

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

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2016

or

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

For the transition period from _____ to _____
Commission File Number 001-37367

OPGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

06-1614015

(I.R.S. employer
identification no.)

708 Quince Orchard Road, Suite 205, Gaithersburg, MD

(Address of principal executive offices)

20878

(Zip code)

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>

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

12,581,790 shares of the Company's common stock, par value \$0.01 per share, were outstanding as of May 11, 2016.

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 (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In this quarterly report, 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 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 products, including our QuickFISH® and PNA FISH diagnostic products for infectious diseases, our Acuitas® MDRO test services and our Acuitas Lighthouse™ bioinformatics services;
- our liquidity and working capital requirements, including our cash requirements over the next 12 months and beyond;
- anticipated trends and challenges in our business and the competition that we face;
- the execution of our business plan and our growth strategy;
- our expectations regarding the size of and growth in potential markets;
- our opportunity to successfully enter into new collaborative agreements;
- changes in laws or regulations applicable to our business, including potential regulation by the FDA;
- our ability to develop and commercialize new products and the timing of commercialization;
- integration of the operations of AdvanDx, Inc. acquired by merger on July 14, 2015;
- compliance with the U.S. and international regulations applicable to our business; and
- our expectations regarding future revenue and expenses.

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

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 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.

NOTE REGARDING TRADEMARKS

We own various U.S. federal trademark registrations and applications and unregistered trademarks and servicemarks, including OpGen®, Acuitas®, Acuitas Lighthouse™ Argus®, AdvanDx®, QuickFISH® and PNA FISH®. All other trademarks, servicemarks or trade names referred to in this quarterly report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this quarterly report are sometimes referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies, products or services.

Part I — FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

OpGen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	<u>March 31, 2016</u>	<u>December 31, 2015</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 3,967,957	\$ 7,814,220
Accounts receivable, net	641,575	678,646
Inventory, net	924,345	826,012
Prepaid expenses and other current assets	456,008	566,239
Total current assets	5,989,885	9,885,117
Property and equipment, net	996,564	1,074,710
Goodwill	600,814	637,528
Intangible assets, net	1,821,860	1,888,814
Other noncurrent assets	270,503	270,327
Total assets	\$ 9,679,626	\$ 13,756,496
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 2,205,538	\$ 2,285,792
Accrued compensation and benefits	1,260,839	1,081,270
Accrued liabilities	930,941	920,286
Deferred revenue	51,794	50,925
Current maturities of long-term capital lease obligation	242,459	251,800
Total current liabilities	4,691,571	4,590,073
Deferred rent	461,552	352,985
Long-term capital lease obligation and other noncurrent liabilities	277,190	328,642
Notes payable	994,792	993,750
Total liabilities	6,425,105	6,265,450
Stockholders' equity		
Common stock, \$.01 par value; 200,000,000 shares authorized; 12,576,306 and 12,547,644 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	125,763	125,477
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued at March 31, 2016 and December 31, 2015 (Note 8)	-	-
Additional paid-in capital	121,761,475	121,490,994
Accumulated other comprehensive loss	(2,171)	(1,059)
Accumulated deficit	(118,630,546)	(114,124,366)
Total stockholders' equity	3,254,521	7,491,046
Total liabilities and stockholders' equity	\$ 9,679,626	\$ 13,756,496

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2016	2015
Revenue		
Product sales	\$ 947,219	\$ 184,179
Laboratory services	129,420	35,241
Collaboration revenue	-	252,780
Total revenue	1,076,639	472,200
Operating expenses		
Cost of products sold	345,967	115,389
Cost of services	315,709	95,430
Research and development	1,953,429	1,108,602
General and administrative	1,538,046	659,392
Sales and marketing	1,399,435	1,024,029
Total operating expenses	5,552,586	3,002,842
Operating loss	(4,475,947)	(2,530,642)
Other income (expense)		
Interest and other income	173	35
Interest expense	(41,734)	(96,397)
Foreign currency transaction gains	11,328	-
Change in fair value of derivative financial instruments	-	31,831
Total other income (expense)	(30,233)	(64,531)
Net loss	(4,506,180)	(2,595,173)
Preferred stock dividends	-	(171,741)
Net loss available to common stockholders	\$ (4,506,180)	\$ (2,766,914)
Net loss per common share - basic and diluted	\$ (0.36)	\$ (5.61)
Weighted average shares outstanding - basic and diluted	12,568,941	493,463
Net loss	\$ (4,506,180)	\$ (2,595,173)
Other comprehensive loss - foreign currency translation	(1,112)	-
Comprehensive loss	\$ (4,507,292)	\$ (2,595,173)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities		
Net loss	\$ (4,506,180)	\$ (2,595,173)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	168,440	106,133
Loss on disposal of property and equipment	6,068	-
Noncash interest expense	1,042	17,123
Share-based compensation	261,497	590,603
Inventory obsolescence	15,034	3,604
Change in fair value of derivative financial instruments	-	(31,831)
Changes in operating assets and liabilities, net of effects of acquisition:		
Accounts receivable	39,411	411,999
Inventory	(112,883)	45,331
All other assets	199,182	(25,854)
Accounts payable	(80,276)	(319,483)
Accrued compensation and other liabilities	211,979	145,016
Deferred revenue	869	(64,619)
Net cash used in operating activities	(3,795,817)	(1,717,151)
Cash flows from investing activities		
Purchases of property and equipment (net of proceeds on disposals)	(1,644)	(10,034)
Net cash used in investing activities	(1,644)	(10,034)
Cash flows from financing activities		
Proceeds from issuance of convertible notes and warrants, net of issuance costs	-	1,388,913
Proceeds from issuance of promissory notes, net of issuance costs	-	500,000
Proceeds from exercise of stock options and warrants	9,271	55
Proceeds from initial public offering, net of issuance costs paid in 2015	-	(252,715)
Payments on debt	-	(1,250)
Payments on capital lease obligations	(63,327)	(25,640)
Net cash provided by (used in) financing activities	(54,056)	1,609,363
Effects of exchange rates on cash	5,254	-
Net decrease in cash and cash equivalents	(3,846,263)	(117,822)
Cash and cash equivalents at beginning of period	7,814,220	749,517
Cash and cash equivalents at end of period	\$ 3,967,957	\$ 631,695
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	\$ 13,021	\$ 6,865
Supplemental disclosure of noncash investing and financing activities:		
Acquisition of equipment purchased through capital leases	\$ -	\$ 76,745
Property and equipment purchased on credit	\$ 27,767	\$ -
Deferred and accrued financing costs	\$ 52,210	\$ 218,656
Exchange of demand note for convertible debt	\$ -	\$ 300,000

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
March 31, 2016

Note 1 - Organization

OpGen, Inc. (“OpGen” or the “Company”) was incorporated in Delaware in 2001. On July 14, 2015, OpGen completed the strategic acquisition (the “Merger”) of AdvanDx, Inc. and its wholly owned subsidiary AdvanDx A/S (collectively, “AdvanDx”) (see Note 4). Pursuant to the terms of a merger agreement, Velox Acquisition Corp., OpGen’s wholly owned subsidiary formed for the express purpose of effecting the Merger, merged with and into AdvanDx, Inc. with AdvanDx, Inc. surviving as OpGen’s wholly owned subsidiary. OpGen, AdvanDx, Inc. and AdvanDx A/S are collectively referred to hereinafter as the “Company.” The Company’s headquarters are in Gaithersburg, Maryland, and its principal operations are in Gaithersburg, Maryland and Woburn, Massachusetts. The Company also has operations in Copenhagen, Denmark. The Company operates in one business segment.

OpGen is a precision medicine company using molecular diagnostics and informatics to combat infectious disease. OpGen is developing molecular information solutions to combat infectious disease in global healthcare settings, helping to guide clinicians with more rapid information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms. The Company’s proprietary DNA tests and bioinformatics address the rising threat of antibiotic resistance by helping physicians and healthcare providers optimize patient care decisions and protect the hospital biome through customized screening and surveillance solutions. The Company’s molecular information solution combines Acuitas® DNA tests, Acuitas Lighthouse™ bioinformatics and CLIA lab services for MDRO genetic identification, antibiotic resistance gene information and surveillance, and a proprietary data warehouse including genomic data matched with antibiotic susceptibility information for microbes and patient information from healthcare providers. The Company is working to deliver its molecular information products and services to a global network of customers and partners. The Acuitas DNA tests provide rapid microbial ID, and antibiotic resistance gene information. These include the QuickFISH® family of FDA-cleared and CE-marked diagnostic products used to rapidly detect pathogens in positive blood cultures, the MDRO Gene Test to detect, type, track, and trend antibiotic resistant organisms in real-time and a rapid antibiotic resistance test in development.

The Company’s operations are subject to certain risks and uncertainties. The risks include rapid technology changes, the need to manage growth, the need to retain key personnel, the need to protect intellectual property and the need to raise additional capital financing on terms acceptable to the Company. The Company’s success depends, in part, on its ability to develop and commercialize its proprietary technology as well as raise additional capital.

Note 2 – Liquidity and management’s plans

The accompanying unaudited condensed consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Since inception, the Company has incurred, and continues to incur, significant losses from operations. The Company has funded its operations primarily through external investor financing arrangements. The Company raised significant funds in 2015, including:

- \$0.8 million in short-term 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, and in the second quarter of 2015, \$0.2 million of notes from a related party were repaid in cash);
- \$1.5 million through the issuance of convertible notes;
- \$12.1 million in net proceeds from its initial public offering (“IPO”) as discussed further below; and
- \$6.0 million in net proceeds from the issuances of common stock and a senior secured promissory note to Merck Global Health Innovation Fund, LLC (“Merck GHI”).

On May 8, 2015, OpGen completed its IPO pursuant to which it offered and sold 2,850,000 units, each Unit consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of \$6.00 per unit. Of the total gross proceeds of \$17.1 million, approximately \$2.1 million was used to satisfy outstanding demand notes by exchanging such notes for 350,000 Units in the IPO. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds were \$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 OpGen’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 raised \$6.0 million by issuing 1,136,364 shares of common stock at \$4.40 per share and a \$1.0 million senior secured promissory note to Merck GHI. Also in July 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.

On May 11, 2016, the Company priced a private placement financing under which, upon closing, it expects to receive \$10.4 million upon the issuance of units, each unit consisting of one share of common stock and a warrant to acquire 0.75 of a share of common stock.

Current cash on hand will be sufficient to fund operations into the second quarter of 2016. Once the May 2016 financing is closed, cash on hand, plus the net proceeds from the May 2016 financing, will be sufficient to fund operations into the first quarter of 2017. In the event the Company is unable to successfully raise additional capital in or before the first quarter of 2017, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to 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 condensed consolidated 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 and consolidation

The accompanying interim condensed consolidated financial statements are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all the information and footnotes required by U.S. Generally Accepted Accounting Principles ("GAAP") for complete financial statements. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes for the year ended December 31, 2015 previously filed with the SEC. In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all the adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of March 31, 2016 and the results of operations and cash flows for the three months ended March 31, 2016 and 2015. The interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2015 consolidated balance sheet included herein was derived from the audited consolidated financial statements, but do not include all disclosures including notes required by GAAP for complete financial statements.

The accompanying unaudited interim condensed consolidated financial statements include the accounts of OpGen and its wholly owned and controlled subsidiaries; all intercompany transactions and balances have been eliminated. The Company operates in one business segment. Certain prior period information has been reclassified to conform to the current period presentation.

Foreign Currency

AdvanDx A/S is located in Copenhagen, Denmark and uses the Danish Krone as its functional currency. As a result, all assets and liabilities are translated into U.S. dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the average exchange rates prevailing during the reporting period. Translation adjustments are reported in accumulated other comprehensive loss, a component of stockholder's equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive loss at March 31, 2016 and December 31, 2015.

Foreign currency transaction gains and losses, excluding gains and losses on intercompany balances where there is no current intent to settle such amounts in the foreseeable future, are included in the determination of net loss.

Unless otherwise noted, all references to "\$" or "dollar" refer to the U.S. dollar.

Use of estimates

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

Fair value of financial instruments

All financial instruments classified as current assets and liabilities are carried at cost, which approximates fair value, because of the short-term maturities of those instruments. The carrying value of the Company's debt is reflective of fair value based on instruments with similar terms available to the Company.

For additional fair value disclosures, see Note 6.

Cash and cash equivalents

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

At March 31, 2016 and December 31, 2015, the Company has funds totaling \$243,380, which are required as collateral for letters of credit benefiting its landlords and for credit card processors. These funds are reflected in other non-current assets on the accompanying condensed consolidated balance sheets.

Accounts receivable

The Company's accounts receivable result from revenues earned but not collected from customers. Credit is extended based on an evaluation of a customer's financial condition and, generally, collateral is not required. Accounts receivable are due within 30 to 60 days and are stated at amounts due from customers. The Company evaluates if an allowance is necessary by considering a number of factors, including the length of time accounts receivable are past due, the Company's previous loss history and the customer's current ability to pay its obligation. If amounts become uncollectible, they are charged to operations when that determination is made. The allowance for doubtful accounts was \$13,352 and \$15,596 as of March 31, 2016 and December 31, 2015, respectively.

At March 31, 2016, the Company had no accounts receivable from any individual customer in excess of 10% of total accounts receivable. There was no revenue earned from any individual customer in excess of 10% of total revenue during the three months ended March 31, 2016. For the three months ended March 31, 2015, revenue earned from Hitachi High-Technologies Corporation represented 54% of total revenues; this customer contract was completed as of December 31, 2015.

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:

	<u>March 31, 2016</u>	<u>December 31, 2015</u>
Raw materials and supplies	\$ 600,044	\$ 362,526
Work-in process	127,130	150,369
Finished goods	197,171	313,117
Total	<u>\$ 924,345</u>	<u>\$ 826,012</u>

Inventory includes the Argus Whole Genome Mapping Systems, reagents and supplies used for Argus consumable kits, reagents and components for QuickFISH and PNA FISH kit products, and reagents and supplies used for the Company's laboratory services. Inventory reserves for obsolescence and expirations were \$614,109 and \$599,064 at March 31, 2016 and December 31, 2015, respectively.

Long-lived assets

Property and equipment

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the three months ended March 31, 2016 and 2015, the Company determined that its property and equipment was not impaired.

Intangible assets and goodwill

Intangible assets and goodwill as of March 31, 2016 were acquired as part of the Merger, and consist of definite-lived intangible assets and goodwill.

Definite-lived intangible assets

Definite-lived intangible assets include trademarks, developed technology and customer relationships, and are amortized over their useful lives of 10, 7 and 7 years, respectively, and consisted of the following as of March 31, 2016:

	Cost	Accumulated Amortization	Net balance at March 31, 2016
Trademarks and tradenames	\$ 461,000	\$ (32,838)	\$ 428,162
Developed technology	458,000	(46,607)	411,393
Customer relationships	1,094,000	(111,695)	982,305
	<u>\$ 2,013,000</u>	<u>\$ (191,140)</u>	<u>\$ 1,821,860</u>

Total amortization expense of intangible assets was \$66,954 for the three months ended March 31, 2016 (none in the same period of 2015). Amortization of intangible assets is expected to be approximately \$268,000 per year for the next five years.

Definite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any. During the three months ended March 31, 2016 and 2015, the Company determined that its definite-lived intangible assets were not impaired.

Goodwill

Goodwill represents the excess of the purchase price for AdvanDx over the fair values of the acquired tangible or intangible assets and assumed liabilities. Goodwill is not tax deductible in any relevant jurisdictions. As a result of the Merger and subsequent measurement period adjustments recognized in 2016 and 2015, the Company recognized goodwill of \$600,814.

The Company conducts an impairment test of goodwill on an annual basis as of October 1 of each year, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value. During the three months ended March 31, 2016, the Company determined that its goodwill was not impaired.

Redeemable convertible preferred stock

All shares of Series A redeemable convertible preferred stock ("Series A Preferred Stock") (including those shares issued in connection with the conversion of the 2014 and 2015 convertible debt), were converted into 7,374,852 shares of common stock in connection with the Company's IPO (see Notes 7 and 8).

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 March 31, 2015, 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 redemption provisions outside of the Company's control.

Revenue recognition

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

Amounts billed to customers for shipping and handling are included in revenue when the related product or service revenue is recognized. Shipping and handling costs are included in cost of 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 QuickFISH, PNA FISH and XpressFISH diagnostic test products

Revenue is recognized upon shipment to the customer. Sales are recorded net of accruals for estimated rebates, discounts and other deductions and returns.

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 had federal net operating loss ("NOL") carryforwards of \$90,297,000 at December 31, 2015. Despite the NOL carryforwards, which begin to expire in 2022, the Company may have future tax liability due to alternative minimum tax or state tax requirements. Also, use of the NOL carryforwards may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"). To date, the Company has not performed a formal study to determine if any of its remaining NOL and credit attributes might be further limited due to the ownership change rules of Section 382 or Section 383 of the Code. The Company will continue to monitor this matter going forward. There can be no assurance that the NOL carryforwards will ever be fully utilized.

Loss per share

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

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

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The number of anti-dilutive shares, consisting of (i) common stock options, (ii) stock purchase warrants, and (iii) 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 5.9 million shares and 8.9 million shares for the three months ended March 31, 2016 and 2015, respectively. The Company's convertible preferred stock, prior to its conversion, contained non-forfeitable rights to dividends, and therefore was considered to be a participating security; the calculation of basic and diluted income (loss) per share excludes net income (but not net loss) attributable to the convertible preferred stock from the numerator and excludes the impact of those shares from the denominator in periods prior to the IPO.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date, and in April 2016 the FASB issued guidance to clarify the identification of performance obligations and licensing arrangements. The Company is currently evaluating the impact, if any, that this guidance 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 adopted this guidance effective January 1, 2016 on a retrospective basis, and all periods are presented under this guidance.

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

In July 2015, the FASB issued accounting guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using LIFO or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The standard is effective for reporting periods beginning after December 15, 2016. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In February 2016, the FASB issued guidance for the accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In March 2016, the FASB issued guidance to clarify the requirements for assessing whether contingent call or put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. The guidance is effective for reporting periods beginning after December 15, 2016, and early adoption is permitted. Entities are required to apply the guidance to existing debt instruments using a modified retrospective transition method as of beginning of the fiscal year of adoption. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In March 2016, the FASB issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards. Under the guidance, all excess tax benefits and tax deficiencies related to stock-based compensation awards are to be recognized as income tax expenses or benefits in the income statement and excess tax benefits should be classified along with other income tax cash flows in the operating activities section of the statement of cash flows. Under the guidance, companies can also elect to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. In addition, the guidance amends some of the other stock-based compensation awards guidance to more clearly articulate the requirements and cash flow presentation for withholding shares for tax-withholding purposes. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted, though all amendments of the guidance must be adopted in the same period. The adoption of certain amendments of the guidance must be applied prospectively, and adoption of the remaining amendments must be applied either on a modified retrospective basis or retrospectively to all periods presented. 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 – Business Combination

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

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

The Company accounted for its acquisition of AdvanDx by recording all tangible and intangible assets acquired and liabilities assumed at their estimated fair values on the acquisition date, with the remaining unallocated purchase price recorded as goodwill. The fair value assigned to identifiable intangible assets acquired was determined using an income approach for trade names and customer relationships, and a cost approach for technology. The fair values are preliminary, are based on the Company's estimates and may be adjusted from time to time, but no later than July 13, 2016, as better information becomes available. The Company received carryover tax basis in the acquired assets and liabilities and no tax basis in the intangible assets (including goodwill) established on the acquisition date. As a result, the Company recognized deferred tax assets related to foreign taxing jurisdictions of \$4.3 million (fully offset by a corresponding valuation allowance) and net deferred tax liabilities of \$0.1 million in the U.S. taxing jurisdiction. The net deferred tax liability in the U.S. taxing jurisdiction resulted in an income tax benefit related to a reduction in the Company's previously established valuation allowance (which reduction is accounted for outside of purchase accounting). The following represents the preliminary allocation of the purchase price (as adjusted for measurement period adjustments):

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

The total consideration paid in the acquisition exceeded the estimated fair value of the tangible and identifiable intangible assets acquired and liabilities assumed, resulting in approximately \$0.6 million of goodwill. Goodwill, primarily related to expected synergies gained from combining operations, sales growth from future product offerings and customers, together with certain intangible assets that do not qualify for separate recognition, including assembled workforce, is not tax deductible. The Company expensed acquisition-related costs of approximately \$0.5 million related to the Merger in 2015.

Adjustments to Goodwill

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

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

	As previously reported (1)	Adjustment	Adjusted amount
Accounts payable	\$ 2,285,792	\$ (36,714)	\$ 2,249,078
Goodwill	637,528	(36,714)	600,814

(1) As reported on Form 10-K for the year ended December 31, 2015

Pro Forma Disclosures (unaudited)

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

Unaudited pro forma results	Three Months Ended March 31,	
	2015	
Revenues	\$	1,429,686
Net loss	\$	(3,797,029)
Net loss per share	\$	(3.38)

Note 5 – Merck GHI Financing

On July 14, 2015, as a condition to the Merger, the Company entered into a Common Stock and Note Purchase Agreement (the "Purchase Agreement") with Merck GHI, pursuant to which Merck GHI purchased 1,136,364 shares of common stock of the Company at \$4.40 per share for gross proceeds of \$5.0 million. Pursuant to the Purchase Agreement, the Company also issued to Merck GHI a 8% Senior Secured Promissory Note (the "Note") in the principal amount of \$1.0 million with a two-year maturity date from the date of issuance. The Company's obligations under the Note are secured by a lien on all of the Company's assets.

The Company incurred issuance costs of approximately \$50,000 related to the financing, of which approximately \$8,000 was deferred as debt issuance costs and netted against notes payable in the accompanying condensed consolidated balance sheets as a result of the Company's adoption of new accounting guidance in 2016, and are being amortized as interest expense over the life of the Note, and \$42,000 was charged to additional paid-in capital.

Note 6 - Fair value measurements

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

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

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

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

Prior to its IPO, certain stock purchase warrants contained cash settlement features and, accordingly, the Company considered them to be derivative financial instruments and accounted for them at fair value using level 3 inputs. As a result of the Company's IPO and elimination of the cash settlement features pursuant to their terms, those stock purchase warrants were reclassified to equity. For periods prior to the IPO, the Company determined the fair value of these derivative liabilities using a hybrid valuation method that consisted of a probability weighted expected return method that values the Company's equity securities assuming various possible future economic outcomes while using an option pricing method (that treated all equity linked instruments as call options on the Company's equity value with exercise prices based on the liquidation preference of the Series A Preferred Stock) to estimate the allocation of value within one or more of the scenarios. Using this hybrid method, unobservable inputs included the Company's equity value, the exercise price for each option value, expected timing of possible economic outcomes such as initial public offering, risk free interest rates and stock price volatility. The following tables set forth a summary of changes in the fair value of Level 3 liabilities measured at fair value on a recurring basis for the year ended December 31, 2015:

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

The Company has no financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2016.

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

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

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

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

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

The Company measures its long-lived assets, including property and equipment and intangible assets (including goodwill), at fair value on a non-recurring basis when they are deemed to be impaired. No such fair value impairment was recognized in the three months ended March 31, 2016 and 2015.

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

Note 7 - Debt

All the Company's outstanding demand notes and convertible notes were exchanged for units in the Company's IPO or otherwise were 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. In July 2015, the Company issued a \$1.0 million 8% senior secured promissory note to Merck GHI (see Note 5). As of March 31, 2016 and December 31, 2015, the only debt outstanding was the \$1.0 million Notes with Merck GHI that are due in July 2017.

In 2009, the Company entered into loan agreements with the Department of Business and Economic Development, a principal department of the State of Maryland, and Montgomery County, Maryland. Under the terms of the agreements, the State of Maryland and Montgomery County loaned the Company \$100,000 and \$10,000, respectively, to assist in the relocation of the Company's operations from Wisconsin to Gaithersburg, Maryland. Interest on the loans accrued at 3%. The interest was deferred and the loans were forgivable under certain conditions, including the Company maintaining operations in Gaithersburg, Maryland, and attaining a specified level of staffing at that site on or before December 31, 2012. The Company did not attain the required level of staffing at December 31, 2012, and, as a result, these notes and accrued interest became due in 2013. The Company negotiated a settlement with the State of Maryland under which it paid \$75,000 in June 2013 in full satisfaction of the \$100,000 loan principal balance and accrued interest of \$11,811. The Company also negotiated a settlement with Montgomery County under which accrued interest due under the loan provisions was forgiven and the loan would be paid in equal quarterly installments over the eight quarters ending December 31, 2015. The loan was paid in full during 2015 and no amounts remain outstanding.

Demand notes

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

2014 convertible debt

In July, August and September 2014, the Company raised \$1.5 million through the issuance of convertible debt. All outstanding 2014 convertible debt was converted into Series A Preferred Stock and then into 1,500,000 shares of common stock in connection with the Company's IPO (see Note 8). Prior to its conversion, the debt was convertible, at the option of the holders or in certain cases at the Company's option, into shares of Series A 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 8). Prior to its conversion, the 2015 convertible notes were prepayable by the Company without penalty at any time following the three-month anniversary of the closing of the IPO (provided that before the six-month anniversary of the closing of an IPO, the 2015 convertible notes could only be prepaid out of newly issued capital subsequent to the IPO), and were puttable by the holder to the Company in the event of a defined default. The 2015 convertible notes were each convertible, at the election of the holder, into (i) shares of Series A 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, or (ii) shares of common stock at a conversion rate of one share of common stock for each \$1.00 converted if the conversion occurs after the closing of an IPO.

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

Total interest expense on all debt instruments was \$31,934 and \$96,397 in the three months ended March 31, 2016 and 2015, respectively.

Note 8 - Stockholders' equity

As of March 31, 2016, the Company has 200,000,000 shares of authorized common shares and 12,576,306 issued and outstanding, and 10,000,000 of authorized preferred shares, none of which were issued or outstanding.

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

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

Stock options

In 2002, the Company adopted the 2002 Stock Option and Restricted Stock Plan (the "2002 Plan"), pursuant to which the Company's Board of Directors could grant either incentive 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 (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 (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 Plan or 2008 Plan. The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Internal Revenue Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for the grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants.

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 1,355,000 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date, that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by the Company's Board of Directors. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled, or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. As of March 31, 2016, 748,479 shares remain available for issuance under the 2015 Plan, which includes 501,907 shares automatically added to the 2015 Plan on January 1, 2016.

For the three months ended March 31, 2016 and 2015, the Company recorded \$0.3 million and \$0.6 million, respectively, of stock compensation expense. No income tax benefit for stock-based compensation arrangements was recognized in the condensed consolidated statements of operations due to the Company's net loss position. The allocation of share-based compensation expense by operating expenses is as follows:

	Three months ended March 31,	
	2016	2015
Costs of services	\$ 4,312	\$ -
Research and development	62,218	36,456
General and administrative	172,103	83,299
Sales and marketing	22,864	470,848
	<u>\$ 261,497</u>	<u>\$ 590,603</u>

During the three months ended March 31, 2016, the Company granted stock options to acquire 30,000 shares of common stock at a weighted average exercise price of \$1.53 per share. The 2016 awards had a weighted average grant date fair value per share of \$0.73. The Company has total stock options to acquire 2,119,140 shares of common stock outstanding at March 31, 2016.

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 ("CEO"). The restricted stock units were compensation for his service as 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. In the fourth quarter of 2015, the Company granted additional restricted stock units to acquire 75,000 shares of common stock, with a weighted average grant date fair value of \$1.70 per share, all of which remain outstanding as of March 31, 2016.

Stock purchase warrants

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

Issuance	Exercise Price	Expiration	Shares of Common Stock Subject to Warrants
August 2007	\$ 7.91	August 2017	8,921
March 2008	\$ 790.54	March 2018	46
November 2009	\$ 7.91	November 2019	6,674
January 2010	\$ 7.91	January 2020	6,674
March 2010	\$ 7.91	March 2020	1,277
November 2011	\$ 7.91	November 2021	5,213
December 2011	\$ 7.91	December 2021	664
March 2012	\$ 109.90	March 2019	4,125
February 2015	\$ 6.60	February 2025	225,011
May 2015	\$ 6.60	May 2020	3,457,750
			<u>3,716,355</u>

The warrants listed above were issued in connection with various debt, preferred stock or development contract agreements. The warrants issued in February 2015 were initially classified as a liability since the exercise price was variable. The exercise price became fixed as a result of the Company's IPO and, as such, the warrant liability was marked to fair value at that time and reclassified to equity (see Note 6).

Note 9 - Commitments and contingencies

Operating leases

During the second quarter 2015, the Company extended the term of its Gaithersburg, Maryland office lease, effective May 7, 2015, through January 31, 2021, with one additional five-year renewal at the Company's election. The Company is responsible for all utilities, repairs, insurance, and taxes under this operating lease. Effective July 1, 2015, the Company further modified its lease agreement to add additional leased space to its headquarters. The Company also leases a facility in Woburn, Massachusetts under an operating lease that expires in January 2017, and provides the Company with options to extend the lease beyond the current expiration date. Additionally, the Company leases office space in Denmark; this lease is currently on a month-to-month basis. Rent expense under the Company's facility operating leases for the three months ended March 31, 2016 and 2015 was \$254,044 and \$183,154, respectively.

Capital leases

The Company leases computer equipment, office furniture, and equipment under various capital leases. The leases expire at various dates through 2020. The leases require monthly principal and interest payments.

Registration and other shareholder rights

In connection with the Merger and the investment transactions (see Notes 4 and 5), the Company 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.

On December 18, 2013, the Company entered into the Third Amended and Restated Investors' Rights Agreement (the "Investors' Rights Agreement") with investors acquiring promissory notes convertible into shares of the Company's Series A Preferred Stock. Following the IPO, the holders of 20% or more of such shares of common stock subject to the Investors' Rights Agreement have demand registration rights and piggyback registration rights in connection with subsequent registered offerings of the Company's common stock.

Note 10 - License agreements, research collaborations and development agreements

The Company is a party to three 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 recognized \$69,854 and \$23,038 of royalty expense for the three months ended March 31, 2016 and 2015, respectively. In 2016, future minimum royalty fees are approximately \$270,000 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. 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 which ended in December 2015. The Company recognized total revenue of \$252,780 during the three months ended March 31, 2015 (none in 2016) relating to this arrangement.

Note 11 - Related party transactions

In March 2014, the Company entered into a supply agreement with Fluidigm Corporation (“Fluidigm”) under which Fluidigm supplies the Company with its microfluidic test platform for use in manufacturing the Acuitas MDRO Gene Test. The Company’s CEO and Chairman of the Board of Directors is a director of Fluidigm. On July 12, 2015, the Company entered into a letter agreement (the “Fluidigm Agreement”) with Fluidigm to expand the companies’ existing relationship to include collaborating on the development of test kits and custom analytic instruments for identification, screening and surveillance testing of MDROs. The Fluidigm Agreement also expands the existing Supply Agreement between the Company and Fluidigm, and provides for expansion of the gene targets and organisms to be tested on the Company’s existing CLIA lab-based tests, the Acuitas MDRO Gene Test and the Acuitas Resistome Test, using Fluidigm technologies and products. Additionally, Fluidigm has agreed not to develop or directly collaborate with any third party to develop an FDA approved or CE-marked diagnostic test for the purpose of detecting resistome genes for identified MDROs if the Company meets certain minimum purchase commitments and other requirements. The initial term of the Fluidigm Agreement is five years. Both parties have the ability to extend the term for an additional five years. Under the expanded Supply Agreement, the term 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. The Company paid \$93,224 and \$87,028 related to these agreements in the three months ended March 31, 2016 and 2015, respectively.

In the three months ended March 31, 2016 and 2015, The Company incurred \$67,775 and \$83,516, respectively, of inventory purchases under the agreements with Fluidigm. In addition, the Company has several capital lease arrangements for laboratory equipment manufactured by Fluidigm. The Company paid \$45,106 and \$14,853 related to the leased equipment in the 2016 and 2015 quarterly periods, respectively.

Note 12 – Subsequent events

On April 28, 2016, the Board of Directors made a stock option award to the Company’s Chief Executive Officer and Chair of the Board. The non-qualified stock option award to acquire 766,500 shares of common stock represents approximately 6% of outstanding shares of common stock as of the record date for the Company’s upcoming 2016 Annual Meeting of Stockholders. The stock option grant has an exercise price of \$1.35 per share, which is the fair market value of the common stock on the date of grant, a ten year term and a vesting schedule of 25% vesting of the award on the first annual anniversary of the date of grant and then 6.25% vesting each quarter thereafter over three additional years. The stock option award is contingent on receipt of stockholder approval at the Company’s 2016 Annual Meeting of Stockholders, as the award was made outside of the Company’s stockholder-approved incentive plans. If the stockholders do not approve the award, the stock option award will terminate.

On May 11, 2016, the Company priced a private placement financing under which, upon closing, it expects to receive \$10.4 million upon the issuance of units, each unit consisting of one share of common stock and a warrant to acquire 0.75 of a share of common stock.

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" of this quarterly report on Form 10-Q and Part 1, Item 1A of our annual report on Form 10-K.

Overview

OpGen, Inc. ("OpGen" or the "Company") was incorporated in Delaware in 2001. On July 14, 2015, OpGen completed the strategic acquisition (the "Merger") of AdvanDx, Inc. and its wholly owned subsidiary AdvanDx A/S (collectively, "AdvanDx"). Pursuant to the terms of a merger agreement, Velox Acquisition Corp., OpGen's wholly owned subsidiary formed for the express purpose of effecting the Merger, merged with and into AdvanDx, Inc. with AdvanDx, Inc. surviving as OpGen's wholly owned subsidiary. OpGen, AdvanDx, Inc. and AdvanDx A/S are collectively referred to hereinafter as the "Company." The Company's headquarters are in Gaithersburg, Maryland, and its principal operations are in Gaithersburg, Maryland and Woburn, Massachusetts. The Company also has operations in Copenhagen, Denmark. The Company operates in one business segment.

OpGen is a precision medicine company using molecular diagnostics and informatics to combat infectious disease. OpGen is developing molecular information solutions to combat infectious disease in global healthcare settings, helping to guide clinicians with more rapid information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms. The Company's proprietary DNA tests and bioinformatics address the rising threat of antibiotic resistance by helping physicians and healthcare providers optimize patient care decisions and protect the hospital biome through customized screening and surveillance solutions. The Company's molecular information solution combines Acuitas® DNA tests, Acuitas Lighthouse™ bioinformatics and CLIA lab services for MDRO genetic identification, antibiotic resistance gene information and surveillance, and a proprietary data warehouse including genomic data matched with antibiotic susceptibility information for microbes and patient information from healthcare providers. The Company is working to deliver its molecular information products and services to a global network of customers and partners. The Acuitas DNA tests provide rapid microbial ID, and antibiotic resistance gene information. These include the QuickFISH® family of FDA-cleared and CE-marked diagnostic products used to rapidly detect pathogens in positive blood cultures, the MDRO Gene Test to detect, type, track, and trend antibiotic resistant organisms in real-time and a rapid antibiotic resistance test in development.

The Company's operations are subject to certain risks and uncertainties. The risks include rapid technology changes, the need to manage growth, the need to retain key personnel, the need to protect intellectual property and the need to raise additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop and commercialize its proprietary technology as well as raise additional capital.

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. The Company raised significant funds in 2015, including:

- \$0.8 million in short-term 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, and in the second quarter of 2015, \$0.2 million of notes from a related party were repaid in cash);
- \$1.5 million through the issuance of convertible notes;
- \$12.1 million in net proceeds from its initial public offering ("IPO") as discussed further below; and
- \$6.0 million in net proceeds from the issuances of common stock and a senior secured promissory note to Merck Global Health Innovation Fund, LLC ("Merck GHI").

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

Current cash on hand will be sufficient to fund operations into the second quarter of 2016. Once the May 2016 financing is closed, cash on hand, plus the net proceeds from the May 2016 financing, will be sufficient to fund operations into the first quarter of 2017. In the event the Company is unable to successfully raise additional capital in or before the first quarter of 2017, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to 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 consolidated 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.

Results of operations for the three months ended March 31, 2016 and 2015

Revenues

<i>Revenue</i>	Three months ended March 31,	
	2016	2015
Product sales	\$ 947,219	\$ 184,179
Laboratory services	129,420	35,241
Collaboration revenue	-	252,780
Total revenue	\$ 1,076,639	\$ 472,200

Our total revenue for the three months ended March 31, 2016 increased 128%, to \$1.1 million from \$0.5 million, when compared to the same period in 2015. This increase is primarily attributable to:

- Product Sales: an increase in revenue of 414% in the 2016 period as compared to the 2015 period is primarily attributable to sales of QuickFISH and PNA FISH diagnostic products acquired from AdvanDx in July 2015;
- Laboratory Services: an increase in revenue of 267% in the 2016 period as compared to the 2015 period as a result of increases in sales of our Acuitas MDRO test services and Acuitas Lighthouse services; and
- Collaboration Revenue: a decrease in revenue generated under a certain collaborative arrangement of 100% in the 2016 period as compared to the 2015 period as a result of the completion of a technology development agreement with Hitachi High-Technologies Corporation in the fourth quarter of 2015.

The Company expects revenues for 2016 to exceed 2015 revenues as a result of a strategic shift away from Argus and Whole Genome Mapping product sales and collaborations to a focus on its QuickFISH and PNAFISH diagnostic products, Acuitas MDRO test and Acuitas Lighthouse services.

Operating expenses

	Three months ended March 31,	
	2016	2015
Cost of products sold	\$ 345,867	\$ 115,389
Cost of services	315,709	95,430
Research and development	1,953,429	1,108,602
General and administrative	1,538,046	659,392
Sales and marketing	1,399,435	1,024,029
Total operating expenses	\$ 5,552,486	\$ 3,002,842

The Company's total operating expenses for the three months ended March 31, 2016 increased 85%, to \$5.6 million from \$3.0 million, when compared to the same period in 2015. This increase is primarily attributable to:

- Costs of products sold: costs of product sales for the three months ended March 31, 2016 increased 200% when compared to the same period in 2015. The change in costs of products sold is primarily attributable to an increase in sales of QuickFISH and PNA FISH products acquired from AdvanDx in July 2015;

- Costs of services: costs of services increased 231%, when compared to the same period in 2015. The change in costs of services is primarily attributable to an increase in sales of Acuitas Lighthouse services;
- Research and Development: an increase in expenses of 76% when compared to the same period in 2015, primarily due to the continued development of the automation of our QuickFISH products;
- General and Administrative: an increase in expenses of 133% when compared to the same period in 2015, primarily due to salaries of \$0.3 million for new personnel, public company costs of \$0.3 million, share-based compensation costs of \$0.1 million, legal costs of \$0.1 million, along with \$0.1 million of other support costs; and
- Sales and Marketing: an increase in expenses of 37% when compared to the same period in 2015, primarily due to increased salaries.

In the three months ended March 31, 2016 and 2015, the Company incurred \$67,775 and \$83,516, respectively, of inventory purchases under agreements with Fluidigm Corporation, a related party. Fluidigm Corporation supplies the Company with its microfluidic test platform for use in manufacturing the Acuitas MDRO Gene Test.

The Company expects operating expenses for 2016 to exceed 2015 operating expenses as a result of increased sales relating to a strategic shift from Argus and Whole Genome Mapping product sales and collaborations to a focus on its QuickFISH and PNAFISH diagnostic products, Acuitas MDRO test and Acuitas Lighthouse services.

Other income (expense)

	Three months ended March 31,	
	2016	2015
Interest income	\$ 173	\$ 35
Interest expense	(41,734)	(96,397)
Foreign currency transaction gains (losses)	11,328	-
Change in fair value of derivative financial instruments	-	31,831
Total other income (expense)	\$ (30,233)	\$ (64,531)

Other income (expense) for the three months ended March 31, 2016 decreased to a net expense of \$30,233 from a net expense of \$64,531 in the same period of 2015, and was primarily the result of a reduction in interest expense due to the settlement of a significant portion of our debt upon the closing of our IPO and the reclassification of derivative warrant liabilities, which were reclassified to stockholders' equity upon the closing of our IPO when their net cash-settlement features lapsed.

Liquidity and capital resources

At March 31, 2016, the Company had cash and cash equivalents of \$3,967,957 compared to \$7,814,220 at December 31, 2015. The Company raised significant funds in 2015, including:

- \$0.8 million in short-term 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, and in the second quarter of 2015, \$0.2 million of notes from a related party were repaid in cash);
- \$1.5 million through the issuance of convertible notes;
- \$12.1 million in net proceeds from its IPO as discussed further below; and
- \$6.0 million in net proceeds from the issuances of common stock and a senior secured promissory note to Merck Global Health Innovation Fund, LLC ("Merck GHI").

On May 8, 2015, OpGen completed its IPO pursuant to which it offered and sold 2,850,000 units, each Unit consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of \$6.00 per unit. Of the total gross proceeds of \$17.1 million, approximately \$2.1 million was used to satisfy outstanding demand notes by exchanging such notes for 350,000 Units in the IPO. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds were \$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 OpGen'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 raised \$6.0 million by issuing 1,136,364 shares of common stock at \$4.40 per share and a \$1.0 million senior secured promissory note to Merck GHI. Also in July 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.

On May 11, 2016, the Company priced a private placement financing under which, upon closing, it expects to receive \$10.4 million upon the issuance of units, each unit consisting of one share of common stock and a warrant to acquire 0.75 of a share of common stock.

The Company's primary cash requirements are to fund operations as well as research and development activities and collaborations and to support general and administrative activities, and to fund acquisitions of products and businesses. Current cash on hand will be sufficient to fund operations into the second quarter of 2016. Once the May 2016 financing is closed, cash on hand, plus the net proceeds from the May 2016 financing, will be sufficient to fund operations into the first quarter of 2017. In the event the Company is unable to successfully raise additional capital in or before the first quarter of 2017, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to 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 consolidated 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.

Sources and uses of cash

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

	Three months ended March 31,	
	2016	2015
Net cash used in operating activities	\$ (3,795,817)	\$ (1,717,151)
Net cash used in investing activities	(1,644)	(10,034)
Net cash provided by (used in) financing activities	(54,056)	1,609,363

Net cash used in operating activities

Net cash used in operating activities for the three months ended March 31, 2016 consists primarily of our net loss of \$4.5 million, reduced by certain non-cash items, including depreciation and amortization expense of \$0.2 million, share-based compensation expense of \$0.3 million, and the net change in operating assets and liabilities of \$0.3 million. Net cash used in operating activities for the three months ended March 31, 2015 consists primarily of our net loss of \$2.6 million, reduced by certain non-cash items, including depreciation and amortization expense of \$0.1 million, share-based compensation expense of \$0.6 million, and the net change in operating assets and liabilities of \$0.2 million.

Net cash used in investing activities

Net cash used in investing activities in the three months ended March 31, 2016 and 2015 consisted solely of purchases of property and equipment (net of proceeds from sales of property and equipment in 2016 of \$1,695).

Net cash provided by (used in) financing activities

Net cash used in financing activities for the three months ended March 31, 2016 of \$54,056 consisted primarily of payments on capital leases. Net cash provided by financing activities for the three months ended March 31, 2015 of \$1.6 million consisted primarily of net proceeds from the issuance of convertible and promissory notes.

Critical accounting policies and use of estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our unaudited condensed consolidated financial statements, estimates are used for, but not limited to, share-based compensation, allowances for doubtful accounts and inventories, valuation of derivative financial instruments, 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 consolidated 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 its products and services when the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the selling price is fixed or determinable; and collectability is reasonably assured. At times, the Company sells products and services, or performs software development, under multiple-element arrangements with separate units of accounting; in these situations, total consideration is allocated to the identified units of accounting based on their relative selling prices and revenue is then recognized for each unit based on its specific characteristics.

Amounts billed to customers for shipping and handling are included in revenue when the related product or service revenue is recognized. Shipping and handling costs are included in cost of 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 QuickFISH, PNA FISH and XpressFISH diagnostic test products

Revenue is recognized upon shipment to the customer. Sales are recorded net of accruals for estimated rebates, discounts and other deductions and returns.

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.

Impairment of Long-Lived Assets

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets.

Definite-lived intangible assets include trademarks, developed technology and customer relationships. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any.

Goodwill represents the excess of the purchase price for AdvanDx over the fair values of the acquired tangible or intangible assets and assumed liabilities. The Company will conduct an impairment test of goodwill on an annual basis as of October 1 of each year, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value.

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.

Recently issued accounting pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date, and in April 2016 the FASB issued guidance to clarify the identification of performance obligations and licensing arrangements. The Company is currently evaluating the impact, if any, that this guidance 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 adopted this guidance effective January 1, 2016 on a retrospective basis, and all periods are presented under this guidance.

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

In July 2015, the FASB issued accounting guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using LIFO or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The standard is effective for reporting periods beginning after December 15, 2016. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In February 2016, the FASB issued guidance for the accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In March 2016, the FASB issued guidance to clarify the requirements for assessing whether contingent call or put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. The guidance is effective for reporting periods beginning after December 15, 2016, and early adoption is permitted. Entities are required to apply the guidance to existing debt instruments using a modified retrospective transition method as of beginning of the fiscal year of adoption. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In March 2016, the FASB issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards. Under the guidance, all excess tax benefits and tax deficiencies related to stock-based compensation awards are to be recognized as income tax expenses or benefits in the income statement and excess tax benefits should be classified along with other income tax cash flows in the operating activities section of the statement of cash flows. Under the guidance, companies can also elect to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. In addition, the guidance amends some of the other stock-based compensation awards guidance to more clearly articulate the requirements and cash flow presentation for withholding shares for tax-withholding purposes. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted, though all amendments of the guidance must be adopted in the same period. The adoption of certain amendments of the guidance must be applied prospectively, and adoption of the remaining amendments must be applied either on a modified retrospective basis or retrospectively to all periods presented. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

Contractual obligations and off-balance sheet arrangements

As of March 31, 2016 and December 31, 2015, 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 March 31, 2016. 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

On July 14, 2015, the Company completed the Merger by acquiring 100% of the capital stock of AdvanDx in the Merger. The Company has not yet completed an assessment of the design and/or operating effectiveness of AdvanDx's 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

The following are significant factors known to us that could materially harm our business, financial condition or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this quarterly report. The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, also may adversely affect our business, financial condition and operating results. If any of these risks actually occur, our business, financial condition, and operating results could suffer significantly. These risk factors are supplemented by the Risk Factors included in Section 1.A. of our Annual Report on Form 10-K for the year ended December 31, 2015 under the headings “Risks Related to Regulation of our Business,” “Risks Related to Compliance with Healthcare and Other Regulations”, and “Risks Related to our Intellectual Property.”

Risks Related to our Business

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, 2015 and 2014 contains explanatory language that substantial doubt exists about our ability to continue as a going concern.

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the years ended December 31, 2015 and 2014 we had a net loss of \$17.4 million and \$5.7 million, respectively and for the three months ended March 31, 2016 our net loss was \$4.5 million. From our inception through March 31, 2016, we had an accumulated deficit of \$118.6 million. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2015 and 2014 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. We completed a number of financings in the last twelve months, including our IPO, pursuant to which we offered and sold 2,850,000 units, each unit consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of \$6.00 per unit, with total net cash proceeds of \$12.1 million, and an additional investment in our common stock in July 2015 by Merck GHI.

The July 2015 investment by Merck GHI includes a \$1 million senior secured promissory note secured by a security interest in substantially all of our assets, including our intellectual property assets. The secured promissory note requires interest-only payments at a rate of 8% per annum for two years, with the principal due and payable on July 14, 2017. Such secured creditor rights could negatively impact our ability to raise money in the future. If we default on payments under the promissory note, Merck GHI has the rights of a secured creditor. If those rights are exercised, it could have a material adverse effect on our financial condition.

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 diagnostic test products and Acuitas MDRO and Acuitas Lighthouse bioinformatics services and developing rapid molecular diagnostic products and services;
- developing, presenting and publishing additional clinical and economic utility data intended to increase clinician adoption of our current and future products and services, including the efficacy of use of our products in MDRO surveillance activities;
- 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; and
- continued focus on recruiting and retaining our quality assurance and compliance personnel and activities.

Even if we achieve significant revenues, we may not become profitable, and even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain consistently profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business or continue to pursue our growth strategy. We anticipate that our current capital is sufficient to fund our operations into the second quarter of 2016. Once the May 2016 financing is closed, cash on hand, plus the net proceeds from the May 2016 financing, will be sufficient to fund operations into the first quarter of 2017. 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.

Our products and services may never achieve significant commercial market acceptance.

Our products and services may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits for us. Our ability to achieve commercial market acceptance for our products will depend on several factors, including:

- our ability to convince the medical community of the clinical utility of our products and services and their potential advantages over existing tests;
- our ability to successfully develop a surveillance services offering and convince hospitals and other healthcare providers of the patient safety, improved patient outcomes and potential cost savings that could result despite the lack of reimbursement for such services;
- our ability to successfully develop more rapid diagnostic products and services;
- our ability to convince the medical community of the accuracy and speed of our products and services, as contrasted with the current methods available; and
- the willingness of hospitals and physicians to use our products and services.

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

The current customers we are targeting for our Acuitas MDRO test products and services are acute care hospitals, particularly those with advanced care units, such as intensive care units, and community-based hospitals. We need to provide a compelling case for the savings, patient safety and recovery, reduced length of stay and reduced costs that come from adopting our MDRO diagnosis and management products and services. If we are not able to successfully increase our customer base, sales of our products and our margins may not meet expectations. Attracting new customers and introducing new products and services requires substantial time and expense. Any failure to expand our existing customer base, or launch new products and services, would adversely affect our ability to improve our operating results.

We have seen declining revenues from our current customers for our QuickFISH products as we work to automate and expand our product offerings. We may not be successful in developing such automated and rapid diagnostic test products, which would materially, adversely affect our business.

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

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

We expect to make significant additional investment in the future related to our diagnostic products and services. If we are unable to make such investments our business will suffer.

We anticipate that we will need to make significant investments in the Acuitas MDRO tests and QuickFISH products and services in order to make our business profitable. We have identified potential synergies for future rapid diagnostic test developments based on our existing product and service offerings, but need to expend significant investments to develop such products and services. There can be no assurance that we can obtain sufficient resources or capital from operations or future financings to support these development activities. In the event we are 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 we would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing, or pursue other strategic alternatives which may include licensing and/or partnering arrangements or mergers and acquisitions.

We have in the past, and in the future may, enter into collaborations with third parties to develop product and services candidates. If these collaborations are not successful, our business could be adversely affected.

We have entered into licensing and collaboration agreements with third parties in the past related to our Whole Genome Mapping products and services and may enter into additional collaborations in the future related to our MDRO and bioinformatics products and services. Such collaborations may be with pharmaceutical companies, platform companies or other participants in our industry. We have limited control over the amount and timing of resources that any such collaborators could dedicate to the development or commercialization of the subject matter of any such collaboration. Our ability to generate revenues from these arrangements would depend on our and our collaborator's abilities to successfully perform the functions assigned to each of us in these arrangements. Our relationships with future collaborators may pose several risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- we may not achieve any milestones, or receive any milestone payments, under our collaborations, including milestones and/or payments that we expect to achieve or receive;
- the clinical trials, if any, conducted as part of these collaborations may not be successful;
- a collaborator might elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors, such as an acquisition, that diverts resources or creates competing priorities;
- we may not have access to, or may be restricted from disclosing, certain information regarding product or services candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product or services candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product or services candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product or services, which may cause collaborators to cease to devote resources to the commercialization of our product or services candidates;
- a collaborator with marketing and distribution rights to one or more of our product or services candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product or services candidates, may cause delays or termination of the research, development or commercialization of such product or services candidates, may lead to additional responsibilities for us with respect to such product or services candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to a collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product or services candidates.

If our future collaborations do not result in the successful development and commercialization of products or services, we may not receive any future research funding or milestone or royalty payments under the collaborations. If we do not receive the funding we would expect under these agreements, our development of product and services candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product and services development, regulatory approval and commercialization described in this “Risk Factors” section and in the “Risk Factors” section of our Form 10-K for the year ended December 31, 2015 related to risks related to the regulation of our business, healthcare regulatory compliance and intellectual property, apply to the potential activities of any collaborators.

We may not be successful in finding strategic collaborators for continuing development of certain of our product or services candidates or successfully commercializing or competing in the market for certain indications.

We may seek to develop strategic partnerships for developing certain of our product or services candidates, due to capital costs required to develop the product or services candidates or manufacturing constraints. We may not be successful in our efforts to establish such a strategic partnership or other alternative arrangements for our product or services candidates because our research and development pipeline may be insufficient, our product or services candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product or services candidates as having the requisite potential to demonstrate commercial success.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product or service candidate, reduce or delay our development program, delay our potential commercialization, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates and our business, financial condition, results of operations and prospects may be materially and adversely affected.

We may enter into agreements with U.S. or other government agencies, which could be subject to uncertain future funding.

The presence of MDROs and the need for antibiotic stewardship activities have prompted state, federal and international government agencies to develop programs to combat the effects of MDROs. In the future, we may seek to enter into agreements with governmental funding sources or contract with government healthcare organizations to sell our products and services. If we enter into such funding agreements, we would rely on the continued performance by these government agencies of their responsibilities under these agreements, including adequate continued funding of the agencies and their programs. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal.

Government agencies may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies. In addition, we may fail to perform our responsibilities under these agreements. Any government agreements would be subject to audits, which may occur several years after the period to which the audit relates. If an audit identified significant unallowable costs, we could incur a material charge to our earnings or reduction in our cash position. As a result, we may be unsuccessful entering, or ineligible to enter, into future government agreements.

We are developing new diagnostic products for the more rapid identification of MDROs and antibiotic therapy selection. If we are unable to successfully develop, receive regulatory clearance or approval for or commercialize such new products, our business will be materially, adversely affected.

We are currently beginning development of a new one-hour rapid array diagnostic product that we believe could help address many of the current issues with the need for more rapid identification of infectious diseases and testing for antibiotic resistance. Development of new diagnostic products is difficult and we cannot assure you that we will be successful in such product development efforts, or, if successful, that we will receive the necessary regulatory clearances to commercialize such products. Our intent is to identify over 100 antibiotic resistance genes to help guide clinician antibiotic therapy decisions when test results are evaluated using the Acuitas Lighthouse. Although we have demonstrated preliminary feasibility, such product development efforts will require us to work collaboratively with other companies, academic and government laboratories, and healthcare providers to access sufficient numbers of microbial isolates, develop the diagnostic tests, identify and license a third party rapid array platform, successfully conduct the necessary clinical trials and apply for and receive regulatory clearances or approvals for the intended use of such diagnostic tests. In addition, we would need to successfully commercialize such products. Such product development, clearance or approval and commercialization activities are time-consuming, expensive and we are not assured that we will have sufficient funds to successfully complete such efforts. We currently estimate that such rapid array diagnostic tests will be commercially available by 2019. Any significant delays or failures in this process could have a material adverse effect on our business and financial condition.

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

We rely principally on the commercialization of our QuickFISH and Acuitas MDRO test products and our Acuitas Lighthouse bioinformatics system and services to generate future revenue growth. To date, the Acuitas MDRO test products and Acuitas Lighthouse products and services have delivered only minimal revenue. We believe that our commercialization success is dependent upon our ability to significantly increase the number of hospitals, long-term care facilities and other inpatient healthcare settings that use our products. We have experienced very limited revenue and customer adoption for our Acuitas MDRO products and services to date. If demand for products does not increase as quickly as we have planned, we may be unable to increase our revenue levels as expected. We are currently not profitable. Even if we succeed in increasing adoption of our products by our target markets, maintaining and creating relationships with our existing and new customers and developing and commercializing additional molecular testing products, we may not be able to generate sufficient revenue to achieve or sustain profitability.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists and laboratory and field personnel could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team. The efforts of each of these persons will be critical to us as we continue to develop our products and services and as we attempt to transition to a company with broader product offerings. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians, particularly as we seek to further integrate operations of the combined company. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses. We also face competition from universities, public and private research institutions and other organizations in recruiting and retaining highly qualified scientific personnel.

In addition, our success depends on our ability to attract and retain laboratory and field personnel with extensive experience in infection control in inpatient settings. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our current and future products and service offerings. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our discovery, development, verification and commercialization programs.

We have limited experience in marketing and selling our products, and if we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our product and we may never generate sufficient revenue to achieve or sustain profitability.

We sell our products through our own direct sales force, which sells our Acuitas MDRO test products and services, which includes our QuickFISH products, and our Acuitas Lighthouse bioinformatics services and surveillance product and services offerings. All of these products and services may be offered and sold to different potential customers or involve discussions with multiple personnel in in-patient facilities. Our future sales will depend in large part on our ability to increase our marketing efforts and adequately address our customers' needs. The inpatient health care facility industry is a large and diverse market. As a result, we believe it is necessary to maintain a sales force that includes sales representatives with specific technical backgrounds that can support our customers' needs. We will also need to attract and develop sales and marketing personnel with industry expertise. Competition for such employees is intense. We may not be able to attract and retain sufficient personnel to maintain an effective sales and marketing force. If we are unable to successfully market our products and adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenue to achieve or sustain profitability.

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

We commenced the formal commercial launch of our CLIA lab in late 2013, launched our Acuitas MDRO Gene Test in the second quarter of 2014, launched our Acuitas CR Elite Test in December 2014, our Acuitas Resistome Test in the second quarter of 2015, and we began providing Acuitas Lighthouse portal services in December 2015. In addition, we integrated the sales of our QuickFISH products beginning in the third quarter of 2015. We anticipate future growth in our business operations. This future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales force management. We may not be able to maintain the quality or expected turn-around times of our diagnostic or screening results, or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement the systems to handle such growth is uncertain, and failure to complete this in a timely and efficient manner could adversely affect our operations.

If the utility of our current products and products in development is not supported by studies published in peer-reviewed medical publications, the rate of adoption of our current and future products and services by clinicians and healthcare facilities may be negatively affected.

The results of our clinical and economic validation studies involving our Acuitas MDRO test products and services have been presented at major infectious disease and infection control society meetings. We need to maintain and grow a continued presence in peer-reviewed publications to promote clinician adoption of our products. We believe that peer-reviewed journal articles that provide evidence of the utility of our current and future solutions and adoption by key opinion leaders in the infectious disease market are very important to the commercial success of our current and any future products. Clinicians typically take a significant amount of time to adopt new products and testing practices, partly because of perceived liability risks and the uncertainty of a favorable cost/benefit analysis. It is critical to the success of our sales efforts that we educate a sufficient number of clinicians and administrators about our products and demonstrate the clinical benefits of these solutions. Clinicians may not adopt our current and future solutions unless they determine, based on published peer-reviewed journal articles and the experience of other clinicians, that our products provide accurate, reliable, useful and cost-effective information that is useful in MDRO diagnosis, screening and outbreak prevention. If our current and future solutions or the technology underlying our products and services or our future product offerings do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption could be negatively affected. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing our products, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenue from any product that is the subject of a study.

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

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

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

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

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

- coordinating research and development activities to enhance the introduction of new diagnostic tests and technology of the combined business;
- failure to successfully integrate and harmonize financial reporting and information technology systems of the two companies;

- retaining each company's relationships with its partners;
- retaining and integrating key employees from OpGen and AdvanDx;
- managing effectively the diversion of management's attention from business matters to integration issues;
- combining research and development capabilities effectively and quickly;
- integrating partnership efforts so that new partners acquired can easily do business with us; and
- transitioning all facilities to a common information technology environment.

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

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 OpGen 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. Furthermore, if we are unable to achieve this net benefit from the acquisition, our financial condition, liquidity and results of operations will suffer.

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

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

If our sole laboratory facility becomes inoperable, we will be unable to perform Acuitas MDRO test services and our business will be harmed.

We perform all of our Acuitas MDRO and Acuitas Lighthouse services in our CLIA laboratory located in Gaithersburg, Maryland. We do not have redundant laboratory facilities. Our facility and the equipment we use to perform our diagnostic and screening assays would be costly to replace and could require substantial lead time to repair or replace, if damaged or destroyed. The facility may be harmed or rendered inoperable by natural or man-made disasters, including flooding and power outages, which may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

In order to establish a redundant laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. Additionally, any new clinical laboratory facility opened by us would be required to be certified under CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. We would also be required to secure and maintain state licenses required by several states, including Maryland, California, Florida, New York and Pennsylvania which can take a significant amount of time and result in delays in our ability to begin operations at that facility. We have active licenses in Maryland, Florida and Pennsylvania. If we failed to secure any such licenses, we would not be able to process samples from recipients in such states. We also expect that it would be difficult, time-consuming and costly to train, equip and use a third-party to perform tests on our behalf. We could only use another facility with the established state licensures and CLIA certification necessary to perform our current or future tests following validation and other required procedures. We cannot assure you that we would be able to find another CLIA-certified facility willing or able to adopt our current or future tests and comply with the required procedures, or that this laboratory would be willing or able to perform the tests for us on commercially reasonable terms.

In order to meet the turn-around time required for our Acuitas MDRO test services, we rely on transport of specimens to our sole laboratory facility; any disruption in such transport could significantly adversely affect our business.

Our current customers for our Acuitas MDRO test services are located near our sole laboratory facility in Gaithersburg, Maryland. As we expand our customer base, and the jurisdictions where we are licensed to provide our CLIA laboratory services, we will need to secure the proper licenses for shipment of specimens and rely on accurate and timely delivery of the specimens by overnight delivery services such as FedEx. Any failure to procure the proper licenses, to comply with the license regulations or to receive undamaged specimens from overnight delivery services could adversely affect our business and reputation.

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

We rely on several sole suppliers and manufacturers, including Fluidigm Corporation, for supplying certain laboratory reagents, raw materials, supplies and substances which we use in our laboratory operations and products and to manufacture our products. An interruption in our operations could occur if we encounter delays or difficulties in securing these items or manufacturing our products, and if we cannot, then obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation.

We believe that there are only a few other equipment manufacturers that are currently capable of supplying and servicing the equipment and other supplies and materials necessary for our laboratory operations. The use of equipment or materials furnished by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our products. There can be no assurance that we will be able to secure alternative equipment and other materials, and bring such equipment and materials on line and revalidate them without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the equipment we require for our products, our business, financial condition, results of operations and reputation could be adversely affected.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenue or achieve and sustain profitability.

Our competitors include rapid diagnostic testing and traditional microbiology companies, commercial laboratories, information technology companies, and hospital laboratories who may internally develop testing capabilities. Principal competitive factors in our target market include: organizational size, scale, and breadth of product offerings; rapidity of test results; quality and strength of clinical and analytical validation data and confidence in diagnostic results; cost effectiveness; ease of use; and regulatory approval status.

Our principal competition comes from traditional methods used by healthcare providers to diagnose and screen for MDROs and from other molecular diagnostic companies creating screening and diagnostic products such as Cepheid, Becton-Dickinson, bioMerieux, Accelerate Diagnostics, T2 Biosystems and Nanosphere.

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

Competitors may develop their own versions of our solution in countries where we do not have patents or where our intellectual property rights are not recognized.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical, research and development and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by hospitals, physicians and payers as functionally equivalent to our solution, or offer solutions at prices designed to promote market penetration, which could force us to lower the list prices of our solutions and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

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

A key element of our strategy is to discover, develop, validate and commercialize a portfolio of additional diagnostic and screening products and services to rapidly diagnose and effectively treat MDRO infections and reduce the associated costs to patients, inpatient facilities and the health care industry. We cannot assure you that we will be able to successfully complete development of or commercialize any of our planned future products and services, or that they will be clinically usable. The product development process involves a high degree of risk and may take up to several years or more. Our new product development efforts may fail for many reasons, including:

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

Few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of new products, or we may be required to expend considerable resources repeating clinical studies or trials, which would adversely impact the timing for generating potential revenues from those new products. In addition, as we develop new products, we will have to make additional investments in our sales and marketing operations, which may be prematurely or unnecessarily incurred if the commercial launch of a product is abandoned or delayed.

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employee benefits liability, property, umbrella, business interruption, workers' compensation, product liability, errors and omissions and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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

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

If we are sued for product liability or errors and omissions liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our products could lead to product liability claims if someone were to allege that a product failed to perform as it was designed. We may also be subject to liability for errors in the results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. For example, if we diagnosed a patient as having an MDRO but such result was a false positive, the patient could be unnecessarily isolated in an in-patient setting or receive inappropriate treatment. We may also be subject to similar types of claims related to products we may develop in the future. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain product liability and errors and omissions insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or errors and omissions liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our products and solutions. The occurrence of any of these events could have an adverse effect on our business and results of operations.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred net losses since inception and do not expect to become profitable in 2016 or for several years thereafter. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. We may be unable to use these net operating loss carryforwards ("NOLs"), and certain tax credit carryforwards to offset income before such unused NOLs tax credit carryforwards expire. Under Section 382 of the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be further limited. The Merger with AdvanDx resulted in an ownership change for AdvanDx and, accordingly, AdvanDx's net operating loss carryforwards and certain other tax attributes in U.S. taxing jurisdictions are subject to limitations on their use after the Merger. OpGen's net operating loss carryforwards may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. Additional ownership changes in the future could result in additional limitations on our net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. We have not performed an analysis on previous ownership changes. It is possible that we have experienced an ownership change, or that we will experience an ownership change in the future. We had U.S. federal NOL carryforwards of \$90.3 million and research and development tax credits of \$2.0 million as of December 31, 2015, that may already be or could be limited if we experience an ownership change.

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

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

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

Risks Related to our Securities and Public Company Status

Trading of our common stock is limited, and trading restrictions imposed on us by applicable regulations may further reduce trading in our common stock, making it difficult for our stockholders to sell their shares; and future sales of common stock could reduce our stock price.

Trading of our common stock is currently conducted on the Nasdaq Capital Market. The liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also as it may be adversely affected by delays in the timing of transactions and reduction in security analysts' and the media's coverage of us, if at all. As of March 31, 2016, a significant number of the issued and outstanding shares of our common stock were held by officers, directors and beneficial owners of at least 10% of our outstanding shares, each of whom is subject to certain restrictions with regard to trading our common stock. These factors may result in different prices for our common stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and asked prices for our common stock. In addition, without a large public float, our common stock is less liquid than the stock of companies with broader public ownership, and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future, if at all.

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

Our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 78% of our outstanding common stock as of the date of this filing. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of the Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

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

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

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

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

As a public company, we will be required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our annual report for the year ending December 31, 2016, provide a management report on the internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We are in the process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act of 2002. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

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

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

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

We are an emerging growth company, as defined under the Securities Act. We will remain an emerging growth company for up to five years, although if our revenue exceeds \$1 billion in any fiscal year before that time, we would cease to be an emerging growth company as of the end of that fiscal year. In addition, if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our second fiscal quarter of any fiscal year before the end of that five-year period, we would cease to be an emerging growth company as of December 31 of that year. As an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to certain other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced financial statement and financial-related disclosures, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirement of holding a nonbinding advisory vote on executive compensation and obtaining stockholder approval of any golden parachute payments not previously approved by our stockholders. We cannot predict whether investors will find our common stock less attractive if we choose to rely on any of these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure we may make, there may be a less active trading market for our common stock and our stock price may be more volatile.

Item 2. Unregistered Sales of Equity and Use of Proceeds

Unregistered Sales of Equity Securities

The Company issued no unregistered securities in the first quarter of 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 Unit consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of \$6.00 per unit. Of the total gross proceeds of \$17.1 million, approximately \$2.1 million was used to satisfy outstanding demand notes by exchanging such notes for 350,000 Units in the IPO. After considering the demand notes, 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 originally intended 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 tests and, when development was completed, our Acuitas Lighthouse Services, 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 Acuitas Lighthouse and future products and services 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.

As of March 31, 2016 we have used all of the net proceeds from our IPO for sales and marketing, research and development and working capital purposes. There has been no material change in the original planned use of proceeds. 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/ Timothy C. Dec
Timothy C. Dec
Chief Financial Officer

Date: May 16, 2016

EXHIBIT INDEX

Exhibit Number	Description
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 or furnished herewith

**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: May 16, 2016

/s/ Evan Jones

Evan Jones

Chief Executive Officer (principal executive officer)

**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: May 16, 2016

/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 March 31, 2016 (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: May 16, 2016

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

Date: May 16, 2016

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.
