March 5, 2012 through October 26, 2012, the Company sold an aggregate of 126,802,946 shares of its Series C Convertible Preferred Stock to 28 new and existing institutional and individual accredited investors at a purchase price of \$0.138 per share. Each share of the Series C Convertible Preferred Stock was convertible, at the option of the holder, at any time and without payment of additional consideration, into a number of fully paid and non-assessable shares of common stock equal to the number of Series A Preferred Stock being converted multiplied by a fraction, the numerator of which is the Series A original issue price, and the denominator of which is the Series A conversion price in effect at the time of the conversion. The purchase price for the shares of Series C Convertible Preferred Stock was paid in cash or by tendering the convertible notes issued in November and December 2011. All outstanding convertible notes were converted in such financing.

3. On March 5, 2012 the Company issued a warrant to purchase 4,125 shares of Series C Convertible Preferred Stock to In-Q-Tel, Inc. The warrant expires on March 5, 2019. Upon exercise, In-Q-Tel receives the number of shares purchasable under the warrant multiplied by the difference of the fair market value of one exercise share (to be determined by the Company's Board of Directors, in good faith; or the per share offering price to the public if the warrant is exercised in connection with an initial public offering) minus the exercise price. That product is then divided by the fair market value of one exercised share.
4. On December 18, 2013, the Company effected a recapitalization whereby all of the then existing preferred stock was converted into common stock, all accrued and unpaid cumulative dividends on the preferred stock were cancelled, and a 1 for 790.5407 reverse stock split was effected on all outstanding shares of common stock. In connection with the recapitalization, the Company issued to existing investors convertible notes in an aggregate principal amount of \$2,000,000 that were convertible into a new Series A Convertible Preferred Stock. The notes were convertible at the option of the note holder at any time. Upon conversion, each note holder received one share of new Series A Convertible Preferred Stock in exchange for each \$1.00 principal amount of the notes owned by the converting holder. All of these convertible notes were converted into shares of Series A Convertible Preferred Stock by all of the investors in December 2013.
5. From February 19, 2014 through April 2, 2014, the Company sold 2,000,000 shares of its Series A Convertible Preferred Stock to existing investors at a purchase price of \$1.00 per share. Each share of Series A Preferred Stock is convertible, at the option of the holder, at any time, into a number of fully paid and non-assessable shares of common stock equal to the number of Series A Preferred Stock being converted multiplied by a fraction, the numerator of which is the Series A original issue price, and the denominator of which is the Series A conversion price in effect at the time of the conversion.
6. 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 are 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 conducted by the Company following this financing at a conversion price equal to the price per share of new preferred stock issued in the next financing of the Company, less twenty-five percent
7. 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 have a term of four months. In both October and November 2014, the Company drew down \$500,000 from the aggregate amount. The Company plans to draw down an additional \$500,000 on December 29, 2014. If necessary, the Company plans to draw down the remaining \$500,000 in early 2015.
8. In March 2014, the Company issued 130,640 restricted stock units to acquire a like number of shares of common stock to Evan Jones, its Chief Executive Officer, in lieu of cash compensation for serving as Chief Executive Officer. The restricted stock units were subject to forfeiture until October 24, 2014, when the forfeiture restrictions lapsed.
9. Since January 1, 2011, we have issued to employees, consultants, and members of the Board of Directors options to purchase an aggregate of 402,065 shares of our common stock at a weighted-average exercise price of \$0.46 per share as of October 31, 2014.
10. As of October 31, 2014, 24,865 of the options issued since January 1, 2011 had been exercised or forfeited.
11. As of October 31, 2014, no warrants issued since January 1, 2011 had been exercised or forfeited.

We deemed the offers, sales and issuances of the securities described in paragraphs (1) through (7) above, and the issuance of the restricted stock units described in paragraph (8), to be exempt from registration under the Securities Act, in reliance on Section 4(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.

We deemed the grants of stock options described in paragraph (9) and the issuances of shares of common stock upon the exercise of stock options described in paragraph (10) as exempt pursuant to Section 4(2) of the Securities Act or to be exempt from registration under the Securities Act in reliance on Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

We deemed the shares of common stock issued pursuant to the conversion of our preferred stock described in paragraph (4) as exempt pursuant to Section 3(a)(9) of the Securities Act, which exemption is available for transactions involving securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange.

No warrants described in paragraph (11) were exercised during the applicable time period. Thus, no shares of common stock were issued pursuant to the exercise of the warrants.

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.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the 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 Securities and Exchange Commission 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 Registrant hereby undertakes that:

- (a) The Registrant will provide to the underwriter at the closing as specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.
- (b) 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.
- (c) 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 December 31, 2014.

OPGEN, INC.

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

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the date indicated.

Signature	Title	Date
<u>/s/ Evan Jones</u> Evan Jones	President, Chief Executive Officer and Director (principal executive officer)	December 31, 2014
<u>/s/ C. Eric Winzer</u> C. Eric Winzer	Senior Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	December 31, 2014
<u>*</u> Brian G. Atwood	Director	December 31, 2014
<u></u> Timothy Howe	Director	December 31, 2014
<u>*</u> Laurence R. McCarthy	Director	December 31, 2014
<u>*</u> Misti Ushio	Director	December 31, 2014

*By: /s/ C. Eric Winzer
C. Eric Winzer
Attorney-in-fact

EXHIBIT INDEX

Exhibit Number	Description
1.1	* Form of Underwriting Agreement.
3.1	** Ninth Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.
3.1.1	* Form of Tenth Amended and Restated Certificate of Incorporation, to be in effect immediately prior to the consummation of this offering.
3.2	** Bylaws of the Registrant
3.2.1	* Amended and Restated Bylaws of the Registrant.
4.1	* Form of Common Stock Certificate of the Registrant.
4.2	** Third Amended and Restated Investors' Rights Agreement, dated as of December 18, 2013, among the Registrant and certain investors.
4.3	** Third Amended and Restated Right of First Refusal and Co-Sale Agreement, dated as of December 18, 2013, among the Registrant and certain investors.
4.4	** Third Amended and Restated Voting Agreement, dated as of December 18, 2013, among the Registrant and certain investors.
4.4.1	** Amendment No. 1 to the Third Amended and Restated Voting Agreement, dated as of February 18, 2014, among the Registrant and certain investors.
4.5	** Stockholders' Agreements Amendment, dated as of July 11, 2014, among the Registrant and certain investors.
4.6	** Form of Warrant to Purchase Common Stock of the Registrant.
5.1	** Opinion of Ballard Spahr LLP.
10.1	** Lease Agreement, dated as of June 30, 2008, between the Registrant and ARE-708 Quince Orchard, LLC (the "Landlord").
10.1.1	** First Amendment to Lease, dated as of April 4, 2011, between the Registrant and the Landlord.
10.1.2	** Second Amendment to Lease, dated as of August 15, 2012, between the Registrant and the Landlord.
10.1.3	** Third Amendment to Lease, dated as of December 30, 2013, between the Registrant and the Landlord.
10.1.4	** Fourth Amendment to Lease, dated as of March 21, 2014, between the Registrant and the Landlord.
10.2	** Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.
10.3	# 2008 Stock Option and Restricted Stock Plan of the Registrant, including amendments thereto.
10.4	** Amended and Restated Chief Executive Officer Letter Agreement, dated March 3, 2014, between the Registrant and Evan Jones.
10.5	** Executive Change in Control and Severance Benefits Agreement, dated January 19, 2011, between the Registrant and C. Eric Winzer.
10.5.1	** Amendment to Executive Change in Control and Severance Benefits Agreement, dated as of November 1, 2013, between the Registrant and C. Eric Winzer.
10.6	*± Master Services Agreement, dated as of August 1, 2012, between the Registrant and GGA Software Services LLC.
10.7	*± Technology Development Agreement, dated September 25, 2013, between the Registrant and Hitachi High-Technologies Corporation.
10.7.1	*± Amendment No. 1 to Technology Development Agreement, dated March 27, 2014, between the Registrant and Hitachi High-Technologies Corporation.
10.8	*± Supply Agreement, dated March 17, 2014, between the Registrant and Fluidigm Corporation.
16.1	Letter re change in certifying accountant.
23.1	** Consent of Ballard Spahr LLP (included in Exhibit 5.1).
24.1	** Power of Attorney (see page II-4 of this Registration Statement).

* To be filed with an amendment.

** Previously filed.

± Confidential treatment to be requested.

Management contract or compensatory arrangement.

Ernst & Young LLP
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8484 Westpark Drive
McLean, VA 22102

Tel: +1 703 747 0000
Fax: +1 703 747 0100
ey.com

December 31, 2014

Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549

Ladies and Gentlemen:

We have read the section titled "Experts" included within the Registration Statement on Form S-1, Amendment No. 1, dated December 31, 2014, of OpGen, Inc. and are in agreement with the statements contained in the paragraphs on page 107 therein. We have no basis to agree or disagree with other statements of the registrant contained therein.

/s/ Ernst & Young LLP