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

FORM 10-Q

(Mark one)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2015

or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 001-37367

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

Delaware	**06-1614015**
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
708 Quince Orchard Road, Suite 160, Gaithersburg, MD	**20878**
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: **(240) 813-1260**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes o No x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files) . Yes o No x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

10,718,347 shares of the Company's common stock, par value $0.01 per share, were outstanding as of June 10, 2015.

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q of OpGen, Inc. and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. In this Form 10-Q, we refer to OpGen, Inc. as the "Company," "we," "our" or "us." All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect" or the negative version of these words and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II Item 1A "Risk Factors." In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed included herein may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- *the commercialization of our current Acuitas® MDRO test products and completed development and commercialization of our Acuitas 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; and*
- *our expectations regarding future revenue and expenses.*

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statement made by us in this quarterly report on Form 10-Q 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 quarterly report on Form 10-Q to confirm these statements to actual results or revised expectations.

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to this quarterly report on Form 10-Q, including the factors described in "Item 1A. Risk Factors," as well as our prospectus filed with the SEC on May 5, 2015. Other risks may be described from time to time in our filings made under the securities laws. New risks emerge from time to time. It is not possible for our management to predict all risks. All forward-looking statements in this quarterly report on Form 10-Q speak only as of the date made and are based on our current beliefs and expectations. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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OpGen, Inc.
Condensed Balance Sheets

(unaudited)

	March 31, 2015	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	$ 631,695	$ 749,517
Accounts receivable, net	91,984	503,983
Inventory, net	320,807	369,742
Prepaid expenses and other current assets	210,057	90,233
Total current assets	**1,254,543**	**1,713,475**
Property and equipment, net	568,602	587,956
Deferred IPO issuance costs	767,412	296,041
Other noncurrent assets	57,460	57,459
Total assets	**$ 2,648,017**	**$ 2,654,931**
Liabilities, Preferred Stock and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 1,059,253	$ 1,160,081
Accrued compensation and benefits	430,972	423,099
Accrued liabilities	1,130,800	993,657
Deferred revenue	274,552	339,171
Derivative financial instruments	40,502	—
Short term notes payable	2,003,750	1,505,000
Current maturities of long-term capital lease obligation	122,027	100,499
Short-term convertible notes, net of discounts	1,500,006	1,500,000
Total current liabilities	**6,561,862**	**6,021,507**
Long-term capital lease obligation, less current maturities	163,726	134,149
Total liabilities	**6,725,588**	**6,155,656**
Commitments and contingencies (Note 10)		
Redeemable convertible preferred stock		
Series A redeemable convertible preferred stock, $.01 par value; 6,000,000 shares authorized; 3,999,864 shares issued and outstanding at March 31, 2015 and December 31, 2014, repsectively; aggregate liquidation preference of $7,999,728 at March 31, 2015 and December 31, 2014	4,736,640	4,564,899
Total redeemable convertible preferred stock	**4,736,640**	**4,564,899**
Stockholders' deficit		
Common stock, $.01 par value; 7,500,000 shares authorized; 493,483 and 493,178 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	4,936	4,932
Additional paid-in capital	90,548,318	88,701,737
Accumulated deficit	(99,367,465)	(96,772,293)
Total stockholders' deficit	**(8,814,211)**	**(8,065,624)**
Total liabilities, preferred stock and stockholders' deficit	**$ 2,648,017**	**$ 2,654,931**

See accompanying notes to unaudited condensed financial statements.

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OpGen, Inc.
Condensed Statements of Operations
Three Months Ended March 31,
(unaudited)

	2015	2014
Revenue		
Product sales	$ 184,179	$ 300,175
Laboratory services	35,241	169,250
Collaborations revenue	252,780	627,780
Total revenue	**472,200**	**1,097,205**
Operating expenses		
Cost of products sold	115,389	136,107
Cost of services	95,430	97,918
Research and development	1,108,602	952,791
General and administrative	659,392	554,954
Sales and marketing	1,024,029	547,471
Total operating expenses	**3,002,842**	**2,289,241**

Operating loss	**(2,530,642)**	**(1,192,036)**
Other income (expense)		
Interest income	35	37
Interest expense	(96,397)	(8,202)
Change in fair value of derivative financial instruments	31,831	—
Total other income (expense)	**(64,531)**	**(8,165)**
Net loss	**(2,595,173)**	**(1,200,201)**
Preferred stock dividends	(171,741)	(110,815)
Net loss available to common stockholders	**$ (2,766,914)**	**$ (1,311,016)**
Net loss per common share - basic and diluted	**$ (5.61)**	**$ (3.62)**
Weighted average shares outstanding - basic and diluted	493,463	362,537

See accompanying notes to unaudited condensed financial statements.

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OpGen, Inc.
Condensed Statements of Cash Flows
Three Months Ended March 31,
(unaudited)

	2015	2014
Cash flows from operating activities		
Net loss	$ (2,595,173)	$ (1,200,201)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	106,133	161,537
Noncash interest expense	17,123	—
Recovery of bad debt	—	(8,400)
Share-based compensation expense	590,603	28,927
Inventory obsolescence expense	3,604	80,842
Change in fair value of derivative financial instruments	(31,831)	—
Changes in operating assets and liabilities:		
Accounts receivable	411,999	(617,535)
Inventory	45,331	(155,759)
All other assets	(25,854)	69,092
Accounts payable	(319,483)	69,811
Accrued compensation and other liabilities	145,016	(193,343)
Deferred revenue	(64,619)	451,372
Net cash used in operating activities	**(1,717,151)**	**(1,313,657)**
Cash flows from investing activities		
Purchases of property and equipment	(10,034)	(25,926)
Net cash used in investing activities	**(10,034)**	**(25,926)**
Cash flows from financing activities		
Proceeds from issuance of preferred stock, net of issuance costs	—	1,420,543
Proceeds from issuance of convertible notes and warrants, net of issuance costs	1,388,913	—
Proceeds from issuance of short term notes	500,000	—
Proceeds from exercise of stock options and warrants	55	—
Deferred IPO costs	(252,715)	—
Payments on debt	(1,250)	(1,250)
Payments on capital lease obligations	(25,640)	(27,443)
Net cash provided by financing activities	**1,609,363**	**1,391,850**
Net (decrease) increase in cash and cash equivalents	(117,822)	52,267
Cash and cash equivalents at beginning of period	749,517	1,400,345
Cash and cash equivalents at end of period	**$ 631,695**	**$ 1,452,612**
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 6,865	$ 13,322
Supplemental disclosure of noncash investing and financing activities:		
Acquisition of equipment purchased through capital leases	$ 76,745	$ —
Exchange of demand note for convertible debt	$ 300,000	$ —
IPO costs deferred and unpaid	$ 218,656	$ —

See accompanying notes to unaudited condensed financial statements.

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Notes to Unaudited Condensed Financial Statements
March 31, 2015

Note 1 - Organization

OpGen, Inc., or the Company, was incorporated in Delaware in 2001. The Company's headquarters and principal operations are in Gaithersburg, Maryland. The Company operates in one business segment.

The Company is an early-stage company using rapid molecular testing and bioinformatics to assist healthcare providers to combat multi-drug resistant infections, or MDROs, 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 its 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 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 - Liquidity 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.

The Company has funded its operations primarily through external investor financing arrangements. The Company raised significant funds in 2013, 2014 and 2015, including:

- $4.0 million in two Series A Preferred Stock offerings during 2014 and 2013,
- $1.5 million through the issuance of convertible notes in 2014,
- $2.3 million in short-term demand notes in 2015 and 2014 (in the first quarter of 2015, $0.3 million of demand notes, held by an entity controlled by our chief executive officer, were settled as partial payment for a 2015 convertible note), and
- $1.5 million through the issuance of convertible notes in 2015.

Subsequent to the first quarter, in April 2015, the Company raised $0.1 million through the issuance of additional demand notes with terms similar to the 2014 demand notes (Note 6) and $0.2 million through the issuance of an unsecured promissory note. In May 2015, the Company completed its initial public offering, or IPO, pursuant to which the Company offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of $6.00 per unit (Note 11). Of the total gross proceeds of $17.1 million, approximately $2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds to the Company was $12.8 million. In connection with the IPO, all of the Company's outstanding Series A Preferred Stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,864 shares of common stock.

The principal purposes of the IPO were to obtain additional capital to support operations, establish a public market for the Company's common stock and to facilitate its future access to the public capital markets. The Company currently intends to use the net proceeds as follows:

- approximately $5.0 million for sales and marketing activities, including expansion of the Company's sales force to support the ongoing commercialization of the Acuitas MDRO gene test products and, when development is completed, the Acuitas 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 the completion of the development of the Acuitas Lighthouse MDRO Management System and future products in its pipeline; and
- the remainder for general and administrative expenses and for working capital and other general corporate purposes.

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The Company's current operating assumptions (following the IPO), which include management's best estimate of future revenue and operating expenses, indicate that current cash on hand will be sufficient to fund operations through at least the end of 2015. In the event the Company is unable to successfully raise additional capital in 2016, 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. The financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Note 3 - Summary of significant accounting policies

Basis of presentation

The accompanying interim condensed financial statements are unaudited. These unaudited condensed financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission, or SEC, for interim financial information. Accordingly, they do not include all the information and footnotes required by Generally Accepted Accounting Principles, or GAAP, for complete financial statements. These

unaudited interim condensed financial statements should be read in conjunction with the audited financial statements and accompanying notes for the year ended December 31, 2014. The unaudited interim condensed financial statements have been prepared on the same basis as the annual financial statements included in the Company's registration statement on Form S-1 and, in the opinion of management, reflect all the adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of March 31, 2015 and the results of operations and cash flows for the three months ended March 31, 2015 and 2014. The interim condensed results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2014 balance sheet included herein was derived from the audited financial statements, but may not include all disclosures including notes required by GAAP for complete financial statements.

Use of estimates

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

Fair value of financial instruments

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

Cash and cash equivalents

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

Accounts receivable

The Company's accounts receivable result from revenues earned but not collected from customers. Credit is extended based on an evaluation of a customer's financial condition and, generally, collateral is not required. Accounts receivable are due within 30 to 45 days and are stated at amounts due from customers. The Company evaluates if an allowance is necessary by considering a number of factors, including the length of time accounts receivable are past due, the Company's previous loss history and the customer's current ability to pay its obligation. If amounts become uncollectible, they are charged to operations when that determination is made. The allowance for doubtful accounts was $79,697 as of March 31, 2015 and December 31, 2014.

At March 31, 2015, the Company had accounts receivable from three customers which individually represent 43%, 14% and 13% of total accounts receivable.

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:

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	March 31, 2015	December 31, 2014
Raw materials and supplies	$ 123,569	$ 40,749
Work-in process	113,540	135,625
Finished goods	83,698	193,368
Total	$ 320,807	$ 369,742

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 $871,420 and $867,816 at March 31, 2015 and December 31, 2014, respectively.

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. There are no capitalized software costs at March 31, 2015 and December 31, 2014.

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

	March 31, 2015	December 31, 2014
Balance at beginning of period and year	$ 2,750	$ 6,500
Warranty expense	750	4,077

Cost of replacement parts and related delivery	(1,500)	(7,827)
Balance at end of period and year	$ 2,000	$ 2,750

Impairment of long-lived assets

The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. An impairment loss would be measured as the amount by which the carrying value of the asset exceeds the estimated fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less costs to sell. During the three months ended March 31, 2015 and 2014, the Company determined that there were no impaired long-lived assets.

Deferred IPO issuance costs

As of March 31, 2015 and December 31, 2014, the Company had deferred approximately $767,412 and $296,041 of legal and accounting fees related to its anticipated IPO. The IPO was completed in the second quarter of 2015 and, as such, deferred and other IPO costs will be offset against IPO proceeds upon the consummation of the IPO. See Note 11.

Redeemable convertible preferred stock

The carrying value of the Company's redeemable convertible preferred stock is increased by the accretion of related discounts, issuance costs and accrued but unpaid dividends so that the carrying amount will equal the redemption amount at the dates the stock becomes redeemable. As of March 31, 2015 and December 31, 2014, the Company has 3,999,864 of Series A redeemable convertible preferred stock, or Series A Preferred Stock, outstanding. The Series A Preferred Stock is redeemable at the option of the holders of 70% of the outstanding shares of preferred stock, subject to certain additional requirements. The Company's redeemable convertible preferred stock is classified as temporary equity due to redemptions provisions outside of the Company's control. The redeemable convertible preferred stock was converted into shares of common stock in connection with the Company's IPO in the second quarter of 2015. See Note 11.

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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 $4,048 and $7,094 in the quarters ended March 31, 2015 and 2014, respectively, for shipping and handling.

Revenue from sales of the Argus System

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

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

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

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

Revenue from extended warranty service contracts

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

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.

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 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.

Option valuation models, including the Black-Scholes model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the expected future tax consequences attributable to temporary differences between financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax

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assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred income tax assets to the amount expected to be realized.

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

The Company has federal net operating loss, or NOL, carryforwards of $76,267,809 at December 31, 2014. Despite the NOL carryforwards, which begin to expire in 2022, the Company may have future tax liability due to alternative minimum tax or state tax requirements. Also, use of the NOL carryforwards may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. There can be no assurance that the NOL carryforwards will ever be fully utilized.

Loss per share

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

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

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The number of anti-dilutive shares, consisting of common stock options, restricted stock units (in 2014), stock purchase warrants, convertible preferred stock and convertible debt (in 2015) exercisable or exchangeable into common stock which have been excluded from the computation of diluted loss per share, was 8.9 million and 3.6 million for the three months ended March 31, 2015 and 2014, respectively. The Company’s convertible preferred stock contains 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.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. The standard is effective for the Company’s reporting year beginning January 1, 2017 and early adoption is not permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In August 2014, the FASB issued guidance requiring management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity’s ability to continue as a going concern. The guidance 1) provides a definition for the term ‘‘substantial doubt,’’ 2) requires an evaluation every reporting period, interim periods included, 3) provides principles for considering the mitigating effect of management’s plans to alleviate the substantial doubt, 4) requires certain disclosures if the substantial doubt is alleviated as a result of management’s plans, 5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and 6) requires an assessment period of one year from the date the financial statements are issued. The standard is effective for the Company’s reporting year beginning January 1, 2017 and early adoption is permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In April 2015, the FASB issued accounting guidance requiring that debt issuance costs related to a recognized liability be presented on the balance sheet as a direct reduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected. The standard is effective for reporting periods beginning after December 15, 2015. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

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

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Note 4 - Fair value measurements

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

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

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

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the hierarchy. 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 March 31, 2015 and December 31, 2014:

	Fair value at March 31, 2015	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 631,695	$ 631,695	$ —	$ —
Derivative warrant liability	$ 40,502	$ —	$ —	$ 40,502

	Fair value at December 31, 2014	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 749,517	$ 748,048	$ 1,469	$ —

The Company's Level 1 securities primarily consist of cash and cash equivalents, including money market funds and U.S Treasury Notes; 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 accounts for its derivative financial instruments, consisting solely of certain stock purchase warrants that contain non-standard anti-dilution provisions and/or cash settlement features, at fair value using level 3 inputs. We determine the fair value of these derivative liabilities using a hybrid valuation method that consists of a probability weighted expected return method that values the Company's equity securities assuming various possible future economic outcomes while using an option pricing method (that treats all equity linked instruments as call options on the Company's equity value with exercise prices based on the liquidation preference of the Series A Preferred Stock) to estimate the allocation of value within one or more of the scenarios. Using this hybrid method, unobservable inputs included the Company's equity value, the exercise price for each option value, expected timing of possible economic outcomes such as initial public offering, risk free interest rates and stock price volatility. The following tables set forth a summary of changes in the fair value of Level 3 liabilities measured at fair value on a recurring basis for the quarter ended March 31, 2015:

Description	Balance at December 31, 2014	Established in 2015	Change in Fair Value	Balance at March 31, 2015
Derivative warrant liability	$ —	$ 72,333	$ (31,831)	$ 40,502

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.

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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 periods ended March 31, 2015 and 2014.

Note 5 - Series A redeemable convertible preferred stock

The Company's Series A Preferred Stock is classified as temporary equity due to redemption provisions outside of the Company's control.

The Company issued 1,999,864 shares of Series A Preferred Stock in December 2013 at $1.00 per share in exchange for $1,999,864 in Convertible Promissory Notes. In February 2014, the Company sold 1,405,096 shares of Series A 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. As of March 31, 2015 and 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.

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

The Series A Preferred Stock was converted into shares of common stock in connection with the Company's IPO in the second quarter of 2015. See Note 11.

Note 6 - Debt

Demand notes

In the fourth quarter of 2014 and first quarter of 2015, the Company raised $2.3 million through the issuance of short-term demand notes. In the first quarter of 2015, $0.3 million of demand notes, held by an entity controlled by our chief executive officer, were settled as partial payment for a 2015 convertible note. The demand notes bear interest at 8% per annum, have a first priority security interest in the assets of the Company, and a term of approximately 4 months before the holder can demand payment. The demand notes were tendered as payment for units in the Company's IPO. See Note 11.

2014 convertible debt

In July, August and September 2014, the Company raised $1.5 million through the issuance of convertible debt. The debt is convertible, at the option of the holders or in certain cases at the Company's option, into shares of Series A Preferred Stock or other potential equity securities. The debt bears interest at 8% and is due in full on July 11, 2015. The 2014 convertible debt was converted in connection with the Company's IPO in the second quarter of 2015. See Note 11.

2015 convertible debt

In February and March 2015, the Company raised $1.5 million in capital through the issuance of 8% secured convertible notes with detachable stock purchase warrants. The 2015 convertible notes were pre-payable by the Company without penalty at any time following the three month anniversary of the closing of an IPO; provided that before the six-month anniversary of the closing of an IPO, the 2015 convertible notes could only be prepaid out of newly issued capital subsequent to the IPO, and 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 IPO, 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 IPO. The 2015 convertible note holders also received detachable stock purchase warrants exercisable for 225,011 shares of common stock at 110% of the IPO price and exercisable only if the IPO occurred, and then exercisable beginning on the six month anniversary of the closing of the IPO.

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As a result of net settlement features, the stock purchase warrants are considered derivative liabilities, were initially recorded at fair value (resulting in a debt discount) and are marked-to-market at each balance sheet date through earnings. Additionally, the conversion option embedded in the convertible notes was determined to contain beneficial conversion features, resulting in the bifurcation of those features as an equity instrument (resulting in an additional debt discount). After allocation of the gross proceeds to the detachable stock purchase warrants and beneficial conversion feature, the total debt discount recognized was equal to the face value of the 2015 convertible notes. During the first quarter of 2015, the Company recognized a gain on the change in fair value of the derivative warrant liability of $31,831.

The 2015 convertible debt was converted in connection with the Company's IPO in the second quarter of 2015. See Note 11.

Note 7 - Stockholders' equity (deficit)

Stock options

In 2002, the Company adopted the 2002 Stock Option and Restricted Stock Plan, or the 2002 plan, pursuant to which the Company's Board of Directors could grant either incentive stock options or non-qualified stock options, shares of restricted stock, shares of unrestricted common stock, and other share-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, or 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. The Company increased the number of shares of common stock available under the 2008 plan several times and as of March 31, 2015 there were 217,992 shares available for grant under the 2008 plan. 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.

For the three months ended March 31, 2015 and 2014, the Company recorded $590,603 and $28,927, respectively, of stock compensation expense. The allocation of share-based compensation expense by operating expenses is as follows:

	Three months ended March 31,	
	2015	2014
Research and development	$ 36,456	$ 6,094
General and administrative	83,299	22,060
Sales and marketing	470,848	773
	$ 590,603	$ 28,927

During the three months ended March 31, 2015, the Company granted stock options to acquire 826,500 shares of common stock at an exercise price of $0.61 per share. The 2015 awards had a weighted average grant date fair value per share of $4.21. The Company made no grants in the first quarter of 2014. The Company has total stock options to acquire 1,229,494 shares of common stock outstanding at March 31, 2015.

Restricted stock units

In March 2014, the Company awarded 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, or CEO, from October 2013 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.

Stock purchase warrants

The Company has total stock purchase warrants to acquire 258,605 and 33,594 shares of common stock outstanding at March 31, 2015 and December 31, 2014, respectively. In the second quarter of 2015 in connection with the Company’s IPO, the Company issued additional stock purchase warrants to investors and to its investment bankers. See Note 11.

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Note 8 - Commitments and contingencies

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. On March 20, 2015, the Company executed the Fifth Amendment to Lease Agreement, or 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 existing lease by 69 months effective May 1, 2015, with one additional five-year renewal at the Company’s election; the Company has the option to terminate the Fifth Amendment and extend the lease for up to one year. The new extension contained similar terms and conditions, except that 50% of the monthly rental fee for October and November 2014 was 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 three months ended March 31, 2015 and 2014 was $183,154 and $221,856, 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 interest payments.

Note 9 - License agreements, research collaborations and development agreements

The Company is a party to two license agreements to acquire certain patent rights and technologies. Royalties are incurred upon the sale of a product or service which utilizes the licensed technology. Certain of the agreements require the Company to pay minimum royalties or license maintenance fees. The accompanying financial statements reflect $23,028 and $25,034 of total royalty expense for the three months ended March 31, 2015 and 2014, respectively. In 2015, future minimum royalty fees are $20,000 under these agreements.

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 recognizes revenue in the periods in which the substantive milestones are achieved; the Company attained sixteen milestones during 2014. In addition, the Company received an upfront payment of $250,000, which is recognized on a straight-line basis over the term of the technology development agreement. The Company recognized total revenue of $252,780 and $627,780 during the three months ended March 31, 2015 and 2014, respectively, relating to this arrangement.

Note 10 - Related person transactions

In December 2013, the Company purchased a BioMark HD DNA detection system and related instruments from Fluidigm Corporation, or 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 the Acuitas MDRO Gene Test. The Company’s Chief Executive Officer and Chair of the Board of the Company, is a director of Fluidigm.

Note 11 - Subsequent events

Equity plan

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

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 1,355,000 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan 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

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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.

Initial public offering

On May 8, 2015, the Company completed its IPO pursuant to which the Company offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of $6.00 per unit. Of the total gross proceeds of $17.1 million, approximately $2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds to the Company was $12.8 million. On the IPO closing date, the underwriters exercised their over-allotment option to acquire an additional 422,500 stock purchase warrants. In connection with the IPO, all of the Company's outstanding Series A Preferred Stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,864 shares of common stock.

The principal purposes of the IPO were to obtain additional capital to support the Company's operations, establish a public market for its common stock and to facilitate its future access to the public capital markets. The Company currently intends to use the net proceeds from this offering as follows:

- approximately $5.0 million for sales and marketing activities, including expansion of the Company's sales force to support the ongoing commercialization of the Acuitas MDRO gene test products and, when development is completed, the Acuitas 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 the Company's completion of the development of the Acuitas Lighthouse MDRO Management System and future products in its pipeline; and
- the remainder for general and administrative expenses and for working capital and other general corporate purposes.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited condensed financial statements and the accompanying notes thereto included in Part I, Item 1 of this quarterly report on Form 10-Q. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under Item 1A "Risk Factors" as well as our prospectus filed with the SEC on May 5, 2015.

Overview

The Company is an early-stage company using rapid molecular testing and bioinformatics to combat multi-drug resistant infections. The Company's products and services enable healthcare providers to rapidly identify hospital patients who are colonized with multi-drug resistant organisms, or MDROs, and other potentially life threatening microbes. Its products are enabled by our Acuitas Lighthouse™ bioinformatics platform which provides detailed MDRO molecular information about an individual patient's resistance profile and integrates this information with data from other patients and hospital wide aggregate results to help improve overall patient outcomes and to reduce hospital costs. The Company's lead product is the Acuitas® MDRO Gene Test, a lab based test performed in the Company's clinical laboratory certified under the Commercial Laboratory Improvements Act, or CLIA, to provide a comprehensive profile of MDRO resistance genes from acute care patients screened for colonization or infection. The Company's headquarters and principal operations are in Gaithersburg, Maryland. The Company had an additional facility in Madison, Wisconsin, which was closed in April 2013. The Company operates in one business segment.

Recent Developments

Since inception, the Company has incurred, and continues to incur, significant losses from operations. The Company has funded its operations primarily through external investor financing arrangements and raised significant funds in 2013, 2014 and in the first quarter of 2015, including:

- $4.0 million in two Series A Preferred Stock offerings during 2014 and 2013,
- $1.5 million through the issuance of convertible notes in 2014,
- $2.3 million in short-term demand notes in 2015 and 2014 (in the first quarter of 2015, $0.3 million of demand notes, held by an entity controlled by our chief executive officer, were settled as partial payment for a 2015 convertible note), and
- $1.5 million through the issuance of convertible notes in 2015.

Subsequent to the first quarter, in April 2015, the Company raised $0.1 million through the issuance of additional demand notes with terms similar to the 2014 demand notes and $0.2 million through the issuance of an unsecured promissory note. In May 2015, the Company completed its IPO pursuant to which the Company offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of $6.00 per unit. Of the total gross proceeds of $17.1 million, approximately $2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds to the Company was $12.8 million. In connection with the IPO, all of the Company's outstanding Series A Preferred Stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,864 shares of common stock.

The Company's current operating assumptions (following the IPO), which include management's best estimate of future revenue and operating expenses, indicate that current cash on hand will be sufficient to fund operations through at least the end of 2015. In the event the Company is unable to successfully raise additional capital in 2016, 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.

Results of operations for the three months ended March 31, 2015 and 2014

Revenues

	Three months ended March 31,	
	2015	2014
Product sales	$ 184,179	$ 300,175
Laboratory services	35,241	169,250
Collaboration revenue	252,780	627,780
Total revenue	$ 472,200	$ 1,097,205

Our total revenue for the three months ended March 31, 2015 decreased 57%, from $1.1 million to $0.5 million, when compared to the same period in 2014. This decrease is primarily attributable to:

- A decrease of 39% in products sales. The decrease in product sales in 2015 as compared to 2014 is attributable to a reduction in the sale of our Argus products;
- A decrease of 79% in laboratory services revenue. Laboratory services decreased in 2015 as compared to 2014 as a result of a reduction in sales of mapping products; and
- A decrease of 60% in revenue generated under collaborative arrangements. Revenue generated under collaborative arrangements decreased in 2015 as compared to 2014 as a result of nearing completion of a technology development agreement.

The Company expects revenues for the year ending December 31, 2015 to remain below 2014 levels as a result of a strategic shift from Argus and Whole Genome Mapping product sales and collaborations to a focus on Acuitas MDRO test products and Acuitas Lighthouse Management System products and services.

Operating expenses

	Three months ended March 31,	
	2015	2014
Cost of product sales	$ 115,389	$ 136,107
Cost of services	95,430	97,918
Research and development	1,108,602	952,791
General and administrative	659,392	554,954
Sales and marketing	1,024,029	547,471
Total operating expenses	$ 3,002,842	$ 2,289,241

The Company's total operating expenses for the three months ended March 31, 2015 increased 31%, from $2.3 million to $3.0 million, when compared to the same period in 2014. This increase is primarily attributable to:

- an increase in share-based compensation, from $28,927 in 2014 to $590,603 in 2015. The increase of $561,676 is attributable solely to share-based compensation expense recognized in the first quarter of 2015 related to stock options granted by the Board of Directors in October 2014 contingent upon obtaining and approving an independent valuation of the fair value of the Company's common stock, which valuation was subsequently received and approved in February 2015. Share-based compensation expense is recognized in operating expenses as follows:

	Three months ended March 31,	
	2015	2014
Research and development	$ 36,456	$ 6,094
General and administrative	83,299	22,060
Sales and marketing	470,848	773
	$ 590,603	$ 28,927

- an increase in research and development expenses (not including stock-based compensation expense) of $125,449 (or 13%) from 2014 to 2015, relating primarily to set up and establishment of our CLIA laboratory.

The Company expects that operating expenses will remain level for the remainder of 2015 as compared to the first quarter of 2015.

Other income (expense)

	Three months ended March 31,	
	2015	2014
Interest income	$ 35	$ 37
Interest expense	(96,397)	(8,202)
Change in fair value of derivative financial instruments	31,831	—
Total other income (expense)	$ (64,531)	$ (8,165)

Other income (expense) for the three months ended March 31, 2015 increased from a net expense of ($8,165) in 2014 to a net expense of ($64,531), and was primarily the result of interest expense recognized on the convertible debt and demand notes issued in late 2014 and in 2015, reduced in part by a gain related to the change in the fair value of our liability classified stock purchase warrants issued in 2015.

Liquidity and capital resources

At March 31, 2015, the Company had cash and cash equivalents of $631,695, compared to $749,517 at December 31, 2014.

During the first quarter 2015, the Company raised $0.5 million in short-term demand notes, and $1.5 million through the issuance of convertible notes. Subsequent to the first quarter, in April 2015, the Company raised $0.1 million through the issuance of an additional demand note with terms similar to the 2014 demand notes and $0.2 million through the issuance of an unsecured promissory note. In May 2015, the Company completed its IPO pursuant to which the Company offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of $6.00 per unit. Of the total gross proceeds of $17.1 million, approximately $2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds to the Company was $12.8 million. In connection with the IPO, all of the Company's outstanding Series A Preferred Stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,864 shares of common stock.

The principal purposes of the IPO were to obtain additional capital to support operations, establish a public market for the Company's common stock and to facilitate its future access to the public capital markets. The Company currently intends to use the net proceeds as follows:

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- approximately $5.0 million for sales and marketing activities, including expansion of the Company's sales force to support the ongoing commercialization of the Acuitas MDRO gene test products and, when development is completed, the Acuitas 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 the completion of the development of the Acuitas Lighthouse MDRO Management System and future products in our pipeline; and
- the remainder for general and administrative expenses and for working capital and other general corporate purposes.

The Company does not currently have any bank credit lines. In the future, if the Company does not turn profitable or generate cash from operations as anticipated and additional capital is needed to support operations, management may be unable to obtain such financing, or obtain it on favorable terms. In the event the Company is unable to successfully raise additional capital, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing.

The Company's primary cash requirements are to fund operations as well as research and development programs and collaborations, and to support general and administrative activities, and to fund acquisitions of products or businesses. The Company's current operating assumptions (following the IPO), which include management's best estimate of future revenue and operating expenses, indicate that current cash on hand will be sufficient to fund operations through at least the end of 2015. In the event the Company is unable to successfully raise additional capital in 2016, 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.

Sources and uses of cash

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

	Three months ended March 31,	
	2015	2014
Net cash used in operating activities	$ (1,717,151)	$ (1,313,657)
Net cash used in investing activities	(10,034)	(25,926)
Net cash provided by financing activities	1,609,363	1,391,850

Net cash used in operating activities

Net cash used in operating activities for the three months ended March 31, 2015 consists primarily of our net loss of ($2.6) million, reduced by certain non-cash items, including depreciation and amortization expense of $0.1 million, share-based compensation expense of $0.6 million, and the net change in operating assets and liabilities of $0.2 million. Net cash used in operating activities for the three months ended March 31, 2014 consists primarily of our net

loss of ($1.2) million, reduced by certain non-cash items, including depreciation and amortization expense of $0.2 million, and increased by certain other non-cash items including the net change in operating assets and liabilities of $(0.4) million and change in inventory valuation allowance of ($0.1) million.

Net cash used in investing activities

Net cash used in investing activities in 2015 and 2014 included solely cash paid for the purchase or property and equipment.

Net cash provided by financing activities

Net cash provided by financing activities for the three months ended March 31, 2015 of $1.6 million consisted primarily of net proceeds from the issuance of debt instruments of $1.9 million, offset in part by costs incurred and paid related to our May 2015 IPO of $0.3 million. Net cash provided by financing activities for the three months ended March 31, 2014 of $1.4 million consisted primarily of net proceeds from the issuance of preferred stock.

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Critical accounting policies and use of estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited condensed financial statements, which have been prepared in accordance with GAAP. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our unaudited condensed financial statements, estimates are used for, but not limited to, share-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.

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

Revenue Recognition

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.

Derivative Financial Instruments

The Company accounts for its derivative financial instruments, consisting solely of certain stock purchase warrants that contain non-standard anti-dilutions provisions and/or cash settlement features, at fair value using level 3 inputs. Fair value of these derivative liabilities is determined using a hybrid valuation method that consists of a probability weighted expected return method that values the Company's equity securities assuming various possible future economic outcomes while using an option pricing method (that treats all equity linked instruments as call options on the Company's equity value with exercise prices based on the liquidation preference of the Series A preferred stock) to estimate the allocation of value within one or more of the scenarios. Using this hybrid method,

unobservable inputs included the Company's equity value, the exercise price for each option value, expected timing of possible economic outcomes such as initial public offering, risk free interest rates and stock price volatility.

Share-Based Compensation

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

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

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

Recently issued accounting pronouncements

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

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

Contractual obligations and off-balance sheet arrangements

As of March 31, 2015 and December 31, 2014, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption

of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more;

(ii) December 31, 2019; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of March 31, 2015. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting during the last quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

We are an early commercial stage company and our Acuitas MDRO test products and Acuitas 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 Acuitas 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

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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 Acuitas 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 Acuitas 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 three month periods ended March 31, 2015 and 2014 we had a net loss of $2.6 million and $1.2 million, respectively, and 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 March 31, 2015, we had an accumulated deficit of $99.4 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. During the first quarter 2015, the Company raised $0.5 million in short-term demand notes, and $1.5 million through the issuance of our 2015 convertible notes. Subsequent to the first quarter, in April 2015, the Company raised $0.1 million through the issuance of an additional demand note with terms similar to the 2014 demand notes and $0.2 million through the issuance of an unsecured promissory note. In May 2015, the Company completed its IPO pursuant to which the Company offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of $6.00 per unit. Of the total gross proceeds of $17.1 million, approximately $2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds to the Company was $12.8 million. In connection with the IPO, all of the Company's outstanding Series A preferred stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,864 shares of common stock.

The principal purposes of the IPO were to obtain additional capital to support operations, establish a public market for the Company's common stock and to facilitate its future access to the public capital markets. The Company currently intends to use the net proceeds as follows:

- approximately $5.0 million for sales and marketing activities, including expansion of the Company's sales force to support the ongoing commercialization of the Acuitas MDRO gene test products and, when development is completed, the Acuitas 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 the completion of the development of the Acuitas Lighthouse MDRO Management System and future products in our pipeline; and
- the remainder for general and administrative expenses and for working capital and other general corporate purposes.

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 Acuitas Lighthouse MDRO Management System and potential future diagnostic and screening products and services;

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- 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.

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 Acuitas 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 Acuitas 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 Acuitas 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

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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 have procured key man insurance for Evan Jones, our CEO.

Our Chief Financial Officer, Eric Winzer, submitted his resignation effective May 1, 2015. His decision to resign as our Chief Financial Officer was made for personal reasons unrelated to the Company. On April 17, 2015, we entered into a letter agreement with Timothy Dec, to serve as our interim Chief Financial Officer. Mr. Dec became our CFO in early June 2015. In addition, Kevin Krenitsky became our President on June 1, 2015. We cannot assure you that the transition of senior leadership will not cause 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 Acuitas 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.

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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 Acuitas 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 profitability and improve clinical outcomes, 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 an unfavorable 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

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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.

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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 Acuitas Lighthouse MDRO Management System products and services, and develop future Acuitas and Acuitas 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:

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- 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 Acuitas 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,

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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

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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.

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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 constitute promotion of a use for which premarket clearance or approval is required, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions, including 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

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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

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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.

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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

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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

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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 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 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

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that we have experienced an ownership change, or that we will experience an ownership change in the future. 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.

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We may generate a portion of our future revenue internationally 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, or FCPA, and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- foreign exchange controls;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties protecting or procuring intellectual property rights.

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

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

We face the risk of potential liability under the 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 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.

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

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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 of 2002. 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. 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.

Item 2. Unregistered Sales of Equity and Use of Proceeds

Unregistered Stales of Equity Securities

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, held by an entity controlled by our chief executive officer). 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 IPO, 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 IPO, 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

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outstanding holders. 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 IPO price, exercisable only if the IPO occurs, and then exercisable beginning on the six month anniversary of the closing of the IPO, and not automatically exercised in any situation. In May 2015, all of the holders of the 2015 convertible notes converted such notes into shares of our Series A Preferred Stock, which shares then converted into our common stock in the IPO. The offers, sales and issuances of the 2015 convertible notes were deemed to be exempt from registration under the Securities Act, in reliance on Section 4(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, regarding transactions by an issuer not involving a public offering. All purchasers of securities in transactions exempt from registration pursuant to Regulation D represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

2015 Demand Notes

Because we were in need of additional bridge funding to support our operations until the closing of our IPO, on March 26, 2015, the Board approved additional funding, up to $2.0 million principal amount, of secured demand notes. $600,000 aggregate principal amount of 2015 demand notes were subscribed for by existing investors in March 2015 and April 2015. The offer and issuances of the 2015 demand notes were deemed to be exempt from registration under the Securities Act, in reliance on Section 4(2) of the Securities Act regarding transactions by an issuer with a limited number of its existing investors not involving a public offering. All purchasers of securities represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

Use of Proceeds

On May 4, 2015 our registration statement on Form S-1 (File No. 333-202478) was declared effective by the SEC for our IPO. Maxim Group LLC acted as the sole book-running manager and National Securities Corporation acted as co-manager for the offering. On May 8, 2015, we completed our IPO pursuant to which we offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an IPO price of $6.00 per unit. Of the total gross proceeds of $17.1 million, approximately $2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds to the Company was $12.8 million.

The principal purposes of our IPO were 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 Acuitas MDRO gene test products and, when development is completed, our Acuitas 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 Acuitas 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.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on May 5, 2015. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries.

Item 3. Defaults Upon Senior Securities

None.

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Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits listed in the Exhibit Index, which is incorporated herein by reference, are filed or furnished as part of this quarterly report on Form 10-Q.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OPGEN, INC.

Date: June 18, 2015

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

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EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Registrant (incorporated by reference to Exhibit 3.1 of Form 8-K, File No. 001-37367, filed on May 13, 2015).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 of Form S-1, File No. 333-202478, filed on March 3, 2015).
4.1	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 of Form S-1/A, File No. 333-202478, filed on April 28, 2015).
4.2	Second Stockholders' Agreements Amendment, dated as of February 7, 2015, among the Registrant and certain investors (incorporated by reference to Exhibit 4.4 of Form S-1, File No. 333-202478, filed on March 3, 2015).
4.3	Form of 2015 Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.6 of Form S-1/A, File

	No. 333-202478, filed on March 20, 2015).
4.4	Form of Underwriters' Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K, filed on May 13, 2015).
4.5	Form of Offered Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.8 of Form S-1/A, File No. 333-202478, filed on April 23, 2015).
10.1.1	Fifth Amendment to Lease, dated as of March 20, 2015, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1.5 of Form S-1/A, File No. 333-202478, filed on March 20, 2015).
10.1.2	Sixth Amendment to Lease, dated as of April 30, 2015, between the Registrant and the Landlord (incorporated by reference to Exhibit 10.1.6 of Form S-1/A, File No. 333-202478, filed on May 1, 2015).
10.2	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.2 of Form S-1, File No. 333-202478, filed on March 3, 2015).
10.3	Notes Purchase Agreement, dated February 17, 2015, by and among the Registrant and the investors party thereto (including as Exhibit B the form of convertible note) (incorporated by reference to Exhibit 10.9 of Form S-1, File No. 333-202478, filed on March 3, 2015).
10.4	Form of Amended and Restated Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.10 of Form S-1/A, File No. 333-202478, filed on March 20, 2015).
10.5	Amended and Restated Intercreditor Agreement, dated as of February 17, 2015, by and among, the Registrant, Harris & Harris Group, Inc., as collateral agent, and each of the Secured Parties party thereto (incorporated by reference to Exhibit 10.11 of Form S-1/A, File No. 333-202478, filed on March 20, 2015).
10.6	Form of Security Agreement, by and among the Registrant, the Secured Parties party thereto and Harris & Harris Group, Inc., as collateral agent (incorporated by reference to Exhibit 10.12 of Form S-1/A, File No. 333-202478, filed on March 20, 2015).
10.7	2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.13 of Form S-1/A, File No. 333-202478, filed on April 6, 2015).
10.8	Consulting Agreement, effective May 4, 2015, by and between the Registrant and C. Eric Winzer (incorporated by reference to Exhibit 10.14 of Form S-1/A, File No. 333-202478, filed on April 6, 2015).
10.9	Form of Secured Demand Note (incorporated by reference to Exhibit 10.15 of Form S-1/A, File No. 333-202478, filed on April 6, 2015).
10.10	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.16 of Form S-1/A, File No. 333-202478, filed on April 6, 2015).

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Exhibit Number	Description
10.11	Executive Employment, Change in Control and Severance Agreements, dated April 17, 2015, by and between the Registrant and Kevin Krenitsky, M.D. (incorporated by reference to Exhibit 10.17 of Form S-1/A, File No. 333-202478, filed on April 17, 2015).
10.12	Employment Agreement, dated April 17, 2015, by and between the Registrant and Timothy C. Dec (incorporated by reference to Exhibit 10.18 of Form S-1/A, File No. 333-202478, filed on April 17, 2015).
10.13	Warrant Agreement, dated as of May 8, 2015, between OpGen, Inc. and Philadelphia Stock Transfer, Inc., as warrant agent (incorporated by reference to Exhibit 10.1 of the registrant's Current Report on Form 8-K, filed on May 13, 2015).
10.14*	Form of Stock Option Agreement under the 2015 Stock Incentive Plan
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	Interactive data files pursuant to Rule 405 of Regulation S-T; (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of Cash Flows and (iv) the Notes to Unaudited Condensed Financial Statements.

* Filed herewith

Stock Option Award Agreement
Granted Under OpGen, Inc. 2015 Equity Incentive Plan

1. Grant of Option. This certificate evidences [an incentive stock option] [a nonstatutory] stock option (this "Stock Option") granted by OpGen, Inc., a Delaware corporation (the "Company"), on , (the "Grant Date"), to (the "Participant"), pursuant to the Company's 2015 Equity Incentive Plan (as from time to time in effect, the "Plan"). Under this Stock Option, the Participant may purchase, in whole or in part, on the terms herein provided, a total of shares of common stock of the Company (the "Shares") at $0.01 per Share, which is equal to the fair market value of the Shares on the Grant Date. The latest date on which this Stock Option, or any part thereof, may be exercised is , (the "Final Exercise Date"). The Stock Option evidenced by this certificate is intended to be, and is hereby designated, as [an incentive stock option as defined in section 422 of the Internal Revenue Code of 1986, as amended from time to time (the "Code")] [a nonstatutory option, that is, an option that does *not* qualify as an incentive stock option as defined in section 422 of the Internal Revenue Code of 1986, as amended from time to time (the "Code")]. Defined terms used in this Award Agreement without definition have the meanings set forth in the Plan.

This Stock Option is exercisable in the following installments prior to the Final Exercise Date: of the Stock Option to acquire of the underlying Shares shall ratably vest and become exercisable on (the "Vesting Commencement Date"), and the remainder of the Stock Option shall ratably vest .

2. Exercise of Stock Option. Each election to exercise this Stock Option shall be in writing, signed by the Participant or the Participant's executor, administrator, or legally appointed representative (in the event of the Participant's incapacity) or the person or persons to whom this Stock Option is transferred by will or the applicable laws of descent and distribution (collectively, the "Option Holder"), and received by the Company at its principal office, accompanied by this certificate and payment in full as provided in the Plan. Subject to the further terms and conditions provided in the Plan, the purchase price may be paid as follows: (a) cash or check, (b) Shares (including, in the case of payment of the exercise price of an Award, Shares issuable pursuant to the exercise of the Award) or Shares held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences, in each case, having a Fair Market Value on the date of delivery equal to the aggregate payments required, (c) delivery of a written or electronic notice that the Option Holder has placed a market sell order with a broker acceptable to the Company with respect to Shares then issuable upon exercise or vesting of an Award, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the aggregate payments required; provided that payment of such proceeds is then made to the Company upon settlement of such sale. In the event that this Stock Option is exercised by an Option Holder other than the Participant, the Company will be under no obligation to deliver Shares hereunder unless and until it is satisfied as to the authority of the Option Holder to exercise this Stock Option.

3. Notice of Disposition. The person exercising this Stock Option shall notify the Company when making any disposition of the Shares acquired upon exercise of this Stock Option, whether by sale, gift or otherwise.

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4. Restrictions on Transfer of Shares. If at the time this Stock Option is exercised, the Company and any of its stockholders is a party to any agreement restricting the transfer of any outstanding shares of the Company's common stock, the Administrator may provide that this Stock Option may be exercised only if the Shares so acquired are made subject to the transfer restrictions set forth in that agreement (or if more than one such agreement is then in effect, the agreement or agreements specified by the Administrator).

5. Withholding; Agreement to Provide Security. If at the time this Stock Option is exercised the Company determines that under applicable law and regulations it could be liable for the withholding of any federal or state tax upon exercise or with respect to a disposition of any Shares acquired upon exercise of this Stock Option, this Stock Option may not be exercised unless the person exercising this Stock Option remits to the Company any amounts determined by the Company to be required to be withheld upon exercise (or makes other arrangements satisfactory to the Company for the payment of such taxes) and gives such security as the Company deems adequate to meet its potential liability for the withholding of tax upon a disposition of the Shares and agrees to augment such security from time to time in any amount reasonably determined by the Company to be necessary to preserve the adequacy of such security.

6. Nontransferability of Stock Option. This Stock Option is not transferable by the Participant otherwise than by will or the laws of descent and distribution and is exercisable during the Participant's lifetime only by the Participant (or in the event of the Participant's incapacity, the person or persons legally appointed to act on the Participant's behalf).

7. Provisions of the Plan. This Stock Option is subject to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the date of the grant of this Stock Option has been furnished to the Participant. By exercising all or any part of this Stock Option, the Participant agrees to be bound by the terms of the Plan and this certificate. All initially capitalized terms used herein will have the meaning specified in the Plan, unless another meaning is specified herein.

[The remainder of this page is intentionally left blank]

IN WITNESS WHEREOF, the Company has caused this instrument to be executed by its duly authorized officer.

OpGen, Inc.

Dated:

By:
Title:

Acknowledged and agreed:
Participant

Dated:

Name:

[Stock Option Award Agreement Signature Page]

Exhibit 31.1

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

I, Evan Jones, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OpGen, Inc.

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

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

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

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

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

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

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

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

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

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

Date: June 18, 2015

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

Exhibit 31.2

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

I, Timothy C. Dec, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OpGen, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: June 18, 2015

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

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of OpGen, Inc. (the "Company") for the quarterly period ended March 31, 2015 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

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

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

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

Date: June 18, 2015

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

Date: June 18, 2015

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

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