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Filed Pursuant to Rule 424(b)(4)  
Registration No. 333-202478

Prospectus



## 2,500,000 Units to New and Existing Investors 350,000 Units to Certain Existing Investors

OpGen, Inc. is offering 2,850,000 units, each of which consists of one share of our common stock, and one warrant to purchase one additional share of our common stock, at an exercise price of 110% of the public offering price per unit, exercisable from the date of issuance until five years thereafter. We refer to these warrants as the Offered Warrants. Of these units, we are offering 2,500,000 units to new and existing investors and 350,000 units to existing stockholders identified below in exchange for tendered secured demand notes, and cancellation of that indebtedness by us. This is our initial public offering and no public market currently exists for our shares. The initial public offering price is \$6.00 per unit.

The units will immediately and automatically separate upon issuance, and each of the common stock and Offered Warrants will trade separately. The common stock and the Offered Warrants will be listed on The NASDAQ Capital Market under the symbols "OPGN" and "OPGNW," respectively.

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.**

**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(1)	Per Offered Warrant(1)	Total
Public offering price	\$5.99	\$0.01	\$17,100,000
Underwriting discount and commissions(2)	\$0.4720	\$0.0008	\$1,347,480
Proceeds, before expenses, to OpGen, Inc.(3)	\$5.518	\$0.0092	\$15,752,520

(1) Each unit consists of one share of common stock and one Offered Warrant to purchase one share of common stock.

(2) See "Underwriting" for additional information regarding underwriter compensation.

(3) We estimate our total expenses for this offering to be approximately \$880,645.

We have granted the underwriters an option to purchase up to an additional 427,500 shares and/or up to an additional 427,500 Offered Warrants, at the public offering price less the underwriting discount and commissions, solely to cover over-allotments. See "Underwriting."

Persons affiliated with jVen Capital, LLC, entities affiliated with Versant Ventures, Harris & Harris Group, Inc., entities affiliated with CHL Medical Partners and entities affiliated with Cross Creek Capital, L.P., each of which are existing stockholders of OpGen, Inc., have indicated an interest in purchasing up to an aggregate of \$5.1 million of units in this offering at the initial public offering price. Because these indications of interest are not binding agreements or commitments to purchase, these existing stockholders may elect not to purchase units in this offering or the underwriters may elect not to sell any units in this offering to such stockholders. In addition, persons affiliated with jVen Capital, LLC, affiliates of Versant Ventures, Harris & Harris Group, Inc. and entities affiliated with Cross Creek Capital, L.P., who are holders of our outstanding secured demand notes in the aggregate principal amount of \$2.1 million are expected to tender such demand notes as payment for 350,000 units purchased in this offering.

If certain of our existing stockholders elect to purchase an aggregate of \$5.1 million of units in this offering and tender an aggregate of \$2.1 million of demand notes as described above, upon completion of this offering, such stockholders would beneficially own, in the aggregate, approximately 72.6% of our outstanding capital stock. If these existing stockholders do not purchase the aggregate of \$5.1 million of units in this offering or the underwriters elect not to sell the aggregate of \$5.1 million of units in this offering to such stockholders, then our executive officers, directors and 5% or greater stockholders will beneficially own, in the aggregate, approximately 63.5% of our outstanding capital stock.

The underwriters expect to deliver the units to purchasers against payment on or about May 8, 2015.

Sole Book-Running Manager

**Maxim Group LLC**

# National Securities Corporation

Prospectus dated May 4, 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 units 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.

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, including, if applicable to you, 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. When we refer to OpGen, Inc. we use the terms "OpGen," "the Company," "us," "we" and "our."*

**Please refer to the Glossary on page 92 of this prospectus for definitions or descriptions of scientific, health care, regulatory and OpGen-specific terms used in the prospectus.**

### Overview

We are an early commercial stage company using molecular testing and bioinformatics to assist healthcare providers 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 products and products in development are:

- Our Acuitas® MDRO Gene Test, which is currently available for sale is, to our knowledge, the first CLIA lab-based test able to provide information regarding the presence of ten MDRO resistance genes from one patient specimen. The ten drug-resistant genes identified by our Acuitas MDRO Gene Test are associated with CRE (Carbapenem-resistant Enterobacteriaceae), ESBL (extended spectrum beta lactamase) and VRE (vancomycin resistance enterobacteria) organisms, and are gastrointestinal organisms frequently associated with antibiotic-resistant infections. The test results can be used by healthcare providers to identify patients who are colonized with one of the drug-resistant genes or who are actively infected. To date, eight acute care hospitals and long-term care facilities have partnered with us to evaluate the capabilities and uses of our Acuitas MDRO Gene Test.
- Our Acuitas CR Elite Test, which is also commercially available, adds the ability for the healthcare provider to order a traditional microbiology culture result to be performed from the same specimen sent for our Acuitas MDRO Gene Test, thereby providing additional information about the organism or organisms associated with an active infection, as well as an antibiotic susceptibility profile for such organism or organisms.
- Our Lighthouse™ MDRO Management System, or Lighthouse MDRO Management System, which is currently in development, will be able to provide detailed MDRO molecular information about an individual patient's resistance profile, gleaned from our Acuitas MDRO Gene Test results, and integrate this data with other patient and hospital-wide data to help improve overall patient outcomes and to reduce hospital costs. We anticipate that this product will be launched commercially in the third quarter of 2015.

The CDC estimates that in the United States more than two million people are sickened every year with antibiotic-resistant infections, with at least 23,000 dying as a result. Antibiotic-resistant infections add considerable but often avoidable costs to the U.S. healthcare system. In most cases, these infections require prolonged and/or costlier treatments, extended hospital stays, additional doctor visits and healthcare facilities use, and result in greater disability and death compared with infections that are treatable with antibiotics. Estimates for the total economic cost to the U.S. economy range between \$20 and \$35 billion annually. As described in a December 2014 report issued by the Review on Antimicrobial Resistance commissioned by the U.K. Prime Minister titled "*Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations*," 300 million people are expected to die

prematurely because of drug resistance over the next 35 years, which could result in \$60 to \$100 trillion worth of economic output if the problem of antimicrobial drug resistance is not resolved.

We believe we have an important first-mover advantage in developing and bringing to market the combined package of Acuitas-enabled molecular information about key drug-resistant genes associated with MDRO organisms, with specific genetic information about an acute care hospital's MDRO gene profile, including antibiotic resistance. We are aware of other products currently available that use molecular diagnostics to identify selected MDRO gene species or drug-resistant genes. However, we believe our Acuitas products can test for a larger number of gastrointestinal-based drug-resistant genes, particularly those most commonly associated with infections or colonization in hospitalized patients.

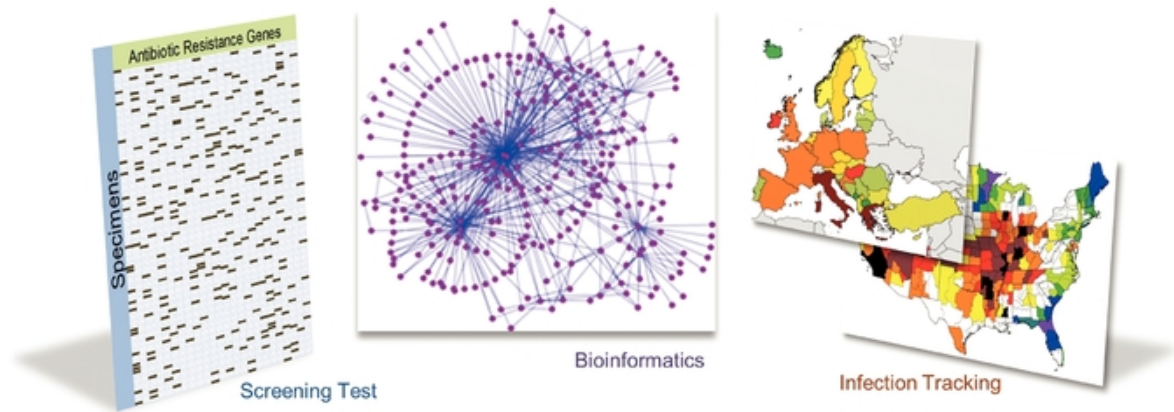
Our Acuitas MDRO Gene Test and our Acuitas CR Elite Test products, which we refer to as our Acuitas MDRO test products, provide results directly from a patient sample, and provide results that can be used by healthcare providers in the spectrum of activities that include identifying colonized patients, managing outbreaks and treating MDRO infections. 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. In addition, we believe we are closer to commercializing a companion bioinformatics product than our competitors. We anticipate that our Lighthouse MDRO Management System will provide meaningful information to healthcare providers to help proactively deal with colonized patients, leading to improved monitoring and antibiotic stewardship.

We introduced our lead MDRO product, our Acuitas MDRO Gene Test, in the first half of 2014, and introduced our Acuitas CR Elite Test in December 2014. In 2014, we achieved minimal revenues from sales of these products. To date, eight acute care hospitals and long-term care facilities have participated in our early look "Partner-Pilot-Program" described in the "Business" section of this prospectus under the heading "Commercialization Strategy and Plans."

We expanded the focus of the Company beginning in 2013 to develop screening and diagnostic products for MDROs, as described. Prior to that time, we had developed and commercialized our Argus® Whole Genome Mapping System, MapIt® Services and MapSolver™ bioinformatics products and services. We have more than ten years of experience mapping microbial genomes. Our customers for these products include government and public health agencies such as the CDC, FDA, USDA and biodefense organizations, who use the Argus and MapSolver products in research and development, food safety and public health settings. We continue to provide these products and services to existing customers, however, we anticipate that such revenues will decline as we have shifted our focus to our MDRO and bioinformatics products and services.

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 DNA. In conjunction with Hitachi, we are developing cloud-based genome assembly capabilities for human genomes. We intend to continue commercializing microbial applications 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.

## Our Solution



We intend 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. As depicted above, we are developing 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 allow targeted antibiotic therapy earlier and more effectively.

We have developed an approach for screening for MDROs in hospitals using DNA testing. Our Acuitas MDRO Gene Test and Acuitas CR Elite Test are commercially available and will be integrated with our Lighthouse MDRO Management System in 2015 to provide real-time information on the MDRO colonization status for patients and hospitals and long-term care facilities. Lighthouse MDRO Management System profiles will facilitate MDRO tracking and integrate de-identified patient-specific and aggregated hospital data to provide customized reports including alerts, prevalence information, trend analysis and transmission information. We anticipate providing this information on a local, regional and national basis to our customers, public health organizations and others to help reduce overall disease rates and to strengthen the national capacity to detect and manage treatment of drug-resistant bacterial strains. We intend to launch our Lighthouse MDRO Management System in the third quarter of 2015.

## Our Revenue Model

Our Acuitas MDRO test products are, and our Lighthouse MDRO Management System and other future products and services will be, sold to hospitals and public health organizations on a fee-for-service basis. We envision selling our Lighthouse MDRO Management System to health systems, hospitals and long-term care facilities under capitated, flat-rate contracts. Health systems and hospitals absorb the costs of extended stay from HAIs and poor treatment outcomes. For healthcare providers to support the use of our tests and services, we need to demonstrate improved outcomes and reduced costs. Various studies have documented increased hospital stays of six days or more for patients infected with MDROs, resulting in increased costs of \$14,000 to \$33,000 per infected patient. Determining if an infection is hospital-acquired or was originally obtained from another source is an

important issue for hospitals. We believe our tests will help adjudicate payment favorably for hospitals. Isolation procedures are also costly to hospitals, so it is critical that isolation/de-isolation decisions are made accurately. Two recent studies documented a daily extra cost of approximately \$101 for contact precaution equipment and approximately \$57 for nursing time and contact precaution supplies for each infected patient. In addition to costs to individual hospitals, estimates of the economic costs of antibiotic resistance to the U.S. economy range from \$20 billion to \$35 billion annually.

### **Our Strategy**

- Accelerate the commercialization of our Acuitas MDRO Gene Test and Acuitas CR Elite Test.
- Complete development of and commercialize our Lighthouse MDRO Management System to healthcare providers, governments and diagnostic companies.
- 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 with patient specific data for healthcare providers. These infection control, antibiotic stewardship and patient management data product capabilities will be difficult for future market entrants to replicate.
- Develop and commercialize additional proprietary molecular diagnostic products with companion data offerings that provide the ability to efficiently analyze data about MDROs present in a patient sample.
- Expand our lab service offerings and capabilities through the supply of kits for use on our DNA probe assay platform and commercially available rapid diagnostic testing systems, develop additional 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 Management System on a global basis.
- Build on our established Whole Genome Mapping position through our collaboration 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 losses for the foreseeable future and may never achieve or sustain profitability. For the years ended December 31, 2014 and 2013, we had a net loss of \$5.7 million and \$10.1 million, respectively. From our inception through December 31, 2014, we had an accumulated deficit of \$96.8 million. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2014 and 2013 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. Our monthly cash burn rate is approximately \$500,000, and we have required bridge funding from our current investors to maintain our cash position until consummation of the offering contemplated in this prospectus.

- We may not be able to generate sufficient revenue from our Acuitas MDRO test products and Lighthouse MDRO Management System or our relationships with hospitals to achieve or maintain profitability.
- Our success depends on the market acceptance of our Acuitas MDRO test products and Lighthouse MDRO Management System. If physicians do not believe our Acuitas MDRO Gene Test, Acuitas CR Elite 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, and our business could suffer.
- If we are unable to scale our operations to support increased demand for our Acuitas MDRO test products and Lighthouse MDRO Management System, our business could suffer.
- Our information technology systems 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 and Acuitas CR Elite Test and our future products, including our Lighthouse MDRO Management System, 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 we 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 other approvals.
- Our patent and intellectual property rights may not adequately protect our technologies, products and services.

#### **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, Suite 160, Gaithersburg, Maryland, 20878, and our telephone number is (301) 869-9683. Our website address is [www.opgen.com](http://www.opgen.com). We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or accessible 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 common stock, stock options, restricted stock units 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™ and EP1™ are trademarks of Fluidigm Corporation and Human Chromosome Explorer<sup>SM</sup> 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, products or services.

### **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.

In this prospectus, we have elected to take advantage of certain of the reduced disclosure obligations, 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 from what 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, at the same time, as other public companies that are not emerging growth companies.

## THE OFFERING

Securities offered by us	2,850,000 units, each consisting of one share of our common stock and one Offered Warrant to purchase one share of our common stock. Of these units, we are offering 2,500,000 units to new and existing investors and 350,000 units to existing stockholders identified below in exchange for tendered secured demand notes, and cancellation of that indebtedness by us.
Common stock outstanding before this offering	7,868,347 shares
Common stock to be outstanding after this offering	10,718,347 shares (11,145,847 shares if the underwriters exercise their over-allotment option in full)
Terms of Offered Warrants issued as part of the units	<p>The exercise price of the Offered Warrants is \$6.60.</p> <p>Each Offered Warrant is exercisable for one share of common stock, subject to adjustment as described in the Warrant Agreement. A holder may not exercise any portion of an Offered Warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would own more than 4.99% of the outstanding common stock after exercise, as such percentage ownership is determined in accordance with the terms of the Warrant Agreement. The foregoing limitation on exercise shall not apply to any registered holder of Offered Warrants who, together with his, her or it affiliates, and any persons acting as a group together with such registered holder and such registered holder's affiliates, owns in excess of 4.99% of our common stock immediately prior to the closing of this offering. In addition, upon at least 61 days' notice from the holder to us, the holder may waive such limitation.</p> <p>Each Offered Warrant will be exercisable immediately following the closing of this offering and will expire on May 8, 2020, or earlier upon dissolution or winding up of the Company.</p> <p>The terms of the Offered Warrants will be governed by the Warrant Agreement, dated May 8, 2015, between us and Philadelphia Stock Transfer, Inc., or the Warrant Agent. See "Description of Securities—Offered Warrants."</p>
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to an additional 427,500 shares and/or up to an additional 427,500 Offered Warrants, at the public offering price less the underwriting discount and commissions, solely to cover over-allotments.
Use of proceeds	We estimate that we will receive net proceeds from this offering of approximately \$12,771,875, or approximately

\$15,134,753 if the underwriters exercise their option to purchase additional units in full, based upon the initial public offering price of \$6.00 per unit, and after deducting the underwriting discount, commissions and estimated offering expenses. See "Underwriting" for additional information. Our net proceeds do not include proceeds from the expected purchase of 350,000 of the offered units by persons affiliated with jVen Capital, LLC, affiliates of Versant Ventures, Harris & Harris Group, Inc. and entities affiliated with Cross Creek Capital, L.P. in exchange for tendered secured demand notes in the aggregate principal amount of \$2.1 million, and cancellation of that indebtedness by us. If a holder does tender a secured demand note as payment for such units in the offering, each \$1.00 of principal or interest so tendered will equal \$1.00 of purchase price at the initial public offering price; there is no discount provided to such holder against the initial public offering price. We expect to use the net proceeds from this offering to fund increased sales and marketing activities for our Acuitas MDRO test products and Lighthouse MDRO Management System, research and development activities to complete the development of our Lighthouse MDRO Management System and future product development, for general and administrative expenses and for working capital purposes. See "Use of Proceeds" for additional information.

NASDAQ Capital Market symbols reserved for the common stock and Offered Warrants

OPGN and OPGNW

Trading commencement and separation of common stock and Offered Warrants

The units will immediately and automatically separate upon issuance and shares of our common stock and the Offered Warrants will trade separately.

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.

Persons affiliated with jVen Capital, LLC, entities affiliated with Versant Ventures, Harris & Harris Group, Inc., entities affiliated with CHL Medical Partners and entities affiliated with Cross Creek Capital, L.P., each of which are existing stockholders, have indicated an interest in purchasing up to an aggregate of \$5.1 million of units in this offering at the initial public offering price. Because these indications of interest are not binding agreements or commitments to purchase, these existing stockholders may elect not to purchase units in this offering or the underwriters may elect not to sell any units in this offering to such stockholders. In addition, persons affiliated with jVen Capital, LLC, affiliates of Versant Ventures, Harris & Harris Group, Inc. and entities affiliated with Cross Creek Capital, L.P., who are holders of our outstanding secured demand notes in the aggregate principal amount of \$2.1 million are expected to tender such demand notes as payment for 350,000 units purchased in this offering. As noted above, no discount is provided to such holders against the initial public offering price.

All outstanding shares of our Series A Redeemable Convertible Preferred Stock, or Series A Preferred Stock, and all outstanding convertible notes issued in 2014 and convertible into shares of Series A Preferred Stock, or the 2014 convertible notes, will convert into shares of our common stock upon completion of the offering contemplated by this prospectus. All outstanding convertible notes issued in 2015, or the 2015 convertible notes, are convertible at the election of the holder into up to 1,875,000 shares of Series A Preferred Stock, which Series A Preferred Stock will convert into common stock upon completion of the offering contemplated by this prospectus. The number of shares of our common stock to be outstanding after this offering is based on 7,868,042 shares of our common stock outstanding as of December 31, 2014, on an as-converted basis, assuming conversion of all of our outstanding Series A Preferred Stock, 2014 convertible notes, and 2015 convertible notes, plus common stock acquired upon the exercise of stock options in 2015 to date, but excluding:

- 1,230,772 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2014 at a weighted-average exercise price of \$0.78 per share;
- 217,019 shares of common stock reserved for future issuance under our 2008 Stock Option and Restricted Stock Plan, as amended, or the 2008 Plan;
- 258,605 shares of common stock issuable upon the exercise of outstanding warrants to purchase our common stock; and
- warrants to purchase 185,250 shares (or 213,038 shares in the event that the underwriters' over-allotment option is exercised in full) of common stock to be issued to the underwriters in connection with this offering.

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

- no issuance or exercise of derivative securities on or after December 31, 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, 2014 and 2013, and the balance sheet data as of December 31, 2014, have been derived from our audited financial statements included elsewhere in this prospectus.

	<u>Year Ended December 31,</u>	
	<u>2014</u>	<u>2013</u>
	(In thousands, except share and per share data)	
<b>Statements of Operations Data:</b>		
Revenue	\$ 4,126	\$ 2,411
Operating expenses:		
Cost of sales	952	1,823
Research and development(1)	4,368	4,152
General and administrative(1)	2,313	2,762
Sales and marketing(1)	2,058	3,053
Argus Whole Genome obsolescence	—	951
Total operating expenses(1)	<u>9,691</u>	<u>12,741</u>
Loss from operations	(5,565)	(10,330)
Interest income	—	1
Interest expense	(111)	(32)
Change in fair value of warrant liability	—	135
Other income (expense), net	5	91
Net loss	<u>\$ (5,671)</u>	<u>\$ (10,135)</u>
Net loss available to common stockholders(2)	<u>\$ (6,299)</u>	<u>\$ (15,508)</u>
Net loss per common share, basic and diluted	<u>\$ (16.25)</u>	<u>\$ (896.09)</u>
Shares used in computing net loss per common share, basic and diluted	<u>387,590</u>	<u>17,306</u>
Pro forma net loss per common share, basic and diluted (unaudited)(3)	<u>\$ (1.20)</u>	
Pro forma shares used in computing pro forma net loss per common share, basic and diluted (unaudited)(3)	<u>4,687,713</u>	

(1) Includes stock-based compensation as follows:

	<u>Year Ended</u>	
	<u>December 31,</u>	<u>2013</u>
	<u>2014</u>	<u>2013</u>
	(In thousands)	
Research and development	\$ 5	\$ 8
General and administrative	56	143
Sales and marketing	3	2
Total stock-based compensation	<u>\$ 64</u>	<u>\$ 153</u>

(2) Net loss reduced by preferred stock dividends.

- (3) Pro forma net loss per common share, basic and diluted, is calculated assuming the conversion of all shares of Series A Preferred Stock and our 2014 convertible notes into common stock outstanding at the beginning of the period or at the original date of issuance, if later, up to December 31, 2014, but does not include 1,875,000 shares of common stock that may be issued upon the conversion of the 2015 convertible notes that were not outstanding at December 31, 2014.

	As of December 31, 2014		Pro Forma As Adjusted(2)
	Actual	Pro Forma(1)	
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 750	\$ 750	\$ 13,583
Working capital (deficiency)	(4,308)	(2,808)	11,511
Total assets	2,655	2,655	15,192
Series A Preferred Stock	4,565	—	—
Accumulated deficit	(96,772)	(96,772)	(96,772)
Total stockholders' equity (deficit)	(8,066)	(2,001)	12,318

- (1) The pro forma presentation does not include 1,875,000 shares of common stock that may be issued upon the conversion of the 2015 convertible notes (assuming that the holders of the 2015 convertible notes convert all such notes into shares of Series A Preferred Stock at a rate of 1.25 shares per \$1.00 of outstanding principal amount, and such shares of Series A Preferred Stock are converted into common stock upon completion of this offering).
- (2) The pro forma as adjusted presentation does not include the 100,000 units issued in cancellation of indebtedness of \$0.6 million of secured demand note indebtedness that was not outstanding at December 31, 2014.

The preceding table presents a summary of our audited balance sheet data as of December 31, 2014:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our Series A Preferred Stock and convertible notes outstanding at December 31, 2014 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 net proceeds from the sale of 2,750,000 units in this offering at the initial public offering price of \$6.00 per unit, and after deducting the underwriting discount 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 test products and Lighthouse MDRO Management System may never achieve significant commercial market acceptance.***

Currently, we rely principally on the commercialization of our Acuitas MDRO test products, and will rely on the launch and commercialization of our Lighthouse MDRO Management System products and services, to generate future revenue growth. To date, such Acuitas MDRO test products have delivered only minimal revenue. We believe that our commercialization success is dependent upon our ability to significantly increase the number of hospitals, long-term care facilities and other inpatient healthcare settings that use our products. We achieved our first commercial sales of our Acuitas MDRO Gene Tests in the third quarter of 2014, and experienced very limited revenue and customer adoption during 2014. In addition, demand for our Acuitas MDRO test products and Lighthouse MDRO Management System 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 products 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, Acuitas CR Elite Test and Lighthouse MDRO Management System products and services may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits for us. Our ability to achieve commercial market acceptance for our products will depend on several factors, including:

- our ability to convince the medical community of the clinical utility of our products and services and their potential advantages over existing tests;
- our ability to convince the medical community of the accuracy and speed of our products and services, as contrasted with the current methods available;
- the willingness of hospitals and physicians to use our products and services; and
- the recognition by inpatient health care facilities of the patient safety, improved outcome and cost-effectiveness benefits of using our products and the willingness to pay for them without reimbursement.

***We have a history of losses, and we expect to incur losses for the next several years. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2014 and 2013 contains explanatory language that substantial doubt exists about our ability to continue as a going concern.***

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the years ended December 31, 2014 and 2013, we had a

net loss of \$5.7 million and \$10.1 million, respectively. From our inception through December 31, 2014, we had an accumulated deficit of \$96.8 million. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2014 and 2013 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. Our monthly cash burn rate is approximately \$500,000. From October 2014 through January 2015 we received bridge funding on a monthly basis from our current investors to maintain our cash position. In February and March 2015, we raised an additional \$1.5 million through the issuance of convertible notes, or the 2015 notes offering. See the description of the 2015 convertible notes offering beginning on page 127 of this prospectus. In addition, we raised \$600,000 through the issuance of secured demand notes in March and April 2015. We believe such additional funding will help us 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:

- commercializing our Acuitas MDRO test products and Lighthouse MDRO Management System and potential future diagnostic and screening products and services;
- developing, presenting and publishing additional clinical and economic utility data intended to increase clinician adoption of our current and future products and services;
- expansion of our operating capabilities;
- 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 products and services;
- 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 commercialization of our Acuitas MDRO test products 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 test products and Lighthouse MDRO Management System products and services. 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, many of whom 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.



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

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, patient safety and recovery, reduced length of stay and reduced costs that come from adopting our MDRO diagnosis and management products and services. If we are not able to successfully increase our customer base, sales of our products and our margins may not meet expectations. Attracting new customers and introducing new products and services requires substantial time and expense. Any failure to expand our existing customer base, or launch new products and services, would adversely affect our ability to improve our operating results.

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

***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. We are in the process of procuring key man insurance for Evan Jones, our CEO.

Our Chief Financial Officer, Eric Winzer, has submitted his resignation effective May 1, 2015. His decision to resign as our Chief Financial Officer was made for personal reasons unrelated to OpGen. On April 17, 2015, we entered into a letter agreement with Timothy Dec to serve as our interim Chief Financial Officer. Mr. Winzer has agreed to consult with us through a transition period. We cannot assure you that the transition will not lead to inefficiencies.

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.

***We have limited experience in marketing and selling our Acuitas 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 test products through our own direct sales force. We have limited experience in marketing and selling these products, which had their formal commercial launch in 2014. In addition, our Acuitas MDRO tests and Lighthouse MDRO 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, launched our Acuitas MDRO Gene Test in the second quarter of 2014, and launched our Acuitas CR Elite Test in December 2014. 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 turn-around 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 utility of our current products and products in development is not supported by studies published in peer-reviewed medical publications, the rate of adoption of our current and future products and services by clinicians and healthcare facilities may be negatively affected.***

The results of our clinical and economic validation studies involving our Acuitas MDRO test products 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. If our current and future solutions or the technology underlying Acuitas MDRO test products 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.

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

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

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

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

***If we cannot enter into and maintain new clinical collaborations, our efforts to commercialize our existing products, and to further develop our products in development 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. In addition, in 2014, Hitachi represented our most significant source of revenue (64%), and no other customer represented more

than 10% of our revenues. We believe the collaboration with Hitachi is important to our business, and the loss of such relationship could have a material effect on our business.

We also seek collaborations with MDRO-related industry participants, which may include companies developing rapid diagnostic tests for MDROs, and partner with acute care hospitals in conducting clinical evaluations of our Acuitas MDRO test products. These collaborations are important to us. In the future, we intend to work with our clinical collaborators to commercialize our Acuitas MDRO test products and may work with a clinical collaborator to further develop our test products as diagnostic kits for which FDA clearance or other approvals will be sought. If any of our collaborators decides not to work with us in the future, or, if acute care hospital partners or long-term care facilities do not convert to customers, it could materially adversely affect our business.

***If our sole laboratory facility becomes inoperable, we will be unable to perform Acuitas MDRO test products 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 test products, 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 such as FedEx. Any failure to procure the proper licenses, to comply with the license regulations or to receive undamaged specimens from overnight delivery services could adversely affect our business and reputation.

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

We rely on several sole suppliers, 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 the commercialization of our Acuitas MDRO test products, complete the development of our Lighthouse MDRO Management System products and services, and develop future Acuitas and Lighthouse 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 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.

***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 and/or less costly, 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.

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

A key element of our strategy is to discover, develop, validate and commercialize a portfolio of additional diagnostic and screening products and services to 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 products and services, or that they will be clinically usable. The product development process involves a high degree of risk and may take up to several years or more. Our new product development efforts may fail for many reasons, including:

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

***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.

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

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

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

Clinical laboratory tests, like our Acuitas MDRO Gene Test, are regulated under CLIA, as well as by applicable state laws. Historically, most laboratory developed tests, or LDTs, were not subject to FDA regulations applicable to medical devices, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. The FDA defines the term "laboratory developed test" as an *in vitro* diagnostic test that is intended for clinical use and designed, manufactured and used within a single laboratory. We believe that our Acuitas MDRO test products are LDTs. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug, and Cosmetic Act, 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, the FDA plans to use advisory panels to provide recommendations to the agency on LDT risks, classification and prioritization of enforcement of applicable regulatory requirements on certain categories of LDTs, as appropriate.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could



be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. We cannot predict the timing or content of future legislation enacted, regulations promulgated or guidance issued regarding LDTs, or how it will affect our business.

If FDA premarket review, including clearance or approval, is required for our Acuitas MDRO test products or any of our future tests (either alone or together with sample collection devices), products or services we may develop, or we decide to voluntarily pursue FDA clearance or approval, we may be forced to stop selling our tests while we work to obtain such FDA clearance or approval. Our business would be negatively affected until such review was completed and clearance to market or approval was obtained. The regulatory process may involve, among other things, successfully completing additional clinical studies and submitting premarket notification or filing a premarket approval application with the FDA. If premarket review is required by the FDA or if we decide to voluntarily pursue FDA premarket review of our tests, there can be no assurance that our Acuitas MDRO Gene Test or any tests, products or services we may develop in the future will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of 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 required to but fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our products or product enhancements, our ability to commercially distribute and market our products could suffer.***

If the FDA determines that enforcement discretion is not appropriate or that LDTs are generally subject to FDA regulation and that premarket review, including clearance or approval, is required for our Acuitas MDRO Gene Test or any of our future tests, diagnostic test kits that we may develop, or other products that would be classified as medical devices, the process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other 510(k)-cleared products. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. Our currently commercialized products have not received FDA clearance or approval, as they are marketed under the FDA's enforcement discretion for LDTs or are class I medical devices, which are exempt from the requirement for FDA clearance or approval.

Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil

penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products internationally, we may be subject to rigorous international regulation in the future. In these circumstances, we would rely significantly on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

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

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

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

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

***Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA, or other foreign regulatory authority, requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.***

Any product regulated as a medical device, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers would be required to comply with FDA's Quality System Regulations, or QSR, and International Standards Organization, or ISO, regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory

bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions: (1) untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products; (7) operating restrictions; (8) withdrawing 510(k) clearances or PMA approvals that have already been granted; (9) refusal to grant export approval for our products; or (10) criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

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

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

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

The FDA and similar foreign governmental authorities have the authority to require the recall of regulated products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within

10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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

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

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

We believe that our Acuitas MDRO test products are LDTs, subject to the FDA's enforcement discretion. To remain within the FDA's enforcement discretion, we are restricted in the ways we can promote and market our products. Furthermore, certain of our future products, including specimen transport containers we may develop such as Grow on the Go, might be regulated as class I medical devices for which premarket clearance or approval is not required, subject to certain limitations. We believe that our promotional activities for our products fall within the scope of the FDA's enforcement discretion and applicable premarket exemptions. However, the FDA could disagree and require us to stop promoting our products in certain ways unless and until we obtain FDA clearance or approval for them. In addition, because our products are not currently cleared or approved by the FDA, if the FDA determines that our promotional materials constitutes promotion of a use for which premarket clearance or approval is required, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

***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 our Acuitas MDRO Gene Test are medical devices. Our Acuitas

MDRO test products are 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 2021 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 or regulatory changes will be adopted or how such changes would affect our industry generally or our ability to successfully commercialize our product candidates, if approved. 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.

***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 December 31, 2014, we had license or ownership rights to 72 patents, including 30 pending United States non-provisional patent applications and 19 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, business interruption, workers' compensation, product liability, errors and omissions and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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

Our activities currently require the use of hazardous materials and the handling of patient samples. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We are, or may be in the future, subject to compliance with additional laws and regulations relating to the protection of the environment and human health and safety, and including those relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and Occupational Health and Safety, or OSHA, requirements.

***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 Securities and Exchange Commission, or 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 our Acuitas MDRO test products could lead to product liability claims if someone were to allege that an Acuitas MDRO test product failed to perform as it was designed. We may also be subject to liability for errors in the results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. For example, if we diagnosed a patient as having an MDRO but such result was a false positive, the patient could be unnecessarily isolated in an in-patient setting or receive inappropriate treatment. We may also be subject to similar types of claims related to products we may develop in the future. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain product liability and errors and omissions insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or errors and omissions liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our products and 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 net operating loss carryforwards, or NOLs, and certain tax credit carryforwards to offset income before such unused NOLs tax credit carryforwards expire. Under Section 382 of the Internal Revenue Code 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 NOLs and other pre-change tax attributes to offset its post-change income may be further limited. We have not performed an analysis on whether we have experienced any ownership changes in the past. It is possible that we have experienced an ownership change, or that we will experience an ownership change in the future, including pursuant to

this initial public offering. We had federal NOL carryforwards of \$76.3 million and research and development tax credits of \$1.9 million as of December 31, 2014, that may already be or could be limited if we experience an ownership change.

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

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

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

***If we accept payment from federal and state healthcare programs in the future, 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 any 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.

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

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

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

As we expand internationally, our results of operations and cash flows would become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States. If the

value of the U.S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected as we convert future revenue from local currencies to U.S. dollars.

If we dedicate resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer.

***We face the risk of potential liability under the U.S. Foreign Corrupt Practices Act for past international distributions of products and to the extent we distribute products or otherwise operate internationally in the future.***

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

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

If hospital patient volumes drop as a result of severe economic conditions, or other unforeseen changes in health care provision or affordability, 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.

### **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 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, 2016, 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 Series A Preferred Stock and 2014 convertible notes will convert into common stock upon the closing of the offering contemplated by this prospectus, but our 2015 convertible notes will only convert at the election of the holders of such notes. If the 2015 convertible notes are not converted by their holders, we may need to use proceeds from this offering to repay the 2015 convertible notes at maturity.***

Our Ninth Amended and Restated Certification of Incorporation, as amended, as currently in effect provides for the automatic conversion of our Series A Preferred Stock and our 2014 convertible notes if our initial public offering is a "Qualified IPO"—a firm commitment underwritten public offering with net cash proceeds to us (after underwriting discount, commissions and fees) of at least \$30.0 million. Regardless of whether the offering contemplated by this prospectus will constitute a Qualified IPO, therefore the holders of 70% of our Series A Preferred Stock, voting as a separate class, have approved a conversion of all outstanding shares of Series A Preferred Stock into common stock if the offering contemplated by this prospectus is consummated. In addition, the holders of 67% of the principal amount of the 2014 convertible notes have approved conversion of such notes into Series A Preferred Stock, and then automatically into common stock, if the offering contemplated by this prospectus is consummated.

We have \$1.5 million aggregate principal amount of outstanding 2015 convertible notes as of the date of this prospectus. Our 2015 convertible notes can only be converted at the election of each holder. If such conversion occurs prior to the consummation of this offering, the 2015 convertible note would be converted into Series A Preferred Stock at a conversion rate of 1.25 shares of Series A Preferred Stock for each \$1.00 of principal converted, which would then automatically convert into common stock on a one-to-one basis upon closing of the offering contemplated by this prospectus. If the conversion takes place after this offering closes, the 2015 convertible note would be converted into one share of common stock for each \$1.00 of principal converted. We assume that the holders of the 2015 convertible notes will convert such notes prior to the closing of the offering, therefore 1,875,000 shares of Series A Preferred Stock would be issued and converted into 1,875,000 shares of common stock upon the closing of the offering. The 2015 convertible notes have a maturity date of February 17, 2016. It is possible that if the 2015 convertible notes are not converted by the holders, we will need to use some proceeds from this offering to repay such 2015 convertible notes. In such event, the Company will have less funds available to finance the sales and marketing and research and development activities described under "Use of Proceeds."

***The prices of our common stock and Offered Warrants may be volatile, and you may not be able to sell your securities at or above the public offering price.***

Prior to this offering, there has been no public market for our common stock, and an active public market for our securities may not develop or be sustained after this offering. There has been significant volatility in the market price and trading volume of equity securities, which is unrelated to the financial performance of the companies issuing the securities. In addition, equity markets have experienced significant price and volume fluctuations that have affected the market prices for the securities of life science companies and also newly public companies for a number of reasons, including reasons that may be unrelated to the business or operating performance of the companies. These broad market fluctuations may negatively affect the market price of our common stock. The public offering price for the units being sold in this offering will be determined by negotiations between the representatives of the underwriters and us and may not be indicative of prices that will prevail in the open market following this offering. You may not be able to resell your offered securities at or above the public offering price due to fluctuations in the market price of these securities caused by changes in our operating performance or prospects and other factors. 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.

***The offered securities have no prior public market, and our common stock and Offered Warrant prices could be volatile and could decline after this offering.***

This offering constitutes the initial public offering of our units, which are immediately separable at issuance, and no public market for shares of our common stock or Offered Warrants currently exists. There can be no assurance that an active trading market for any of our offered securities will develop or be sustained after this offering is completed. We have negotiated the initial public offering price per unit with the representative of the underwriters and, therefore, that price may not be indicative of the market prices of our common stock or the Offered Warrants after the offering. Our common stock and our Offered Warrants will be listed on the NASDAQ Capital Market in connection with this offering. However, we cannot ensure that an active public market for any of these securities will develop after this offering, or that if it does develop, it will be sustained. In the absence of a public trading market:

- you may not be able to liquidate your investment in our common stock or the Offered Warrants;
- you may not be able to resell your shares or the Offered Warrants at or above the initial public offering prices;
- the market price of our common stock or the Offered Warrants may experience more price volatility; and
- there may be less efficiency in carrying out your purchase and sale orders.

***We will be required to meet the NASDAQ Capital Market's continued listing requirements and other NASDAQ rules, or we may risk delisting. Delisting could negatively affect the price of our common stock and the Offered Warrants, which could make it more difficult for us to sell securities in a future financing or for you to sell the common stock or Offered Warrants.***

We will be required to meet the continued listing requirements of the NASDAQ Capital Market and other NASDAQ rules, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum bid price for our listed common stock of \$1.00 per share. If we do not meet these continued listing requirements, our common stock and the Offered Warrants could be delisted. Delisting from the NASDAQ Capital Market would cause us to pursue eligibility for trading of these securities on other markets or exchanges, or on the "pink sheets." In such case, our stockholders' ability to trade, or obtain quotations of the market value of our common stock and the Offered Warrants would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of these securities. There can be no assurance that the offered securities, if delisted from the NASDAQ Capital Market in the future, would be listed on a national securities exchange, a national quotation service, the over-the-counter markets or the pink sheets. Delisting from the NASDAQ Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of the offered securities, decrease securities analysts' coverage of us or diminish investor, supplier and employee confidence.

***We may issue additional common shares, warrants or other securities to finance our growth.***

We may finance the development of our products and services or generate additional working capital through additional equity financing. Therefore, subject to the rules of the NASDAQ Capital Market, we may issue additional shares of our common stock, warrants and other equity securities of equal or senior rank, with or without stockholder approval, in a number of circumstances from time to time. The issuance by us of shares of our common stock, warrants or other equity securities of equal or senior rank will have the following effects:

- the proportionate ownership interest in us held by our existing stockholders will decrease;
- the relative voting strength of each previously outstanding share of common stock may be diminished; and
- the market price of our common stock or the Offered Warrants may decline.

In addition, if we issue our shares of our common stock and/or warrants in a future offering at a price lower than the price in this offering, it will be dilutive to purchasers of the offered securities in this offering.

***Future sales of the shares of our common stock or the Offered Warrants may cause the market price of the offered securities to decline.***

Sales of substantial amounts of the shares of our common stock or the Offered Warrants in the public market after this offering, or the perception that these sales may occur, could adversely affect the price of the offered securities and impair our ability to raise capital through the sale of additional equity securities. Upon completion of this offering, we will have 10.7 million shares of common stock outstanding. Of these outstanding shares, the shares of common stock sold in this offering will be freely tradable, without restriction, in the public market unless purchased by our "affiliates," as defined under Rule 144 of the Securities Act of 1933, as amended, or the Securities Act. The remaining shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities

Act, and will be freely tradable subject to the applicable holding period, volume, manner of sale and other limitations under Rule 144 or Rule 701 of the Securities Act.

Upon completion of this offering, most of the restricted securities will be subject to lock-up agreements with the underwriters, restricting the sale of such shares for 180 days after the date of this offering. These lock-up agreements are subject to a number of exceptions, however, and holders may be released from this agreement with the prior written consent of the representative of the underwriters.

Additionally, we intend to register all shares of our common stock that we may issue under our employee benefit plans. Once we register these shares, they can be freely sold in the public market upon issuance, unless pursuant to their terms these stock awards have transfer restrictions attached to them.

***If the shares of our common stock or the Offered Warrants become subject to the penny stock rules, it would become more difficult to trade them.***

The SEC has adopted regulations which generally define a "penny stock" to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to specific exemptions, including an exemption for any securities listed on a national securities exchange. The rules impose additional sales practice requirements on broker-dealers for transactions involving "penny stock," with some exceptions. If the shares of our common stock or the Offered Warrants were delisted from the NASDAQ Capital Market and determined to be "penny stock," broker-dealers may find it more difficult to trade such securities and investors may find it more difficult to acquire or dispose of such securities on the secondary market.

***The Offered Warrants are a risky investment. You may be unable to exercise your Offered Warrants for a profit.***

The amount paid for the units in this offering in excess of the value of our shares of common stock represents the value of your investment in the Offered Warrants. The value of the Offered Warrants will depend on the value of our common stock, which will depend on factors related and unrelated to the success of our commercialization and product development activities, and cannot be predicted at this time. The Offered Warrants have an exercise period of 60 months.

If the price of shares of our common stock does not increase to an amount sufficiently above the exercise price of the Offered Warrants during the exercise period of the Offered Warrants, you may be unable to recover any of your investment in the Offered Warrants. There can be no assurance that any of the factors that could impact the trading price of our common stock will result in the trading price increasing to an amount that will exceed the exercise price or the price required for you to achieve a positive return on your investment in the Offered Warrants.

***Holders of the Offered Warrants will have no rights as common stockholders until they acquire our common stock.***

Until you acquire shares of our common stock upon exercise of the Offered Warrants, you will have no rights with respect to our common stock issuable upon exercise of the Offered Warrants, including the right to receive dividend payments, vote or respond to tender offers. Upon exercise of your Offered Warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

***Although we are required to use our reasonable best efforts to have an effective registration statement covering the issuance of the shares of common stock underlying the Offered Warrants at the time that holders of our Offered Warrants exercise their Offered Warrants, we cannot guarantee that a registration statement will be effective, in which case holders of our Offered Warrants may not be able to receive freely tradable shares of our common stock upon exercise of the Offered Warrants.***

Holders of our Offered Warrants will be able to exercise the Offered Warrants and receive freely tradable shares only if (i) a current registration statement under the Securities Act relating to the shares of our common stock underlying the Offered Warrants is then effective, or an exemption from such registration is available, and (ii) such shares of our common stock are qualified for sale or exempt from qualification under the applicable securities laws of the states in which the various holders of Offered Warrants reside, unless such holders are willing and able to exercise their Offered Warrants on a cashless basis, as further described in the Warrant Agreement. Although we have undertaken in the Warrant Agreement, and therefore have a contractual obligation, to use our reasonable best efforts to maintain a current registration statement covering the shares of common stock underlying the Offered Warrants following completion of this offering to the extent required by federal securities laws, and we intend to comply with our undertaking, we may not be able to do so. If we are not able to do so, holders may not be able to exercise their Offered Warrants and receive freely tradable shares of our common stock but rather may only be able to receive restricted shares upon exercise. In addition, we have agreed to use our reasonable best efforts to register the shares of our common stock underlying the Offered Warrants under the blue sky laws of the states of residence of the existing holders of the Offered Warrants, to the extent an exemption is not available. The value of the Offered Warrants may be greatly reduced if a registration statement covering the shares of our common stock issuable upon exercise of the Offered Warrants is not kept current or if the securities are not qualified, or exempt from qualification, in the states in which the holders of Offered Warrants reside.

***The Offered Warrants included in this offering may not have any value.***

The Offered Warrants will expire on the 60-month anniversary of the closing of the offering. In the event our common stock price does not exceed the exercise price of the Offered Warrants during the period in which the Offered Warrants are exercisable, the Offered Warrants may not have any value.

***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.

***Participation in this offering by certain of our existing stockholders would reduce the available public float for our shares.***

Persons affiliated with jVen Capital, LLC, entities affiliated with Versant Ventures, Harris & Harris Group, Inc., entities affiliated with CHL Medical Partners and entities affiliated with Cross Creek Capital, L.P., each of which are our existing stockholders, have indicated an interest in purchasing up to an aggregate of \$5.1 million of units in this offering at the initial public offering price. Because these indications of interest are not binding agreements or commitments to purchase, these existing

stockholders may elect not to purchase units in this offering or the underwriters may elect not to sell any units in this offering to such stockholders. If such stockholders were to purchase all of these units, they would beneficially own approximately 72.6% of our outstanding common stock after this offering.

If our stockholders are allocated all or a portion of the units in which they have indicated an interest in this offering and purchase any such units, such purchase would reduce the available public float for our shares because such stockholders would be restricted from selling the units by a lock-up agreement they have entered into with our underwriters and/or by restrictions under applicable securities laws. As a result, any purchase of units by such stockholders in this offering may reduce the liquidity of our common stock relative to what it would have been had these units been purchased by investors that were not affiliated with us.

***Future sales of securities 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 April 28, 2015, on an as converted basis, and assuming the conversion of all of our then-outstanding Series A Preferred Stock and all convertible notes (including the conversion of all 2015 convertible notes into 1,875,000 shares of Series A Preferred Stock and the conversion of such shares into 1,875,000 shares of common stock), upon the closing of this offering, we will have outstanding a total of 10,718,347 shares of common stock. Of these shares, 300,640 will be freely tradable, without restriction, in the public market immediately after the offering. Additionally, 8,333 shares held by investors who are then no longer affiliates of the Company will be eligible for sale in the public market 90 days after the closing of this offering. Each of our directors and officers and holders of 1% or more of our common stock has entered into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares. The lock-up agreements pertaining to this offering will expire 180 days after 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 April 28, 2015, up to an additional 7,934,362 shares of common stock will be eligible for sale in the public market, of which 6,581,746 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, 1,229,494 shares of common stock that are subject to outstanding options, and 258,605 shares of common stock that are subject to outstanding warrants 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 April 28, 2015, directors and executive officers and their affiliates beneficially owned, in the aggregate, approximately 58.9% of our outstanding capital stock. After the consummation of this offering, this will be 72.9% assuming that all 2015 convertible notes are converted into 1,875,000 shares of Series A Preferred Stock and such shares of Series A Preferred Stock are converted to common stock upon the closing of this offering, and assuming the purchase by such stockholders of all units contemplated by this offering. 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 10,000,000 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 this offering for selling and marketing activities, including expansion of our sales force to accelerate the ongoing commercialization of our Acuitas MDRO test products, for research and development activities, including finalizing development of our Lighthouse MDRO Management System, as well as the development of our product pipeline, including our Acuitas Resistome Test, 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 units is substantially higher than the net tangible book value per share of our common stock immediately after this offering. Therefore, if you purchase units in this offering, you will incur an immediate dilution in pro forma net tangible book value per share of \$4.59 from the price you paid, based on the initial public offering price of \$6.00 per unit. In addition, new investors who purchase units in this offering will contribute approximately 17.8% of the total amount of equity capital raised by us through the date of this offering, and will own approximately 31.5% of the outstanding equity. The exercise of the Offered Warrants and/or 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. 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 securities 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 units 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 commercialization of our current Acuitas MDRO test products and completed development and commercialization of our Lighthouse MDRO Management System products and services;
- 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 SEC 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 units in this offering will be approximately \$12,771,875, based upon the initial public offering price of \$6.00 per unit, and after deducting the underwriting discount and commissions and estimated offering expenses payable by us. If the underwriters' over-allotment option to purchase additional shares of our common stock and/or Offered Warrants from us is exercised in full, we estimate that our net proceeds will be approximately \$15,134,753. Our net proceeds do not include proceeds from the expected purchase of 350,000 of the offered units by persons affiliated with jVen Capital, LLC, affiliates of Versant Ventures, Harris & Harris Group, Inc. and entities affiliated with Cross Creek Capital, L.P. in exchange for tendered secured demand notes in the aggregate principal amount of \$2.1 million, and cancellation of that indebtedness by us.

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 \$5.0 million for sales and marketing activities, including expansion of our sales force to support the ongoing commercialization of our MDRO gene test products and, when development is completed, our Lighthouse MDRO Management System, and for working capital and general and administrative purposes;
- approximately \$4.0 million for research and development related to the continued support of our completion of the development of our Lighthouse MDRO Management System and future products in our 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.

We estimate that the net proceeds from this offering will allow us to pursue our planned sales and marketing activities through the end of calendar year 2016. 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 selling and marketing or research and development activities 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. 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 December 31, 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 2014 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 net proceeds from the sale of 2,750,000 units in this offering at the initial public offering price of \$6.00 per unit, and after deducting the underwriting discount 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 December 31, 2014		
	Actual	Pro Forma	Pro Forma as Adjusted(1)
	(In thousands, except share data) (Unaudited)		
Cash and cash equivalents	\$ 750	\$ 750	\$ 13,583
Convertible notes	\$ 1,500	\$ —	\$ —
Promissory notes (secured demand notes)	1,500	1,500	—
Long-term debt	235	235	235
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.	4,565	—	—
Stockholder's (deficit) equity:			
Common stock, par value \$0.01 per share: 7,500,000 shares authorized, 493,178 shares issued and outstanding, actual; 7,500,000 shares authorized, 5,993,042 shares issued and outstanding, pro forma; and 200,000,000 shares authorized, 8,743,042 shares issued and outstanding, pro forma, as adjusted	5	60	88
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	88,701	94,711	109,003
Accumulated deficit	(96,772)	(96,772)	(96,772)
Total stockholders' equity (deficit)	(8,066)	(2,001)	12,318
Total capitalization	\$ (266)	\$ (266)	\$ 12,553

- (1) The pro forma as adjusted presentation does not include the 100,000 units issued in cancellation of indebtedness of \$0.6 million of secured demand note indebtedness that was not outstanding at December 31, 2014.

If the underwriters' over-allotment option is exercised in full, pro forma as adjusted cash and cash equivalents, common stock, additional paid-in capital, total stockholders' equity and common stock issued and outstanding as of December 31, 2014 would be \$15.9 million, \$0.1 million, \$111.4 million, \$14.7 million and 9.2 million, respectively.

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

- 1,230,772 shares of common stock issuable upon the exercise of options outstanding at December 31, 2014 at a weighted average exercise price of \$0.78 per share;
- 217,019 shares of common stock reserved for future issuance under our 2008 Plan;
- up to 1,875,000 shares of common stock reserved for future issuance upon the conversion of our 2015 convertible notes into a like number of shares of Series A Preferred Stock, assuming the holders of such notes convert such notes prior to the consummation of this offering;
- 258,605 shares of common stock issuable upon the exercise of warrants to purchase our common stock; and
- warrants to purchase 185,250 shares (or 213,038 shares in the event that the underwriters' over-allotment option is exercised in full) of common stock to be issued to the underwriters in connection with this offering.

## 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 unit and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value per share is determined by dividing our total tangible assets less our total liabilities by the total number of shares of common stock outstanding as of December 31, 2014. Our historical net tangible book value (deficit) as of December 31, 2014, was (\$3.8) million, or (\$7.70) per share of common stock. Our pro forma net tangible book value (deficit) as of December 31, 2014 was (\$2.3) million, or (\$0.38) per share of common stock. Our pro forma net tangible book value is determined by our total tangible assets less our total liabilities divided by the total number of shares of common stock outstanding as of December 31, 2014, assuming conversion of all shares of Series A Preferred Stock and all convertible notes outstanding at December 31, 2014.

The pro forma presentation does not include up to 1,875,000 shares of common stock that may be issued upon the elective conversion of the 2015 convertible notes that were not outstanding at December 31, 2014 or the issuance of 100,000 units in cancellation of indebtedness of \$0.6 million of secured demand note indebtedness that was not outstanding at December 31, 2014.

After giving effect to the sale of units in this offering at the initial public offering price of \$6.00 per unit, after deducting the underwriting discount and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2014 would have been \$12.3 million, or \$1.41 per share. This represents an immediate increase in pro forma net tangible book value of \$1.79 per share to existing stockholders and an immediate dilution in pro forma net tangible book value of \$4.59 per share to purchasers of units in this offering, as illustrated in the following table:

Initial public offering price per unit	\$ 6.00
Pro forma net tangible book value per share as of December 31, 2014	\$ (0.38)
Increase in pro forma net tangible book value per share attributable to new investors	<u>1.79</u>
Pro forma as adjusted net tangible book value per share after this offering	1.41
Dilution per share to investors participating in this offering	<u>\$ 4.59</u>

If the underwriters' over-allotment option to purchase additional shares of our common stock and/or Offered Warrants is exercised in full, the pro forma as adjusted net tangible book value per share after this offering would be \$1.60 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be \$1.98 per share and the dilution to new investors purchasing units in this offering would be \$4.40 per share.

The following table presents, on a pro forma as adjusted basis as of December 31, 2014, the differences between existing stockholders and purchasers of units in this offering with respect to the number of units purchased from us, the total consideration paid and the average price paid per share, which, with respect to the purchasers of units in this offering, is based on the initial public offering

price of \$6.00 per unit, and before deducting the underwriting discount 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	5,993,042	68.5%	\$ 76,267,396	82.2%	\$ 12.73
Purchasers of units in this offering	2,750,000	31.5%	\$ 16,500,000	17.8%	\$ 6.00
Total	8,743,042	100.0%	\$ 92,767,396	100.0%	\$ 10.75

If the underwriters' over-allotment option to purchase additional shares is exercised in full, existing stockholders would own 65% and new investors would own 35% of the total number of shares of our common stock outstanding immediately after this offering.

The calculations above are based on 5,993,042 shares outstanding as of December 31, 2014, after giving effect to the automatic conversion of all then-outstanding shares of Series A Preferred Stock and 2014 convertible notes into common stock upon the closing of this offering and exclude:

- 1,230,772 shares of common stock issuable upon the exercise of options outstanding at December 31, 2014, at a weighted average exercise price of \$0.78 per share;
- 217,019 shares of common stock reserved for future issuance under our 2008 Plan;
- up to 1,875,000 shares of common stock reserved for future issuance upon the conversion of our 2015 convertible notes into a like number of shares of Series A Preferred Stock, assuming the holders of such notes convert such notes prior to the consummation of this offering or the issuance of 100,000 units in cancellation of indebtedness of \$0.6 million of secured demand note indebtedness that was not outstanding at December 31, 2014;
- 258,605 shares of common stock issuable upon the exercise of warrants to purchase our common stock; and
- warrants to purchase 185,250 shares (or 213,038 shares in the event that the underwriters' over-allotment option is exercised in full) of common stock to be issued to the underwriters in connection with this offering.

To the extent that any outstanding options or warrants are exercised or new shares, stock awards or stock options (which are then exercised) 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, 2014 and 2013, and the selected actual balance sheet data as of December 31, 2014 and 2013, from our audited financial statements included elsewhere in this prospectus. 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 and related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2014	2013
(In thousands, except share and per share data)		
<b>Statements of Operations Data:</b>		
Revenue	\$ 4,126	\$ 2,411
Operating expenses:		
Cost of sales	952	1,823
Research and development(1)	4,368	4,152
General and administrative(1)	2,313	2,762
Sales and marketing(1)	2,058	3,053
Argus Whole Genome obsolescence	—	951
Total operating expenses(1)	9,691	12,741
Loss from operations	(5,565)	(10,330)
Interest income	—	1
Interest expense	(111)	(32)
Change in fair value of warrant liability	—	135
Other income (expense), net	5	91
Net loss	\$ (5,671)	\$ (10,135)
Net loss available to common stockholders(2)	\$ (6,299)	\$ (15,508)
Net loss per common share, basic and diluted	\$ (16.25)	\$ (896.09)
Shares used in computing net loss per common share, basic and diluted	387,590	17,306
Pro forma net loss per common share, basic and diluted (unaudited)(3)	\$ (1.20)	
Pro forma shares used in computing net loss per common share, basic and diluted (unaudited)(3)	4,687,713	

(1) Includes stock-based compensation as follows:

	Year Ended December 31,	
	2014	2013
(In Thousands)		
Research and development	\$ 5	\$ 8
General and administrative	56	143
Sales and marketing	3	2
Total stock-based compensation	\$ 64	\$ 153

(2) Net loss reduced by preferred stock dividends.

- (3) Pro forma net loss per common share, basic and diluted, is calculated assuming the conversion of all shares of Series A Preferred Stock and our 2014 convertible notes into common stock outstanding at the beginning of the period or at the original date of issuance, if later, up to December 31, 2014, but does not include up to 1,875,000 shares of common stock that may be issued upon the elective conversion of the 2015 convertible notes by the holders thereof into 1,875,000 shares of Series A Preferred Stock that were not outstanding at December 31, 2014, or the issuance of 350,000 units in cancellation of indebtedness of \$2.1 million of secured demand note indebtedness (\$1.5 million of which was outstanding at December 31, 2014).

	December 31, 2014	December 31, 2013
<b>Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 750	\$ 1,400
Working capital deficiency	(4,308)	(791)
Total assets	2,655	3,159
Series A Preferred Stock	4,565	2,000
Accumulated deficit	(96,772)	(91,101)
Total stockholders' deficit	(8,066)	(1,831)

	As of December 31, 2014		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 750	\$ 750	\$ 13,583
Working capital (deficiency)	(4,308)	(2,808)	11,511
Total assets	2,655	2,655	15,192
Series A Preferred Stock	4,565	—	—
Accumulated deficit	(96,772)	(96,772)	(96,772)
Total stockholders' equity (deficit)	(8,066)	(2,001)	12,318

- (1) The pro forma presentation above does not include up to 1,875,000 shares of common stock that may be issued upon the elective conversion of the 2015 convertible notes by the holders thereof, that were not outstanding at December 31, 2014, into 1,875,000 shares of Series A Preferred Stock.
- (2) The pro forma as adjusted presentation does not include the 100,000 units issued in cancellation of indebtedness of \$0.6 million of secured demand note indebtedness that was not outstanding at December 31, 2014.



## 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.

### Overview

OpGen, Inc. was incorporated in Delaware on January 22, 2001. We are an early commercial stage company using rapid molecular testing and bioinformatics to assist healthcare providers 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 MDRO-focused 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. These products can be enabled by our Lighthouse MDRO Management System in development, which can provide 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 MDRO product is our Acuitas® MDRO Gene Test, a CLIA-Lab-based test that provides a 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 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-focus into its CLIA lab molecular testing business for MDROs. 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's current technology development activities with Hitachi are scheduled to be completed in the second quarter of 2015 and provide up to \$0.5 million in revenue in 2015, upon achievement of designated milestones. The technology development agreement term expires on December 31, 2015.

The Company has experienced declining revenues from its Whole Genome Mapping products and services, beginning in 2012. Management believes improvements in DNA sequencing techniques and products have contributed to this decline. While the Company continues to provide Whole Genome Mapping products and services to existing customers it anticipates that such revenues will be replaced by revenue from its Hitachi collaboration-based products or continue to decline, particularly in view of the Company's focus on its MDRO and bioinformatics products and services.

In December 2013, management conducted a 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 ended 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 whose sales had been declining. Management believes it is likely that revenues will continue to decline for these applications.

In late 2013 and throughout 2014 and 2015, the Company has continued to seek to raise capital to further its business. We raised an aggregate of \$4.0 million in a convertible notes offering during the fourth quarter of 2013 from current investors, which notes were converted into shares of Series A Preferred Stock on December 30, 2013, and a Series A Preferred Stock offering from current investors in early 2014, raised \$1.5 million through the issuance of secured convertible notes in the third quarter of 2014 from current investors, raised another \$1.5 million through the issuance of secured demand notes in the fourth quarter of 2014 from current investors, and raised another \$1.5 million through the issuance of secured convertible notes in the first quarter of 2015 from current investors. In March 2015, the Board approved an additional \$2.0 million of bridge funding through the issuance of secured demand notes. We issued a secured demand note in the principal amount of \$0.5 million to an existing investor on March 30, 2015. The secured notes referred to above are secured against substantially all of the Company's assets. Management remains actively engaged in efforts to raise additional capital. Please see the "Description of Indebtedness" beginning on page 127 of this prospectus for additional information regarding our current indebtedness.

### **Going Concern**

The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2014 and 2013 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. Our monthly cash burn rate is approximately \$500,000. Our current operating assumptions, which include our best estimate of future revenue and operating expenses, indicate that our current cash on hand as of December 31, 2014 of approximately \$0.7 million, plus the 2015 convertible note funding and additional secured demand note funding in 2015, will not be sufficient to fund operations through the second quarter of 2015.

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, 2014 and 2013****Revenues**

	Year ended December 31,	
	2014	2013
Product sales	\$ 1,236,349	\$ 1,735,517
Laboratory services	478,909	630,851
Collaboration revenue	2,411,120	44,239
<b>Total revenue</b>	<b>\$ 4,126,378</b>	<b>\$ 2,410,607</b>

The Company's total revenue increased 71% from 2013 to 2014, from \$2.4 million to \$4.1 million. This change in revenues was primarily attributable to:

- Collaboration revenue of \$2.4 million in 2014 compared with \$0.04 million in 2013. Collaboration revenue in 2014 was from the Hitachi technology development collaboration which started in late 2013.
- A decrease of 29% in products sales as Whole Genome Mapping system and consumable sales declined \$0.6 million, partially offset by an increase of \$0.1 million in Argus™ System service revenues.
- A decrease of 24% in Laboratory services revenue. Laboratory services revenue in 2014 for non-human Whole Genome Mapping applications decreased 60% compared with 2013. This decline was partially offset by \$225,000 of service revenue related to the Hitachi technology development collaboration and \$2,000 of CLIA service revenues compared with no revenues in 2013 from these activities.

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 may decrease in 2015 over 2014. Collaboration revenue in 2015 related to the Hitachi technology development agreement will be up to \$0.5 million upon achievement of designated milestones, unless the agreement is amended to provide for additional activities or scope, or unless other projects are undertaken. Whole Genome Mapping revenues are projected to decline in 2015 while CLIA services revenues are expected to increase.

**Operating Expenses**

	Year ended December 31,	
	2014	2013
Cost of product sales	\$ 425,541	\$ 1,501,648
Cost of services	526,196	320,938
Argus Whole Genome obsolescence	—	950,881
Research and development	4,368,302	4,151,936
General and administrative	2,312,935	2,762,205
Sales and marketing	2,058,085	3,053,394
<b>Total operating expenses</b>	<b>\$ 9,691,059</b>	<b>\$ 12,741,002</b>

In 2014, the Company's total operating expenses decreased 24% from 2013, from \$12.7 million to \$9.7 million. This decrease is primarily attributable to:

- A decrease of 72% in cost of product sales. This decrease resulted from lower manufacturing costs, lower unit volumes and lower royalty expense;
- A write-down of the Company's Whole Genome Mapping inventory of approximately \$1.0 million in 2013 that did not reoccur in 2014;
- A 5% increase in research and development costs;
- A decrease of 16% in general and administrative expenses. Lower payroll, stock-based compensation and legal expenses were the principal reason general and administrative expenses declined;
- A decrease of 33% in sales and marketing expenses. Payroll, travel and outside marketing expenses for sales and marketing activities were \$0.9 million lower in the 2014 period, reflecting lower costs after the 2013 restructuring; and
- An increase of 64% in cost of services revenues which partially offset the decreases described above. The increase in costs of services in 2014 was principally related to costs to run human genome samples in support of the Hitachi technology development collaboration.

#### **Other Income (Expense)**

	Year ended December 31,	
	2014	2013
Interest income	\$ 156	\$ 1,222
Interest expense	(111,345)	(31,598)
Change in fair value of derivative financial instruments	—	134,560
Other income (expense)	4,400	91,390
<b>Total other income (expense)</b>	<b>\$ (106,789)</b>	<b>\$ 195,574</b>

Total net other expense was \$0.1 million in 2014 as compared to total net other income of \$0.2 million in 2013. Significant changes from 2013 to 2014 include:

- our interest expense being higher in 2014 due to our outstanding notes due to stockholders in 2014;
- 2013 including \$0.1 million of gains on the change in the fair value of derivatives, and derivative liabilities being reduced to zero in 2014 due to our recapitalization; and
- other income (expense) in 2013 including \$0.04 million of loan forgiveness and the reversal of \$0.04 million of bad debt expense.

#### **Liquidity and Capital Resources**

At December 31, 2014, the Company had approximately \$0.7 million in cash and cash equivalents, compared to \$1.4 million at December 31, 2013. During 2014, the Company raised gross proceeds of approximately \$5.0 million through the issuance of its Series A Preferred Stock, convertible notes and secured demand notes, all from existing investors. In February and March 2015, the Company issued to existing investors \$1.5 million principal amount of convertible notes, or 2015 convertible notes, which are convertible, at the election of each holder, into shares of Series A Preferred Stock at a conversion rate of 1.25 shares of Series A Preferred Stock for each \$1.00 of principal converted, if no public offering has occurred at the time of conversion, or into shares of common stock, at a conversion rate of

one share of common stock for each \$1.00 of principal or interest converted, if the public offering contemplated by this prospectus has occurred prior to such conversion. The 2015 convertible note holders were also issued an aggregate of 225,011 warrants, exercisable for shares of common stock at 110% of the initial public offering price and exercisable only if the offering contemplated by this prospectus is consummated. The Company is in the process of determining the appropriate accounting treatment for the 2015 convertible notes, including whether a beneficial conversion feature exists with respect to the 2015 convertible notes, the classification of the stock purchase warrants as equity or a liability and the fair value of the common stock issuable under such 2015 convertible notes and stock purchase warrants. The final determination could have a significant impact on the accounting for the 2015 convertible notes. Please see the "Description of Indebtedness" beginning on page 127 of this prospectus for additional information regarding our indebtedness, including the 2015 convertible notes, and Note 15 of the "Notes to Financial Statements" for more information.

Management remains actively engaged in efforts to raise additional capital. Our monthly cash burn rate is approximately \$500,000. In March 2015 and April 2015 we issued secured demand notes to existing investors in the aggregate principal amount of \$600,000 and an unsecured promissory note in the principal amount of \$150,000 to support our operations. Our current operating assumptions, which include our best estimate of future revenue and operating expenses, indicate that our current cash on hand as of December 31, 2014 of approximately \$0.7 million, plus the 2015 convertible note funding, will not be sufficient to fund operations through the second quarter of 2015. The Company is continuing to seek sources of additional funding, including the offering contemplated by this prospectus.

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, and may be required to commence a wind-down of its operations if no such financing is available. See "—Going Concern" earlier in this Management's Discussion and Analysis and Results of Operations.

The Company's primary cash requirements are to fund operations, as well as research and development programs and collaborations, 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 \$5.0 million through the issuance of Series A Preferred Stock, convertible notes and secured demand 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,	
	2014	2013
Net cash used in operating activities	\$ (5,385,542)	\$ (7,487,822)
Net cash used in investing activities	\$ (39,537)	\$ (109,871)
Net cash provided by financing activities	\$ 4,774,251	\$ 1,880,324

#### ***Net Cash Used In Operating Activities***

Net cash used in operating activities was \$5.4 million for the year ended December 31, 2014, compared to \$7.5 million for 2013. The decrease was primarily due to a \$4.5 million decrease in net loss in 2014, offset by a \$1.6 million net increase in cash used for 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 Financing Activities***

Net cash provided by financing activities was \$4.8 million during 2014, as compared to \$1.9 million during 2013. The primary sources and uses of financing activities in both periods were capital raised from the sale of Series A Preferred Stock and from the issuance of convertible notes and secured demand notes, offset in part by principal payments on debt and capital lease obligations.

#### ***Critical Accounting Policies and 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, depreciation and amortization and estimated useful lives of long-lived assets. Actual results could differ from those estimates.

#### ***Revenue Recognition***

The Company recognizes revenue primarily from sales of 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. the 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.

The Company is also in the process of determining the share-based compensation expense for the first quarter of 2015 related to stock options to purchase an aggregate of 826,000 shares of its common stock. Considerations inherent in making such determination include the fair value of the common stock issuable upon the exercise of such stock options. The Company believes the share-based compensation expense related to such stock option is likely to be significant, although it is not currently able to estimate the aggregate expense to be reported as part of its first quarter financial statements. Some of the fair value factors being analyzed by the Company include the ongoing capital requirements of the Company during the first quarter 2015, its receipt of bridge financing from existing investors during such period, including the 2015 convertible notes and the demand notes, and its obligations thereunder, the progress and uncertainties during the quarter related to the Company's pursuit of its initial public offering as contemplated by this prospectus, and the market demand and potential for success of such initial public offering.

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 3 and 8 to the financial statements as of and for the years ended December 31, 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 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, at the same time, as other public companies that are not emerging growth companies.

### ***Recently Issued Accounting Standards***

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 other 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.

## BUSINESS

### Overview

We are an early commercial stage company using molecular testing and bioinformatics to assist healthcare providers 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 products and products in development are:

- Our Acuitas MDRO Gene Test, which is currently available for sale, is, to our knowledge, the first CLIA lab-based test able to provide information regarding the presence of ten MDRO resistance genes from one patient specimen. The ten drug-resistant genes identified by our Acuitas MDRO Gene Test are associated with CRE (Carbapenem-resistant Enterobacteriaceae), ESBL (extended spectrum beta lactamase) and VRE (vancomycin resistance enterobacteria) organisms, and are gastrointestinal organisms frequently associated with antibiotic-resistant infections. The test results can be used by healthcare providers to identify patients who are colonized with one of the drug-resistant genes or who are actively infected. To date, eight acute care hospitals and long-term care facilities have partnered with us to evaluate the capabilities and uses of our Acuitas MDRO Gene Test.
- Our Acuitas CR Elite Test, which is also commercially available, adds the ability for the healthcare provider to order a traditional microbiology culture result to be performed from the same specimen sent for our Acuitas MDRO Gene Test, thereby providing additional information about the organism or organisms associated with an active infection, as well as an antibiotic susceptibility profile for such organism or organisms.
- Our Lighthouse MDRO Management System, currently in development, will be able to provide detailed MDRO molecular information about an individual patient's resistance profile, gleaned from our Acuitas MDRO Gene Test results, and integrate this data with other patient and hospital-wide data to help improve overall patient outcomes and to reduce hospital costs. We anticipate that this product will be launched commercially in the third quarter of 2015.

We believe we have an important first-mover advantage in developing and bringing to market the combined package of Acuitas-enabled molecular information about key drug-resistant genes associated with MDRO organisms, with specific genetic information about an acute care hospital's MDRO gene profile, including antibiotic resistance. We are aware of other products currently available that use molecular diagnostics to identify selected MDRO gene species or drug-resistant genes. However, we believe our Acuitas products can test for a larger number of gastrointestinal-based drug-resistant genes, particularly those most commonly associated with infections or colonization in hospitalized patients.

Our Acuitas products provide results directly from a patient sample, and provide results that can be used by healthcare providers in the spectrum of activities that include identifying colonized patients, managing outbreaks and treating MDRO infections. 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. In addition, we believe we are closer to commercializing a companion bioinformatics product than our competitors. We anticipate that our Lighthouse MDRO Management System will provide meaningful information to healthcare providers to help proactively deal with colonized patients, leading to improved monitoring and antibiotic stewardship.

We introduced our lead MDRO product, our Acuitas MDRO Gene Test, in the first half of 2014, and introduced our Acuitas CR Elite Test in December 2014. In 2014 we achieved minimal revenues from sales of these products. To date, eight acute care hospitals and long-term care facilities have participated in our early look "Partner-Pilot-Program" described in this "Business" section under the heading "Commercialization Strategy and Plans." During our Partner-Pilot-Program process we first

work with clinical teams at the partner institution to exhibit the clinical benefits of the use of our products for surveillance and diagnosis of MDRO-resistant genes, and the potential resource savings of such program for the institution. After completion of such pilot, we frequently need to widen the presentation of information to other departments and executives within the institution to provide information regarding the potential financial benefits that may be realized by the institution following the adoption of the use of our products and services by such institution. This may result in a lengthy sales cycle. During 2015, we are working to convert these acute hospitals and long-term care facilities to become 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. Please see "Business—Our Solution—Our Products in the Near-Term Pipeline" for a description of our products in development.

We expanded the focus of the Company beginning in 2013 to develop screening and diagnostic products for MDROs as described. Prior to that time, we had developed and commercialized our Argus® Whole Genome Mapping System, MapIt® Services and MapSolver™ bioinformatics products and services. Such products and services were and are sold to academic, public health and corporate customers to allow them to perform Whole Genome Mapping and analysis of microbial, plant, animal and human genomes for life sciences applications. Additional information about these whole genome mapping products and services is set forth below in this Business section under the heading "Microbial and human genome mapping and sequencing." 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" and in this "Business" section under the heading "Microbial and human genome mapping and sequencing."

Please refer to the Glossary on page 92 of this prospectus for definitions or descriptions of scientific, diagnostic, health care and regulatory terms used in this prospectus.

### ***Antimicrobial Resistance—An Urgent Global Issue***

Antimicrobial resistance is an urgent global healthcare issue. 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 often avoidable costs to the U.S. healthcare system. In most cases, these infections require prolonged and/or costlier treatments, extended hospital stays, additional doctor visits and healthcare facilities use, and result in greater disability and death compared with infections that are treatable with antibiotics. Estimates for the total economic cost to the U.S. economy range between \$20 and \$35 billion annually. As described in a December 2014 report issued by the Review on Antimicrobial Resistance commissioned by the U.K. Prime Minister titled "*Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations*," 300 million people are expected to die prematurely because of drug resistance over the next 35 years, which could result in \$60 to \$100 trillion worth of economic output if the problem of antimicrobial drug resistance is not resolved.

In the United States, as reported by CMS on August 1, 2014, CMS issued a final rule under the Affordable Care Act that, among other things, establishes CMS' financial incentive program to hospitals that can demonstrate reduction in HAIs; the estimated amount available for these value-based incentive payments in fiscal year 2015 will be approximately \$1.4 billion. On the other hand, in December 2014, CMS announced its Hospital Acquired Condition Reduction Program, under which

CMS will penalize hospitals for excess rates of infections and other patient injuries by reducing Medicare payments. Total penalties are estimated to be approximately \$373 million in the first year.

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. The 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 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 epidemiologically linked contacts.

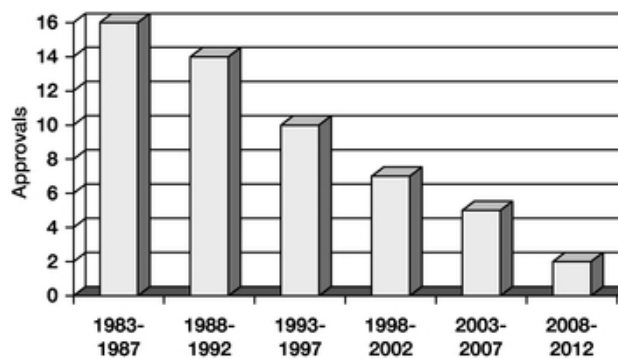
Our Acuitas MDRO Gene Test detects the presence of CRE resistance genes with higher sensitivity and specificity than conventional screening methods. In the summer of 2014, we conducted a comparison on samples of patients known to have CRE infections, using both our Acuitas MDRO Gene Test and a standard microbial culture testing method, and had the microbial culture results confirmed by a national reference lab. In such comparison, our Acuitas MDRO Gene Test was 100% sensitive, while the standard culture method was 72% sensitive. We also tested the rate of false positive results, *i.e.*, identification of MDRO-resistant genes when they were not present, from our Acuitas MDRO Gene Test and conventional culture methods. Thirty-two percent of the initial culture screen results were false positives, while our Acuitas MDRO Gene Test had no false positives—all results matched the known 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 pneumoniae*, or *K. pneumoniae*, is responsible for roughly 15% of gram-negative infections in hospital intensive care units. Infections caused by *Klebsiella pneumoniae* 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 KPC strains is their propensity to cause outbreaks in healthcare institutions. These pathogens persist both in the flora of hospitalized patients and in the hospital environment and they have the capacity to silently colonize patients or hospital personnel by establishing residence in the gastrointestinal tract without causing any signs of infection. Individuals can be silently colonized or become asymptomatic carriers for long periods of time, with detection of these carriers often proving difficult. These silent carriers act as reservoirs for continued transmission, which makes subsequent spread difficult to control and outbreaks difficult to stop. In addition, KPC strains can survive for several hours on the hands of hospital personnel, which likely facilitates spread from patient to patient. Effective control of KPC outbreaks requires a detailed understanding of how transmission occurs, but current technologies do not allow healthcare providers to routinely perform these investigations.

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. As a result, screening, infection control and antibiotic stewardship have become the most powerful weapons in the fight to contain this threat.



New systemic antibacterial agents approved by the FDA per 5-year period, through 2012. From Boucher et al. See references.

### ***Carbapenem-Resistant ESBL Gram-Negative Bacteria***

When gram-negative ESBL bacteria become resistant to carbapenem antibiotics, a Superbug resistant to virtually all currently available 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 human gastrointestinal flora and are frequent causes of urinary tract, bloodstream and intra-abdominal community-acquired and healthcare-associated infections.  $\beta$ -lactamases are enzymes produced by some of these bacteria that, depending on the type of enzyme, can make them resistant to various classes of  $\beta$ -lactam antibiotics, the main treatment for these infections. In the mid-1980's, a new group of these enzymes was detected, the extended-spectrum  $\beta$ -lactamases, ESBLs, which confer resistance to expanded-spectrum cephalosporin antibiotics 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  $\beta$ -lactamases, have emerged and spread among Enterobacteriaceae. Carbapenemases are enzymes that can efficiently hydrolyse most  $\beta$ -lactams, including carbapenems. Some prevalent and emerging types of carbapenemases are KPC, Verona integron-encoded metallo- $\beta$ -lactamases, or VIM, OXA type 48  $\beta$ -lactamase, or OXA-48, and recently New Delhi metallo- $\beta$ -lactamase, or NDM. Many carbapenemase producing Enterobacteriaceae strains frequently carry additional resistance determinants to other non  $\beta$ -lactam antibiotics, making them highly antibiotic-resistant. The most common last resort antibiotics for treating these drug-resistant infections 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 benefit infection control programs and antibiotic stewardship.

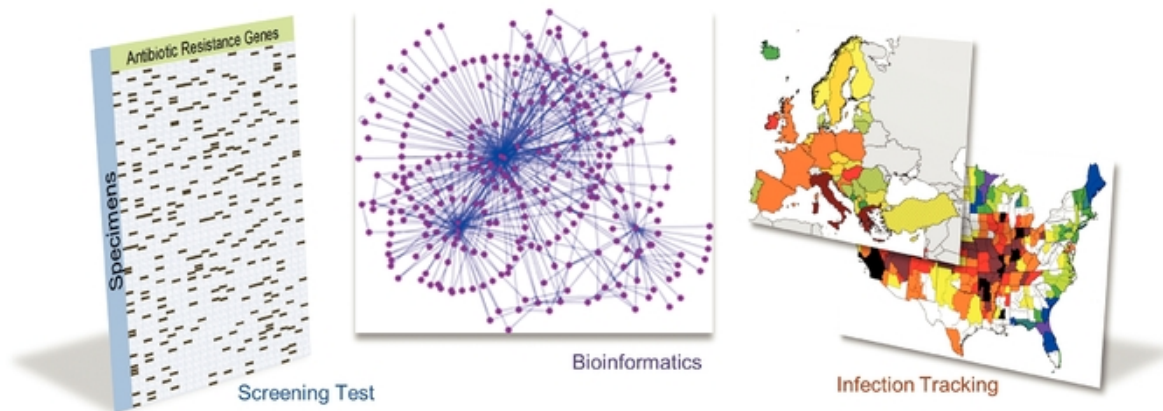
### **The Opportunity**

The discovery of antibiotics in the early 20<sup>th</sup> 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. 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, 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. However, we believe the

potential for improvements based on cell culture have reached a plateau. In contrast, 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 have the potential to transform clinical and public health microbiology practice. Using technologies developed for production genetics applications and high resolution genome sequencing, it is now possible to achieve 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. This breakthrough combined with the speed, reliability and increased information content available with evolving DNA detection methods is leading to the opportunity to dramatically improve patient outcomes.

## Our Solution



We intend 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. As depicted above, we are developing 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 allow targeted antibiotic therapy earlier and more effectively.

We have developed an approach for screening for MDROs in hospitals using DNA testing. Our Acuitas MDRO test products are commercially available and will be integrated with our Lighthouse MDRO Management System and laboratory information products in 2015 to provide real-time information on the MDRO colonization status for patients, acute care ICUs, and hospitals. Lighthouse MDRO Management System profiles will facilitate MDRO tracking and integrate de-identified patient-specific and aggregated 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 our customers, public health organizations and others to help reduce overall disease rates and to strengthen the national capacity to detect and manage treatment of drug-resistant bacterial strains. We intend to launch our Lighthouse MDRO Management System in the third quarter of 2015.

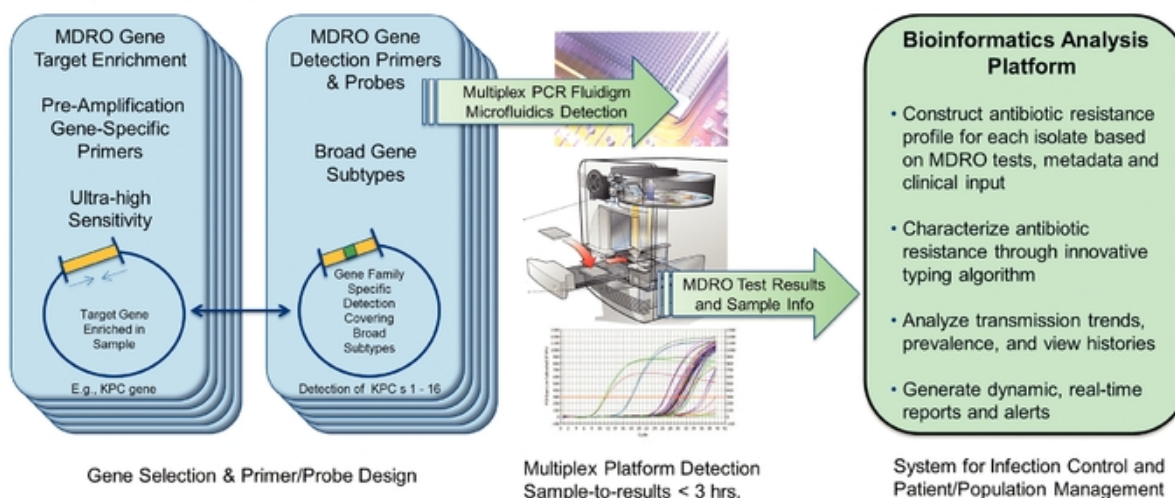
Active surveillance for antibiotic-resistant microbial colonization has been shown to reduce overall infection rates and to help reduce hospital costs by avoiding unnecessary hospital days per patient. For example, Israel had a country-wide outbreak of KPC from 2005 to 2008. In late 2005, one patient 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, 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.

### Current Products

#### Acuitas MDRO Gene Test and Acuitas CR Elite Test

Our Acuitas MDRO Gene Test detects ten critical MDRO genes from one patient swab obtained using commercially available collection devices. The test provides fast, molecular results for genes associated with CRE (7 genes), ESBL (extended spectrum beta lactamase) (2 genes) and VRE (vancomycin resistance enterobacteria) resistant genes. In our CLIA lab validation studies and partner test programs, the test has been proven to be highly sensitive and specific for the presence of these resistant genes when compared to established reference methods, demonstrating nearly 100% correlation in identifying patients carrying MDROs and those free of MDRO bacteria. Our Acuitas CR Elite Test adds the ability to procure a standard microbiological culture result that provides additional information about the identified MDRO gene and its antibiotic susceptibility profile.

### Acuitas™ Platform Multiplex MDRO Gene Detection



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

Our Acuitas MDRO Gene Test is currently offered as a service through our CLIA laboratory for surveillance of antibiotic-resistant microbial colonization with 24 hour turn-around time. OpGen's initial target markets are acute care hospitals, long-term acute care hospitals and long-term care facilities. In the future, the Acuitas MDRO test products may be further developed to be used on rapid, acute care testing systems located in the in-house laboratories of such facilities, with the ability to provide test

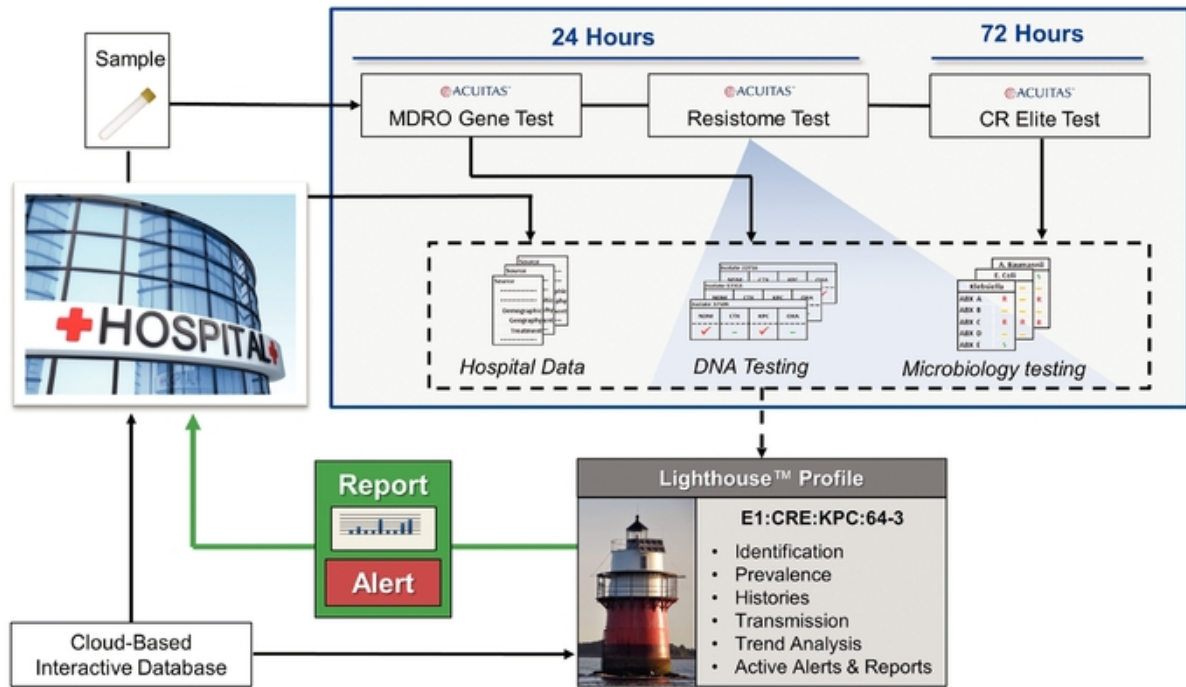


results with 2-3 hour turn-around time. These systems are currently in use for acute care needs such as confirming the identity of an organism or resistance gene in a blood infection.

**Other Products in Development**

**Lighthouse MDRO Management System**

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. Our Lighthouse MDRO Management System's dynamic profiling incorporates identity, phenotype and MDRO gene presence and assigns unique microbe identifiers, Lighthouse MDRO Management System profiles, based on MDRO gene composition, and antibiotic susceptibility, or AST, data. We believe our Lighthouse MDRO Management System profiling will provide the first diagnostic tracking tool for MDRO infections in the hospital setting. Our Lighthouse MDRO Management System is based on our CLIA and HIPAA compliant LIMS database system. We are developing a web-based portal to allow our customers access to LIMS-based lab reports and Lighthouse MDRO Management System data reports. We anticipate commercializing our Lighthouse MDRO Management System in the third quarter of 2015. A schematic description of our Lighthouse MDRO Management System in development is set forth below:



**Acuitas Resistome Test**

We are using our production genomics capabilities to develop our Acuitas Resistome Test. Our Acuitas Resistome Test includes additional resistance genes for carbapenems, ESBLs and ampicillin-resistant class C cephalosporinases, or AmpC, genes in replacement of the vancomycin resistant genes. We believe the AmpC targets are more specific for gram negative bacteria, thereby strengthening the coverage provided by our Acuitas Resistome Test. We will use our Acuitas Resistome Test results for Lighthouse MDRO Management System profiling of specimens collected in hospitals for MDRO



surveillance, and clinical isolates from infected patients. Information from our Acuitas Resistome Test will provide additional gene detection information to supplement our Acuitas MDRO Gene Test. We expect that our Acuitas Resistome Test will be used in conjunction with the CR Elite Test to provide high resolution Lighthouse profiles. Our goal is to provide Lighthouse MDRO profiles based on Acuitas Resistome Test results within 24 hours of sample receipt, and, using the CR Elite Test, to supplement our Lighthouse profiles with biologically derived antibiotic susceptibility data within 72 hours. We anticipate improving the accuracy of our Acuitas Resistome Test over time by performing DNA sequence analysis of our Lighthouse Profile database. We believe our Lighthouse MDRO Management System profiles will enable improved infection control procedures, antibiotic stewardship and individualized patient care. We also anticipate combining tests for infectious diseases such as C. difficile, MRSA and others to provide enhanced MDRO screening and patient management solutions. Our Acuitas Resistome Test is undergoing CLIA lab validation studies and is currently available for research use only. We expect that our Acuitas Resistome Test will be launched as a CLIA lab product in the second quarter of 2015. The following chart presents information regarding the changes between our Acuitas MDRO Gene Test and our Acuitas Resistome Test:



Our approach provides high resolution organism ID & captures antibiotic resistances information

<b>Carbapenemase Genes</b> KPC NDM OXA-48 OXA-23 OXA-51 VIM IMP
<b>ESBL Genes</b> CTX-M-1 CTX-M-2
<b>VRE Genes</b> VanA

**MDRO Gene Test**

<b>Carbapenemase Genes</b> (25 including 7 MDRO Gene Test targets)
<b>ESBL Genes</b> (13 including 2 MDRO Gene Test targets)
<b>AmpC Genes</b> (11 targets)

**Resistome Test**

***Grow on the Go***

We are developing our Grow on the Go technology to use with specimens transported to our CLIA lab. With Grow on the Go, the culturing process starts while the specimen is being transported to our CLIA lab via overnight shipping. This will allow us to immediately begin the microbial culture analysis on receipt at our CLIA lab.

Please see the tabular and other information about additional MDRO- and Lighthouse MDRO Management System-related products in our research and development pipeline, beginning on page 76 of this prospectus.

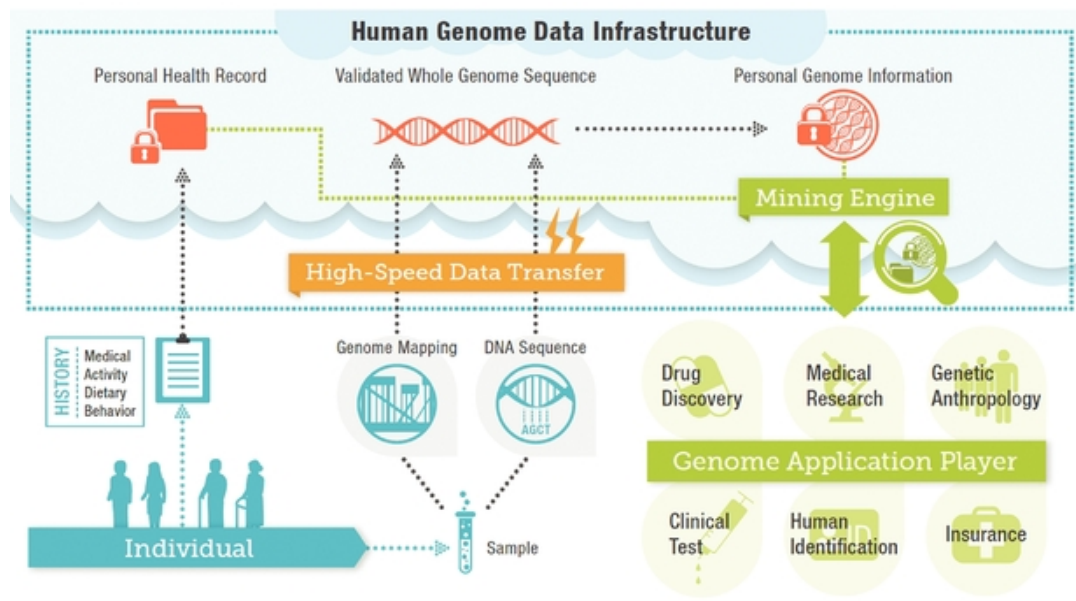
**Microbial and human genome mapping and sequencing**

Infectious disease testing is undergoing a transformation in which DNA testing is replacing classical culture-based methods because of its accuracy and speed. DNA tests make it possible to simultaneously detect drug-resistant 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 analyze the presence of such antibiotic-resistant genes to track the spread of the associated organisms 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 and public health agencies such as the CDC, FDA, USDA and biodefense organizations, who use the Argus and MapSolver products in research and development, food safety and public health settings. We continue to provide these products and services to existing customers, however, we anticipate that such revenues will decline as we have shifted our focus to our MDRO and bioinformatics products and services.

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 DNA. In conjunction with Hitachi, we are developing cloud-based genome assembly capabilities for human genomes. We intend to continue commercializing microbial applications 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 our collaboration with Hitachi:



During 2013, four customers of our Whole Genome Mapping and MapIt Services offerings each represented at least 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 internal projects and external events causing them to increase or decrease the use of our products.

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. For the fiscal year ended December 31, 2014, Hitachi represented our most significant source of revenue under the collaboration described above (64% of our revenue) and no other customer represented 10% or more of our revenues in 2014. 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**

- Accelerate the commercialization of our Acuitas MDRO Gene Test and Acuitas CR Elite Test.
- Complete development of and commercialize our Lighthouse MDRO Management System to healthcare providers, governments and diagnostic companies.
- 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 with patient specific data for healthcare providers. These infection control, antibiotic stewardship and patient management data product capabilities will be difficult for future market entrants to replicate.
- Develop and commercialize additional proprietary molecular diagnostic products with companion data offerings that provide the ability to efficiently analyze data about MDROs present in a patient sample.
- Expand our lab service offerings and capabilities through the supply of kits for use on our DNA probe assay platform and commercially available rapid diagnostic testing systems, develop additional 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 Management System on a global basis.
- Build on our established Whole Genome Mapping position through our collaboration 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, which may include companies developing rapid diagnostic tests for MDROs, sponsored research programs with governments and industry and strategic acquisitions.

## **Market Opportunities**

We operate in the approximately \$850 million annual U.S. market for MDRO-screening and testing for hospital acquired infections. Our initial focus is the U.S. hospital market where there are approximately 5,000 hospitals and a potential market opportunity of 6 million tests annually for our

Acuitas MDRO Gene Test. According to *AHA Hospitals Statistics, 2011*, there are 1,395 acute care hospitals in the U.S. with 200 or more beds that are candidates for weekly screening of the approximately 20% of patients who are at high risk for MDRO colonization or infection. There are also 290 long term acute care hospitals where we believe all patients are candidates for bi-weekly screening. We believe the high-risk MDRO testing market opportunity in the U.S. is approximately \$400 million. The trend toward consolidated health systems is resulting in the combination of small and mid-sized hospitals into large health systems that are the initial targets for our test and informatics products. 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 them an attractive target market for us.

The trend towards forming accountable care organizations, or ACOs, is expected to increase the focus on reducing length of stay and the overall cost of hospital procedures. Since HAIs result in increased costs of approximately \$24,000 per affected patient, we anticipate ACOs will be particularly receptive to our MDRO management solutions. According to *Diagnostic Kit—second edition, March 2014* by Cowen & Co., the MRSA surveillance testing market and *C. difficile* testing market in the U.S. are approximately \$300 million and \$150 million, respectively.

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 solutions to state public health organizations and federal government agencies and internationally in the hospital market and to sovereign governments.

### **Commercialization Strategy and Plans**

Our strategy is to help establish our Acuitas MDRO test products and our Lighthouse MDRO Management System products and services 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 test products will improve clinical outcomes and, with the addition of our Lighthouse MDRO Management System in development, will 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, 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 partner to provide the information necessary so that healthcare providers can manage infection control on an institution-wide basis.
- Pilot. A 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 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.

During our Partner-Pilot-Program process we first work with clinical teams at the partner institution to exhibit the clinical benefits of the use of our products for surveillance and diagnosis of MDRO-resistant genes, and the potential resource savings of such program for the institution. After completion of such pilot, we frequently need to widen the presentation of information within the institution to provide information regarding the potential financial benefits that may be realized following the adoption of the use of our products and services by such institution. This may result in a lengthy sales cycle. To date, approximately 1,000 clinical tests and 14,000 Acuitas MDRO Gene Tests have been performed across eight acute care hospitals and long-term care facilities which have participated in our Partner-Pilot-Program process, one of which initiated modest product purchases in 2014.

The potential impediments we foresee to more rapid adoption of the use of our products and services are related to the changes that may need to occur to a hospital's standard operating procedures, and the reluctance of hospital administration to spend funds that will not be immediately and directly reimbursed by third party payors. We believe we have compelling evidence to support the proposition that adoption of a surveillance program, using our products for at-risk patients, such as those admitted to intensive care units, trauma patients, transplant or other patients with compromised immune systems, or those patients admitted from long-term care facilities, will lead to (1) more rapid identification of patients who are colonized with MDROs but not yet actively infected, (2) rapid and accurate identification of the MDRO genes present, and diagnosis of the underlying infection, (3) better utilization of isolation and other infection control resources within the hospital, (4) identification of potential outbreaks; (5) reduction in patient infections; and (6) restoration of reimbursement from government payors and reduced risk of incurring future penalties associated with high infection rates. Nevertheless, we anticipate that we will need to present the benefits of this program to multiple executives within the hospital setting, from infection control physicians, laboratory personnel, finance department executives and other healthcare providers. We also anticipate that there will be some normal resistance to adding another task to the patient admission process, although collection of the specimen needed to perform our Acuitas MDRO test products is not technically difficult or time consuming.

We may also enter into performance-based risk sharing arrangements with hospitals and healthcare systems to promote the use of our diagnostic and screening products and services on an institution-wide basis. Under these arrangements, part of our fees would be a performance-based share of increased customer revenue or reduced customer expenses related to MDRO screening, better infection control resource utilization and antibiotic stewardship improvements.

A second major initiative is to develop institution-wide Lighthouse MDRO Management System surveillance programs as a new standard of care. We intend to establish and brand our Lighthouse MDRO Management System surveillance and control management systems, with fees based on a capitated approach. We believe our surveillance testing program is intended to bring the following benefits to participating institutions:

- Platinum status as a proactive MDRO surveillance and "best practices" institution;
- Patient safety and enhanced hospital reputational 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 reputational harm from undetected MDRO hospital wide outbreaks.

Establishing MDRO surveillance screening as the standard of care in the U.S. is an important corporate objective. 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:

- Sell to early adopter institutions;
- Demonstrate the value of our solutions in clinical practice;
- Educate healthcare providers regarding the clinical validation, clinical utility and improved outcomes that can be obtained with our solutions;
- 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 solution***

We believe our products and services can be integrated into a single solution for healthcare providers. By seeking to address institutional needs for informatics, genetic analysis and microbiologic testing, we are working to establish a market leadership position in MDRO testing. The OpGen solution is intended to help hospitals reduce hospital acquired infection rates by helping to rapidly identify patients colonized with MDROs who should receive contact precautions, and helping to guide antibiotic therapy. Additional products in development are outlined below.

#### ***R&D***

For the years ended December 31, 2014 and 2013, our research and development expenditures were \$4,368,302 and \$4,151,936, respectively.

We intend to continue to invest in the development of additional Acuitas gene tests and Lighthouse MDRO Management System product offerings. Our current focus is on completing the development of our Lighthouse MDRO Management System. Our ongoing research and development efforts include:

- Investments in information technology including our Lighthouse MDRO Management System portal database interpretation capabilities, and next generation sequencing assembly and bioinformatics;
- Further development of additional Acuitas gene tests;
- Improved microbiology methods for MDRO culture screening such as our Grow on the Go technology, ESBL culture method and additional culture methods to help improve test workflows;
- Combined testing methods from new sample types;
- Multiplex tests addressing newly identified clinical needs; and
- Converting our CLIA lab-based products to *in vitro* diagnostic kits that could be sold, upon receipt of FDA clearance and other approvals, directly to our customers and to other clinical reference laboratories.

#### ***Acuitas Resistome Test***

We are developing our Acuitas Resistome Test for rapid, high resolution testing of microbial isolates. The Resistome Test adds additional resistant genes for carbapenems and ESBLs, and AmpC as contrasted with our Acuitas MDRO Gene Test, and would enable higher resolution Lighthouse MDRO Management System profiling for patients with positive gene test results.

**Lighthouse MDRO Management System Web Portal**

We are developing our Lighthouse MDRO Management System web portal to house Lighthouse MDRO Management System bioinformatics information, which could be used by an institution to provide to a range of infection control personnel and physicians, access to data from our CLIA lab and to allow users to generate customized tracking reports for MDROs in the institution.

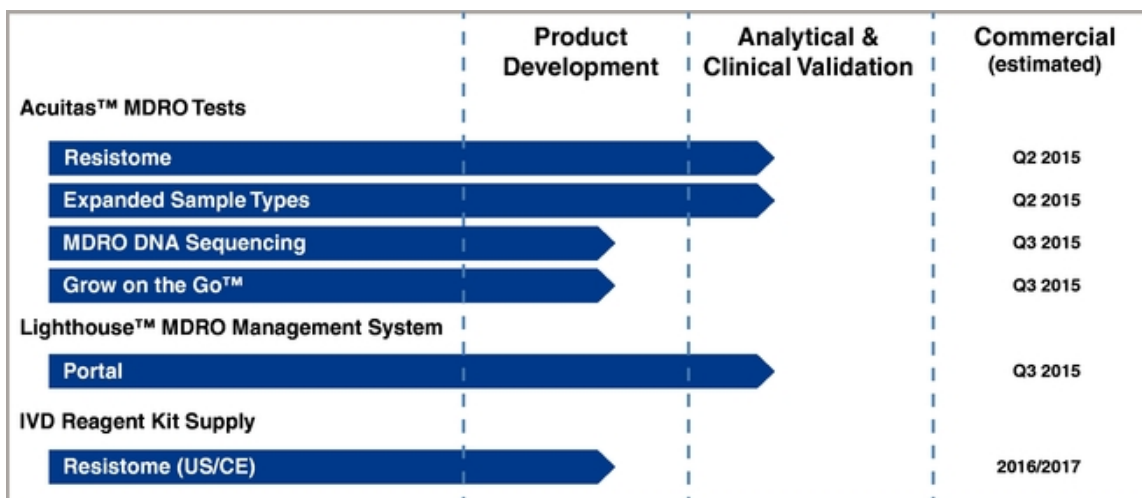
**Acuitas MDRO DNA Sequencing**

Our Acuitas MDRO DNA sequencing tests under development would allow healthcare providers to conduct high resolution typing of MDRO isolates with the same Lighthouse MDRO Management System profile to determine if patients are infected with the same organism or different ones. We anticipate healthcare providers will use this information to help address infection rates, track outbreaks, and adjudicate claims with payors to prove if an infection is hospital-acquired or was colonized on the patient on arrival.

**Expanded Sample Types**

Our Acuitas MDRO Gene Test is CLIA lab-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. We expect that the expanded sample types will open new market opportunities for the Company, including the ability to offer combined C. difficile/MDRO testing and MRSA/MDRO testing, and to expand our environment testing service offerings.

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



**Clinical Studies and Validation Testing**

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 study 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 our Lighthouse MDRO Management System will enable clinical decisions that favorably improve patient outcomes reduce length of stay and hospital costs, and help to reduce the overall level of infectious disease in hospital systems.

Such clinical studies have been completed with the Children's National Medical Center, the University of Maryland Medical System, and the University of Louisville Hospital as part of our Partner-Pilot-Program. These studies compared the performance of our Acuitas MDRO Gene test with standard microbiology culture results. In a separate comparison with perianal swabs spiked with known levels of MDROs, our Acuitas MDRO Gene test was 100% sensitive and specific while the standard culture method at a national reference lab was just 72% sensitive. The studies also demonstrated that the standard culture method creates many false positive results after the initial culture, which potentially result in patients receiving unnecessary and costly contact precautions.

We have also completed CLIA lab-validation studies for our MRSA, *C. difficile* and MDRO gene tests and for our CR Elite CRE culture test. These validation studies were designed to show the accuracy, sensitivity, specificity and reproducibility of our test result. Accuracy testing reveals how often a test correctly detects the organism or gene that is being tested for. The sensitivity of a test reflects the probability that a patient with a specific bacterial organism present will have a positive test result. Specificity reflects the probability that a patient without the specific bacterial organism will have a negative test result. Reproducibility reflects the consistency of the test results over time.

The CLIA validation study for our Acuitas MDRO Gene Test showed that the test detected the presence of antibiotic resistant genes in specimens containing as few as 13 to 250 bacterial cells. The following table shows the number of bacterial cells (Limit of Detection) present in samples associated with the listed bacterial organisms and associated presence of antibiotic resistant genes:

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

In addition, the CLIA validation study for our Acuitas MDRO Gene Test showed that positive results occurred only when bacteria containing antibiotic resistant genes are present. The CLIA validation study also looked at the reproducibility of test results over time, *i.e.*, will a test that is



negative on day one turn to positive on day three. As shown below, our Acuitas MDRO Gene Test results are highly reproducible when testing is performed on three successive days:

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

With respect to specificity and sensitivity, we performed over 1,600 gene detection tests for MDROs in a blinded study with 42 known MDROs present and 10 clinical isolates without known MDRO genes. As the following table shows, our Acuitas MDRO Gene Test results achieved 100% sensitivity and 99.87% specificity.

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

We or our collaborators also present clinical study data at industry conferences and professional meetings. The latest presentation was at the 25<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases in April 2015.

## Payments and Reimbursement

Our Acuitas MDRO test products are, and our Lighthouse MDRO Management System and other future products and services will be, sold to hospitals and public health organizations on a fee-for-service basis. We envision selling our Lighthouse MDRO Management System to health systems, hospitals and long-term care facilities under capitated, flat-rate contracts. Health systems and hospitals absorb the costs of extended stay from HAIs and poor treatment outcomes. For healthcare providers to support the use of our tests and services, OpGen needs to demonstrate improved outcomes and reduced costs. Various studies have documented increased hospital stays of six days or more for patients infected with MDROs, resulting in increased costs of \$14,000 to \$33,000 per infected patient. Determining if an infection is hospital-acquired or was originally obtained from another source is an important issue for hospitals. We believe our tests will help adjudicate payment favorably for hospitals. Isolation procedures are also costly to hospitals, so it is critical that isolation/de-isolation decisions are made accurately. Two recent studies documented a daily extra cost of approximately \$101 for contact precaution equipment and approximately \$57 for nursing time and contact precaution supplies for each infected patient. In addition to costs to individual hospitals, estimates of the economic costs of antibiotic resistance to the U.S. economy range from \$20 billion to \$35 billion annually.

Our marketing strategy focuses on the rapid turn-around time of our Acuitas MDRO test results and the panel of results available from one patient sample. We believe the combination of our Acuitas MDRO test products and our 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: (1) reduced lengths of stays; (2) cost savings and improved patient outcomes; and (3) 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 solutions in order to drive adoption. As part of our marketing strategy, we educate hospitals, other health care institutions, and healthcare professionals about our value proposition. We intend to expand our marketing efforts using proceeds from this offering to increase these activities by expanding our sales and marketing efforts to microbiology and infection control professionals and hospital executives. We anticipate supporting efforts to advocate for expanded MDRO hospital surveillance, legislation at the state and federal level to encourage best practices for MDRO surveillance, and clinical practice guidelines. Finally, our website serves as a portal for educational material for hospitals, healthcare professionals and patients.

### ***Third Party Payors***

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

- Meet the evidence standards necessary to be consistent with leading clinical guidelines. We believe demonstrating that our solution meets leading clinical practice guidelines plays a critical role in payors' coverage decisions.
- Engage reimbursement specialists to ensure the payor outreach strategy reacts to and anticipates the changing needs of our customer base. A customer service team would be an integral part of our reimbursement strategy, working with hospitals to navigate the claims process.

- Cultivate a network of key opinion leaders. Key opinion leaders are able to influence clinical practice by publishing research and determining whether new tests should be integrated into practice guidelines. We would collaborate with key opinion leaders early in the development process to ensure our clinical studies are designed and executed in a way that clearly demonstrates the benefits of our tests to physicians and payors.
- Compile a library of peer-reviewed studies that demonstrate that our Acuitas MDRO test products are 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 kits for use on Fluidigm instrument systems. As of December 31, 2014, Fluidigm reported an installed base of 1,325 units, including 645 genomics analytical systems (Biomark, Biomark HD and EP1™ systems). We believe that such installed base provides us with 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 MDRO test products.

#### ***Hitachi High-Technologies Collaboration***

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 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. We are 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 us, the Hitachi relationship is strategically important because it serves as a way for us to leverage our 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, Maryland, where we perform all Acuitas MDRO testing. Once received, samples are processed through our automated accessioning system, prepared for review and analyzed. 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.

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

## **Quality Assurance**

Our quality assurance function oversees the quality of our laboratory 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 across our entire business, including implementation and maintenance, document control, supplier qualification, corrective or preventive actions oversight, and employee training processes. We monitor and seek to improve our quality over time.

## **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 and from other molecular diagnostic companies creating screening and diagnostic products such as Cepheid, Becton-Dickinson, bioMerieux and Nanosphere. We believe our focus on identifying antibiotic-resistant genes, rather than organisms, the genes and associated diseases included in our gene tests, and our Lighthouse MDRO Management System products and services to come help to distinguish us from such competitors.

We also face competition from commercial laboratories, such as Bio-Reference Laboratories, Inc., Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated, which have strong infrastructure to support the commercialization of diagnostic services.

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.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical, research and development and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by 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 prices 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 December 31, 2014, we had license or ownership rights to 72 patents, including 30 pending United States non-provisional patent applications, and 19 issued United States patents. Our issued patents begin to expire in December 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 Test, Acuitas CR Elite Test and our 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 Test, Acuitas CR Elite Test and our Lighthouse MDRO Management System and to educate health care organizations about our products. 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 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 might become necessary for us to shift our priorities and our plans, abandon or delay one or more of our planned activities, or otherwise adjust

our plans. Please see "Risk Factors" for a discussion of these risks and events, and their potential effects on our business.

## **Regulation**

The following is a summary of the regulations materially affecting our business and operations.

### ***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 perform clinical laboratory tests and report test results. If we were to be found out of compliance with CLIA requirements and subjected to sanction, our business could be harmed.

### ***Federal Oversight of Laboratory Developed Tests and Research Use Only Products***

Clinical laboratory tests, like our Acuitas MDRO Gene Test, are regulated under CLIA, as well as by applicable state laws. Historically, most laboratory developed tests, or LDTs, were not subject to FDA regulations applicable to medical devices, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. 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 our Acuitas MDRO test products are LDTs. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug and Cosmetic Act 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 are 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. The FDA may determine that the device is intended for use in clinical diagnosis based on other evidence, including how the device is marketed.

We cannot predict the potential effect the FDA's current and forthcoming guidance on LDTs and IUOs/RUOs will have on our 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 surveillance and diagnostic services, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. 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.

#### ***U.S. Food and Drug Administration***

Collection systems, like the Copan ESwab we currently purchase and send to customers to procure specimens, and some of our products in development, such as our Acuitas Resistome Test, or specimen collection systems such as Grow on the Go that we develop in the future, may be regulated as medical devices subject to extensive regulation by the FDA and other U.S. federal and state regulatory bodies and comparable authorities in other countries. To ensure that medical products distributed domestically and internationally are safe and effective for their intended use, the FDA and comparable authorities in other countries have imposed regulations that govern, among other things, the following activities that we or our partners perform or could perform: product design and development; product testing; product manufacturing; product labeling; product storage; premarket clearance or approval; advertising and promotion; product marketing, sales and distribution; and post-market surveillance reporting death or serious injuries and medical device reporting. 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 with a list of the devices that they handle at their facilities. We may need to comply with these requirements in the future.

After a medical 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, or MDR, regulations (which requires the manufacturer to report to the FDA if its device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulations (which requires manufacturers to report certain recalls and field actions to the FDA).

## ***FDA's Premarket Clearance and Approval Requirements***

The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, requiring premarket approval. Our current products are Class II devices marketed under FDA 510(k) premarket clearance. Both premarket clearance and premarket approval, or PMA, applications are subject to the payment of user fees, paid at the time of submission for FDA review.

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. 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.

### ***510(k) Clearance Pathway***

If required to obtain 510(k) clearance for our future products, such as Acuitas Resistome Test, or conversion of our Acuitas MDRO test products to diagnostic kits, such tests would be classified as medical devices and we would have to submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of premarket approval applications. FDA's 510(k) clearance pathway usually takes from three to twelve months, but it can take significantly longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

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

### ***Premarket Approval Pathway***

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



After a premarket approval application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application can take between one and three years, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. New premarket approval applications or premarket approval application supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and may not require as extensive clinical data or the convening of an advisory panel. None of our products are currently approved under a premarket approval.

### ***Clinical Trials***

Clinical trials are almost always required to support a premarket approval application and are sometimes required for a 510(k) premarket notification. Clinical trials may also be required to support certain marketing claims. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an investigational device exemption, or IDE, application with the FDA and obtain IDE approval prior to commencing the human clinical trials. The investigational device exemption application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The investigational device exemption application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a "non-significant risk" device and eligible for more abbreviated investigational device exemption requirements. Clinical trials for a significant risk device may begin once the investigational device exemption application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites. Future clinical trials of our motion preservation designs will require that we obtain an investigational device exemption from the FDA prior to commencing clinical trials and that the trial be conducted under the oversight of an institutional review board at the clinical trial site. Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare privacy. A clinical trial may be suspended by the FDA or the investigational review board at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the study. Even if a study is completed, the results of our clinical testing may not demonstrate the safety and efficacy of the device, or may be equivocal or otherwise not be sufficient to obtain approval of our product. Similarly, in Europe the clinical study must be approved by the local ethics committee and in some cases, including studies of high-risk devices, by the Ministry of Health in the applicable country.

### ***Pervasive and Continuing FDA Regulation***

If any of our products classified as devices are placed on the market, numerous regulatory requirements would continue to apply. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;

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

We and any third-party manufacturers of such devices would need to register with the FDA as medical device manufacturers and obtain all necessary state permits or licenses to operate our business. We and any third-party manufacturers would be subject to announced and unannounced inspections by the FDA to determine our compliance with quality system regulation and other regulations. We have not yet been inspected by the FDA.

Failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, which might include any of the following sanctions: (1) untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products; (7) operating restrictions; (8) withdrawing 510(k) clearances or PMA approvals that have already been granted; (9) refusal to grant export approval for our products; or (10) criminal prosecution.

#### ***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. If our business expands internationally, we would be subject to compliance with other laws regarding confidentiality of health information and privacy.

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

### ***Federal and State Physician Self-referral Prohibitions***

As a clinical laboratory, 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.

### **International Regulation**

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

### **Employees**

As of March 31, 2015, we had 29 employees, of which 10 work in laboratory operations, 7 in research and development and clinical development, 5 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 would have expired in the second quarter of 2015. On March 20, 2015, we executed the Fifth Amendment to Lease Agreement, or the Amendment, with respect to such lease. The Amendment, which includes an initial rent abatement period and subsequent annual rate increases, extends the term of the existing lease by 69 months effective May 1, 2015, with one additional five-year renewal at the Company's election; provided, that if the offering contemplated by the prospectus is not consummated with proceeds of at least \$25.9 million, the Company has the option to terminate the Amendment and extend the lease for up to one year. We believe that our existing facilities are, or any such new facilities will be, adequate to meet our business requirements for at least the next 18 months and that additional space will be available on commercially reasonable terms, if required.

### **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 our 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 alternative sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective or whether alternative sources will be available when we need them. If these suppliers can no longer provide us with the materials we need to perform our Acuitas MDRO Gene

Test, 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:

"2015 convertible notes" means the \$1.5 million aggregate of convertible notes offered to certain of our existing investors in February 2015.

"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 CR Elite" is our culture test designed for culture-based confirmation of CRE resistance with our Acuitas MDRO Gene Test.

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

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

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

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

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

"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, antibiotic stewardship, and the development of associated analysis tools, or the 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, an MDRO that causes intestinal tract infections that can lead to sepsis.

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

"CRE" means Carbapenem-resistant Enterobacteraceae, an MDRO.

"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 molecule.

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

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

"ESBL" means extended spectrum beta lactamase bacteria.

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

"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 patient, colonized with an organism, developing an active infection once admitted to the hospital or other healthcare setting.

"HIPAA" means the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act. HIPAA and HITECH 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, an MDRO.

"Lighthouse MDRO Management System" is our product being internally developed to provide real-time information on the MDRO colonization status for patients and hospitals. We combine our molecular test information and microbiology test results from our customized CLIA-based tests to create Lighthouse MDRO Management System profiles for hospitals. Lighthouse MDRO Management System profiling facilitates MDRO tracking and results can be 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 multiple antibiotic treatment alternatives. MDR-GNBs include the following organisms—MDR-Klebsiella pneumonia, MDR-Pseudomonas aeruginosa, MDR-Acinetobacter baumannii and Enterobacteraceae producing extended-spectrum b-lactamases (ESBL) and carbapenemases.

"MDRO" means a 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.

"nosocomial" means hospital acquired.



"Partner-Pilot-Program" is the Company's program of partnering with hospitals and healthcare systems to demonstrate the performance of our products and that implementation will result in more accurate and timely patient isolation, isolation decisions and infection control procedures, and demonstrate the potential for improved antibiotic stewardship by appropriate antibiotic selection.

"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.

"sensitivity" of a clinical laboratory test reflects the probability that a patient with a specific bacterial organism present will have a positive test result.

"specificity" of a clinical laboratory test reflects the probability that a patient without the specific bacterial organism will have a negative test result.

"WHO" means the World Health Organization.

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

**MANAGEMENT****Directors and Executive Officers**

Our executive officers and directors and their respective ages and positions as of April 28, 2015 are set forth below:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<i>Executive officers:</i>		
Evan Jones(1)	58	Chief Executive Officer and Chair of the Board
Kevin Krenitsky, M.D.*	48	President
C. Eric Winzer**	58	Senior Vice President, Finance and Chief Financial Officer
Timothy C. Dec***	56	Interim Chief Financial Officer
G. Terrance Walker, Ph.D.	55	Senior Vice President, Research and Development
Vadim Sapiro	43	Chief Information Officer
David Hoekzema	52	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 J.R. Harris, Ph.D.	64	Director
Timothy Howe(1)(2)	57	Director
Laurence R. McCarthy Ph.D.(1)(2)	70	Director
Misti Ushio, Ph.D.(1)(2)	43	Director

(1) Member of the Compensation Committee.

(2) Member of the Audit Committee.

\* Dr. Krenitsky joined the Company as President in April 2015.

\*\* Mr. Winzer tendered his resignation as our Chief Financial Officer on March 23, 2015, effective May 1, 2015 in order to pursue other interests.

\*\*\* Mr. Dec joined the Company on April 22, 2015, as interim Chief Financial Officer.

**Executive Officers**

*Evan Jones* has served as our President, Chief Executive Officer and Chair of the Board since October 2013. Prior thereto he served as Executive Chair of our board of directors from September 2010 to October 2013. 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 Chair of the Board.

*Kevin Krenitsky, M.D.*, joined OpGen as our President in April 2015. Prior to joining OpGen, he served as Chief Operating Officer of Foundation Medicine, Inc., or Foundation Medicine, from June 2011 to January 2013, as Foundation Medicine's Chief Commercial Officer and Senior Vice President, International Strategy from January 2013 to December 2014, and as a consultant to Foundation Medicine until April 2015. Prior to Foundation Medicine, Dr. Krenitsky was president of Enzo Clinical Labs, Inc., or Enzo, from March 2009 to June 2011. Before his employment at Enzo, he was the chief executive officer of BioServe Biotechnologies, Ltd., a global biotechnology company specializing in processing genetic diagnostic tests, from 2007 to February 2009. From 2005 to 2006, he was the interim chief executive officer of Parkway Clinical Laboratories Inc., a clinical diagnostic lab providing comprehensive routine and esoteric testing. Dr. Krenitsky received a B.S. in business management from the University of Scranton and an M.D. from Jefferson Medical College.

*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) from July 2007 to May 2009, a biotechnology company developing targeted therapeutics for oncology. Prior to Avalon, from March 1986 to April 2006, 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 various financial positions at Genex Corporation. Currently, Mr. Winzer serves as director and audit committee chair at NUO Therapeutics, Inc. (OTCQX: NUOT). 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. Mr. Winzer tendered his resignation as our Chief Financial Officer on March 23, 2015, effective May 1, 2015 in order to pursue other interests.

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

*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 led drug target validation, biomarker discovery and clinical diagnostic development across most disease areas and stages of development from discovery through late clinical trials at Pfizer Inc. (NYSE: PFE), from January 2011 to April 2012, at Duke University and The Biomarker Factory, from February 2009 to December 2010, at GlaxoSmithKline plc (NYSE: GSK), from January 2001 to September 2009, and at Becton, Dickinson and Company (NYSE: BDX), from March 1998 to December 2000. 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, or SAIC, from June 2008 to December 2011, 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, from July 1999 to May 2008, 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, including at SAIC, where he was Vice President, Business Development from April 2008 to July 2012 and led the formation of technology partnerships for Frederick National Laboratory for Cancer Research, at QIAGEN NV (NASDAQ: QGEN), from October 2005 to January 2008, at Cambrex Corporation (NYSE: CBM) from November 2001 to September 2005, at Life Technologies, from April 1999 to January 2001, and at Advanced Biotechnologies Inc., from May 1985 to April 1999. 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 from 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 J.R. Harris, Ph.D., D.Sc.* was elected as a director of OpGen in April 2015. Dr. Harris 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 Precision Medicine at Biogen Idec Inc. (NASDAQ: BIIB), a position he has held since March 2015. Prior thereto he was Senior Vice President for Translational Medicine and Technology at Biogen Idec from June 2011 to February 2015. Before joining Biogen Idec he was the Chief Technology Officer and Director of the Advanced Technology Program at SAIC-Frederick, Inc. in Maryland from January 2007 to June 2011, which operates the National Cancer Institute's leading center for cancer and AIDS research (now Frederick National Laboratory operated by Leidos Biomedical Research, Inc.). His professional experience includes senior executive positions at a number of companies, including Novasite Pharmaceuticals, where he has served as President and Chief Executive Officer from January 2005 to September 2006. Dr. Harris 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 in 2005. Before founding SGX, Dr. Harris was Senior Vice President, Research and Development at Axys 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. Dr. Harris is currently a member of the Board of Directors of BG Medicine (Waltham Mass) a position he has held since 2007, and serves on its Audit Committee. In January 2015, Dr. Harris was elected as an observer to the

Stratified Medicine Scotland-Innovation Centre Board of Directors in Glasgow, Scotland. Dr. Harris brings the following qualifications and skills to his service on the Board—his extensive executive officer experience at publicly held and privately owned pharmaceutical and biotechnology companies, and his scientific experience, coupled with his familiarity with, and contributions to, OpGen from his service on the Clinical and Scientific Advisory Board since 2010.

*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 past 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.), and Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN), and is currently a board member of 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, 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 technical expertise in infectious disease, as well as his senior management experience, faculty positions and 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 experience in many biotechnology and life science companies gives him an understanding and appreciation of the many regulatory and developmental issues confronting diagnostic laboratory and biotechnology companies. Dr. McCarthy is not affiliated with any of our significant investors.

*Misti Ushio, Ph.D.* has been a director of OpGen since March 2012. Dr. Ushio is a Managing Director at Harris & Harris Group, Inc., or 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)), TetraVitae (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 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 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 and surveillance of antibiotic resistant organisms, and strategies for gaining acceptance among healthcare providers for our products.

*Timothy J.R. Harris, Ph.D., D.Sc.* See Dr. Harris' biography above.

*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.

*Laurence R. McCarthy, Ph.D.*—see Dr. McCarthy's biography above.

*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. The University of Louisville Hospital is one of the acute care hospitals that participated in our Partner-Pilot-Program in 2014.

*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).

Following the closing of the offering contemplated by this prospectus, the Company will pay a customary annual retainer to each member of the Clinical and Scientific Advisory Board.

#### **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 principal 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 principal 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 SEC rules and regulations.

### ***Audit Committee***

Brian Atwood, Timothy Howe, Laurence McCarthy and Misti Ushio 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" and "financially literate" for audit committee purposes as such terms are defined in the rules of the SEC and the applicable NASDAQ Stock Market rules. No Audit Committee member is currently identified as an "audit committee financial expert" as defined in the rules of the SEC. 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 person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

### ***Compensation Committee***

Misti Ushio, Timothy Howe, Laurence McCarthy, and Evan Jones 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, except for Evan Jones who is our Chief Executive Officer. We anticipate that Mr. Jones will not remain on the compensation committee upon the closing of the offering contemplated by this prospectus. 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](http://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 SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**EXECUTIVE COMPENSATION****Compensation Tables****Summary Compensation Table—2014, 2013 and 2012**

The following table presents information regarding the total compensation awarded to, earned by, and paid during the years ended December 31, 2014, 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, 2014. These individuals are our named executive officers for 2014.

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards(1)	NonEquity Incentive Plan Compensation	All Other Compensation	Total
Evan Jones	2014	\$ 95,000	\$ —	\$ 6,532(2)	\$ 74,698	\$ —	\$ —	\$ 176,230
President and Chief Executive Officer(2)	2013	\$ 12,500	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 12,500
	2012	\$ 100,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 100,000
C. Eric Winzer,	2014	\$ 260,000	\$ —	\$ —	\$ 36,967	\$ —	\$ —	\$ 296,967
Executive Vice President, Chief Financial Officer(3)	2013	\$ 260,000	\$ —	\$ 21,667(4)	\$ 6,235	\$ —	\$ 1,600(5)	\$ 289,502
	2012	\$ 256,923	\$ —	\$ —	\$ 1,853	\$ —	\$ 5,000(5)	\$ 263,776
Vadim Sapiro,	2014	\$ 237,260	\$ —	\$ —	\$ 17,523	\$ —	\$ —	\$ 254,783
Chief Information Officer	2013	\$ 232,740	\$ —	\$ 19,583(4)	\$ 4,530	\$ —	\$ 1,446(5)	\$ 258,299
	2012	\$ 230,481	\$ —	\$ —	\$ 4,418	\$ —	\$ 3,435(5)	\$ 238,334

- (1) 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.
- (2) Mr. Jones serves as our Chief Executive Officer and Chair of the Board. From October 2013 to April 2015, he served as our President, Chief Executive Officer and Chair of the Board. Previously he served as Executive Chair of the board of directors from September 2011 to October 2013. During 2012 and the first quarter of 2013, he received compensation for serving as our Executive Chair. When he assumed the role of Chief Executive Officer, he agreed to receive base compensation for all of his positions through the issuance of restricted stock units, in lieu of cash salary, for the period from October 25, 2013 to June 30, 2014. The restricted stock units were issued to him in March 2014 and vested on October 24, 2014. In addition, in 2014, Mr. Jones was awarded stock options to acquire 374,235 shares of common stock.
- (3) Mr. Winzer tendered his resignation as our Chief Financial Officer on March 23, 2015, effective May 1, 2015 in order to pursue other interests.
- (4) Represents restricted preferred stock units awarded to each of Mr. Winzer and Mr. Sapiro as compensation for revising his change in control and severance arrangement in November 2013. Mr. Winzer and Mr. Sapiro each relinquished his award of restricted preferred stock units in December 2014.
- (5) Represents a 401(k) match for the periods indicated.

**Employment Agreements with Our Named Executive Officers**

We have entered into an employment agreement with each of our 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 that Mr. Jones will serve as our President and Chief Executive Officer at the equivalent of seventy percent (70%) of a full-time commitment. His initial base salary of \$190,000 reflected that pro rata adjustment. When he assumed the role of Chief Executive Officer, he agreed to receive base compensation for all of his

positions through the issuance of restricted stock units, in lieu of cash salary, for the period from October 25, 2013 to June 30, 2014. Mr. Jones receives 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, restricted stock units to acquire 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. Our agreement with Mr. Jones also includes standard confidentiality, general release and other provisions.

*C. Eric Winzer and Vadim Sapiro*—On January 19, 2011 and December 19, 2011, respectively, we entered into an executive change in control and severance benefits agreement with each of Eric Winzer, our Chief Financial Officer, and Vadim Sapiro, our Chief Information Officer, respectively, each, an Executive. Each agreement was amended on November 1, 2013. Under each agreement, as amended, upon any termination of the employment of the Executive without "cause" that constitutes a "separation from service" under Section 409A of the Internal Revenue Code, the Executive will receive severance compensation equal to his base salary at the time of termination for six months. Each agreement provided for the acceleration, in whole or in part, of stock option awards made to the Executive prior to December 31, 2011 in the event of a change in control or termination in connection with a change in control, however all such stock options are fully vested as of the date of this prospectus. In addition, the Executive can terminate his agreement for "good reason" within 12 months after a change in control and be entitled to his severance payments. Each agreement, as amended, continues in full force and effect unless and until the Company terminates the agreement by providing the Executive with 60 days prior written notice. Each agreement, as amended, includes standard confidentiality, general release and other provisions.

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

Mr. Winzer's executive change in control and severance benefits agreement with OpGen will terminate on May 1, 2015. We have entered into a consulting agreement with Mr. Winzer with an effective date of May 4, 2015 and a term ending on June 30, 2015. Under that consulting agreement Mr. Winzer will provide services to assist OpGen with the transition of his principal financial officer and Finance Department leadership responsibilities. In addition to cash compensation, his outstanding equity awards will continue to vest, and stock options to acquire 19,700 shares of common stock from his October 2014 stock option award will have their vesting accelerated if he continues to provide consulting services to OpGen through June 30, 2015. He will be entitled to exercise all vested stock options held at June 30, 2015 for one year.

## **Employment Agreements with Our Newly Hired Officers**

On April 17, 2015, we entered into an executive employment, change in control and severance benefits agreement with Kevin Krenitsky, our President. Under the agreement, Dr. Krenitsky will work 10% of his professional time until May 31, 2015 and join the Company full time in June 2015. His initial base salary is \$325,000 and annual bonus opportunity, based on performance goals determined by our board, is a target bonus of 40% of annual base salary. In addition, Dr. Krenitsky will receive an award of stock options to acquire two and one-half percent (2.5%) of the fully diluted equity of the Company. Under the agreement, upon any termination of Dr. Krenitsky's employment without "cause" that constitutes a "separation from service" under Section 409A of the Internal Revenue Code, he will receive severance compensation equal to his base salary at the time of termination for six months. The agreement provides for the acceleration of the vesting, or lapse of forfeiture restrictions on his then-outstanding equity awards in the event of termination of employment in connection with a change in control, if the then-outstanding equity awards are not continued, assumed or substituted and would otherwise terminate and expire upon the change in control. In addition, the agreement provides that, for 12 months following a change in control, if Dr. Krenitsky terminates the agreement for good reason or the Company or a successor terminates the agreement without cause, Dr. Krenitsky will receive severance payments for six months and all outstanding equity awards will vest, or have lapse of forfeiture restrictions, as applicable, as of the effective date of the termination of employment. The definitions of "cause," "change in control" and "good reason" are as set forth above.

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

**Outstanding Equity Awards at Fiscal Year-End Table—2014**

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, 2014. 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 2014										
Name	OPTION AWARDS					STOCK AWARDS				
	(1) Number of Securities Underlying Unexercised Options Exercisable	(1) Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price (\$)	Option Expiration Date	Number of Shares of Stock that have not Vested	Market Value of Shares of Stock that have not Vested (\$)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that have not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or other Rights that have not Vested(5)	
Evan Jones(2)	89	—	—	79.05	07/23/2018	—	—	—	—	
	1,847	—	—	110.68	09/21/2020	—	—	—	—	
C. Eric Winzer(3)	—	174,235	—	0.05	04/24/2024	—	—	—	—	
	—	200,000	—	0.61	10/23/2024	—	—	—	—	
	253	—	—	79.05	06/15/2019	—	—	—	—	
	190	—	—	79.05	04/15/2020	—	—	—	—	
	137	—	—	110.68	02/15/2021	—	—	—	—	
	318	30	—	110.68	02/15/2021	—	—	—	—	
	278	134	—	7.91	03/23/2022	—	—	—	—	
	191	252	—	7.91	02/12/2023	—	—	—	—	
	296	653	—	7.91	07/25/2023	—	—	—	—	
	3,338	10,014	—	0.05	04/24/2024	—	—	—	—	
Vadim Sapiro(4)	—	105,000	—	0.61	10/23/2024	—	—	—	—	
	64	—	—	7.91	03/23/2022	—	—	—	—	
	628	290	—	7.91	03/23/2022	—	—	—	—	
	108	145	—	7.91	02/12/2023	—	—	—	—	
	127	—	—	7.91	02/12/2023	—	—	—	—	
	197	436	—	7.91	07/25/2023	—	—	—	—	
	897	2,692	—	0.05	04/24/2024	—	—	—	—	
—	50,000	—	0.61	10/23/2024	—	—	—	—		

- (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) The stock option awards made to Mr. Jones have the vesting schedule set forth in footnote (1) and were awarded on July 23, 2008 (89 shares), February 15, 2011 (1,847 shares), April 24, 2014 (174,235 shares) and October 23, 2014 (200,000 shares).
- (3) The stock option awards made to Mr. Winzer have the vesting schedule set forth in footnote (1), except as described below, 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), July 25, 2013 (949 shares), April 24, 2014 (13,352 shares) and October 23, 2014 (105,000 shares). The stock options award made to Mr. Winzer on April 24, 2014 had its vesting commence on December 31, 2013. Vesting of 19,700 stock options under the October 2014 award will be accelerated on June 30, 2015 if Mr. Winzer is providing consulting services to the Company through that date.
- (4) The stock option awards made to Mr. Sapiro have the vesting schedule set forth in footnote (1), except as described below, and were awarded on March 23, 2012 (two awards, 64 and 918 shares, respectively), February 12, 2013 (two awards, 253 shares and 127 shares, respectively), July 25, 2013 (633 shares), April 24, 2014 (3,589 shares) and October 23, 2014 (50,000 shares). The stock options award made to Mr. Sapiro on April 24, 2014 had its vesting commence on December 31, 2013.
- (5) The market price for our common stock is based upon the initial public offering price of \$6.00 per unit.

**Director Compensation**

The following table presents the total compensation for each person who served as a member of our board of directors during 2014, 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 2014. Compensation paid to Mr. Jones, who is also our President and Chief Executive Officer, is described above under "Summary Compensation Table—2014 and 2013."

**Director Compensation**

<u>Name</u>	<u>Fees Earned or Paid in Cash</u>	<u>Stock Awards</u>	<u>Option Awards (\$)</u>	<u>Non-Equity Incentive Plan Compensation</u>	<u>Nonqualified Deferred Compensation Earnings</u>	<u>All Other Compensation</u>	<u>Total(\$)</u>
Brian G. Atwood	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Timothy Howe	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Laurence R. McCarthy, Ph.D.	\$ 25,000	\$ —	\$ 5,658	\$ —	\$ —	\$ —	\$ 30,658
Misti Ushio, Ph.D.	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —

- (1) In addition to serving on our board of directors, Dr. McCarthy serves on our Clinical and Scientific Advisory Board. Pursuant to his consulting agreement, he receives compensation of \$10,000 per year for service on our Scientific Advisory Board. On April 24, 2014, Dr. McCarthy received a grant of stock options to acquire 15,001 shares of common stock. Under his consulting agreement, we awarded him stock options sufficient to maintain his ownership of our capital stock at 0.33% on a fully diluted basis. The option value was \$432, the exercise price was \$0.05 per share and the options will vest in December 2017. On October 23, 2014, Dr. McCarthy received a stock option to acquire 15,000 shares of common stock. The option value was \$5,226, the exercise price was \$0.61 per share and the options will vest in December 2018. In addition, as of the date of this prospectus, Dr. McCarthy holds stock options to acquire an aggregate of 31,610 shares of our common stock.

In April 2015, the board of directors approved a director compensation policy to be effective following the consummation of the offering contemplated by this prospectus. Under such policy, each non-employee director will receive an annual cash retainer of \$25,000, payable quarterly, plus additional annual cash compensation for committee chairs (\$15,000 for Audit Committee, \$10,000 for Compensation Committee and \$7,500 for Nominating & Corporate Governance Committee (when constituted by the board of directors)) and for committee members (\$7,000 for Audit Committee, \$5,000 for Compensation Committee and \$3,500 for Nominating & Corporate Governance Committee). In addition, each new director will receive an initial stock option grant to purchase 30,000 shares of common stock and each non-employee director will receive an annual stock option grants to purchase 12,500 shares of common stock. All such awards will be made under the 2015 Equity Incentive Plan. The annual stock option awards may be pro-rated in the first year of service depending on when the non-employee director joins the board of directors.

**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 stockholders in April 2008; subsequent increases in the number of shares available for awards under the 2008 Plan were approved by our board and stockholders in January 2009, February 2011, March 2012, December 2012, April 2014 and October 2014. A total of 1,447,791 shares of our common stock are reserved for issuance under the 2008 Stock Option Plan. As of December 31, 2014, 1,230,772 of these shares were subject to outstanding option awards and 217,019 of these shares remain available for future issuance.

The compensation committee of our board of directors administers the 2008 Plan. Subject to the terms of the 2008 Plan, the committee has the discretionary authority to interpret the 2008 Plan; determine eligibility for and grant awards; determine, modify or waive the terms and conditions of any award; prescribe forms, rules and procedures; and otherwise do all things necessary to carry out the purposes of the 2008 Plan. Awards under the 2008 Plan may be granted to key employees 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 exercisability of an award.

Under the 2008 Plan, in the event of any dissolution or liquidation of the Company, the sale of all or substantially all of the Company's assets, or the merger or consolidation of the Company where the Company is not the surviving entity or which results in the acquisition of all or substantially all of the Company's then outstanding common stock, the 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.

### ***2015 Plan***

Our 2015 Equity Incentive Plan, or the 2015 Plan, was adopted by our board of directors and approved by stockholders in April 2015. We expect the 2015 Plan will become effective upon the execution and delivery of the underwriting agreement for this offering. Once the 2015 Plan is effective, no further grants will be made under the 2008 Plan.

The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Internal Revenue Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for the grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants.

*Administration.* The compensation committee of our board of directors acting as a committee, will administer the 2015 Plan, including the determination of the recipient of an award, the number of shares or amount of cash subject to each award, whether an option is to be classified as an incentive stock option or non-qualified stock option, and the terms and conditions of each award, including the exercise and purchase prices and the vesting or duration of the award.

At the discretion of our board of directors, our compensation committee may consist of two or more non-employee directors.. Our board of directors may appoint one or more separate committees of our board of directors, each consisting of one or more members of our board of directors, to administer our 2015 Plan with respect to employees who are not subject to Section 16 of the Exchange Act. Subject to applicable law, our board of directors may also authorize one or more officers to designate employees, other than employees who are subject to Section 16 of the Exchange Act, to receive awards under our 2015 Plan and/or determine the number of such awards to be received by such employees subject to limits specified by our board of directors.

*Authorized shares.* Under our 2015 Plan, the aggregate number of shares of our common stock authorized for issuance may not exceed (1) 1,355,000 plus (2) the sum of number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited or terminated for any reason before being exercised or settled, plus the number of shares subject to vesting restrictions under the 2008 Plan on the 2015 Plan's effective date that are subsequently forfeited.. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by our board of directors. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled, or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. No more than 4,000,000 shares may be delivered upon the exercise of incentive stock options granted under the 2015 Plan. During any time when the tax deduction limitations of Section 162(m) of the Internal Revenue Code apply to awards under the 2015 Plan, and options or stock appreciation rights are intended to qualify as "performance-based compensation" under Section 162(m), no person may receive options or stock appreciation rights in any calendar year for an aggregate of more than 2,000,000 shares, and no more than two times this amount in the first year of employment.

### *Types of awards*

*Stock options.* A stock option is the right to purchase a certain number of shares of stock, at a certain exercise price, in the future. Under our 2015 Plan, incentive stock options and non-qualified options must be granted with an exercise price of at least 100% of the fair market value of our common stock on the date of grant. Incentive stock options granted to any holder of more than 10% of our voting shares must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. The stock option agreement specifies the date when all or any installment of the option is to become exercisable. Payment of the exercise price may be made in cash or, if provided for in the stock option agreement evidencing the award, (1) by surrendering, or attesting to the ownership of, shares which have already been owned by the optionee, (2) by delivery of an irrevocable direction to a securities broker to sell shares and to deliver all or part of the sale proceeds to us in payment of the aggregate exercise price, (3) by a "net exercise" arrangement, or (5) by any other form that is consistent with applicable laws, regulations and rules.

*Restricted stock.* Restricted stock is a share award that may be subject to vesting conditioned upon continued service, the achievement of performance objectives or the satisfaction of any other condition

as specified in a restricted stock agreement. Participants who are granted restricted stock awards generally have all of the rights of a stockholder with respect to such stock, other than the right to transfer such stock prior to vesting.

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

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

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

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

#### **Other plan features**

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

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

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

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

#### **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 time-specific performance goals related to the sale of Argus Systems and MapIt Services, establishment of a clinical laboratory meeting 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. In 2014, the incentive compensation bonus plan consisted of time-specific performance goals related to the early commercialization of our Acuitas MDRO Gene Test, achieving program development milestones under the collaboration with Hitachi and financial performance goals, including fundraising. The board of directors has not yet determined whether the performance goals for 2014 were achieved, in whole or in part.

#### **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 made discretionary matching contributions to the 401(k) plan. In April 2013, the Company match was discontinued. The retirement plan is intended to qualify under Section 401(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 2015. 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, or Prior Series B 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, members 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, or Prior Series C 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 prior series of 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 new Series A 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 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 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 are convertible into Series A Preferred Stock. The 2014 convertible notes are secured by a lien on substantially all of the assets of the Company. 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.

In October 2014, the board of directors authorized the Company to raise bridge funding up to an aggregate of \$2.0 million pursuant to the issuance and sale of secured demand notes to existing investors. The demand notes are secured by a lien on substantially all of the assets of the Company. There was no firm commitment on the part of any investor to participate in such bridge funding. The secured demand notes each have a term of up to four months. The Company drew down an aggregate of \$1.8 million of such bridge funding between October 2014 and January 2015. Investors participating in the bridge funding included an affiliate of Evan Jones (subscribed for \$1.0 million of the demand notes), affiliates of Brian Atwood (subscribed for \$0.2 million of the demand notes) and an affiliate of Misti Ushio (subscribed for \$0.55 million of the demand notes) each of whom was at the time a member of the Company's board of directors. In connection with the issuance of the secured demand notes, the Company entered into an intercreditor agreement with Harris & Harris Group, Inc., as collateral agent in connection with the 2014 convertible notes and the demand notes, and the secured parties named therein in order to provide for the pro rata allocation of the assets of the Company among the holders of the 2014 convertible notes and the demand notes in the event of the occurrence of a foreclosure on the Company's assets by the collateral agent.

In February and March 2015, the Company issued to existing investors \$1.5 million principal amount of convertible notes, or 2015 convertible notes. Each 2015 convertible note is convertible, at the election of the holder, into shares of Series A Preferred Stock, at a conversion rate of 1.25 shares of Series A Preferred Stock for each \$1.00 of principal or interest converted, if no public offering has occurred at the time of conversion, or shares of common stock, at a conversion rate of one share of common stock for each \$1.00 of principal or interest converted, if conversion occurs after the public offering contemplated by this prospectus is consummated. The 2015 convertible notes were issued pursuant to a Notes Purchase Agreement, dated as of February 11, 2015. The 2015 convertible note holders were also issued an aggregate of 225,011 warrants, exercisable for shares of common stock at 110% of the initial public offering price and exercisable only if the offering contemplated by this prospectus is consummated. There was no firm commitment on the part of any investor to participate in the 2015 convertible notes offering. Investors participating in the offering included affiliates of Evan Jones (approximately \$0.62 million, including tendering the \$0.3 million demand note issued in January 2015), Brian Atwood (approximately \$0.4 million) and Misti Ushio (approximately \$0.2 million), each of whom was at the time a member of the Company's board of directors.

In March 2015 the Company issued a secured demand note in the principal amount of \$500,000 to an affiliate of Evan Jones and in April 2015 the Company issued a secured demand note in the principal amount of \$100,000 to Harris & Harris Group, Inc.

Please see the "Description of Indebtedness" beginning on page 127 of this prospectus for more information regarding our existing indebtedness.

Holders of our Series A 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 Series A Preferred Stock and convertible notes, respectively, which conversion (other than in the case of the 2015 convertible notes) 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 Clinical and 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 Clinical and Scientific Advisory Board is for one (1) year, commencing on July 1, 2013, and automatically renews 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 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 for his service on the Clinical and Scientific Advisory Board and \$25,000 annually for his service on our board of directors. Under this agreement, Dr. McCarthy earned \$35,000 during the year ended December 31, 2014.

### ***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.

### ***Participation in our Initial Public Offering***

Persons affiliated with jVen Capital, LLC, entities affiliated with Versant Ventures, Harris & Harris Group, Inc., entities affiliated with CHL Medical Partners and entities affiliated with Cross Creek Capital, L.P., each of which are existing stockholders, have indicated an interest in purchasing up to an aggregate of \$5.1 million of units in this offering at the initial public offering price. Because these indications of interest are not binding agreements or commitments to purchase, these existing stockholders may elect not to purchase units in this offering or the underwriters may elect not to sell any units in this offering to such stockholders. In addition, persons affiliated with jVen Capital, LLC, affiliates of Versant Ventures, Harris & Harris Group, Inc. and entities affiliated with Cross Creek Capital, L.P., who are holders of our outstanding secured demand notes in the aggregate principal amount of \$2.1 million are expected to tender such demand notes as payment for 350,000 units purchased in this offering.

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

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

**PRINCIPAL STOCKHOLDERS**

The following table and footnotes set forth certain information known to us regarding beneficial ownership of our capital stock as of April 28, 2015, 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 SEC 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 7,868,347 shares of common stock outstanding as of April 28, 2015 and also lists applicable percentage ownership based on 10,718,347 shares of common stock to be outstanding after the closing of this offering and assuming no exercise of the underwriters' over-allotment option. The number of shares beneficially owned and the number of shares outstanding reflected in the table below assume conversion of all outstanding 2015 convertible notes at a rate of 1.25 shares of Series A Preferred Stock for each \$1.00 of principal converted and the conversion of all such shares of Series A Preferred Stock into common stock. Options and warrants to purchase shares of common stock that are exercisable within 60 days of April 28, 2015 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.

<u>Name and Address of Beneficial Owner(1)</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percentage of Outstanding Common Stock</u>	
		<u>Before Offering</u>	<u>After Offering</u>
<b>5% Stockholders</b>			
jVen Capital, LLC(2)(14)	2,485,685	31.6%	23.2%
Entities affiliated with Versant Ventures(3)(14)	2,147,286	27.3%	20.0%
Harris & Harris Group, Inc.(4)(14)	1,108,963	14.1%	10.3%
Entities affiliated with Mason Wells(5)(14)	445,546	5.7%	4.2%
<b>Directors and Executive Officers</b>			
Evan Jones(6)	2,654,052	33.5%	24.7%
Brian G. Atwood(7)	2,147,286	27.3%	20.0%
Timothy J.R. Harris, Ph.D.	2,502	*	*
Timothy Howe(8)	383,155	4.9%	3.6%
Laurence R. McCarthy, Ph.D.(9)	5,388	*	*
Misti Ushio, Ph.D.(10)	1,108,963	14.1%	10.3%
C. Eric Winzer(11)	6,103	*	*
Vadim Sapiro(12)	2,356	*	*
Directors and Executive Officers as a group (13 persons)(13)	6,436,458	79.7%	58.9%

\* Less than 1%



- (1) Unless otherwise noted, the business address of each beneficial owner is c/o OpGen, Inc., 708 Quince Orchard Road, Suite 160, Gaithersburg, Maryland 20878.
- (2) Includes 1,059,213 shares of common stock issuable upon the conversion of 1,059,213 shares of Series A Preferred Stock, 1,424,919 shares of common stock issuable upon the conversion of convertible notes in the aggregate principal amount of \$1,289,809 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, 902,913 shares of common stock issuable upon conversion of convertible notes in the principal amount of \$802,800 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, 5,334 shares of common stock issuable upon conversion of convertible notes in the principal amount of \$4,743 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 469,063 shares of common stock issuable upon conversion of convertible notes in the principal amount of \$417,055. The address for Harris & Harris Group, Inc. is 1450 Broadway, 24<sup>th</sup> 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 17,805 shares of common stock, 104,477 shares of common stock issuable upon conversion of convertible notes in the principal amount of \$83,582 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.
- (6) Includes vested stock options to purchase 45,494 shares of common stock. Also includes 19,011 shares of common stock issuable upon the conversion of 19,011 shares of Series A Preferred Stock, 103,812 shares of common stock issuable upon conversion of convertible notes in the principal amount of \$83,050 and warrants to purchase 50 shares of common stock owned by his wife. Also includes an aggregate of 2,485,685 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).
- (7) Consists of 2,147,286 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).

- (8) 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).
- (9) Consists of vested options to purchase 5,388 shares of common stock.
- (10) Consists of 1,108,963 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).
- (11) Includes 127 shares of common stock and vested options to purchase 5,976 shares of common stock.
- (12) Consists of vested options to purchase 2,356 shares of common stock.
- (13) In addition to the beneficial ownership described in footnotes (2) through (12), includes vested stock options to purchase 126,653 shares of common stock held by other executive officers.
- (14) Certain persons and entities, including persons or entities associated with jVen Capital, LLC, Versant Ventures, Harris & Harris Group, Inc., CHL Medical Partners and Cross Creek Capital, L.P., each of which are our existing stockholders, have indicated an interest in purchasing up to an aggregate of \$5.1 million of units in this offering at the initial public offering price. Because these indications of interest are not binding agreements or commitments to purchase, these existing stockholders may elect not to purchase units in this offering or the underwriters may elect not to sell any shares in this offering to such stockholders. In addition, persons affiliated with jVen Capital, LLC, affiliates of Versant Ventures, Harris & Harris Group, Inc. and entities affiliated with Cross Creek Capital, L.P., who are holders of our outstanding secured demand notes in the aggregate principal amount of \$2.1 million are expected to tender such demand notes as payment for 350,000 units purchased in this offering. However, if any units are purchased by these stockholders, the number of shares of common stock beneficially owned after this offering and the percentage of common stock beneficially owned after this offering will differ from that set forth in the table above. If such stockholders were to purchase all of these units plus tender an aggregate of \$2.1 million of demand notes for additional units, they would beneficially own approximately 72.6% of our outstanding common stock after this offering.

## DESCRIPTION OF SECURITIES

*The following descriptions are summaries of the material terms of our current certificate of incorporation as in effect on the date of this prospectus, and summaries of the material terms of our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the closing of the offering contemplated by this prospectus.*

### General

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

### Current Certificate of Incorporation

Pursuant to our current certificate of incorporation, our authorized capital stock consists of 10,000,000 shares of common stock, par value \$0.01 per share, and 7,500,000 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 December 31, 2014, 5,993,042 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 the 2014 convertible notes), were outstanding and held by 83 stockholders of record. In addition, as of December 31, 2014, we had outstanding options to purchase 1,230,772 shares of our common stock, at a weighted average exercise price of \$0.78 per share, 55,670 of which were exercisable.

Our current certificate of incorporation provides that, upon the closing of a "Qualified IPO"—a firm commitment underwritten public offering with net cash proceeds to us (after underwriting discount, commissions and fees) of at least \$30.0 million, each share of Series A Preferred Stock will automatically convert into shares of common stock at the then-effective conversion price, which is \$1.00 per share for the Series A Preferred Stock. Regardless of whether the offering contemplated by this prospectus will constitute a Qualified IPO, the holders of at least 70% of our Series A Preferred Stock, voting as a separate class, have approved a conversion of all outstanding shares of Series A Preferred Stock into common stock, and the holders of 67% of the principal amount of the 2014 convertible notes have approved conversion of such notes into Series A Preferred Stock, and therefore, into common stock upon the closing of the offering contemplated by this prospectus. Accordingly, upon the closing of this offering, each outstanding share of our Series A Preferred Stock, including those underlying the 2014 convertible notes and the 2015 convertible notes, will be converted automatically into one share of common stock, or an aggregate of 7,374,864 shares of common stock, assuming that the holders of the 2015 convertible notes do elect to convert such notes into 1,875,000 shares of Series A Preferred Stock prior to the consummation of this offering.

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.

Our Series A Preferred Stock has the following principal terms: (1) non-cumulative dividends, at the rate of 8% per annum accrue when and if declared by the board of directors; (2) a preference upon liquidation, dissolution or winding up, or in defined corporate transactions, such a merger, consolidation or sale of substantially all of our assets, equal to two times the Series A issue price of \$1.00 per share; (3) the right to vote on an as converted basis with the common stockholders as a single class and the right to vote as a separate class on designated matters, with an approval requirement of 70% of the outstanding Series A Preferred Stock on a per-preferred share basis; (4) the optional and mandatory conversion rights described above; and (5) redemption rights, which take effect

at any time after the sixth anniversary of the date shares of Series A Preferred Stock were issued, which was December 30, 2013.

### **Amended and Restated Certificate of Incorporation and Bylaws**

The following is a summary of the rights of our common stock and preferred stock and certain provisions of our amended and 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 amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part.

Upon the closing of this offering, we will amend and restate our certificate of incorporation and bylaws to make certain changes to our capital stock, including the deletion of all references to the Series A Preferred Stock. Immediately following the closing of this offering, our authorized capital stock will consist of 200,000,000 shares of common stock, par value of \$0.01 per share, and 10,000,000 shares of preferred stock, par value \$0.01. We will have 10,718,347 shares of common stock issued and outstanding from the conversion of the outstanding shares of Series A Preferred Stock, the 2014 convertible notes and the 2015 convertible notes, assuming full conversion, at the election of the holders, into shares of Series A Preferred Stock prior to the closing of the offering. No shares of preferred stock will be outstanding after the offering.

#### ***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 board of directors will have the authority, without further action by our stockholders, to issue from time to time up to 10,000,000 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.

## **Offered Warrants**

In connection with this offering, we are issuing the Offered Warrants.

The Offered Warrants issued in this offering entitle the registered holder to purchase one share of our common stock at a price equal to \$6.60 per unit, subject to adjustment as discussed below, immediately following the issuance of such Offered Warrants and terminating at 5:00 p.m., New York City time, 60 months after the closing of this offering or earlier upon the dissolution or winding up of the Company. The Offered Warrants will be listed on the NASDAQ Capital Market, as a standalone security under the symbol "OPGNW."

The Offered Warrants will be issued pursuant to a Warrant Agreement between us and the Warrant Agent. Certain provisions of the Offered Warrants are set forth herein but are only a summary and are qualified in their entirety by the relevant provisions of such Warrant Agreement, the form of which has been filed as an exhibit to the registration statement of which this prospectus forms a part.

The exercise price and number of shares of common stock issuable upon exercise of the Offered Warrants may be adjusted in certain circumstances, including in the event of a stock dividend or recapitalization, reorganization, merger or consolidation.

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

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

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

## **Registration Rights**

The holders of our registrable shares, as described in the Third Amended and Restated Investors' Rights Agreement, or the investors' rights agreement, between us and the holders of these shares, 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. For purposes of this description, we have included information regarding all shares of common stock outstanding after conversion of all shares of Series A Preferred Stock and all convertible notes, including the 2015 convertible notes on a pre-initial public offering as-converted basis, but have not included any shares of common stock underlying outstanding stock options and warrants.

#### ***Demand Registration Rights***

As of April 28, 2015, the holders of 7,592,568 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 April 28, 2015, the holders of 7,592,568 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 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 April 28, 2015, the holders of 7,592,568 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 the Chair of the Board, the Chief Executive Officer or a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

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

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

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

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

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

Our certificate of incorporation upon the closing of this offering will provide for 10,000,000 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, once our common stock is a "covered security," unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar exclusive forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could rule that this provision in our certificate of incorporation is inapplicable or unenforceable.

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

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

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or



- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

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

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

#### **Transfer Agent and Registrar**

The transfer agent for our common stock is Philadelphia Stock Transfer, Inc.

#### **Warrant Agent**

The Warrant Agent for the Offered Warrants is Philadelphia Stock Transfer, Inc.

#### **Exchange Listing**

Our common stock and Offered Warrants will be listed on the NASDAQ Capital Market under the symbols "OPGN" and "OPGNW," respectively.

## DESCRIPTION OF INDEBTEDNESS

We have the following indebtedness outstanding as of the date of this prospectus:

- **2014 Convertible Notes.** In July through September 2014, we issued secured promissory notes with an aggregate principal amount of \$1.5 million. The 2014 convertible notes are convertible into shares of the Company's Series A Preferred Stock, with a conversion rate of one share of Series A Preferred Stock for each \$1.00 principal amount of the 2014 convertible notes. The 2014 convertible notes were issued to existing investors of the Company who were signatory to the Company's Third Amended and Restated Investors' Rights Agreement, as amended, or the Investors' Rights Agreement. Under the Investors' Rights Agreement, the investors signatory thereto have the right to participate in new issuances of our securities, such as the 2014 convertible notes, to maintain their percentage ownership of the Company prior to the initial public offering. The 2014 convertible notes may be automatically converted into shares of Series A Preferred Stock upon the consent of the holders of at least 70% of the aggregate principal amount of the notes.
- **2014 Demand Notes.** In October 2014, the Board approved up to \$2.0 million of bridge funding to support our operations while we pursued an initial public offering. The bridge funding consists of secured demand notes with an interest rate of 8% per annum, a first priority security interest in the assets of the Company, and a term of approximately 4 months before the holder can demand payment. We issued an aggregate of \$1.5 million of these 2014 demand notes between October and December 2014. An additional demand note with a principal amount of \$0.3 million was issued in January 2015, and was tendered to us as partial payment of a 2015 convertible note. The holders of the 2014 demand notes are existing investors who have indicated an interest in participating in the initial public offering contemplated by this prospectus. Such holders have the right to tender the principal and interest of any outstanding 2014 demand note to the Company as payment for shares in this initial public offering.
- **2015 Convertible Notes.** In February and March 2015, we issued secured promissory notes with an aggregate principal amount of \$1.5 million (\$0.3 million was paid by tender of a January 2015 secured demand note). Each 2015 convertible note is convertible at the option of the holder at any time. If a holder elects to convert a 2015 convertible note at any time prior to the completion of an initial public offering, the 2015 convertible note will convert into shares of Series A Preferred Stock, at a conversion rate of 1.25 shares of Series A Preferred Stock for each \$1.00 of principal converted. If a holder elects to convert a 2015 convertible note after the completion of an initial public offering, the 2015 convertible note will convert into common stock at a conversion rate of one share of common stock for each \$1.00 of principal converted. The 2015 convertible notes do not provide for automatic conversion of the notes at our election or with the approval of less than all of the outstanding holders. The 2015 convertible notes were issued to existing investors in accordance with the participation rights contained in the Investors' Rights Agreement. The 2015 convertible notes are secured by a first priority security interest *pari passu* with the 2014 demand notes and senior to the 2014 convertible notes. The 2015 convertible notes were issued with 15% warrant coverage (an aggregate of 225,011 warrants), with such warrants exercisable for common stock at an exercise price equal to 110% of the initial public offering price, exercisable only if the initial public offering occurs, and then exercisable beginning on the six month anniversary of the closing of the initial public offering, and not automatically exercised in any situation.
- **2015 Demand Notes.** Because we are in need of additional bridge funding to support our operations prior to the closing of this offering, on March 26, 2015, the Board approved additional funding, up to \$2.0 million principal amount, of secured demand notes with the same

terms as the 2014 demand notes described above. To date, \$600,000 aggregate principal amount of 2015 demand notes were subscribed for by existing investors in March 2015 and April 2015.

In connection with the original issuance of the 2015 convertible notes, we entered into an Amended and Restated Intercreditor Agreement with Harris & Harris Group, Inc., as collateral agent, in connection with the 2014 convertible notes, the demand notes and the 2015 convertible notes, and the secured parties named therein in order to provide for the allocation of assets of the Company in the event of the occurrence of a foreclosure on the Company's assets by the collateral agent. The Amended and Restated Intercreditor Agreement provides that the holders of the outstanding secured demand notes, including the March 2015 secured demand note, and 2015 convertible notes have a first lien on the assets of the Company in the event of a foreclosure by the collateral agent and will share in the Company's assets on a pro rata basis. The holders of the outstanding 2014 convertible notes have a second lien interest in the assets of the Company in the event of a foreclosure by the collateral agent and will not be entitled to recover principal, interest or any other amounts due on such 2014 convertible notes from the assets of the Company until the holders of the outstanding demand notes and the 2015 convertible notes have been repaid in full on the outstanding principal, interest and all other amounts due under such notes.

We have used the capital raised through the issuances of this indebtedness to support our operations as we have continued to pursue the initial public offering contemplated by this prospectus. All of this capital has been provided by existing investors in the Company. The 2014 convertible notes are convertible into Series A Preferred Stock, as are the 2015 convertible notes, if they are converted at the election of the holders prior to the closing of the initial public offering. Such shares of Series A Preferred Stock are convertible into common stock at a conversion rate of one share of common stock for each share of Series A Preferred Stock. The Company anticipates that all of the 2014 convertible notes and all of the 2015 convertible notes will be converted into shares of Series A Preferred Stock prior to the closing of the initial public offering, and all outstanding shares of Series A Preferred Stock will be converted into shares of common stock immediately prior to the closing of the initial public offering. The aggregate number of shares of common stock that would be outstanding if all such conversions were effected is 7,868,347 shares, plus warrants to purchase 225,011 shares of common stock issued to the holders of the 2015 convertible notes. The following table shows the effects of the conversion of the Series A Preferred stock and the 2014 and 2015 convertible notes, assuming they are all converted immediately prior to the initial public offering:

<u>Debt/Equity</u>	<u>Outstanding at April 22, 2015</u>	<u>Convertible into Series A Preferred</u>	<u>Conversion to Common Stock</u>
Series A Preferred Stock(1)	3,999,864	N/A	3,999,864
2014 convertible notes(2)	\$ 1,500,000	1,500,000	1,500,000
2015 convertible notes(3)	\$ 1,500,000	1,875,000	1,875,000
Common stock	493,483	N/A	N/A

- (1) The holders of 70% of the Series A Preferred Stock or the Company can force a conversion upon closing of the initial public offering.
- (2) The holders of 70% of the 2014 convertible notes or the Company can force a conversion upon closing of the initial public offering.
- (3) If converted by all holders prior to the closing of the initial public offering. If a holder of a 2015 convertible note waits until after the closing of the initial public offering, the 2015 convertible note would be convertible into common stock at a conversion rate of one share of common stock for each \$1.00 converted. In addition, the holder could elect to retain the 2015 convertible note as a debt instrument, and be repaid in cash at maturity

on February 17, 2016. If that occurs, the Company may need to use a portion of the proceeds of this offering to repay such note(s).

In addition, the holders of \$2.1 million outstanding aggregate principal amount of demand notes who have indicated an intent to participate in the offering may elect to tender the principal and accrued interest of such demand notes to us as payment for units in the initial public offering at the initial public offering price. If that occurs, we will not receive cash proceeds for such units, but will be able to retire such indebtedness upon the issuance of such units.

## 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 April 28, 2015, upon the completion of this offering, 10,718,347 shares of our common stock will be outstanding, assuming (i) conversion of all outstanding shares of series A Preferred Stock and all outstanding convertible notes into shares of common stock, (ii) no exercise of the underwriters' option to purchase additional shares and (iii) no exercise of outstanding options or warrants. Except for approximately 7.6 million 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 107,183 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 December 31, 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, that 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, and the holders of 1% or more of our common stock have agreed to enter into lock-up agreements with the underwriters. See "Underwriting" for more information.

**Registration Rights**

As of April 22, 2015, the holders of 7,592,568 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 that are subject to lock-up agreements will be eligible for resale until the expiration of the lock-up period 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 our units, shares of our common stock, and the Offered Warrants, which we refer to collectively as our securities below, issued pursuant to this offering. This summary deals only with our securities 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 securities as part of a hedging, integrated, conversion or straddle transaction or a person deemed to sell our securities 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 securities 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 holders of our securities 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 securities 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 securities 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 securities, 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 securities 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 securities are urged to consult their own tax advisors concerning the tax considerations related to the acquisition, ownership and disposition of our securities 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.**

## **Tax Treatment of Units**

There is no authority addressing the treatment, for U.S. federal income tax purposes, of securities with terms substantially the same as the units, and, therefore, that treatment is not entirely clear. The acquisition of a unit should be treated for U.S. federal income tax purposes as the acquisition of one share of our common stock and one Offered Warrant to acquire one share of our common stock. Each holder of a unit must allocate the purchase price paid by such holder for such unit between the share of common stock and the Offered Warrant based on their respective relative fair market values. A holder's initial tax basis in the common stock and the Offered Warrant included in each unit should equal the portion of the purchase price of the unit allocated thereto. Any disposition of a unit should be treated for U.S. federal income tax purposes as a disposition of the common stock and the Offered Warrant comprising the unit, and the amount realized on the disposition should be allocated between the common stock and the Offered Warrant based on their respective relative fair market values. The separation of the common stock and the Offered Warrant comprising a unit should not be a taxable event for U.S. federal income tax purposes.

The foregoing treatment of the common stock and the Offered Warrants and a holder's purchase price allocation are not binding on the IRS or the courts. Because there are no authorities that directly address instruments that are similar to the units, no assurance can be given that the IRS or the courts will agree with the characterization described above or the discussion below. Accordingly, each prospective investor is urged to consult its own tax advisor regarding the U.S. federal, state, local and any foreign tax consequences of an investment in a unit (including alternative characterizations of a unit). Unless otherwise stated, the following discussions are based on the assumption that the characterization of the common stock and the Offered Warrants and the allocation described above are accepted for U.S. federal income tax purposes.

## **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 and the Offered Warrants.

## ***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.

### ***Exercise of an Offered Warrant***

A U.S. holder will not be required to recognize taxable gain or loss upon exercise of an Offered Warrant. The U.S. holder's tax basis in the share of our common stock received upon exercise of the Offered Warrant generally will be an amount equal to the sum of the U.S. holder's initial investment in the Offered Warrant (i.e., the portion of the U.S. holder's purchase price for a unit that is allocated to the Offered Warrant, as described above under "—Tax Treatment of Units") and the exercise price. The U.S. holder's holding period for shares of our common stock received upon exercise of the Offered Warrant will begin on the date following the date of exercise (or possibly the date of exercise) of the Offered Warrants and will not include the period during which the U.S. holder held the Offered Warrant.

### ***Sale, Taxable Exchange, Redemption or Expiration of an Offered Warrant***

Upon a sale, taxable exchange (other than by exercise), redemption, or expiration of an Offered Warrant, a U.S. holder will be required to recognize taxable gain or loss in an amount equal to the difference between (i) the amount realized upon such disposition or expiration (or, if the Offered Warrant is held as part of a unit at the time of the disposition of the unit, the portion of the amount realized on such disposition that is allocated to the Offered Warrant based on the then fair market values of the Offered Warrant and the common stock included in the unit) and (ii) the U.S. holder's tax basis in the Offered Warrant (that is, the portion of the U.S. holder's purchase price for a unit that is allocated to the Offered Warrant, as described above under "—Tax Treatment of Units"). Such gain or loss would generally be treated as long-term capital gain or loss if the Offered Warrant was held by the U.S. holder for more than one year at the time of such disposition or expiration. As discussed above, the deductibility of capital losses is subject to certain limitations.

### ***Possible Constructive Distributions***

The terms of each Offered Warrant provide for an adjustment to the number of shares of common stock for which the Offered Warrant may be exercised or to the exercise price of the Offered Warrant in certain events. An adjustment which has the effect of preventing dilution generally is not taxable. However, a U.S. holder of Offered Warrants would be treated as receiving a constructive distribution from us if, for example, the adjustment increases the holder's proportionate interest in our assets or earnings and profits (e.g., through an increase in the number of shares of common stock that would be obtained upon exercise) as a result of a distribution of cash to the holders of shares of our common stock which is taxable to the U.S. holders of such shares as described under "U.S. Holders—Distributions" above. Such constructive distribution would be subject to tax as described under that

section in the same manner as if such U.S. holder received a cash distribution from us equal to the fair market value of such increased interest.

### ***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 securities. 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 securities.

### ***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 our common stock or Offered Warrants to U.S. holders that are not exempt recipients, such as corporations. Under U.S. federal income tax law, dividends and proceeds from the sale of our common stock or Offered Warrants 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 securities.

#### ***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 and Offered Warrants." 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."

### ***Exercise of an Offered Warrant***

The U.S. federal income tax treatment of a non-U.S. holder's exercise of an Offered Warrant generally will correspond to the U.S. federal income tax treatment of the exercise of an Offered Warrant by a U.S. holder, as described under "U.S. Holders—Exercise of an Offered Warrant" above.

### ***Sale, Exchange, Redemption or Certain Other Taxable Dispositions of Our Common Stock and Offered Warrants***

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, or Offered Warrants (including an expiration or redemption of our Offered Warrants), in each case without regard to whether those securities were held as part of a unit, 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 or Offered Warrants, 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 securities 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. Special rules may apply to the determination of the 5% threshold in the case of a holder of an Offered Warrant. 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 or Offered Warrants 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 or Offered Warrants 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 and Offered Warrants should consult their tax advisors regarding the possible impact of FATCA on their investment in our common stock and Offered Warrants, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

## UNDERWRITING

We have entered into an underwriting agreement with Maxim Group LLC, acting as the sole book-running manager of this offering and the sole representative of the underwriters named below. Subject to the terms and conditions of the underwriting agreement, the underwriters named below have agreed severally to purchase, and we have agreed to sell to them, the number of units indicated below, at the public offering price less the underwriting discount and commissions described below:

<u>Underwriter</u>	<u>Number of Units</u>
Maxim Group LLC	2,422,500
National Securities Corporation	427,500
Total	2,850,000

The underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the units offered by this prospectus are subject to the approval of certain legal matters by their counsel and to other conditions. The underwriters are obligated to take and pay for all of the units offered by this prospectus if any such units are taken, other than those units covered by the over-allotment option described below.

### Over-Allotment Option

We have granted to the underwriters an option, exercisable no later than 45 calendar days after the date of the underwriting agreement, to purchase from us up to an additional 427,500 shares, at the price of \$5.99 per share and/or up to an additional 427,500 Offered Warrants at the price of \$0.01 per warrant, in each case less the underwriting discount set forth on the cover page of this prospectus and for the commissions described below. The underwriters may exercise this option in part or in full, only to cover over-allotments, if any, made in connection with this offering. To the extent the option is exercised and the conditions of the underwriting agreement are satisfied, we will be obligated to sell to the underwriters, and the underwriters will be obligated to purchase, the additional shares and/or Offered Warrants as to which the option has been exercised.

### Discount and Commissions

We have agreed to pay the underwriters an underwriting discount equal to 7.88% of the aggregate gross proceeds raised in this offering. We have also agreed to pay the underwriters warrants to purchase the number of shares of our common stock equal to 6.5% of all the shares of common stock included in the units sold in this offering (including shares in the over-allotment option, to the extent exercised). Such underwriters' warrants shall have an exercise price equal to \$6.60 per share of common stock underlying such warrants, which is 110% of the public offering price per unit, and shall expire five years after the effective date of the registration statement of which this prospectus forms a part. Such underwriters' warrants will not be subject to redemption by the Company, and will entitle the holder thereof to unlimited "piggyback" registration rights with respect to the shares of common stock underlying such warrants for a period of seven years from the effective date of the registration statement of which this prospectus forms a part at the Company's expense, and one demand registration right at the Company's expense and additional demand registration rights at the warrant holder's expense for a period of five years from the effective date of the registration statement of which this prospectus forms a part. Such underwriters' warrants will be subject to FINRA Rule 5110(g)(1) in that, except as otherwise permitted by FINRA rules, for a period of 180 days following the effective date of the registration statement of which this prospectus forms a part, such underwriters' warrants shall not be (A) sold, transferred, assigned, pledged or hypothecated or (B) the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person.

The representative has advised us that the underwriters propose to offer the units directly to the public at the public offering price set forth on the cover of this prospectus. In addition, the representative may offer some of the units to other securities dealers at such price less a concession of up to \$0.2364 per unit. After the offering to the public, the offering price and other selling terms may be changed by the representative without changing the Company's proceeds from the underwriters' purchase of the units.

The following table summarizes the public offering price per unit, the underwriting discount and commissions and the proceeds, before expenses, to us, assuming both no exercise and the full exercise of the underwriters' over-allotment option.

	Per Share	Per Offered Warrant	Total Without Over-Allotment	Total With Over-Allotment in Full
Public offering price	\$ 5.99	\$ 0.01	\$ 17,100,000	\$ 19,665,000
Underwriting discount and commissions(1)	\$ 0.4720	\$ 0.0008	\$ 1,347,480	\$ 1,549,602
Proceeds, before expenses, to us	\$ 5.518	\$ 0.0092	\$ 15,752,520	\$ 18,115,398

(1) Does not include the warrants to be issued to the underwriters at closing.

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discount and commissions, will be approximately \$880,645.

#### Determination of Public Offering Price

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

- the valuations of publicly traded companies in the United States 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, our past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- various valuation measures of other companies engaged in activities similar to ours.

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

#### Lock-Up Agreements

We and each of our officers, directors and stockholders who own in the aggregate 1.0% or more of our outstanding shares have agreed, subject to certain exceptions, not to offer, sell, agree to offer or sell, solicit offers to purchase, grant any call option or purchase any put option with respect to, pledge, encumber, assign, borrow or otherwise dispose of or transfer any units, shares of our common stock, warrants to purchase our common stock or any other security of ours or any other entity that is convertible into, or exercisable or exchangeable for, our units, common stock or any other equity

security of ours, for a period of six (6) months after the date set forth on the front cover of the final prospectus used in connection with this offering, without the prior written consent of the representative.

The representative may in its discretion consent to release some or all of the securities subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release securities subject to lock-up agreements, the representative will consider, among other factors, the security holder's reasons for requesting the release, the number of securities for which release is being requested and market conditions at the time.

### **Price Stabilization, Short Positions and Penalty Bids**

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our securities. Specifically, the underwriters may over-allot in connection with this offering by selling more units than are set forth on the cover page of this prospectus. This creates a short position in our securities for the underwriters' own accounts. The short position may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriters is not greater than the number of securities they may purchase in the over-allotment option. In a naked short position, the number of securities over-allotted by the underwriters is greater than the number of securities they may purchase in the over-allotment option. To close out a short position, the underwriters may elect to exercise all or part of the over-allotment option. The underwriters may also elect to stabilize the price of our securities, or reduce any short position by bidding for, and purchasing, our securities in the open market.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter or dealer repays selling concessions allowed to it for distributing a security in this offering because the underwriter repurchases that security in stabilizing or short-covering transactions.

Finally, the underwriters may bid for, and purchase, our securities in market making transactions, including "passive" market making transactions as described below.

These activities may stabilize or maintain the market price of our securities at prices that are higher than the prices that might otherwise exist in the absence of these activities. The underwriters are not required to engage in these activities, and may discontinue any of these activities at any time without notice. These transactions may be effected on NASDAQ, in the over-the-counter market or otherwise.

In connection with this offering, the underwriters and selling group members, if any, or their affiliates may engage in passive market making transactions in our securities immediately prior to the commencement of sales in this offering, in accordance with Rule 103 of Regulation M under the Exchange Act. Rule 103 generally provides that:

- a passive market maker may not effect transactions or display bids in excess of the highest independent bid price by persons who are not passive market makers;
- net purchases by a passive market maker on each day are generally limited to 30% of the passive market maker's average daily trading volume during a specified two-month prior period or 200 shares, whichever is greater, and must be discontinued when that limit is reached; and
- passive market making bids must be identified as such.

### **Other Terms**

We have agreed to bear the cost of all actual expenses related to this offering, including without limitation all filing fees and communication expenses relating to the registration of the securities to be sold in this offering. We have paid Maxim Group LLC an advance of \$30,000 for its anticipated



out-of-pocket accountable expenses. Maxim Group LLC will reimburse us for any remaining portion of the advance to the extent such monies were not used for out-of-pocket accountable expenses actually incurred if this offering is not completed. If this offering is completed, we will reimburse Maxim Group LLC for certain out-of-pocket actual expenses related to the offering, including legal fees, expenses incurred to clear the offering with FINRA, background searches of our officers and directors, and roadshow expenses up to a maximum aggregate reimbursement of \$125,000, including the \$30,000 advance already paid (of which a maximum of \$75,000 can be allocated to legal expenses and \$50,000 to non-legal expenses).

We have granted Maxim Group LLC a right of first refusal to act as a co-lead manager and book runner for all future public equity, equity-linked and debt financings (excluding commercial bank debt and credit facilities) for a period of 12 months from the commencement of sales of the offering contemplated by this prospectus.

### **Indemnification**

We have agreed to indemnify the underwriters against liabilities relating to the offering arising under the Securities Act and the Exchange Act and liabilities arising from breaches of some or all of the representations and warranties contained in the underwriting agreement, and to contribute to payments that the underwriters may be required to make for these liabilities.

### **Electronic Distribution**

A prospectus in electronic format may be made available on a website maintained by the representatives and may also be made available on a website maintained by other underwriters. The underwriters may agree to allocate a number of units to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representative to underwriters that may make Internet distributions on the same basis as other allocations. In connection with this offering, the underwriters or syndicate members may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

The underwriters have informed us that they do not expect to confirm sales of units offered by this prospectus to accounts over which they exercise discretionary authority.

Other than the prospectus in electronic format, no information on any underwriter's website and no information contained in any other website maintained by an underwriter is part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

### **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 securities 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:

- (a) 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 securities in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

The securities 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 securities 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 securities 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 securities may not be circulated or distributed, nor may the securities 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) 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 securities 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, securities, debentures and units of securities 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 securities 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 securities offered by this prospectus will be passed upon for us by Ballard Spahr LLP, Philadelphia, Pennsylvania. The underwriters are being represented by Ellenoff Grossman & Schole LLP.

## **EXPERTS**

The financial statements as of December 31, 2014 and 2013 and for the years then ended included in this prospectus have been audited by CohnReznick LLP, an independent registered public accounting firm, as stated in their report, which includes an explanatory paragraph relating to our ability to continue as a going concern, appearing elsewhere in this prospectus. Such financial statements are included in reliance upon the report of such firm given on the authority of said firm as experts in accounting and auditing.

## **WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities 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](http://www.sec.gov). The information on the SEC's website is not part of this prospectus, and any references to this website or any other website 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:

- "AHA Hospital Statistics," 2011 edition.
- "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).
- "Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations," a report of the Review on Antimicrobial Resistance, December 2014.
- "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.
- "Diagnostic Kit," Second Edition by Cowen & Co.
- "Fact Sheets: CMS to Improve Quality of Care during Hospital Inpatient Stays," [www.cms.gov/Newsroom](http://www.cms.gov/Newsroom) (Aug. 4, 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](http://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. Gidycz, Ronald N. Jones, Barbara E. Murray, Robert A. Bonomo and David Gilbert, **Clinical Infectious Diseases**, volume 56, pages 1685-94 (Jun 15, 2013), or Boucher et al.
- "Updated ECDC risk assessment on the spread of new Delhi metallo- $\beta$ -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.a\\_spx?ID=740](http://ecdc.europa.eu/en/publications/Publications/Forms/ECDC_DisForm.a_spx?ID=740) (Sept 13, 2011).

**OPGEN, INC.**  
**Index to Audited Financial Statements**

**Years Ended December 31, 2014 and 2013**

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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 sheets of OpGen, Inc. as of December 31, 2014 and 2013, and the related statements of operations, stockholders' deficit and cash flows for the years 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 audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audits 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 audits provide 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, 2014 and 2013, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying 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 accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ CohnReznick LLP

Vienna, Virginia

March 2, 2015, except for the effects of the matters discussed in the sixth paragraph of Note 15

which is as of March 20, 2015 and the matters discussed in the fourth, fifth, seventh, eighth, and ninth paragraphs of Note 15 which are as of April 3, 2015 and the matters discussed in Note 2 and the tenth paragraph of Note 15 which are as of April 28, 2015.

OpGen, Inc.

Balance Sheets

December 31,

	2014	2013
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 749,517	\$ 1,400,345
Accounts receivable, net	503,983	241,897
Inventory, net	369,742	175,713
Prepaid expenses and other current assets	90,233	146,438
<b>Total current assets</b>	<b>1,713,475</b>	<b>1,964,393</b>
Property and equipment, net	587,956	1,079,423
Licensed technology and other intangible assets, net	—	57,594
Deferred IPO issuance costs	296,041	—
Other noncurrent assets	57,459	57,459
<b>Total assets</b>	<b>\$ 2,654,931</b>	<b>\$ 3,158,869</b>
<b>Liabilities, Preferred Stock and Stockholders' Deficit</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 1,160,081	\$ 869,172
Accrued compensation and benefits	423,099	517,250
Accrued liabilities	993,657	743,767
Deferred revenue	339,171	509,728
Current portion of long-term debt	5,000	10,000
Current maturities of long-term capital lease obligation	100,499	105,967
Convertible notes	1,500,000	—
Secured demand notes	1,500,000	—
<b>Total current liabilities</b>	<b>6,021,507</b>	<b>2,755,884</b>
Long-term capital lease obligation, less current maturities	134,149	234,562
<b>Total liabilities</b>	<b>6,155,656</b>	<b>2,990,446</b>
<b>Commitments and contingencies (note 10)</b>		
<b>Redeemable convertible preferred stock</b>		
Series A redeemable convertible preferred stock, \$.01 par value; 6,000,000 shares authorized; 3,999,864 and 1,999,864 shares issued and outstanding at December 31, 2014 and 2013, respectively; aggregate liquidation preference of \$7,999,728 and \$3,999,728 at December 31, 2014 and 2013, respectively	4,564,899	1,999,864
<b>Total redeemable convertible preferred stock</b>	<b>4,564,899</b>	<b>1,999,864</b>
<b>Stockholders' deficit</b>		
Common stock, \$.01 par value; 7,500,000 shares authorized; 493,178 and 362,537 shares issued and outstanding at December 31, 2014 and 2013, respectively	4,932	3,625
Additional paid-in capital	88,701,737	89,265,757
Accumulated deficit	(96,772,293)	(91,100,823)
<b>Total stockholders' deficit</b>	<b>(8,065,624)</b>	<b>(1,831,441)</b>
<b>Total liabilities, preferred stock and stockholders' deficit</b>	<b>\$ 2,654,931</b>	<b>\$ 3,158,869</b>

See accompanying notes to financial statements.

## OpGen, Inc.

## Statements of Operations

Years ended December 31,

	2014	2013
<b>Revenue</b>		
Product sales	\$ 1,236,349	\$ 1,735,517
Laboratory services	478,909	630,851
Collaborations revenue	2,411,120	44,239
<b>Total revenue</b>	<b>4,126,378</b>	<b>2,410,607</b>
<b>Operating expenses</b>		
Cost of products sold	425,541	1,501,648
Cost of services	526,196	320,938
Argus™ Whole Genome obsolescence	—	950,881
Research and development	4,368,302	4,151,936
General and administrative	2,312,935	2,762,205
Sales and marketing	2,058,085	3,053,394
<b>Total operating expenses</b>	<b>9,691,059</b>	<b>12,741,002</b>
<b>Operating loss</b>	<b>(5,564,681)</b>	<b>(10,330,395)</b>
<b>Other income (expense)</b>		
Interest income	156	1,222
Interest expense	(111,345)	(31,598)
Change in fair value of derivative financial instruments	—	134,560
Other income (expense)	4,400	91,390
<b>Total other income (expense)</b>	<b>(106,789)</b>	<b>195,574</b>
<b>Net loss</b>	<b>\$ (5,671,470)</b>	<b>\$ (10,134,821)</b>
Preferred stock dividends	(627,133)	(5,372,978)
<b>Net loss available to common stockholders</b>	<b>\$ (6,298,603)</b>	<b>\$ (15,507,799)</b>
Net loss per common share—basic and diluted	<b>\$ (16.25)</b>	<b>\$ (896.09)</b>
Weighted average shares outstanding—basic and diluted	387,590	17,306
Pro forma net loss per common share, basic and diluted (unaudited) (note 16)	<b>\$ (1.20)</b>	
Pro forma weighted average shares outstanding—basic and diluted (unaudited) (note 16)	<b>4,687,713</b>	

See accompanying notes to financial statements.



## OpGen, Inc.

## Statements of Stockholders' Deficit

Years ended December 31, 2014 and 2013

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Number of Shares	Amount			
<b>Balances at January 1, 2013</b>	<b>3,517</b>	<b>\$ 35</b>	<b>\$ —</b>	<b>\$ (75,593,024)</b>	<b>\$ (75,592,989)</b>
Stock option exercises	46	—	1,217	—	1,217
Stock compensation expense	—	—	152,753	—	152,753
Accrued dividends, Prior Senior Preferred Stock	—	—	—	(5,058,786)	(5,058,786)
Accretion of Prior Senior Preferred Stock	—	—	—	(314,192)	(314,192)
Conversion of Prior Preferred Stock to common stock	358,974	3,590	89,111,787	—	89,115,377
Net loss	—	—	—	(10,134,821)	(10,134,821)
<b>Balances at December 31, 2013</b>	<b>362,537</b>	<b>3,625</b>	<b>89,265,757</b>	<b>(91,100,823)</b>	<b>(1,831,441)</b>
Stock option exercises	1	—	8	—	8
Restricted stock unit vesting	130,640	1,307	(1,307)	—	—
Stock compensation expense	—	—	64,412	—	64,412
Accretion of Series A Preferred Stock	—	—	(627,133)	—	(627,133)
Net loss	—	—	—	(5,671,470)	(5,671,470)
<b>Balances at December 31, 2014</b>	<b>493,178</b>	<b>\$ 4,932</b>	<b>\$ 88,701,737</b>	<b>\$ (96,772,293)</b>	<b>\$ (8,065,624)</b>

See accompanying notes to financial statements.

**OpGen, Inc.**

**Statements of Cash Flows**

**Years Ended December 31,**

	2014	2013
<b>Cash flows from operating activities</b>		
Net loss	\$ (5,671,470)	\$ (10,134,821)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	573,918	661,807
Amortization of deferred financing costs	19,036	5,406
Non-cash interest expense	65,132	6,334
Bad debt expense	4,000	7,301
Recovery of bad debt	(8,400)	(49,050)
Loan forgiveness	—	(36,811)
Stock compensation expense	64,412	152,753
Inventory obsolescence expense	21,877	924,285
Change in fair value of derivative financial instruments	—	(134,560)
Other non-cash items	14,681	1,639
Changes in operating assets and liabilities:		
Accounts receivable	(257,686)	938,174
Inventory	(215,906)	(506,088)
All other assets	76,554	163,493
Accounts payable	198,177	271,460
Accrued compensation and other liabilities	(99,310)	(112,002)
Deferred revenue	(170,557)	352,858
<b>Net cash used in operating activities</b>	<b>(5,385,542)</b>	<b>(7,487,822)</b>
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(39,537)	(109,871)
<b>Net cash used in investing activities</b>	<b>(39,537)</b>	<b>(109,871)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of preferred stock, net of issuance costs	1,937,902	(2,670)
Proceeds from issuance of convertible notes, net of issuance costs	1,472,386	969,864
Proceeds from issuance of demand notes, net of issuance costs	1,488,229	1,030,000
Proceeds from exercise of stock options and warrants	8	1,217
Payments on debt	(5,000)	(75,000)
Payments on capital lease obligations	(105,881)	(43,087)
Deferred IPO issuance costs	(13,393)	—
<b>Net cash provided by financing activities</b>	<b>4,774,251</b>	<b>1,880,324</b>
Net decrease in cash and cash equivalents	(650,828)	(5,717,369)
Cash and cash equivalents at beginning of year	1,400,345	7,117,714
<b>Cash and cash equivalents at end of year</b>	<b>\$ 749,517</b>	<b>\$ 1,400,345</b>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid during the year for interest	\$ 32,296	\$ 26,088
<b>Supplemental disclosure of noncash investing and financing activities:</b>		
Acquisition of equipment purchased through capital leases	\$ —	\$ 312,105
Conversion of convertible notes to Series A Preferred Stock	\$ —	\$ 1,999,864
Deferred IPO issuance costs included in accounts payable and accrued compensation and other liabilities	\$ 282,648	\$ —

See accompanying notes to financial statements.

**Note 1—Organization**

OpGen, Inc. (OpGen or the Company) was incorporated in Delaware on January 22, 2001. OpGen is an early-stage company using rapid molecular testing and bioinformatics to assist healthcare providers 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 lead MDRO product is our Acuitas™ MDRO Gene Test, a CLIA lab-based test that provides a profile of MDRO resistant genes from patients screened for colonization or infection. In addition, the Company has more than ten years of experience mapping microbial and other genomes using its proprietary Whole Genome Mapping technology and providing related products and services to customers.

The Company's headquarters and principal operations are in Gaithersburg, Maryland. 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 need to raise additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop and commercialize its 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, and has negative operating cash flows and a deficit in stockholders' equity.

As more fully described in Notes 5 and 6, the Company raised the following from existing stockholders of the Company: (i) \$4.0 million in two Series A Preferred Stock offerings during the fourth quarter of 2013 and early 2014, (ii) \$1.5 million through the issuance of convertible notes in the third quarter of 2014, and (iii) \$1.5 million of secured 2014 demand notes in the fourth quarter of 2014. In the first quarter of 2015, the Company raised an additional \$0.3 million from a stockholder and officer through the issuance of a secured demand note which was paid in full in conjunction with participation in the \$1.5 million 2015 convertible notes offering. The Company raised \$1.2 million in the 2015 convertible notes offering from existing stockholders, which closed in February 2015, raised \$0.3 million of additional 2015 convertible notes to other investors with participation rights, and raised \$0.6 million through the issuance of secured demand notes on March 30, 2015 and April 24, 2015, and \$0.15 million through the issuance of an unsecured promissory note on April 24, 2015 (see Note 15). 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 the second quarter of 2015. 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.

#### **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 has certificates of deposit totaling \$57,459, which are required as collateral for a letter of credit benefiting the landlord for its facility lease and by a credit card processor. These certificates of deposits are reflected in other long-term assets on the accompanying balance sheets.

#### **Fair Value**

The Company's balance sheets include various financial instruments (primarily accounts receivable, accounts payable and accrued expenses and other current liabilities) that are carried at cost, which approximates fair value due to the short-term nature of the instruments. Notes payable are reflective of fair value based on market comparable instruments with similar terms.

For additional fair value disclosures, see Note 13.

#### **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 \$4,000 and \$7,301 as bad debt expense within other expense in 2014 and 2013, respectively, for accounts it considered uncollectible. The allowance for doubtful accounts was \$79,697 and \$88,097 as of December 31, 2014 and 2013, respectively. Approximately \$8,400 and \$49,050 was collected from an international distributor during 2014 and 2013, respectively, on the bad debt written off in 2012.

At December 31, 2014, the Company had accounts receivable from two customers which individually represent 79% and 15% of total accounts receivable. At December 31, 2013, the Company had accounts receivable from three customers which individually represent 24%, 20%, and 10% of total

**Note 3—Summary of Significant Accounting Policies (Continued)**

accounts receivable. For the year ended December 31, 2014 one individual customer represented 59% of revenues. For the year ended December 31, 2013 four individual customers represented 12%, 12%, 10% and 10% 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,	
	2014	2013
Raw materials and supplies	\$ 40,749	\$ 51,005
Work-in-process	135,625	63,917
Finished goods	193,368	60,791
Total inventories	<u>\$ 369,742</u>	<u>\$ 175,713</u>

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. Inventory reserve for obsolescence and expirations was \$867,816 and \$1,024,006 at December 31, 2014 and 2013, 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. As a result, there are no capitalized software costs at December 31, 2014 and 2013, 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 twelve months. The reserve is adjusted during the warranty period to reflect the remaining estimated costs under the warranty.

**Note 3—Summary of Significant Accounting Policies (Continued)**

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

	December 31,	
	2014	2013
Balance at beginning of year	\$ 6,500	\$ 19,750
Warranty expense	4,077	8,298
Cost of replacement parts and related delivery	(7,827)	(21,548)
Balance at end of year	<u>\$ 2,750</u>	<u>\$ 6,500</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 in 2013 upon the termination of the fully amortized license.

Total amortization expense was \$57,594 and \$108,452 for the years ended December 31, 2014 and 2013, respectively. Accumulated amortization was \$698,949 and \$641,335 at December 31, 2014 and 2013, respectively. All intangible assets were fully amortized at December 31, 2014.

**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 \$516,324 and \$553,355 for the years ended December 31, 2014 and 2013, respectively. Property and equipment consisted of the following at December 31, 2014 and 2013:

	December 31,	
	2014	2013
Laboratory equipment	\$ 2,304,615	\$ 2,265,717
Office furniture and equipment	691,032	792,129
Computers	1,169,910	1,167,144
Leasehold improvements	245,558	250,442
	<u>4,411,115</u>	<u>4,475,432</u>
Less accumulated depreciation	(3,823,159)	(3,396,009)
Property and equipment, net	<u>\$ 587,956</u>	<u>\$ 1,079,423</u>

In 2012, the Company began to provide Argus™ Whole Genome Mapping Systems under its Argus Reagent Rental Program to customers, in which the Company retains title without requiring customers to purchase the equipment or enter into an equipment lease or rental contract. The costs associated with these instruments are capitalized as fixed assets and charged to sales and marketing on a straight-line basis over the estimated useful life of the instrument, which is approximately four years.

### **Note 3—Summary of Significant Accounting Policies (Continued)**

During the years ended December 31, 2014 and 2013, these costs were approximately \$101,000 and \$81,000, respectively. The costs to maintain these systems are charged to operations as incurred. Proceeds from the sale of Reagent Rental Program Systems to customers are reported as Product sales and the remaining net book value of the system is charged to Cost of products sold.

#### **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 a 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, 2014 and 2013, the Company determined that there were no impaired long-lived assets.

#### **Deferred IPO Issuance Costs**

Deferred initial public offering ("IPO") costs, which primarily consist of legal and accounting fees related to the IPO, are capitalized. Deferred and other IPO costs will be offset against IPO proceeds upon the consummation of the IPO. In the event the offering is terminated, deferred IPO costs will be expensed.

#### **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 handling 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 revenue of \$22,924 and \$35,213 in 2014 and 2013, 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.

**Note 3—Summary of Significant Accounting Policies (Continued)**

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.

**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**

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

Tax benefits are initially recognized in the financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially, and subsequently, measured as the largest amount of tax benefit that is greater than 50% likely of being



### **Note 3—Summary of Significant Accounting Policies (Continued)**

realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts.

#### **Loss Per Share**

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

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

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The number of anti-dilutive shares, consisting of 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 6.0 million and 2.1 million for the years ended December 31, 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.

#### **Redeemable Convertible Preferred Stock**

The carrying value of the Company's current redeemable convertible preferred stock, which is referred to in these Notes as "Series A 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 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 (Note 6). Prior to the December 2013 recapitalization (see Note 5), the Company's preferred stock consisted of its Series A Convertible Preferred Stock ("Prior Series A Preferred Stock"), its Series A-1 Redeemable Preferred Stock ("Prior Series A-1 Preferred Stock"), its Series B Convertible Preferred Stock ("Prior Series B Preferred Stock"), and its Series C Convertible Preferred Stock ("Prior Series C Preferred Stock"). In these Notes, the Prior Series A Preferred Stock, the Prior Series B Preferred Stock and the Prior Series C Preferred Stock are collectively referred to as the "Prior Senior Preferred Stock" and the Prior Senior Preferred Stock with the Prior Series A-1 Preferred Stock are collectively referred to as the "Prior Preferred Stock." The Prior Preferred Stock were converted into common stock in the December 2013 recapitalization (Note 5).

#### **Share-Based Compensation**

Share-based payments are recognized at fair value. The fair value of share-based payments to employees and directors is estimated, on the date of grant, using the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option.

For all time-vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated

**Note 3—Summary of Significant Accounting Policies (Continued)**

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. 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 this peer group.

**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 actual terms of the options and adjust their estimate accordingly so that estimates will approximate actual behavior for similar options.

**Note 3—Summary of Significant Accounting Policies (Continued)**

**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 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. In 2014 the agreement was amended to limit the scope of work to the \$135,557 already incurred and to adjust payment terms, and as of December 31, 2014, \$80,000 was outstanding and is scheduled to be paid in 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 Prior 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 in 2013 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. Upon signing the amendment in December 2011, the Company agreed to issue the governmental entity warrants to purchase Prior Series C Preferred Stock upon the successful close of the Prior Series C Preferred Stock financing; on March 5, 2012, the Company issued a warrant to purchase 3,260,870 shares of Prior Series C Preferred Stock. 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 had a term of seven years. The Company valued the warrant at \$133,899, which was recorded as a liability and recognized charges to other expense of \$1,639 in 2013. The Prior 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 payments for meeting development milestones under the agreement. Since the milestones are substantive, the Company will recognize revenue in the periods in which the substantive milestones are achieved; the Company attained sixteen milestones during the 2014 and recognized \$2.3 million of revenue related to the milestones. In addition, the Company received an upfront payment of \$250,000, which will be recognized on a straight-line basis over the

**Note 3—Summary of Significant Accounting Policies (Continued)**

term of the technology development agreement. The Company recognized total revenue of \$2,411,120 and \$27,778 during 2014 and 2013, respectively, relating to this arrangement.

**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.

**Recent Accounting Pronouncements**

In July 2013, the Financial Accounting Standards Board ("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. 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 permitted.

### **Note 3—Summary of Significant Accounting Policies (Continued)**

We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

We have evaluated all other issued and unadopted Accounting Standards Updates and believe the adoption of these standards will not have a material impact on our results of operations, financial position, or cash flows.

### **Note 4—Restructuring Costs**

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, in 2013 the Company reduced its workforce by approximately 36%, or 16 employees, and incurred and paid \$329,649 of restructuring costs. There were no restructuring costs in 2014.

### **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 of convertible promissory notes (the "2013 convertible notes"), convertible into the Company's new Series A Redeemable Convertible Preferred Stock (the "Series A Preferred Stock") at \$1.00 per share of Series A Preferred Stock. On December 18, 2013, the Company issued \$1,999,864 in 2013 convertible notes in exchange for \$969,864 in cash and in exchange for bridge funding demand notes that had been issued in the fourth quarter of 2013. On December 30, 2013, the 2013 convertible notes were converted into 1,999,864 shares of Series A 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 2013 convertible notes (these actions are collectively referred to as the "December 2013 recapitalization"):

- A mandatory conversion of all outstanding shares of Prior 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 Prior 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 Prior 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 on the reverse stock split terms.

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 Prior Preferred Stock issuances, excluding anti-dilution rights, were convertible into

**Note 5—Recapitalization (Continued)**

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:

	<u>Shares</u>
Prior Series A Preferred Stock	25,205,800
Prior Series A Preferred Stock Anti-dilution rights	35,915,987
Prior Series B Preferred Stock	64,936,385
Prior Series B Preferred Stock Anti-dilution rights	26,036,056
Prior Series C Preferred Stock	126,802,946
Prior Series A-1 Preferred Stock	4,857,621
Common Stock	2,817,182
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.

	<u>Warrants Outstanding</u>
Prior Series A Preferred Stock Warrants	1,140,000
Prior Series A Preferred Stock Anti-dilution rights	1,624,306
Prior Series C Preferred Stock Warrants	3,260,870
Common Stock Warrants	23,254,778
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's current 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 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 Preferred Stock in December 2013 at \$1.00 per share in exchange for \$1,999,864 in 2013 convertible notes (see Note 5). In February 2014, the Company sold 1,405,096 shares of Series A Preferred Stock for gross proceeds of \$1,405,096. In April 2014, the Company sold an additional 594,904 shares of Series A Preferred Stock for gross proceeds of \$594,904. The Company incurred issuance costs of \$62,098 related to the 2014 Series A Preferred Stock sales. As of December 31, 2014, the Company had a total of 3,999,864 shares of Series A Preferred Stock outstanding, convertible into 3,999,864 shares of common stock.

**Note 6—Redeemable Convertible Preferred Stock (Continued)**

The following table presents the changes in the Series A Preferred Stock from the December 2013 recapitalization:

	<u>Shares</u>	<u>Amount</u>
December 30, 2013 Issuance	1,999,864	\$ 1,999,864
2013 Accretion	—	—
Balance at December 31, 2013	<u>1,999,864</u>	<u>1,999,864</u>
February 2014 Issuance, net of costs	1,405,096	1,361,469
April 2014 Issuance, net of costs	594,904	576,433
2014 Accretion	—	627,133
Balance at December 31, 2014	<u><u>3,999,864</u></u>	<u><u>\$ 4,564,899</u></u>

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 Stock holders 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. The \$627,133 of 2014 accretion in the table above consists of \$6,954 of accretion of issuance costs and \$620,179 to accrete the Series A Preferred Stock balance on a straight line basis to its redemption price of two times the original issue price on the redemption date.

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. Beginning in December 2019, 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 Series A 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.

**Prior Senior Preferred Stock**

Holders of the Prior Senior Preferred Stock 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 Prior Senior Preferred Stock holders would have received a greater amount upon the conversion of their shares to common. First, to the holders of Prior Series C Preferred Stock, an amount per share equal to two times the Prior Series C Preferred Stock original issue price; second, to the holders of Prior Series A Preferred Stock and Prior Series B Preferred Stock, *pari passu*, an amount per share equal to the Prior Series A Preferred Stock original issue price and the Prior Series B Preferred Stock original issue price (as applicable); third, to the holders of Prior Series C Preferred Stock an amount equal to all unpaid Prior Series C Preferred Stock dividends; fourth, to the holders of Prior Series A Preferred Stock and Prior Series B Preferred Stock, *pari passu*, an amount equal to all unpaid Prior Series A Preferred Stock and Prior Series B Preferred Stock dividends (as applicable); and the remainder to common stockholders. The Company accrued dividends of \$5,058,786 during 2013 (through the December 2013 recapitalization); all such dividends were eliminated in connection with the December 2013

**Note 6—Redeemable Convertible Preferred Stock (Continued)**

recapitalization (see note 5). All Prior Senior Preferred Stock was converted to common stock in connection with the December 2013 recapitalization.

The holders of the Prior 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 Prior Series A-1 Preferred Stock would have automatically converted into common stock at \$1.02 per share or, at the Company's option, could have been settled in cash for an amount not to exceed \$4,857,622. The Prior Series A-1 Preferred Stock was converted to common stock in connection with the December 2013 recapitalization.

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

<b>Prior Series A-1 Preferred Stock:</b>	
Ending balance, December 31, 2012	\$ 4,924,230
Accretion of issuance costs	<u>6,011</u>
Balance, December 17, 2013	4,930,241
Recapitalization	<u>(4,930,241)</u>
Ending balance, December 31, 2013	<u>\$ —</u>
<b>Prior Series A Preferred Stock:</b>	
Ending balance, December 31, 2012	\$ 33,987,502
Accrual related to cumulative dividends	1,939,120
Accretion of issuance costs	<u>209,512</u>
Balance, December 17, 2013	36,136,134
Recapitalization	<u>(36,136,134)</u>
Ending balance, December 31, 2013	<u>\$ —</u>
<b>Prior Series B Preferred Stock:</b>	
Ending balance, December 31, 2012	\$ 27,096,513
Accrual related to cumulative dividends	1,773,457
Accretion of issuance costs	<u>13,121</u>
Balance, December 17, 2013	28,883,091
Recapitalization	<u>(28,883,091)</u>
Ending balance, December 31, 2013	<u>\$ —</u>
<b>Prior Series C Preferred Stock:</b>	
Ending balance, December 31, 2012	\$ 17,736,824
Accrual related to cumulative dividends	1,346,209
Issuance of Prior Series C—additional costs	(2,670)
Accretion of issuance costs	<u>85,548</u>
Balance, December 17, 2013	19,165,911
Recapitalization	<u>(19,165,911)</u>
Ending balance, December 31, 2013	<u>\$ —</u>



**Note 7—Debt**

Debt consists of the following:

	December 31,	
	2014	2013
Note payable to Montgomery County	\$ 5,000	\$ 10,000
Convertible notes	1,500,000	—
Secured demand notes	1,500,000	—
	<u>\$ 3,005,000</u>	<u>\$ 10,000</u>

In July, August and September 2014, the Company raised \$1.5 million through the issuance of secured convertible debt (the "2014 convertible notes"). The Company granted a security interest to substantially all of its assets to the 2014 convertible note holders. 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 2014 convertible debt holders, into either (i) one share of Series A 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 the event of a Deemed Liquidation Event, as defined in the Company's Ninth Amended and Restated Certificate of Incorporation, as amended, the sum of two times the outstanding principal amount plus any accrued and unpaid interest would be paid to any holder of these 2014 convertible notes.

In October, November and December 2014, the Company raised an additional \$1.5 million through the issuance of 8% secured demand notes, due in February through April 2015 (the "2014 demand notes"). The Company granted a security interest to substantially all of its assets to the 2014 demand note holders, pari passu with the holders of the 2014 convertible notes.

The Company sold \$1,030,000 of demand notes as bridge funding in November 2013 (the "2013 demand notes"). The 2013 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 2013 demand note holders. On December 18, 2013, the Company sold \$1,999,864 of 2013 convertible notes in exchange for the 2013 demand notes and \$969,869 in cash (see note 6). The 2013 convertible notes were due on the earlier of December 18, 2014, an event of default, or a change in control as defined in the 2013 convertible notes. Interest accrued at 8% per annum and the 2013 convertible notes were convertible into one share of Series A Preferred Stock for each \$1.00 principal remaining on each 2013 convertible note. The 2013 convertible notes were unsecured. The 2013 convertible notes were converted into 1,999,864 shares of Series A Preferred Stock on December 30, 2013.

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.

**Note 7—Debt (Continued)**

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 paid \$5,000 of installment payments in 2014. The Company recorded the loan and interest forgiveness of \$36,811 as Other Income in 2013 for these two loans.

The weighted average interest rate in 2014 on the Company's debt instruments was approximately 8%. Total interest expense on all debt instruments was \$65,132 and \$15,887 in 2014 and 2013, respectively.

**Note 8—Shares and Share-Based Compensation**

In December 2013, in conjunction with the December recapitalization (see Note 5), the Company filed its Seventh Amended and Restated Certificate of Incorporation, and increased the number of authorized shares of common stock to 3.5 million and the number of authorized shares of preferred stock to 2.0 million. In February 2014, the Company filed its Eighth Amended and Restated Certificate of Incorporation, and increased the number of authorized shares of common stock to 7.0 million and the number of authorized preferred shares to 6.0 million. In July 2014, in advance of the issuance of notes convertible into additional shares of the Company's Series A Preferred Stock (the "2014 convertible notes"), the Company filed its Ninth Amended and Restated Certificate of Incorporation and increased the number of authorized shares of common stock to 7.5 million.

**Stock options**

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, shares of restricted stock, shares of unrestricted common stock, and other stock-based awards 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, determined at the date of the grant, which became exercisable for the first time during any calendar year, 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% stockholders. 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 adopted the 2008 Stock Option and Restricted Stock Plan (the 2008 plan), pursuant to which the Company's Board of Directors may grant either incentive or non-qualified stock options or shares of restricted stock to directors, key employees, consultants and advisors. Upon adoption, the 2008 plan authorized grants of options to purchase a total of 7,570 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 several times; on January 22, 2009 to 8,739 shares; on February 11, 2011, to 20,332 shares; on March 5, 2012, to 28,322 shares; on December 18, 2012, to 36,669 shares; 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; on April 24, 2014, in conjunction with the 2014 Series A Preferred Stock issuance the Company further increased the number of shares available under the 2008 plan to 505,282; and on October 23, 2014, the Company increased the number of shares of common stock available under the 2008 plan to 1,447,791 shares. At December 31, 2014, there were 1,043,519 shares available for grant under the 2008 plan.

**Note 8—Shares and Share-Based Compensation (Continued)**

For the years ended December 31, 2014 and 2013, the Company recorded \$64,412 and \$152,753, respectively, of stock compensation expense. There were no amounts capitalized for the years ended December 31, 2014 and 2013. The allocation of stock compensation expense by operating expenses category is as follows:

	Year Ended December 31,	
	2014	2013
Research and development	\$ 5,234	\$ 7,876
General and administrative	55,802	142,583
Sales and marketing	3,376	2,294
	<u>\$ 64,412</u>	<u>\$ 152,753</u>

During 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. At December 31, 2014, the Company had unrecognized expense related to its stock options of \$31,718 which will be recognized over a weighted-average period of 2.42 years.

A summary of the status of options granted under the plan is presented below as of and for the years ended December 31, 2014 and 2013:

	Number of Options	Weighted- Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2013	22,128	\$ 70.97	7.9	\$ —
Granted	7,064	\$ 7.91		
Forfeited	(8,190)	\$ 57.86		\$ —
Exercised	(46)	\$ 27.17		
Outstanding at December 31, 2013	20,956		8.1	\$ —
Granted	401,053	\$ 0.05		
Exercised	(1)	\$ 7.91		\$ —
Forfeited	(17,736)	\$ 40.34		
Outstanding at December 31, 2014	<u>404,272</u>	\$ 1.13	9.3	\$ —
Exercisable at December 31, 2014	<u>55,670</u>	\$ 1.47	9.0	\$ —
Vested and expected to vest	<u>371,349</u>	\$ 1.21	9.3	\$ —

The weighted-average grant-date fair value for the option awards granted during the years ended December 31, 2014 and 2013 was \$0.03 and \$3.56, respectively. The total fair value of options vested in the years ended December 31, 2014 and 2013, was \$47,331 and \$164,248, respectively. The fair value of

**Note 8—Shares and Share-Based Compensation (Continued)**

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,	
	2014	2013
Annual dividend	—	—
Expected life (in years)	6.25	6.25
Risk free interest rate	1.84 - 2.02%	.93 - 1.69%
Expected volatility	60%	60%

On October 23, 2014, the Company's Board of Directors approved grants of stock options to acquire 826,500 shares of common stock under the 2008 Plan, contingent upon obtaining and approving an independent valuation of the fair value of the Company's common stock. These options are not included in the above table and disclosures; stock-based compensation expense related to these stock options will begin to be recognized upon approval by the Board of Directors of the independent valuation which occurred in February 2015. Depending on the fair value of the Company's common stock as of the February 2015 grant date and the resultant fair value of the options, stock-based compensation expenses related to these awards, which will be recognized over the vesting period, may be significant.

**Restricted stock units**

In March 2014 the Company awarded 130,640 restricted stock units to acquire 130,640 shares of common stock to its Chief Executive Officer. The restricted stock units were compensation for his service as Chief Executive Officer from before the grant date through June 2014 and were subject to forfeiture if he did not continue to perform management services through October 24, 2014. The restricted stock units vested on October 24, 2014 and 130,640 shares of common stock were issued to the CEO. 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**

At December 31, 2014 and 2013, the following warrants to purchase shares of common stock were outstanding:

Issuance	Number	Exercise Price	Expiration	Outstanding at December 31,	
				2014	2013
August 2007	8,921	\$ 7.91	August 2017	8,921	8,921
September 2007	3,451	\$ 790.54	September 2014	—	3,451
March 2008	46	\$ 790.54	March 2018	46	46
April 2009	33	\$ 790.54	April 2014	—	33
November 2009	6,674	\$ 7.91	November 2019	6,674	6,674
January 2010	6,674	\$ 7.91	January 2020	6,674	6,674
March 2010	1,277	\$ 7.91	March 2020	1,277	1,277
November 2011	5,213	\$ 7.91	November 2021	5,213	5,213
December 2011	664	\$ 7.91	December 2021	664	664
March 2012	4,125	\$ 109.90	March 2019	4,125	4,125
				<u>33,594</u>	<u>37,078</u>

**Note 8—Shares and Share-Based Compensation (Continued)**

The warrants listed above were issued in connection with various debt, preferred stock or development contract agreements. Subsequent to the December 2013 recapitalization, all the above warrants are equity classified.

- The estimated fair value of 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, 2014 and 2013, the Company recognized \$0 and \$5,406, respectively, of amortization expense).
- 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. For the years ended December 31, 2014 and 2013, the Company recognized \$0 and \$314,192, respectively, of accretion related to the warrants.
- Prior to the December 2013 recapitalization, warrants exercisable into Prior Series A Preferred Stock and Prior 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 was redeemable for cash in certain circumstances outside of the Company's control. For the years ended December 31, 2014 and 2013, the Company recorded \$0 and \$134,560, respectively, as a change in the estimated fair value of the warrant liability.
- The estimated fair value of the warrants for Prior Senior Preferred Stock issued in connection with a 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, 2014 and 2013, the Company recorded \$0 and \$1,639, respectively, as other expense.

**Note 9—Income Taxes**

At December 31, 2014 and 2013, the Company has net deferred tax assets of \$31,505,287 and \$28,704,670, respectively, consisting of net operating loss (NOL) carry forwards, research and experimental (R&E) credits, and differences between depreciation and amortization recorded for financial statement and tax purposes. The Company's net deferred tax assets at December 31, 2014 and 2013 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 assets. The Company's deferred tax assets and liabilities as of December 31, 2014 and 2013 are as follows:

	<u>2014</u>	<u>2013</u>
<b>Deferred tax assets:</b>		
NOL carryforward	\$ 28,704,237	\$ 26,137,776
R&E credit carryforward	1,894,478	1,759,478
Share-based compensation	144,742	127,429
Inventory reserve	334,578	377,674
Other	431,935	306,900
Total deferred tax assets	<u>31,509,970</u>	<u>28,709,257</u>
Valuation allowance	(31,505,287)	(28,704,670)
<b>Deferred tax liabilities:</b>		
Fixed assets	(4,683)	(4,587)
<b>Net deferred tax assets</b>	<u>\$ —</u>	<u>\$ —</u>

**Note 9—Income Taxes (Continued)**

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:

	<u>2014</u>	<u>2013</u>
Federal income taxes (benefit) at statutory rates	34.0%	34.0%
State income taxes (benefit), net of Federal benefit	3.6%	2.9%
Change in valuation allowance	(51.1)%	(46.7)%
Change in state tax rates and other	13.5%	9.8%
	<u>0.0%</u>	<u>0.0%</u>

Additionally, despite the NOL carryforwards, the Company may have future tax liability due to alternative minimum tax or state tax requirements. The Company had federal NOL carryforwards of \$76,267,809 and \$70,903,156 at December 31, 2014 and 2013, respectively. The NOL carryforwards 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 utilized.

**Note 10—Lease Commitments****Operating leases**

During 2008, the Company relocated its headquarters to Gaithersburg, Maryland. The operating lease for that facility contained stated monthly rates with annual increases effective each anniversary date, and was scheduled to terminate in September 2012. In April 2011, this lease was modified and extended until September 2014; in March 2014, the Company extended the termination date to April 2015. Management is currently negotiating with the landlord to extend the lease further. The new extension contained similar terms and conditions, except that 50% of the monthly rental fee for October and November 2014 were abated. The Company is responsible for all utilities, repairs, insurance, and taxes under this operating lease. Rent expense under the Company's operating leases for the years ended December 31, 2014 and 2013, was \$883,155 and \$885,310, respectively.

**Capital leases**

The Company leases computer equipment, office furniture, and equipment under various capital leases. The leases expire at various dates through 2018. The leases require monthly principal and

**Note 10—Lease Commitments (Continued)**

interest payments. Following is a schedule by year of the estimated future minimum payments under all operating and capital leases as of December 31, 2014:

<u>Years ending December 31,</u>	<u>Capital Leases</u>	<u>Operating Leases</u>	<u>Total</u>
2015	\$ 117,591	\$ 181,062	\$ 298,653
2016	89,772	—	89,772
2017	29,622	—	29,622
2018	27,153	—	27,153
2019 and thereafter	—	—	—
Total	\$ 264,138	\$ 181,062	\$ 445,200
Less: amount representing interest	(29,490)		
Net present value of future minimum lease payments	\$ 234,648		
Current maturities	(100,499)		
Long-term maturities	\$ 134,149		

Amortization expense associated with equipment under capital leases for the years ended December 31, 2014 and 2013 was \$122,411 and \$52,599, 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>2014</u>	<u>2013</u>
Laboratory equipment	\$ 364,471	\$ 364,471
Computers	153,693	153,693
Less accumulated amortization	(245,030)	(122,619)
Capital lease assets, net	\$ 273,134	\$ 395,545

**Note 11—Employee Benefit Plan**

Substantially all full-time employees are eligible to participate in a retirement Savings Plan, the OpGen 401(k) Plan. The Company made discretionary matching contributions until April 2013 when they were suspended. For the years ended December 31, 2014 and 2013, the Company contributed \$0 and \$27,299, 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 \$97,134 and \$199,449 of total royalty expense for the years ended 2014 and 2013, respectively, which are classified as cost of sales in the accompanying statements of operations. In 2015, future minimum royalty fees are \$90,000 under these agreements.

**Note 13—Fair Value Measurements**

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.

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

Included in the financial statements are certain financial instruments carried at fair value on a recurring basis, including cash and cash equivalents. 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, 2014 and 2013:

<u>Description</u>	<u>Fair Value at December 31, 2014</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Cash and cash equivalents	\$ 749,517	\$ 748,048	\$ 1,469	\$ —

<u>Description</u>	<u>Fair Value at December 31, 2013</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Cash and cash equivalents	\$ 1,400,345	\$ 1,248,885	\$ 151,460	\$ —

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 Prior Series A Preferred Stock warrant derivative liability, which was measured at fair value on a recurring basis using significant unobservable



**Note 13—Fair Value Measurements (Continued)**

inputs (Level 3) prior to its conversion into a common stock warrant in connection with the 2013 recapitalization:

	December 31,	
	2014	2013
Balance beginning of year	\$ —	\$ (661)
Transfers to (from) Level 3	—	—
Total gains realized/unrealized included in earnings	—	661
Balance end of year	<u>\$ —</u>	<u>\$ —</u>

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

	December 31,	
	2014	2013
Balance beginning of year	\$ —	\$ (132,260)
Transfers to (from) Level 3	—	—
Total gains realized/unrealized included in earnings	—	(1,639)
Balance end of year	<u>\$ —</u>	<u>\$ 133,899</u>

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

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

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

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

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

The Company measures its long-lived assets, including property and equipment and intangible assets, at fair value on a non-recurring basis when they are deemed to be impaired. No such fair value impairment was recognized in the years ended December 31, 2014 and 2013.

**Note 14—Related Person Transactions**

In December 2013, the Company purchased a BioMark HD DNA detection system and related instruments from Fluidigm Corporation ("Fluidigm") for a purchase price of \$221,000. In March 2014, the Company entered into a supply agreement with Fluidigm under which Fluidigm supplies the Company with its microfluidic test platform for use in manufacturing our Acutas MDRO Gene Test. The supply agreement terminates in March 2015. Evan Jones, Chief Executive Officer and Chair of the Board of the Company, is a director of Fluidigm. The approximate dollar value of the amount involved

**Note 14—Related Person Transactions (Continued)**

in the transaction with Fluidigm under the supply agreement during 2014 was \$121,000, and the Company had an outstanding payable to Fluidigm of \$17,000 at December 31, 2014.

**Note 15—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 January 2015, the Company engaged an investment bank to pursue a potential public offering of the Company's common stock.

In January 2015, the Company raised \$0.3 million of capital through the issuance of a secured demand note, due in February 2015. This demand note was tendered to the Company in February 2015 as partial payment for a 2015 convertible note.

In February and March 2015, the Company issued to existing investors 8% secured convertible notes (the "2015 convertible notes"), in an aggregate principal amount of \$1.5 million. The 2015 convertible notes are pre-payable by the Company without penalty at any time following the three-month anniversary of an initial public offering; provided that before the six-month anniversary, the 2015 convertible notes can only be prepaid out of newly issued capital subsequent to the initial public offering, and are puttable by the holder to the Company in the event of a defined default. The 2015 convertible notes are each convertible, at the election of the holder, into shares of Series A Preferred Stock, at a conversion rate of 1.25 shares of Preferred Stock for each \$1.00 converted, if the conversion occurs prior to closing of an initial public offering, or into shares of common stock, at a conversion rate of one share of common stock for each \$1.00 converted, if the conversion occurs after the closing of an initial public offering. The 2015 convertible note holders also received detachable stock purchase warrants exercisable for 225,011 shares of common stock at 110% of the initial public offering price and exercisable only if the offering contemplated by the prospectus in which these Notes are included is consummated, and then exercisable beginning on the six month anniversary of the closing of the offering. In conjunction with the 2015 convertible notes offering, the Company amended its Ninth Amended and Restated Certificate of Incorporation to increase the number of authorized shares of its common stock to 10.0 million and its preferred stock to 7.5 million.

The Company has not yet determined the financial statement accounting treatment for the 2015 convertible notes and detachable stock purchase warrants. However, because a portion of the gross proceeds will be allocated to the 2015 convertible notes and a portion to the warrants, it is likely that the Company will recognize and allocate value to an initial beneficial conversion feature, calculated as the intrinsic value of the embedded conversion option as of the issuance dates. Additionally, value may have to be allocated to other embedded features, including the Company's prepayment right and the holders' default put right, among other features. As a result, the Company expects the effective interest rate to be recognized over the debt term to exceed the coupon rate of 8%, and some of the embedded features may qualify for derivative liability treatment requiring periodic mark-to-market calculations that impact net income (loss). Finally, the Company may also recognize contingent beneficial conversion feature in the period when the initial public offering is consummated, as a charge to earnings measured by the intrinsic value of the revised conversion option based on the terms of the financing.

On March 20, 2015, the Company executed the Fifth Amendment to Lease Agreement (the "Fifth Amendment") with respect to the lease of its existing corporate facility. The Fifth Amendment, which includes an initial rent abatement period and subsequent annual rate increases, extends the term of the

**Note 15—Subsequent Events (Continued)**

existing lease by 69 months effective May 1, 2015, with one additional five-year renewal at the Company's election; provided, that if the offering contemplated by the prospectus in which these Notes are included is not consummated with proceeds of at least \$25.9 million, the Company has the option to terminate the Fifth Amendment and extend the lease for up to one year.

On March 30, 2015, the Company raised \$0.5 million of capital through the issuance of a secured demand note bearing interest at 8% per annum, which can be called at any time after April 30, 2015.

The Company's 2015 Equity Incentive Plan (the "Plan") was adopted by the board of directors and approved by stockholders in April 2015. The Company expects that the 2015 Plan will become effective upon the execution and delivery of the underwriting agreement for this offering. Once the 2015 Plan is effective, no further grants will be made under the 2008 Plan. The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Internal Revenue Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for the grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants.

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 1,355,000 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited or terminated for any reason before being exercised or settled, plus the number of shares subject to vesting restrictions under the 2008 Plan on the 2015 Plan's effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by the board of directors. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled, or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited.

On April 24, 2015, the Company raised \$0.1 million of capital through the issuance of a secured demand note bearing interest at 8% per annum and callable at any time after May 31, 2015, and \$0.15 million through the issuance of an unsecured promissory note.

**Note 16—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

**Note 16—Pro Forma Net Loss Per Share Available to Common Stockholders (Unaudited) (Continued)**

as though the conversions had occurred as of the earlier of the specific issuance date or at the beginning of the period:

	<u>Year ended December 31, 2014</u>
Net loss available to common stockholders	\$ (6,298,603)
Interest on convertible notes, including deferred financing costs	63,852
Preferred stock dividends	627,113
Pro forma net loss available to common stockholders	<u>\$ (5,607,618)</u>
Weighted average common shares outstanding—basic and diluted	387,590
Pro forma adjustment to reflect assumed conversion of convertible notes	642,686
Pro forma adjustment to reflect assumed conversion of redeemable convertible preferred stock	3,657,437
Pro forma weighted average common shares outstanding—basic and diluted	<u>4,687,713</u>
Pro forma net loss per common share—basic and diluted	<u>\$ (1.20)</u>



**2,500,000 UNITS TO NEW AND EXISTING INVESTORS  
350,000 UNITS TO CERTAIN EXISTING INVESTORS**

*Sole Book-Running Manager*

**Maxim Group LLC**

*Co-Manager*

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