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

	FORM 10-Q		
(Mark one)			
x QUARTERLY REPORT PURSUANT TO SECTIO	ON 13 OR 15(d) OF THE SECURITIES E	KCHANGE ACT OF 1934	
For	the quarterly period ended June 30, 2015		
	or		
☐ TRANSITION REPORT PURSUANT TO SECTION	ON 13 OR 15(d) OF THE SECURITIES E	XCHANGE ACT OF 1934	
For	the transition period from to		
	Commission File Number 001-37367		
(Exac	OPGEN, INC. t name of registrant as specified in its charte	··)	
<b>Delaware</b> (State or other jurisdiction of incorporation or organization)		<b>06-1614015</b> (I.R.S. employer identification no.)	
<b>708 Quince Orchard Road, Suite 250, Gaithersl</b> (Address of principal executive offices)	burg, MD	20878 (Zip code)	
Registrant's tel	lephone number, including area code: (240	) 813-1260	
Indicate by check mark whether the registrant (1) has file during the preceding 12 months (or for such shorter peri requirements for the past 90 days. Yes $\boxtimes$ No $\square$			
Indicate by check mark whether the registrant has submitted be submitted and posted pursuant to Rule 405 of Regulation submit and post such files) . Yes $\boxtimes$ No $\square$			
Indicate by check mark whether the registrant is a large a definitions of "large accelerated filer," "accelerated filer," a			See
Large accelerated filer $\square$ Non-accelerated filer $\square$	Accelerated filer Smaller reporting com	pany 🗵	
Indicate by check mark whether the registrant is a shell con	npany (as defined in Rule 12b-2 of the Exch	ange Act). Yes □ No ⊠	
12,537,454 shares of the Company's common stock, par va	lue \$0.01 per share, were outstanding as of J	uly 31, 2015.	

# OPGEN, INC.

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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;
- integration of the operations of AdvanDx, Inc. acquired by merger on July 14, 2015;
- · 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 "Part II. Item 1A. Risk Factors," as well as our quarterly report on Form 10-Q for the period ended March 31, 2015 filed with the United States Securities and Exchange Commission, or SEC, on June 18, 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.

# OpGen, Inc. Condensed Balance Sheets (unaudited)

		June 30, 2015	Ι	December 31, 2014
<u>Assets</u>				
Current assets				
Cash and cash equivalents	\$	10,215,809	\$	749,517
Accounts receivable, net		214,043		503,983
Inventory, net		347,463		369,742
Prepaid expenses and other current assets		490,201		90,233
Total current assets		11,267,516		1,713,475
Property and equipment, net		483,147		587,956
Deferred IPO issuance costs		-		296,041
Other noncurrent assets		46,380		57,459
Total assets	\$	11,797,043	\$	2,654,931
Liabilities, Redeemable Preferred Stock and Stockholders' Deficit				
Current liabilities				
Accounts payable	\$	1,115,859	\$	1,160,081
Accrued compensation and benefits	Ψ	702,692	Ψ	423,099
Accrued liabilities		583,851		993,657
Deferred revenue		234,508		339,171
Short term notes payable		2,500		1,505,000
Current maturities of long-term capital lease obligation		118,579		100,499
Short-term convertible notes, net of discounts		110,575		1,500,000
Total current liabilities		2,757,989		<b>6,021,507</b>
Total Current natimues		2,737,909		0,021,307
Long-term capital lease obligations and other noncurrent liabilities		210,758		134,149
Total liabilities		2,968,747		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 December 31, 2014 (none at June 30, 2015); aggregate liquidation preference				
of \$7,999,728 at December 31, 2014 (none at June 30, 2015)		-		4,564,899
Total redeemable convertible preferred stock		_		4,564,899
Stockholders' equtiy (deficit)				
Common stock, \$.01 par value; 200,000,000 shares authorized; 10,719,272 and 493,178 shares issued and				
outstanding at June 30, 2015 and December 31, 2014, respectively		107,193		4,932
Additional paid-in capital		113,447,153		88,701,737
Accumulated deficit		(104,726,050)		(96,772,293)
Total stockholders' equity (deficit)		8,828,296		(8,065,624)
Total liabilities, redeemable preferred stock and stockholders' equity (deficit)	\$	11,797,043	\$	2,654,931
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 $See\ accompanying\ notes\ to\ unaudited\ condensed\ financial\ statements.$ 

# OpGen, Inc. Condensed Statements of Operations (unaudited)

	 three Months 1	Ende	d June 30, 2014	 Six Months Er 2015		June 30, 2014
Revenue						
Product sales	\$ 319,171	\$	272,538	\$ 503,350	\$	572,713
Laboratory services	28,195		121,899	63,436		291,149
Collaborations revenue	27,780		677,780	280,560		1,305,560
Total revenue	375,146		1,072,217	847,346		2,169,422
Operating expenses						
Cost of products sold	48,231		65,102	163,620		201,209
Cost of services	54,794		140,302	150,224		238,220
Research and development	999,699		1,247,077	2,108,301		2,199,868
General and administrative	1,420,219		523,120	2,079,611		1,078,073
Sales and marketing	905,767		546,581	1,929,796		1,094,053
Total operating expenses	 3,428,710		2,522,182	 6,431,552		4,811,423
Operating loss	(3,053,564)		(1,449,965)	(5,584,206)		(2,642,001)
Other income (expense)						
Interest income	7,127		46	7,162		83
Interest expense	(1,632,974)		(6,935)	(1,729,371)		(15,137)
Change in fair value of derivative financial instruments	(679,173)		-	(647,342)		-
Total other income (expense)	(2,305,020)		(6,889)	(2,369,551)		(15,054)
Net loss	(5,358,584)		(1,456,854)	(7,953,757)		(2,657,055)
Preferred stock dividends	(72,767)		(172,738)	(244,508)		(283,553)
Net loss available to common stockholders	\$ (5,431,351)	\$	(1,629,592)	\$ (8,198,265)	\$	(2,940,608)
Net loss per common share - basic and diluted	\$ (0.84)	\$	(4.49)	\$ (2.35)	\$	(8.11)
Weighted average shares outstanding - basic and diluted	6,449,108		362,537	3,487,734		362,537

 $See\ accompanying\ notes\ to\ unaudited\ condensed\ financial\ statements.$ 

# OpGen, Inc. Condensed Statements of Cash Flows Six Months Ended June 30, (unaudited)

		2015	2014
Cash flows from operating activities			
Net loss	\$	(7,953,757)	\$ (2,657,055)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization		207,227	320,372
Noncash interest expense		1,525,849	-
Share-based compensation		910,691	55,480
Inventory obsolescence expense (recovery)		18,223	(12,451)
Change in fair value of derivative financial instruments		647,342	-
Changes in operating assets and liabilities:			
Accounts receivable		289,940	(235,395)
Inventory		4,056	(208,392)
All other assets		(308,042)	82,734
Accounts payable		238,426	(55,930)
Accrued compensation and other liabilities		(56,912)	(21,220)
Deferred revenue		(104,663)	128,435
Net cash used in operating activities		(4,581,620)	(2,603,422)
Cash flows from investing activities		(25 672)	(24 (00)
Purchases of property and equipment		(25,673)	 (34,699)
Net cash used in investing activities		(25,673)	(34,699)
Cash flows from financing activities			
Proceeds from issuance of preferred stock, net of issuance costs			1,937,902
Proceeds from issuance of convertible notes and warrants, net of issuance costs		1,388,815	1,937,902
Proceeds from issuance of short-term notes, net of issuance costs		750,000	-
Proceeds from exercise of stock options and warrants		102	-
Proceeds from initial public offering, net of issuance costs paid in 2015		12,142,526	-
Payments on debt		(152,500)	(2,500)
Payments on capital lease obligations		(55,358)	(55,494)
Net cash provided by financing activities		14,073,585	1,879,908
Net (decrease) increase in cash and cash equivalents		9,466,292	(758,213)
Cash and cash equivalents at beginning of period		749,517	1,400,345
Cash and cash equivalents at end of period	\$	10,215,809	\$ 642,132
	-		
Supplemental disclosure of cash flow information			
Cash paid during the period for interest	\$	203,163	\$ 20,257
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	\$ -
Exchange of demand notes for IPO units sold in initial public offering	\$	2,100,000	\$ -
Conversion of convertible notes into Series A preferred stock	\$	3,000,000	\$ -
Conversion of Series A preferred stock into common shares	\$	8,183,661	\$ -

See accompanying notes to unaudited condensed financial statements.

# Notes to Unaudited Condensed Financial Statements June 30, 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.

In July 2015, the Company acquired AdvanDx, Inc. for 681,818 shares of common stock with a value of \$2.6 million, based on the closing price of our common stock of \$3.79 per share on July 13, 2015 (see Note 11).

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),
- \$0.2 million in unsecured promissory note held by a related party (which was repaid in cash during the second quarter 2015),
  - \$1.5 million through the issuance of convertible notes in 2015, and
- \$12.1 million in net proceeds from its initial public offering, or IPO, as discussed further below.

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 \$12.1 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 7,374,852 shares of common stock.

In July 2015, the Company acquired AdvanDx, Inc. for 681,818 shares of common stock with a value of \$2.6 million (based on the closing price of our common stock of \$3.79 per share on July 13, 2015), and raised \$6.0 million by issuing 1,136,364 shares of common stock (with a value of \$5.0 million at \$4.40 per share) and a \$1.0 million promissory note to Merck Global Health Innovation Fund, LLC, or Merck GHI (see Note 11).

The Company's current operating assumptions, which include management's best estimate of future revenue and operating expenses, indicate that current cash on hand (including the \$6.0 million from Merck GHI) 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, or pursue other strategic alternatives which may include licensing and/or partnering arrangements or mergers and acquisitions. 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 U.S. 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 June 30, 2015 and the results of operations and cash flows for the three and six months ended June 30, 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 June 30, 2015 and December 31, 2014.

At June 30, 2015, the Company had accounts receivable from five customers which individually represented 31%, 20%, 15%, 13% and 10% of total accounts receivable. At December 31, 2014, the Company had accounts receivable from two customers which individually represented 79%, and 15% 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:

	 une 30, 2015	December 31 2014		
Raw materials and supplies	\$ 96,450	\$	40,749	
Work-in process	122,433		135,625	
Finished goods	128,580		193,368	
Total	\$ 347,463	\$	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 \$779,496 and \$867,816 at June 30, 2015 and December 31, 2014, respectively.

# **Product warranty**

A warranty reserve is established upon the sale of any Argus System or Whole Genome Mapping 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 reserve for warranties was \$4,250 and \$2,750 as of June 30, 2015 and December 31, 2014, respectively.

# 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 and six months ended June 30, 2015 and 2014, the Company determined that there were no impaired long-lived assets.

# Redeemable convertible preferred stock

All shares of Series A redeemable convertible preferred stock, or Series A Preferred Stock (including those shares issued in connection with the conversion of the 2014 and 2015 convertible debt (see Note 6)), were converted into 7,374,852 shares of common stock in connection with the Company's IPO (see Note 7).

Prior to the IPO, the carrying value of the Series A Preferred Stock was increased by the accretion of related discounts, issuance costs and accrued but unpaid dividends so that the carrying amount would equal the redemption amount at the dates the stock becomes redeemable. At December 31, 2014, the Company had 3,999,864 shares of Series A Preferred Stock, outstanding. The Series A Preferred Stock was redeemable at the option of the holders of 70% of the outstanding shares of Series A Preferred Stock, subject to certain additional requirements. The Company's redeemable convertible preferred stock was classified as temporary equity due to redemptions provisions outside of the Company's control.

# Revenue recognition

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

# Revenue from sales of the Argus System

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

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

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

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

# Revenue from extended warranty service contracts

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

# Revenue from providing laboratory services

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

# Revenue from funded software development arrangements

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

#### **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. 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 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 (i) common stock options, (ii) restricted stock units (in 2014), (iii) stock purchase warrants, and (iv) prior to the IPO, convertible preferred stock and convertible debt, exercisable or exchangeable into common stock which have been excluded from the computation of diluted loss per share, was 5.4 million and 4.2 million for the six and three months ended June 30, 2015 and 2014, respectively. The Company's convertible preferred stock, prior to its conversion, contained non-forfeitable rights to dividends, and therefore was considered to be a participating security; the calculation of basic and diluted income (loss) per share excludes net income (but not net loss) attributable to the convertible preferred stock from the numerator and excludes the impact of those shares from the denominator in periods prior to the IPO.

# **Recent accounting pronouncements**

In May 2014, the Financial Accounting Standards Board, 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, 2018 and early adoption is permitted starting January 1, 2017. 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.

#### 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 June 30, 2015 and December 31, 2014:

	Fair value at			
	June 30, 2015	Level 1	Level 2	Level 3
Cash and cash equivalents	\$ 10,215,809	\$10,215,809	\$ -	\$ -
	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.

Prior to its IPO, certain stock purchase warrants contained cash settlement features and, accordingly, the Company considered them to be derivative financial instruments and accounted for them at fair value using level 3 inputs. As a result of the Company's IPO and elimination of the cash settlement features pursuant to their terms, those stock purchase warrants were reclassified to equity. For periods prior to the IPO, the Company determined the fair value of these derivative liabilities using a hybrid valuation method that consisted of a probability weighted expected return method that values the Company's equity securities assuming various possible future economic outcomes while using an option pricing method (that treated all equity linked instruments as call options on the Company's equity value with exercise prices based on the liquidation preference of the Series A Preferred Stock ) to estimate the allocation of value within one or more of the scenarios. Using this hybrid method, unobservable inputs included the Company's equity value, the exercise price for each option value, expected timing of possible economic outcomes such as initial public offering, risk free interest rates and stock price volatility. The following tables set forth a summary of changes in the fair value of Level 3 liabilities measured at fair value on a recurring basis for the six months ended June 30, 2015:

Description	Balance at December 31, 2014	Established in 2015	Change in Fair Value	Reclassifed to Equity	Balance at June 30, 2015
Derivative warrant liability	\$ -	\$ 72,333	\$ 647,342	\$ (719,675)	\$ -

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

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

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

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

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

The Company measures its long-lived assets, including property and equipment and intangible assets, 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 June 30, 2015 and 2014.

# Note 5 – Series A redeemable convertible preferred stock

All shares of Series A Preferred Stock (including those shares issued in connection with the conversion of the 2014 and 2015 convertible debt (see Note 6)) were converted into 7,374,852 shares of common stock in connection with the Company's IPO (see Note 7). Prior to the Company's IPO, the Series A Preferred Stock was classified as temporary equity due to redemption provisions outside of the Company's control.

The Company issued 1,999,864 shares of Series A Preferred Stock in December 2013 at \$1.00 per share in exchange for \$1,999,864 in convertible promissory notes. In February 2014, the Company sold 1,405,096 shares of Series A 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. At 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 holders of the Series A Preferred Stock had the right to receive non-cumulative dividends, at a rate of 8% per annum, when and if declared by the Board of Directors. The Series A Preferred Stock had preference of payment over all other classes and series of capital stock of the Company with respect to dividends, payment on liquidation and payment on redemption. The liquidation and redemption preferences were at two times the Series A Preferred Stock purchase price. The Series A Preferred Stock holders were entitled to vote on all matters that come to stockholders on an as-converted basis with holders of the common stock. In addition, the Series A Preferred Stock had broad based anti-dilution rights.

The holders of Series A Preferred Stock had the right to convert such shares, at their option and at any time, into shares of common stock at the then-applicable conversion rate, as defined. The initial conversion rate was one common share for each preferred share, which could be adjusted for specified dilutive transactions. Beginning in December 2020, the Company may have been obligated to redeem shares of Series A Preferred Stock, if requested, by holders of at least 70% of the then-outstanding shares of preferred stock. The redemption, if requested, would have taken place in three equal annual installments. Series A Preferred Stock would have been redeemed at two times the original issue price per share plus all accrued and unpaid dividends. The redemptions were subject to certain equity adjustments for specified anti-dilution transactions, as defined.

# Note 6 - Debt

All the Company's outstanding demand notes and convertible notes was exchanged for units in the Company's IPO or otherwise was converted into Series A Preferred Stock and subsequently converted into shares of common stock in connection with the IPO. A short-term 8% promissory note for \$150,000 issued in April 2015 was repaid in cash in June 2015. As of June 30, 2015, the Company has a total of \$2,500 debt outstanding.

#### **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. All outstanding demand notes were tendered as payment for 350,000 units in the Company's IPO (see Note 7). Prior to settlement, the demand notes bore interest at 8% per annum, had a first priority security interest in the assets of the Company, and a term of approximately four months.

#### 2014 convertible debt

In July, August and September 2014, the Company raised \$1.5 million through the issuance of convertible debt. All outstanding 2014 convertible debt was converted into Series A Preferred Stock and then into 1,500,000 shares of common stock in connection with the Company's IPO (see Note 7). Prior to its conversion, the debt was convertible, at the option of the holders or in certain cases at the Company's option, into shares of Series A Preferred Stock or other potential equity securities, bore interest at 8% and was due in full on July 11, 2015.

# 2015 convertible debt

In February and March 2015, the Company raised \$1.5 million in capital through the issuance of 8% secured convertible notes with detachable stock purchase warrants. All outstanding 2015 convertible debt was converted into Series A Preferred Stock and then into 1,875,000 shares of common stock in connection with the Company's IPO (see Note 7). Prior to its conversion, the 2015 convertible notes were pre-payable by the Company without penalty at any time following the three-month anniversary of the closing of the IPO (provided that before the six-month anniversary of the closing of an IPO, the 2015 convertible notes could only be prepaid out of newly issued capital subsequent to the IPO), and were puttable by the holder to the Company in the event of a defined default. The 2015 convertible notes were each convertible, at the election of the holder, into (i) shares of Series A Preferred Stock, at a conversion rate of 1.25 shares of Series A Preferred Stock for each \$1.00 converted if the conversion occurs prior to closing of an IPO.

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

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

# Note 7 - Stockholders' equity (deficit)

#### **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, and underwriting discounts, commissions and offering expenses of \$2.9 million (which were charged to additional paid in capital), the total net cash proceeds to the Company was \$12.1 million. On the IPO closing date, the underwriters exercised a portion of their over-allotment option to acquire an additional 422,500 stock purchase warrants for cash of \$4,225. In connection with the IPO, all of the Company's outstanding Series A Preferred Stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,852 shares of common stock.

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

# Stock options

In 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. 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.

In April 2015, the Company adopted, and the Company's stockholders approved, the 2015 Equity Incentive Plan, or the 2015 Plan; the 2015 Plan became effective upon the execution and delivery of the underwriting agreement for the Company's IPO. Following the effectiveness of the 2015 Plan, no further grants will be made under the 2002 or 2008 plans. The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for the grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants.

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 1,355,000 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date, that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by the Board of Directors. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled, or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. As of June 30, 2015, there remained 879,571 shares available for issuance under the 2015 Plan.

For the three months ended June 30, 2015 and 2014, the Company recorded \$320,088 and \$26,553, respectively, of stock compensation expense. For the six months ended June 30, 2015 and 2014, the Company recorded \$910,691 and \$55,480, respectively, of stock compensation expense. The allocation of share-based compensation expense by operating expenses is as follows:

	Th	hree months ended June 30,			
		2015		2014	
Research and development	\$	70,228	\$	5,975	
General and administrative		199,179		19,818	
Sales and marketing		50,681		760	
	\$	320,088	\$	26,553	
		Six months	ende	d June 30,	
		2015		2014	
Research and development		\$ 106,684	\$	12,069	
General and administrative		282,478	}	41,878	
Sales and marketing		521,529	)	1,533	

During the six months ended June 30, 2015, the Company granted stock options to acquire 1,406,887 shares of common stock at a weighted average exercise price of \$2.83 per share. The 2015 awards had a weighted average grant date fair value per share of \$3.47. The Company has total stock options to acquire 1,704,959 shares of common stock outstanding at June 30, 2015.

910,691

55 480

# 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 3,716,355 and 33,594 shares of common stock outstanding at June 30, 2015 and December 31, 2014, respectively. In the first quarter of 2015, the Company issued 225,011 warrants in connection with the issuance of its 2015 convertible debt. In the second quarter of 2015 in connection with the Company's IPO, the Company issued 3,457,750 stock purchase warrants to investors and to its investment bankers. As of June 30, 2015, the warrants are classified as equity.

# 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 extended 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 is responsible for all utilities, repairs, insurance, and taxes under this operating lease. Rent expense under the Company's operating leases for the six months ended June 30, 2015 and 2014 was \$380,641 and \$443,713, respectively. Rent expense in 2015 reflected a decrease in pass-through expenses from the landlord as compared to 2014. Effective July 1, 2015, the Company further modified its lease agreement to add additional leased space to its headquarters.

# 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 company re-negotiated one of its license agreements in April 2015 to reduce its annual minimum royalty arrangement and, therefore, the accompanying financial statements reflect \$(44,526) and \$24,298 of net royalty (income) expense for the three months ended June 30, 2015 and 2014, respectively and \$(21,227) and \$49,332 of net royalty (income) expense for the six months ended June 30, 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 \$280,560 and \$1,305,560 during the six months ended June 30, 2015 and 2014, respectively, and \$27,780 and \$677,780 during the three months ended June 30, 2015 and 2014, respectively, relating to this arrangement.

# Note 10 - Related person transactions

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 Directors of the Company, is a director of Fluidigm. See Note 11.

# Note 11 - Subsequent events

On July 12, 2015, the Company entered into a letter agreement, or the Agreement, with Fluidigm Corporation, or Fluidigm, to expand the companies' existing relationship to include collaborating on the development of test kits and custom analytic instruments for identification, screening and surveillance testing of MDROs. The Agreement also expands the existing Supply Agreement between the Company and Fluidigm, and provides for expansion of the gene targets and organisms to be tested on the Company's existing CLIA lab-based tests, the Acuitas MDRO Gene Test and the Acuitas Resistome Test, using Fluidigm technologies and products. Additionally, Fluidigm has agreed not to develop or directly collaborate with any third party to develop an FDA approved or CE marked diagnostic tests for the purpose of detecting resistome genes for identified MDROs if the Company meets certain minimum purchase commitments and other requirements. The initial term of the Agreement is five years. Both parties have the ability to extend the term for an additional five years. Under the expanded Supply Agreement, the term is extended until March 17, 2018, and the Company has the right to extend the term of the Supply Agreement for up to two additional three-year terms.

On July 14, 2015, the Company completed the strategic acquisition of AdvanDx, Inc., or AdvanDx, through consummation of a merger transaction, or the Merger. Pursuant to an Agreement and Plan of Merger, or the Merger Agreement, a newly formed Merger Sub merged with and into AdvanDx, with AdvanDx surviving as a wholly owned subsidiary of the Company in accordance with the General Corporation Law of the State of Delaware. Under the terms of the Merger Agreement, the merger consideration consisted of an aggregate 681,818 shares of the Company's common stock with a value of \$2.6 million (based on the closing sales price of our common stock of \$3.79 per share on July 13, 2015), or the Merger Consideration, which Merger Consideration was distributed in accordance with the liquidation preferences set forth in the AdvanDx Restated Certificate of Incorporation, as amended. The issuance of the Merger Consideration was effected as a private placement of securities under Section 4(a)(2) of the Securities Act of 1933, as amended, or the Securities Act, and Regulation D promulgated thereunder. The Company entered into a Registration Rights Agreement with the AdvanDx stockholders receiving Merger Consideration.

On July 14, 2015, as a condition to the AdvanDx merger, the Company also entered into a Common Stock and Note Purchase Agreement, or the Purchase Agreement, with Merck GHI, pursuant to which Merck GHI purchased 1,136,364 shares of common stock of the Company at \$4.40 per share for gross proceeds of \$5,000,000. Pursuant to the Purchase Agreement, the Company also issued to Merck GHI a Senior Secured Promissory Note, or the Note, and collectively with the shares of common stock purchased, the "Securities," in the principal amount of \$1,000,000 with a two-year maturity date from the date of issuance. The Company's obligations under the Note are secured by a lien on all of the Company's assets pursuant to the terms of a Security Agreement, dated as of July 14, 2015, by and among the Company and AdvanDx, as debtors, and Merck GHI as the secured party. The sale of the Securities was effected as a private placement transaction under Section 4(a)(2) of the Securities Act. The Company intends to use the proceeds from the sale of the Securities for working capital and other general corporate purposes, including funding AdvanDx's capital requirements in 2015 and 2016.

In connection with the consummation of the issuance and sale of the Securities, the Company's Board of Directors elected David M. Rubin, Ph.D., managing director of Merck GHI to the Company's Board of Directors.

In connection with the Merger and the investment transactions, the Company also entered into a Registration Rights Agreement with the AdvanDx stockholders receiving Merger Consideration and with Merck GHI, pursuant to which the investors were granted certain demand registration rights and piggyback registration rights in connection with subsequent registered offerings of the Company's common stock. Merck GHI also received rights to participate on a pro-rata basis in future securities offerings by the Company.

# 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 Part II. Item 1A. "Risk Factors" as well as our Form 10-Q for the period ended March 31, 2015 filed with the SEC on June 18, 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 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 six months 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).
- \$0.2 million in unsecured promissory note held by a related party (which was repaid in cash during the second quarter 2015),
- \$1.5 million through the issuance of convertible notes in 2015, and
- \$12.1 million in net proceeds from its IPO, as discussed further below.

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 \$12.1 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 7,374,852 shares of common stock.

On July 14, 2015, the Company completed the strategic acquisition of AdvanDx. Pursuant to the Merger Agreement, a newly formed Merger Sub merged with and into AdvanDx, with AdvanDx surviving as a wholly owned subsidiary of the Company in accordance with the General Corporation Law of the State of Delaware. Under the terms of the Merger Agreement, the Merger Consideration consisted of an aggregate 681,818 shares of the Company's common stock with a value of \$2.6 million (based on the closing sales price of our common stock of \$3.79 per share on July 13, 2015).

Also on July 14, 2015, as a condition to the AdvanDx merger, the Company entered into the Purchase Agreement with Merck GHI, pursuant to which Merck GHI purchased 1,136,364 shares of common stock of the Company at \$4.40 per share for gross proceeds of \$5,000,000. Pursuant to the Purchase Agreement, the Company also issued to Merck GHI a Senior Secured Promissory Note in the principal amount of \$1,000,000 with a two-year maturity date from the date of issuance. The Company's obligations under the note are secured by a lien on all of the Company's assets pursuant to the terms of a Security Agreement, dated as of July 14, 2015, by and among the Company and AdvanDx, as debtors, and Merck GHI as the secured party. The Company intends to use the proceeds from the sale of the securities for working capital and other general corporate purposes, including funding AdvanDx's capital requirements in 2015 and 2016.

On July 14, 2015, the Company entered into a Registration Rights Agreement with Merck GHI and the AdvanDx stockholders who received Merger Consideration in the Merger, which will require the Company to register such shares of Company common stock for resale by such holders in the future.

Under the Purchase Agreement, Merck GHI has the right to participate in future securities offerings made by the Company. There is no assurance that Merck GHI will exercise such participation rights in the future.

The Company's current operating assumptions, after the IPO and July 2015 acquisition of AdvanDx and the funding provided by Merck GHI, 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, or pursue other strategic alternatives which may include licensing and/or partnering arrangements or mergers and acquisitions.

# Results of operations for the six months ended June 30, 2015 and 2014

#### Revenues

	Six	Six months ended June 30,		
		2015		2014
Product sales	\$	503,350	\$	572,713
Laboratory services		63,436		291,149
Collaboration revenue		280,560		1,305,560
Total revenue	\$	847,346	\$	2,169,422

Our total revenue for the six months ended June 30, 2015 decreased 61%, to \$0.8 million from \$2.2 million, when compared to the same period in 2014. This decrease is primarily attributable to:

- · Product Sales: a decrease in revenue of 12% in 2015 as compared to 2014 is attributable to a reduction in the sale of our Argus products, as we transition from our legacy mapping products to the introduction of Acuitas MDRO products;
- · Laboratory Services: a decrease in revenue of 78% in 2015 as compared to 2014 as a result of a reduction in sales of mapping products, as we transition from our legacy mapping products to the introduction of Acuitas MDRO products; and
- · Collaborative Revenue: a decrease in revenue generated under certain Collaborative Arrangements of 79% 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**

	Six mo	Six months ended June 30,		
	201	5 2014		
		20.000 # 004.000		
Cost of products sold	\$ 16	53,620 \$ 201,209		
Cost of services	15	50,224 238,220		
Research and development	2,10	08,301 2,199,868		
General and administrative	2,07	79,611 1,078,073		
Sales and marketing	1,92	29,796 1,094,053		
Total operating expenses	\$ 6,43	\$1,552 \$ 4,811,423		

The Company's total operating expenses for the six months ended June 30, 2015 increased 34%, to \$6.4 million from \$4.8 million, when compared to the same period in 2014. This increase is primarily attributable to:

- · General and Administrative: an increase in expenses in 2015 primarily due to salaries of \$0.4 million, public company costs of \$0.4 million and share-based compensation costs of \$0.2 million; and
- · Sales and Marketing: an increase in expenses in 2015 primarily due to clinical outcome cost benefit studies costs of \$0.4 million, and share-based compensation costs of \$0.5 million.

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

# Other income (expense)

	Six months e	nded June 30,
	2015	2014
Interest income	\$ 7,162	\$ 83
Interest expense	(1,729,371)	(15,137)
Change in fair value of derivative financial instruments	(647,342)	-
Total other income (expense)	\$ (2,369,551)	\$ (15,054)

Other income (expense) for the six months ended June 30, 2015 increased to a net expense of (\$2.4 million) from a net expense of (\$15,054) in 2014, and was primarily the result of \$1.5 million of non-cash interest expense related to the conversion of our convertible notes in May 2015 and the final mark-to-market adjustment related to our warrant liabilities, which were reclassified to stockholders' on May 8, 2015 when their net cash-settlement features lapsed.

# Results of operations for the three months ended June 30, 2015 and 2014

#### Revenues

	Thi	Three months ended June 30,		
		2015		2014
Product sales	\$	319,171	\$	272,538
Laboratory services		28,195		121,899
Collaboration revenue		27,780		677,780
Total revenue	\$	375,146	\$	1,072,217

Our total revenue for the three months ended June 30, 2015 decreased 65%, to \$0.4 million from \$1.1 million, when compared to the same period in 2014. This decrease is primarily attributable to:

- Product Sales: an increase in revenue of 17% in 2015 as compared to 2014 was primarily due to a whole genome mapping system sale;
- · Laboratory Services: a decrease in revenue of 77% in 2015 as compared to 2014 as a result of a reduction in sales of mapping products, as we transition from our legacy mapping products to the introduction of Acuitas MDRO products; and
- · Collaborative Revenue: a decrease in revenue generated under certain Collaborative Arrangements of 96% 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**

	Th	Three months ended June 30,		
		2015		2014
Cost of products sold	\$	48,231	\$	65,102
Cost of services		54,794		140,302
Research and development		999,699		1,247,077
General and administrative		1,420,219		523,120
Sales and marketing		905,767		546,581
Total operating expenses	\$	3,428,710	\$	2,522,182

The Company's total operating expenses for the three months ended June 30, 2015 increased 36%, to \$3.4 million from \$2.5 million, when compared to the same period in 2014. This increase is primarily attributable to:

- · Research and Development: a decrease in expenses of \$0.2 million primarily due to a reduction in outsourced software development;
- · General and Administrative: an increase in expenses of \$0.9 million primarily due to salary and consulting expenses of \$0.3 million, public company costs of \$0.4 million and share-based compensation costs of \$0.2 million; and
- Sales and Marketing: in increase in expenses of \$0.4 million primarily due to clinical outcome cost benefit studies.

# Other income (expense)

	Tl	Three months ended June 30,			
	_	2015		2014	
Interest income	\$	7,127	\$	46	
Interest expense		(1,632,974)		(6,935)	
Change in fair value of derivative financial instruments		(679,173)		-	
Total other income (expense)	\$	(2,305,020)	\$	(6,889)	

Other income (expense) for the three months ended June 30, 2015 increased to a net expense of (\$2.3 million) from a net expense of (\$6,889) in 2014, and was primarily the result of \$1.5 million of non-cash interest expense related to the conversion of our convertible notes in May 2015 and the final mark-to-market adjustment related to our warrant liabilities, which were reclassified to stockholders' on May 8, 2015 when their net cash-settlement features lapsed.

# Liquidity and capital resources

At June 30, 2015, the Company had cash and cash equivalents of \$10,215,809, compared to \$749,517 at December 31, 2014.

During the first six months of 2015, the Company raised \$0.6 million in short-term demand notes, \$0.2 million through the issuance of an unsecured promissory note, and \$1.5 million through the issuance of convertible notes. 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 \$12.1 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 7,374,852 shares of common stock.

The Company's primary cash requirements are to fund operations as well as research and development programs and collaborations, including those related to AdvanDx acquired in July 2015, and to support general and administrative activities, and to fund acquisitions of products or businesses. The Company's current operating assumptions, after the IPO and July acquisition of AdvanDx and the funding provided by Merck GHI, 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. The Company does not currently have any bank credit lines. In the event the Company is unable to successfully raise additional capital in 2016, the Company may 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, or pursue other strategic alternatives which may include licensing and/or partnering arrangements or mergers and acquisitions.

#### 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:

	S	Six months ended June 30,		
		2015		2014
Net cash used in operating activities	\$	(4,581,620)	\$	(2,603,422)
Net cash used in investing activities		(25,673)		(34,699)
Net cash provided by financing activities		14,073,585		1,879,908

Net cash used in operating activities

Net cash used in operating activities for the six months ended June 30, 2015 consists primarily of our net loss of (\$7.8 million), reduced by certain non-cash items, including depreciation and amortization expense of \$0.2 million, share-based compensation expense of \$0.9 million, change in the fair value of our warrant liability of \$0.6 million, non-cash interest expense including that associated with the conversion of our convertible notes in May 2015 of \$1.5 million, and the net change in operating assets and liabilities of \$0.2 million. Net cash used in operating activities for the six months ended June 30, 2014 consists primarily of our net loss of (\$2.7 million), reduced by certain non-cash items, including depreciation and amortization expense of \$0.3 million, and increased by certain other non-cash items of (\$0.3 million).

Net cash used in investing activities

Net cash used in investing activities in 2015 and 2014 was for the purchase of property and equipment.

Net cash provided by financing activities

Net cash provided by financing activities for the six months ended June 30, 2015 of \$14.1 million consisted primarily of net proceeds from the issuance of debt instruments of \$2.0 million along with the net proceeds from our IPO of \$12.1 million. Net cash provided by financing activities for the six months ended June 30, 2014 of \$1.9 million consisted primarily of net proceeds from the issuance of preferred stock.

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

When an Argus System is sold without the Genome Builder software, total arrangement consideration is recognized as revenue when the System is delivered to the customer. Ancillary performance obligations, including installation, limited customer training and limited consumables, are considered inconsequential and are combined with the Argus System as one unit of accounting. When an Argus System is sold with the Genome Builder software in a multiple-element arrangement, total arrangement consideration is allocated to the Argus System and to the Genome Builder software (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 laboratory services contracts when the service has been performed and reports are made available 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-dilution 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. The Company's sole derivative financial instrument, a warrant liability, was reclassified to equity in May 2015 as its net-cash settlement features lapsed.

# **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, 2018 and early adoption is permitted starting January 1, 2017. 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 June 30, 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 of 2002 and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. 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 June 30, 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

In addition to the Risk Factors included in our Form 10-Q for the first quarter ended March 31, 2015, which are incorporated herein by reference, the Company adds the following risk factors:

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 six month periods ended June 30, 2015 and 2014 we had a net loss of \$8.0 million and \$2.7 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 June 30, 2015, we had an accumulated deficit of \$104.7 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 six months of 2015, the Company raised \$0.6 million in short-term demand notes, \$0.2 million through the issuance of an unsecured promissory note, and \$1.5 million through the issuance of our 2015 convertible notes. 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 \$12.1 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 7,374,852 shares of common stock.

In July 2015, we received an additional investment of \$6.0 million as a result of an investment made in our common stock and a secured promissory note by Merck GHI. In addition, on July 14, 2015, we acquired AdvanDx pursuant to consummation of a merger under the Merger Agreement.

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;
- · integration of the AdvanDx operations;
- · 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. We anticipate that we will need to raise additional capital to support our operations, including the operations of AdvanDx. While Merck GHI has the right to participate in future capital raising transactions, there is no assurance that it will invest further in the Company. We have no committed sources of capital and may find it difficult to raise money on terms favorable to us or at all. The failure to obtain sufficient capital to support our operations could have an adverse effect on our business, financial condition and results of operations.

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

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

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

- · coordinating research and development activities to enhance the introduction of new diagnostic tests and technology acquired in the acquisition;
- failure to successfully integrate and harmonize financial reporting and information technology systems of the two companies;
- · retaining each company's relationships with its partners;
- retaining and integrating key employees from the Company and AdvanDx;
- · managing effectively the diversion of management's attention from business matters to integration issues;
- combining research and development capabilities effectively and quickly;

- · integrating partnership efforts so that new partners acquired can easily do business with us; and
  - transitioning all facilities to a common information technology environment.

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

We have incurred significant costs related to the Merger. If we are unable to offset the costs of the acquisition through realization of efficiencies, our financial condition, liquidity and results of operations will suffer.

We have incurred, and expect to continue to incur, various non-recurring costs associated with combining the operations of the Company and AdvanDx, including, but not limited to, legal, accounting and financial advisory fees. The substantial majority of non-recurring expenses have been composed of these costs and expenses related to the execution of the acquisition, facilities and systems consolidation costs and employment-related costs. We have also incurred fees and costs related to formulating and implementing integration plans. Additional unanticipated costs may be incurred in the integration of the businesses. Although we expect that the elimination of duplicative costs, as well as the realization of other efficiencies related to the integration of the businesses, should allow us to offset incremental acquisition and acquisition-related costs over time, this net benefit may not be achieved in the near term, or at all.

# We expect to make significant additional investment in the future related to the acquisition of AdvanDx.

We anticipate that we will need to make significant investments in the AdvanDx business in order to make it profitable. Investing in the AdvanDx business could distract management attention and resources from the Company's current products and product development efforts. There can be no assurance that we can obtain sufficient resources or capital from operations or future financings to support the combined business operations. 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, or pursue other strategic alternatives which may include licensing and/or partnering arrangements or mergers and acquisitions.

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.

We have an existing collaboration with Hitachi High Technology related to the development of new products using our Whole Genome Mapping technology in human chromosome applications. 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. In addition, AdvanDx is likely to seek collaborative arrangement in the future as well. These collaborations are important to us. If any of our collaborators decides not to work with us in the future, or to curtail the scope of our collaboration, it could materially adversely affect our business.

A number of the AdvanDx products are regulated by the FDA and non-U.S. regulatory authorities. If we or our suppliers fail to comply with ongoing FDA, or other foreign regulatory authority, requirements, or if we experience unanticipated problems with the products, these products could be subject to restrictions or withdrawal from the market.

We do not have significant experience in complying with the rules and regulations of the FDA and foreign regulatory authorities. The AdvanDx products regulated as medical devices, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such products, are subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA's Quality System Regulations, or QSR, and International Standards Organization, or ISO, regulations for the manufacture, labeling, distribution and promotion of the AdvanDx 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 could 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.

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

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

If we were to lose, or have restrictions imposed on, the FDA clearances received to date, our business, operations, financial condition and results of operations is likely to be significantly adversely affected.

# Item 2. Unregistered Sales of Equity and Use of Proceeds

# **Unregistered Sales of Equity Securities**

On July 14, 2015, the Company completed the strategic acquisition of AdvanDx, through consummation of the Merger. Under the terms of the Merger Agreement, the Merger Consideration consisted of an aggregate 681,818 shares of the Company's common stock with a value of \$2.6 million (based on the closing sales price of our common stock of \$3.79 per share on July 13, 2015), which Merger Consideration was distributed in accordance with the liquidation preferences set forth in the AdvanDx Restated Certificate of Incorporation, as amended. The issuance of the Merger Consideration was effected as a private placement of securities deemed exempt from registration under Section 4(a)(2) of the Securities Act, and Rule 506 of Regulation D promulgated thereunder, regarding transactions by an issuer not involving a public offering. All stockholders of AdvanDx receiving Merger Consideration 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 stockholders 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. The Company entered into a Registration Rights Agreement with the AdvanDx stockholders receiving Merger Consideration.

On July 14, 2015, the Company also entered into the Purchase Agreement, with Merck GHI, pursuant to which Merck GHI purchased 1,136,364 shares of common stock of the Company at \$4.40 per share for gross proceeds of \$5,000,000. Pursuant to the Purchase Agreement, the Company also issued to Merck GHI a Senior Secured Promissory Note, in the principal amount of \$1,000,000 with a two-year maturity date from the date of issuance. The Company's obligations under the Note are secured by a lien on all of the Company's assets pursuant to the terms of a Security Agreement, dated as of July 14, 2015, by and among the Company and AdvanDx, as debtors, and Merck GHI as the secured party. The sale of the Securities was effected as a private placement transaction deemed to be exempt from registration under Section 4(a)(2) of the Securities Act regarding transactions by an issuer not involving a public offering. Merck GHI, the sole purchaser of securities deemed to be exempt, represented to us that it was an accredited investor and was acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that it could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchaser 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. The Company intends to use the proceeds from the sale of the Securities for working capital and other general corporate purposes, including funding AdvanDx's capital requirements in 2015 and 2016.

# 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 \$12.1 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.

# 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.

# **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.

By: /s/ Evan Jones

Evan Jones

Chief Executive Officer

Date: August 14, 2015

# EXHIBIT INDEX

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of July 14, 2015, among OpGen, Inc., Velox Acquisition Corp, AdvanDx, Inc., Stockholder Parties and Representatives (incorporated by reference to Exhibit 2.1 of Current Report on Form 8-K, File No. 001-37367, filed on July 16, 2015)
10.1	Agreement and Plan of Merger, dated as of July 14, 2015, among OpGen, Inc., Velox Acquisition Corp, AdvanDx, Inc., Stockholder Parties and Representatives (incorporated by reference to Exhibit 2.1 of Current Report on Form 8-K, File No. 001-37367, filed on July 16, 2015)
10.2	Common Stock and Note Purchase Agreement, dated as of July 14, 2015, between OpGen, Inc. and Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.1 of Current Report on Form 8-K, File No. 001-37367, filed on July 16, 2015)
10.3	Senior Secured Promissory Note, dated as of July 14, 2015, between OpGen, Inc. and Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.1 of Current Report on Form 8-K, File No. 001-37367, filed on July 16, 2015)
10.4	Registration Rights Agreement, dated as of July 14, 2015, among OpGen, Inc., Merck Global Health Innovation Fund, LLC, SLS Invest AB and LD Pensions (incorporated by reference to Exhibit 10.1 of Current Report on Form 8-K, File No. 001-37367, filed on July 16, 2015)
10.5*+	Letter Agreement, dated July 12, 2015, between OpGen, Inc. and Fluidigm Corporation
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
+	Confidential treatment has been requested for certain portions of this agreement pursuant to an application for confidential treatment filed with the Securities and Exchange Commission on August 14, 2015. Such provisions have been filed separately with the Commission.
	30

# EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

OpGen, Inc.

708 Quince Orchard Road Gaithersburg, MD 20878

July 9, 2015

Fluidigm Corporation 7000 Shoreline Court, Suite 100 South San Francisco, CA 94080 Attn: Paul Steinberg

SVP, Commercial Operations

William M. Smith

EVP, Legal Affairs & General Counsel

Dear Paul and Bill:

We are pleased to continue to work with Fluidigm Corporation, a Delaware corporation ("Fluidigm"). This letter agreement sets forth the understanding between Fluidigm and OpGen, Inc., a Delaware corporation ("OpGen") regarding the development, manufacturing, sale, marketing, and distribution of diagnostic and research-use-only tests by OpGen that are based on Fluidigm microfluidic technologies, and to establish the details to be captured in supporting agreements where appropriate. Upon execution of this letter agreement ("Agreement") and OpGen's satisfaction of the purchase requirements set forth in Section 4.A.iii below, each of OpGen and Fluidigm agree to be bound by the terms and conditions of this Agreement.

# 1. Strategic Relationship.

OpGen is developing molecular testing services and molecular information products based on Fluidigm microfluidic products and technologies. This Agreement formalizes the OpGen/Fluidigm relationship and expands the collaboration to include potential development of test kits, custom analytic instruments or preparatory systems, and regulatory compliance capabilities in an agreed upon Field (as defined below).

# 2. Fluidigm Technologies & Products.

Fluidigm has developed and is commercializing various Integrated Fluidic Circuits ("IFCs"), including Dynamic Array IFCs, Access Array IFCs, Digital Array IFCs and the Flex Six IFC. Fluidigm also has developed, and currently manufactures and commercializes, its Biomark HD and EP1 analytical instruments; several preparatory instruments, including the Access Array system and Juno system; and associated assay reagents. Such Fluidigm IFCs, instruments, and reagents are referred to in this Agreement as the "Fluidigm Technologies & Products."

# EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\*\*\*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Fluidigm Corporation July 9, 2015 Page 2

- 3. OpGen Tests. OpGen has developed the Acuitas® MDRO Gene Test and the Acuitas Resistome Test, which are currently available for sale as a CLIA lab-based test, and RUO test, respectively ("Current OpGen Tests"). OpGen anticipates expanding the gene targets and organisms to be tested on the Acuitas Resistome Test using IFCs to include additional MDRO gene targets, microbes, fungus, and viruses ("Expanded OpGen Tests"). OpGen also desires to work with Fluidigm to develop future tests using Fluidigm Technologies & Products ("Future OpGen Tests").
- 4. Supply Agreement, Resale and Distribution.

# A. Supply Agreement.

- i. Attached as Exhibit A is an Amendment to the Supply Agreement (the "Amendment"), effective as of March 17, 2015, between Fluidigm and OpGen (the "Supply Agreement"). Such Amendment extends the term of the Supply Agreement until March 17, 2018, with the option to renew the Supply Agreement subject to the conditions set forth in the Amendment. Any such renewal will be subject to annual CPI adjustment and other commercially reasonable adjustments to be negotiated between the parties. The parties to this Agreement will also negotiate additional terms for the Supply Agreement and this Agreement as may be required.
- ii. In addition, OpGen agrees to evaluate Fluidigm Master Mix (pre-amplification and analytical RT) products and to make reasonable efforts to switch supply to Fluidigm if (a) [\*\*\*\*\*\*\*\*\*\*\*] and (b) [\*\*\*\*\*\*\*\*\*\*\*]. OpGen will not be required to redevelop existing assay products or to develop new assay products using [\*\*\*\*\*].
- iii. As a condition to (a) the effectiveness of this Agreement and (b) obtain Tier 1 pricing under the Supply Agreement, OpGen must purchase under the Supply Agreement prior to June 30, 2015, notwithstanding any purchases prior to the date hereof:
  - a. Each of the items set forth in Quote #Q-10045 at Tier 1 pricing (as set forth in the Supply Agreement), which will be delivered in equal quarterly allotments beginning in the second calendar quarter of 2015 through the first calendar quarter of 2016:
  - b. a BioMark system at discounted pricing; and
  - c. a Juno system at discounted pricing,

in each case as specified in the quotes previously provided to OpGen and attached for convenience hereto as Exhibit B.

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Fluidigm Corporation July 9, 2015 Page 3

- B. Resale and Distribution. OpGen envisions enabling partner commercial laboratories, healthcare provider laboratories, and research or government laboratories to perform Current OpGen Tests, Expanded OpGen Tests and Future OpGen Tests or newly developed OpGen test capabilities using Fluidigm Technologies & Products (collectively, "OpGen Tests"). Fluidigm hereby licenses to OpGen the right to use products purchased by OpGen under the Supply Agreement to perform Current OpGen Tests and the Expanded OpGen Tests. At OpGen's request, the parties will enter into a Fluidigm distributor agreement on commercially reasonable terms for OpGen to purchase and resell Fluidigm-based test components for use only in the OpGen Tests. OpGen will be authorized to sell the Fluidigm-based test components globally on a direct basis, through Fluidigm, or through IVD distribution partners.
- C. <u>Analytical and Preparatory Instruments.</u> OpGen customers will purchase Fluidigm analytical and preparatory instruments directly from Fluidigm and Fluidigm will provide its standard warranty and make available its standard support. In accordance with Fluidigm's standard business practices, Fluidigm and OpGen will negotiate a volume discount schedule, aggregating all OpGen instrument purchases from Fluidigm, that is similar to Fluidigm distributor price volume schedules. OpGen and Fluidigm will negotiate a sales commission for instruments purchased by customers directly for use in OpGen Tests. In accordance with Fluidigm's standard business practices, the parties will negotiate the sales commission taking into account the overall distributor discount schedule noted above.
- D. <u>Research Use Only.</u> OpGen acknowledges that all Fluidigm Technologies & Products are sold: For Research Use Only. Not for use in diagnostic procedures.

# 5. Field.

A. <u>Field.</u> For purposes of this Agreement, the "Field" means diagnostic testing for the purpose of detecting resistome genes, including diagnostic screening testing and diagnostic surveillance testing for the MDRO genes in the Current OpGen Tests and Expanded OpGen Tests including genes for carbapenem resistance, for example, KPC (Klebsiella pneumonia carbapenemase), VIM (Verona integrin-encoded-β-lactamase), OXA β-lactamase including types 23, 48, 51; IMP; New Delhi metallo-β-lactamase, including type NDM-1; and extended spectrum beta-lactamase genes, or ESBL genes, for example CTX-M-1, and CTX-M-2 (see Appendix 1 for Current OpGen Test component genes and gene families).

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Fluidigm Corporation July 9, 2015 Page 4

- B. Certain Restrictions. If OpGen meets the Minimum Purchase Commitment (as defined below) for each applicable Minimum Purchase Commitment Period (as defined below), or even if OpGen does not meet the Minimum Purchase Commitment during such applicable Minimum Purchase Commitment Period but Fluidigm determines in its sole business judgment that OpGen is making reasonable progress commercializing one or more of the OpGen Tests in the Field, then Fluidigm shall not, during the then-immediately subsequent Minimum Purchase Commitment Period, develop, or directly Collaborate (as defined below) with any third party to develop, an FDA approved or CE marked diagnostic test, in each case using Fluidigm products that OpGen is then purchasing from Fluidigm in significant volumes ("Current Products"), in the Field independent of OpGen unless there is a change of control of Fluidigm or OpGen, or if Fluidigm approaches OpGen to develop a specific test for a material new test analyte and OpGen chooses not to promptly develop such test. For clarity, nothing in this Agreement will prevent or restrict Fluidigm from (i) conducting any activities outside of the Field, or (ii) marketing or selling, or providing commercial support in connection with the sale of any, Fluidigm products or services to any person or entity for any purpose or use and without restriction, provided, that Fluidigm shall not Collaborate with any such person or entity. For the purposes of this Agreement, the following terms shall have the meanings set forth below:
  - i. "Collaborate" means the joint development by Fluidigm and any company of a commercial product in the Field. For clarity, the definition of "Collaborate" shall be deemed not include the sale by or on behalf of Fluidigm of any then-current commercially available products or services, or the provision of any standard commercial support in connection with the sale of such products or services, such support to include, without limitation, the provision of any applicable documentation to a customer in connection with the support of a customer's quality system, regulatory, or compliance needs.
  - ii. "Minimum Purchase Commitment" means the number of products OpGen must purchase under the Supply Agreement during any applicable Minimum Purchase Commitment Period that equals or exceeds the number of products that must be purchased to receive [\*\*\*\*\*] volume pricing as set forth in Exhibit A to the Supply Agreement.
  - iii. "Minimum Purchase Commitment Period" means, as applicable, the consecutive twelve (12) month period ending on the third anniversary of the date hereof, and each subsequent twelve (12) month period thereafter.

# 6. Marketing Cooperation.

OpGen and Fluidigm may establish a marketing cooperation agreement to promote the sale of the Current OpGen Tests and the Expanded OpGen Tests to existing Fluidigm customers.

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Fluidigm Corporation July 9, 2015 Page 5

# 7. Joint Development.

- A. Fluidigm and OpGen may evaluate opportunities to develop Future OpGen Tests. Neither company will be obligated to undertake such development work. The companies may also work together to develop improved solutions and workflows and regulatory compliant products. This opportunity to work together is not binding on either company.
- B. In September 2014, The White House issued a National Strategy for combating antibiotic-resistant bacteria. The strategy calls for the strengthening of surveillance efforts to combat resistance, the development and use of innovative diagnostic tests for identification and characterization of resistant bacteria and antibiotic stewardship and development. Fluidigm and OpGen intend to work together to address these needs and to seek government funding for development of new products and technologies based on Fluidigm Technologies & Products and OpGen molecular testing services and products and molecular information products.
- C. To the extent any Current OpGen Tests, Expanded OpGen Tests and Future OpGen Tests rely on Fluidigm instrument output or software analysis features, such as the Biomark HD instrument, the parties will work together to assure that changes by Fluidigm to any such Fluidigm Technologies or Products will continue to support the OpGen test products.

# 8. Quality Systems, Regulatory & Compliance.

Fluidigm and OpGen will work together to support OpGen quality systems, regulatory, and compliance needs. Each company will pay for its own work. If Fluidigm elects not to undertake an OpGen desired regulatory or quality initiative then the companies will work in good faith to develop a plan and activities funded by OpGen to address such needs.

# 9. <u>Term.</u>

The initial term of this Agreement is five (5) years after the date on which this Agreement is signed by duly authorized representatives of both parties. Each party has an option to renew this Agreement for a subsequent five (5) year term at the conclusion of the fourth year of the initial term. The initial term and any subsequent renewal is the "Term" of this Agreement. After the Term, Fluidigm will continue to supply and support OpGen for seven (7) years, provided that such products have not been discontinued by Fluidigm. If Fluidigm discontinues products covered by this Agreement and OpGen determines it has continuing customer demand to be filled then Fluidigm will work in good faith with OpGen to transition OpGen to new versions, if any, of the products.

# 10. Fluidigm Trademarks, Patent Labeling.

Fluidigm and OpGen will work together to address expanded trademark, patent and other labeling requirements that may arise from this Agreement.

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Fluidigm Corporation July 9, 2015 Page 6

# 11. Confidentiality and Public Announcements.

- A. <u>Confidentiality.</u> The terms and conditions of Section 3 of the Supply Agreement shall apply to this Agreement as though set forth in full herein, regardless of any termination or expiration of the Supply Agreement. As applied to this Agreement, any reference, in such Section 3, to "this Agreement" or "herein" or the like shall be a reference to this Agreement.
- B. Public Announcements. Neither OpGen nor Fluidigm shall make any public announcement concerning this Agreement, nor make any public statement which includes the name of the other party or any of its affiliates, or otherwise use the name of the other party or any of its affiliates in any public statement or document without the consent of the other, which consent shall not be unreasonably withheld, except: (a) as may be required by law or judicial order, including required disclosure under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any exchange on which either party's equity securities are listed; (b) as may be contained in joint marketing materials, presentations and related activities; (c) that OpGen and Fluidigm may provide general information, including aggregate revenue information in the normal course of its business and in response to inquiries; or (d) that either party may include in a subsequent public statement or document, information regarding this Agreement which has already been approved for disclosure by the other party.
- C. <u>Confidential Treatment.</u> To the extent either party is required by the rules and regulations of the Securities and Exchange Commission to file this Agreement with its periodic reports or financing documents, the party so filing shall seek confidential treatment for the provisions of this Agreement for which such confidential treatment can be sought. The party filing this Agreement will provide the other party with a reasonable period to review and comment upon the confidential treatment filing.

# 12. OpGen's Obligations.

In addition to OpGen's obligations set forth elsewhere in this Agreement and the Supply Agreement, as amended, OpGen shall after the date of this Agreement:

- A. Use reasonable commercial efforts to promote, develop a market for and sell the Current OpGen Tests and the Expanded OpGen Tests after they are released for sale, utilizing the Fluidigm Technologies & Products, for research-use and human in vitro diagnostics;
- B. Promptly respond to all customer complaints about any Resale or Distribution products, promptly notify Fluidigm of any recall or complaints; and
- C. Obtain, at its own expense, any import or export license, foreign exchange license, foreign exchange permit, or other permit or approval it may need for the resale of Fluidigm Technologies & Products hereunder and otherwise comply with all laws, regulations, rules and requirements governing the sale of the Fluidigm Technologies & Products; provided, however, that, at the request and expense of OpGen, Fluidigm will aid OpGen in gaining regulatory approvals where help and information relating to the Fluidigm Technologies & Products is required.

Fluidigm Corporation July 9, 2015 Page 7

#### 13. OpGen Representations.

OpGen represents to Fluidigm to the best of its knowledge that:

- A. OpGen is duly organized and validly existing in good standing under the laws of the State of Delaware, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof:
- B. OpGen has validly taken all requisite corporate action to properly authorize the execution of this Agreement and to fulfill its obligations bereunder:
- C. OpGen has all the necessary corporate right, power and authority to enter into this Agreement.

#### 14. Fluidigm Representations and Warranties.

In addition to the Fluidigm Sales Terms and Conditions Effective December 26, 2013 incorporated as Exhibit B of the Supply Agreement, as amended, Fluidigm expands its warranties as follows.

- A. Each Fluidigm Product (other than chips) supplied to OpGen will, for the period specified in the product specifications to be agreed upon, conform to such product specifications. At OpGen's request Fluidigm will provide a Certificate of Analysis with each lot of product shipped to OpGen. Fluidigm makes the foregoing warranties to and for the benefit of OpGen only, and they may not be assigned to any other party.
- B. If any Fluidigm Product does not conform with the foregoing warranties, Fluidigm's sole obligation with respect thereto shall be to replace such Fluidigm Technology or Fluidigm Product without charge or expense to OpGen or, at Fluidigm option, to credit OpGen for the amount paid by OpGen to Fluidigm for such Fluidigm Technology or Fluidigm Product.
- C. The above warranties are contingent upon the proper use, storage and shipment of the Fluidigm Technology or Fluidigm Product and shall be void with respect to defects or failures due to disaster, accident, neglect, misuse, or improper storage or shipment (in each case not attributable to Fluidigm).
- $D. \quad Fluidigm \ represents \ to \ OpGen \ to \ the \ best \ of \ its \ knowledge \ that:$ 
  - iv. Fluidigm is duly organized and validly existing in good standing under the laws of the State of Delaware, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
  - v. Fluidigm has validly taken all requisite corporate action to properly authorize the execution of this Agreement and to fulfill its obligations hereunder;
  - vi. Fluidigm has all the necessary corporate right, power and authority to enter into this Agreement and to grant to OpGen.

Fluidigm Corporation July 9, 2015 Page 8

E. One of the supporting documents shall provide protection for recoupment of OpGen damages if known Fluidigm defective product result in product recalls from customers who purchase such Fluidigm products through OpGen.

#### 15. Dispute Resolution.

Within sixty (60) days after the date of this Agreement, the parties will review the dispute resolution procedures in the Supply Agreement, and determine whether to utilize such procedures under this Agreement or develop alternative dispute resolution procedures.

#### 16. Miscellaneous.

- A. Waiver; Amendment. The failure of either Party to enforce its rights under this Agreement at any time for any period shall not be construed as a waiver of such rights. Further, no changes or modifications or waivers can be made to this Agreement unless evidenced in writing and signed by both Parties.
- B. Severability. If any provision of this Agreement shall be determined to be unenforceable, all other provisions shall remain in full force and effect, the affected provision shall be construed so as to be enforceable to the maximum extent possible, and the parties shall negotiate and substitute a suitable and equitable provision in order to carry out, so far as may be valid and enforceable, the intent and purpose of such unenforceable provision.
- C. Assignment. Neither party shall assign, transfer, subdivide or otherwise deal with any obligations or benefit under this Agreement without the prior written consent of the other party. provided that either party may freely assign this Agreement to a successor to all or substantially all of its relevant assets, whether by sale, merger, or otherwise. Any attempted assignment in violation of this section shall be null and void.
- D. Governing Law. 'This Agreement shall be governed by and construed in accordance with the laws of the State of California without regard to any conflicts of laws provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.
- E. <u>Limitation of Liability</u>. IN NO EVENT SHALL FLUIDIGM'S AGGREGATE LIABILITY ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT EXCEED THE AMOUNTS RECEIVED BY FLUIDIGM UNDER THIS AGREEMENT. IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY COSTS OF SUBSTITUTE PRODUCTS OR SERVICES OR FOR ANY LOST PROFITS OR SPECIAL, CONSEQUENTIAL, INDIRECT, OR INCIDENTAL DAMAGES (INCLUDING LOSS OF PROFITS, LOSS OF SALES, LOSS OF REVENUE, LOSS OR WASTE OF MANAGEMENT OR STAFF TIME), HOWEVER CAUSED. ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH

Fluidigm Corporation July 9, 2015 Page 9

DAMAGES, ARISING IN ANY WAY OUT OF OR IN CONNECTION WITH THIS AGREEMENT. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

- F. Force Majeure. Neither party shall be liable for any failure to perform ally term or condition of this Agreement to the extent performance has been delayed, hindered or prevented by tire, earthquake, flood, compliance with requirements of any governmental authority, or by any other circumstances beyond its reasonable control.
- G. Notices. Except as otherwise set forth in this Agreement, any notice required or permitted under this Agreement or required by law must be in writing and must be (i) delivered in person, (ii) sent by registered or certified mail, (iii) sent by overnight air courier, (iv) sent by email, or (v) sent by facsimile, in each case properly posted and fully prepaid to the appropriate address set forth in the table below.

If to OpGen:	If to Fluidigm:
708 Quince Orchard Road	7000 Shoreline Court, Suite 100
Gaithersburg, MD. 20878	South San Francisco, California 94080
Attention: Tim Dec, CFO	Attention: General Counsel
Telephone: 301-869-9683 Ext. 1273	Telephone: (650) 266-6000
email: tdec@opgen.com	email: legal@fluidigm.com
Facsimile: 301-869-9684	Facsimile: (650) 871-7195

Notices under this section will be considered to have been given at the time of actual personal delivery in person, three (3) calendar days (excluding Saturdays, Sundays and public holidays in the United States) after deposit in the mail as set forth above, one day after delivery to an overnight air courier service, upon transmission if by email, or upon confirmed transmission if by facsimile. Either party may change its address or facsimile number for notification purposes by giving the other party written notice of the new address or facsimile number in accordance with this section.

- H. Relationship of Parties. The relationship between the parties will be that of independent contractors. Each party shall not represent itself as the agent or legal representative of the other party for any purpose whatsoever, and shall have no right to create or assume any obligation of any kind, express or implied, for or on behalf of the other party in any way whatsoever. This Agreement will not create or be deemed to create any agency, partnership or joint venture between the parties.
- I. Entire Agreement. This Agreement, and all exhibits attached hereto, constitutes the entire understanding and contract between the parties and supersedes any and all prior and contemporaneous, oral or written representations, communications, understandings, term sheets, and agreements between the parties with respect to the subject matter hereof. The

Fluidigm Corporation July 9, 2015 Page 10

> parties acknowledge and agree that neither of the parties is entering into this Agreement on the basis of any representations or promises not expressly contained herein. This Agreement shall exclusively govern the ordering, purchase, and supply of the Products, and shall nullify any conflicting, amending, and/or additional terms contained in any purchase orders, invoices, or similar documents, which are hereby rejected and shall be null and void.

Counterparts. This Agreement may be executed in any number of counterparts which, when taken together, will constitute one original, and photocopy, facsimile, electronic or other copies shall have the same effect for all purposes as an ink-signed original. Each party hereto consents to be bound by photocopy or facsimile signatures of such party's representative hereto.

We are excited to expand on our relationship with Fluidigm. If you are in agreement with the terms and conditions of this Agreement, please execute this Agreement in the space provided below and return to me.

> Best Regards, OPGEN INC.

/s/ Timothy C. Dec Timothy C. Dec

Chief Financial Officer

AGREED TO BY: FLUIDIGM CORPORATION

By: /s/ Steve McPhail Name: Steve McPhail

Title: GM, Production Genomics

Date: 12 July 2015

## EXHIBIT A TO LETTER AGREEMENT AMENDMENT TO THE SUPPLY AGREEMENT

This Amendment to the Supply Agreement (the "Amendment"), effective as of March 17, 2015 (the "Amendment Effective Date"), amends that certain Supply Agreement, effective as of March 17, 2014 (the "Supply Agreement"), between Fluidigm Corporation ("Fluidigm") and OpGen, Inc. ("OpGen"). All capitalized terms used in this Amendment without definition have the meanings set forth in the Supply Agreement.

WHEREAS, the parties to the Supply Agreement desire to amend the Supply Agreement to extend the term of the Supply Agreement and to add to the Supply Schedule thereto.

NOW, THEREFORE, for good and valuable consideration, Fluidigm and OpGen agree as follows.

- 1. <u>Extension of Term.</u> Section 4.1 of the Supply Agreement is hereby deleted and replaced in its entirety with the following:
  - **"4.1 Term.** This Agreement shall continue in full force and effect from the Effective Date until March 17, 2018, unless and until terminated as set forth in this Agreement. OpGen has the right to extend the term of this Agreement for two (2) additional three-year terms by providing written notice to Fluidigm at least sixty (60) days prior to the end of the then-current term. Any such renewal will be subject to annual CPI adjustment and other commercially reasonable adjustments to be negotiated between the parties."
- 2. <u>Products and Prices</u>. The Exhibit A attached to this Amendment shall be the Exhibit A for the Supply Agreement as of and after the Amendment Effective Date unless further amended by the Parties. In addition, "Products" shall also include Fluidigm's Biomark instruments.
- 3. Supply Agreement in Full Force and Effect. The Supply Agreement, as amended by this Amendment, remains in full force and effect.

[Signatures on Next Page.]

**IN WITNESS WHEREOF**, this Amendment has been executed by duly authorized representatives of the Parties as of the Amendment Effective Date.

FLUIDIGM CORPORATION OPGEN, INC.

By: /s/ Timothy C. Dec By: /s/ Steve McPhail

Timothy C. Dec. Name: Name: Steve McPhail

Chief Financial Officer Title: Title: GM, Production Genomics July 9, 2015 Date:

12 July 2015 Date:

[Signature Page to Amendment to the Supply Agreement]

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### Exhibit A to Supply Agreement Fluidigm/OpGen Supply Agreement Supply Schedule FLDM Products and Specifications

Item No.	Product Name	Description	Unit		
[****	96.96 Dynamic Array Chip for Gene Expression	Microfluidic chip	Chip		
[****	GE 96.96 Dynamic Array	Control line fluid, sample loading reagent, and assay	Kit		
	Sample & Assay Loading Reagent Kit	loading reagent for 10 chips			
[****	192.24 GE Dynamic Array IFC	Microfluidic chip	Chip		
[*****]	192.24 GE Dynamic Array	Control line fluid, sample loading reagent, and assay	Kit		
	Sample & Assay Loading Reagent Kit	loading reagent for 10 chips			

### **FLDM Product Volume Pricing**

Item								
		L	ist Price	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5
OPGN Tests								
(000's)	Quantity			[*****]	[*****]	[*****]	[*****]	[*****]
Total FLDM Chip Forecast (96.96								
and 192.24)	Quantity			[****	[*****]	[*****]	[*****]	[*****]
FLDM 96.96 Dynamic Array Chips								
BMK-M-96.96	Unit Price	\$	[*****]	\$ [*****]	\$ [*****]	\$ [*****]	\$ [*****]	\$ [*****]
FLDM Dynamic Array Loading								
Kits 85000802	Unit Price	\$	[*****]	\$ [*****]	\$ [*****]	\$ [*****]	\$ [*****]	\$ [*****]
FLDM 192.24 Dynamic Array								
Chips								
100-6266	Unit Price	\$	[*****]	\$ [*****]	\$ [*****]	\$ [*****]	\$ [*****]	\$ [*****]
FLDM Dynamic Array Loading								
Kits 100-6267	Unit Price	\$	[*****]	\$ [*****]	\$ [*****]	\$ [*****]	\$ [*****]	\$ [*****]
FLDM Master Mix (STA/RT: 480								
Samples) 100-6301	Unit Price	\$	[*****]	\$ [****	\$ [*****]	\$ [*****]	\$ [****	\$ [*****]

The above price volume schedule is based on total annual number of tests performed by OpGen using either the 96.96 chip format or the 192.24 chip format. All OpGen purchases after March 17, 2014 will count toward OpGen's purchase volume for 2015 pricing.

\*2015 chip quantity includes [\*\*\*\*\*] of 96.96 chips at no-charge to OPGN as a product rebate allowance from FLDM for R&D evaluation of the 96.96 chip format by OPGN.

### EXHIBIT B TO LETTER AGREEMENT

1.	[********
2.	[********
3.	[**********

### Appendix 1 OpGen Current Tests Component Genes/Gene Families

### Acuitas® MDRO Gene Test

KPC, NDM, VIM, IMP, OXA-48, OXA-23, OXA-51, CTX-M, VanA

### Acuitas® Resistome Test

ACC, ACT, BEL, BES, CMY, CTX-M, DHA-1, FOX-1, GIM-1, GES-1, IMI-1/NMCA-1, IMP, KPC-2, MOX-1/CMY-1, NDM-1, OXA, PER-1, SFC-1, SIM-1, SME-1, SHV, SPM-1, TEM, TLA-1, VEB-1, VIM

#### 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: August 14, 2015	
/s/ Evan Jones	
Evan Jones	
Chief Executive Officer (principal executive office	er)

#### 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: August 14, 2015

/s/ Timothy C. Dec

Timothy C. Dec

Chief Financial Officer (principal financial officer and principal accounting

officer)

# 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 June 30, 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: August 14, 2015 By: /s/ Evan Jones

Evan Jones

Chief Executive Officer (principal executive officer)

Date: August 14, 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.