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 September 30, 2017

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	**06-1614015**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. employer identification no.)**
708 Quince Orchard Road, Suite 205, Gaithersburg, MD	**20878**
(Address of principal executive offices)	**(Zip code)**

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ 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, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

54,873,143 shares of the Company's common stock, par value $0.01 per share, were outstanding as of November 6, 2017.

OPGEN, INC.

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q of OpGen, Inc. contains 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:

- our ability to finance our operations;
- the completion of our development efforts for the Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase, and the timing of commercialization;
- the execution of our business plan and our growth strategy;
- our expectations regarding the size of and growth in potential markets;
- our ability to sustain or grow our customer base for our current products;
- our liquidity and working capital requirements, including our cash requirements over the next 12 months and beyond;
- our expectations regarding future revenue and expenses;
- anticipated trends and challenges in our business and the competition that we face;
- our opportunity to successfully enter into new collaborative agreements;
- changes in laws or regulations applicable to our business, including potential regulation by the FDA; and
- compliance with the U.S. and international regulations applicable to our business.

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. These risks should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to the risk factors described in Part II, Item 1A of this quarterly report. 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. and Subsidiaries
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2017	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 4,854,031	$ 4,117,324
Accounts receivable, net	469,954	542,420
Inventory, net	461,129	692,368
Prepaid expenses and other current assets	340,923	329,646
Total current assets	**6,126,037**	**5,681,758**
Property and equipment, net	750,090	800,723
Goodwill	600,814	600,814
Intangible assets, net	1,420,136	1,620,998
Other noncurrent assets	321,592	279,752
Total assets	**$ 9,218,669**	**$ 8,984,045**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,939,175	$ 2,232,563
Accrued compensation and benefits	902,892	578,480
Accrued liabilities	857,024	1,215,283
Deferred revenue	31,239	37,397
Short-term notes payable	1,100,012	1,023,815
Current maturities of long-term capital lease obligation	160,485	184,399
Total current liabilities	**4,990,827**	**5,271,937**
Deferred rent	319,273	398,084
Warrant liability	28,378	—
Long-term capital lease obligation and other noncurrent liabilities	119,764	146,543
Total liabilities	**5,458,242**	**5,816,564**
Commitments (Note 8)		
Stockholders' equity		
Common stock, $0.01 par value; 200,000,000 shares authorized; 51,964,878 and 25,304,270 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	519,648	253,042
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at September 30, 2017 and December 31, 2016, respectively	—	—
Additional paid-in capital	148,994,194	136,199,382
Accumulated other comprehensive (loss)/income	(7,649)	6,176
Accumulated deficit	(145,745,766)	(133,291,119)
Total stockholders' equity	**3,760,427**	**3,167,481**
Total liabilities and stockholders' equity	**$ 9,218,669**	**$ 8,984,045**

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue				
Product sales	$ 729,742	$ 730,325	$ 2,145,371	$ 2,705,690
Laboratory services	9,070	23,036	41,025	182,130
Collaboration revenue	6,302	6,302	33,699	131,302
Total revenue	**745,114**	**759,663**	**2,220,095**	**3,019,122**
Operating expenses				
Cost of products sold	448,407	400,001	1,266,148	1,269,990
Cost of services	49,119	51,802	228,115	528,733
Research and development	1,513,157	2,178,818	5,397,906	6,278,829
General and administrative	1,600,577	1,639,996	5,319,811	4,955,096
Sales and marketing	330,305	1,294,640	2,345,293	4,282,628
Total operating expenses	**3,941,565**	**5,565,257**	**14,557,273**	**17,315,276**
Operating loss	**(3,196,451)**	**(4,805,594)**	**(12,337,178)**	**(14,296,154)**
Other expense				
Other (expense)/income	(87,292)	623	(87,270)	(3,078)
Interest expense	(90,317)	(41,423)	(173,974)	(109,806)
Foreign currency transaction gains/(losses)	8,018	(1,269)	19,636	2,293
Changes in fair value of warrant liabilities	97,395	—	124,139	—
Total other expense	**(72,196)**	**(42,069)**	**(117,469)**	**(110,591)**
Loss before income taxes	**(3,268,647)**	**(4,847,663)**	**(12,454,647)**	**(14,406,745)**
Provision for income taxes	—	—	—	—
Net loss	**(3,268,647)**	**(4,847,663)**	**(12,454,647)**	**(14,406,745)**
Preferred stock dividends and beneficial conversion	—	—	—	(332,550)
Net loss available to common stockholders	**$ (3,268,647)**	**$ (4,847,663)**	**$ (12,454,647)**	**$ (14,739,295)**
Net loss per common share - basic and diluted	**$ (0.07)**	**$ (0.23)**	**$ (0.37)**	**$ (0.92)**
Weighted average shares outstanding - basic and diluted	47,078,415	20,938,700	33,956,494	16,028,047
Net loss	$ (3,268,647)	$ (4,847,663)	$ (12,454,647)	$ (14,406,745)
Other comprehensive (loss)/income - foreign currency translation	(6,234)	672	(13,825)	1,059
Comprehensive loss	**$ (3,274,881)**	**$ (4,846,991)**	**$ (12,468,472)**	**$ (14,405,686)**

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30, 2017	2016
Cash flows from operating activities		
Net loss	$ (12,454,647)	$ (14,406,745)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	499,651	494,828
Loss on disposal of property and equipment	—	6,308
Noncash interest expense	65,511	3,126
Share-based compensation	722,304	706,648
Inventory obsolescence	—	109,367
Change in fair value of warrant liabilities	(124,139)	—
Unamortized discount on bridge loan at repayment	85,932	—
Changes in operating assets and liabilities:		
Accounts receivable	72,466	231,960
Inventory	231,239	(113,560)
Other assets	(337,999)	124,133
Accounts payable	(293,388)	(349,780)
Accrued compensation and other liabilities	337,562	313,644
Deferred revenue	(6,158)	13,499
Net cash used in operating activities	**(11,201,666)**	**(12,866,572)**
Cash flows from investing activities		
Purchases of property and equipment (net of proceeds on disposals)	(142,687)	(87,533)
Net cash used in investing activities	**(142,687)**	**(87,533)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	3,426,050	124
Proceeds from issuance of promissory notes, net of issuance costs	—	204,895
Proceeds from private offering of common stock, preferred stock and warrants, net of issuance costs	—	9,460,751
Proceeds from issuance of units, net of selling costs	8,754,882	—
Proceeds from exercise of stock options and warrants	48,179	23,771
Proceeds from debt, net of issuance costs	1,168,222	—
Payments on debt	(1,146,287)	(101,796)
Payments on capital lease obligations	(156,161)	(188,231)
Net cash provided by financing activities	**12,094,885**	**9,399,514**
Effects of exchange rates on cash	(13,825)	1,276
Net increase/(decrease) in cash and cash equivalents	736,707	(3,553,315)
Cash and cash equivalents at beginning of period	4,117,324	7,814,220
Cash and cash equivalents at end of period	**$ 4,854,031**	**$ 4,260,905**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 108,463	$ 46,022
Supplemental disclosures of noncash investing and financing activities:		
Unpaid deferred offering costs	$ —	$ 137,178
Shares issued to settle obligations	$ 110,000	$ —
Issuance of placement agent warrant	$ 93,677	$ —

See accompanying notes to unaudited condensed consolidated financial statements.

Note 1 – Organization

OpGen, Inc. (“OpGen” or the “Company”) was incorporated in Delaware in 2001. References in this report to the “Company” include OpGen and its wholly-owned subsidiaries. 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 help combat infectious disease. The Company is developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. Its proprietary DNA tests and informatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize care decisions for patients with acute infections.

The Company’s molecular diagnostics and informatics offerings combine its Acuitas DNA tests and Acuitas Lighthouse informatics platform for use with its proprietary, curated MDRO knowledgebase. The Company is working to deliver our products and services, some in development, to a global network of customers and partners. These include:

- Its Acuitas DNA tests provide rapid microbial identification and antibiotic resistance gene information. These products include our Acuitas Rapid Test for complicated urinary tract infection in development, the QuickFISH family of FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures, and its Acuitas Resistome Tests for genetic analysis of hospital surveillance isolates.
- Its Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that combine clinical lab test results with patient and hospital information to provide analytics and actionable insights to help manage MDROs in the hospital and patient care environment. Components of its informatics systems are the Acuitas Lighthouse Knowledgebase, a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens and its Acuitas Lighthouse informatics, which can be specific to a healthcare facility or collaborator, such as a pharmaceutical company.

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 and has raised funds in 2017 and 2016, including:

- On July 18, 2017 the Company closed a public offering of 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million (the “July 2017 Public Offering”). jVen Capital, LLC, a Delaware limited liability company ("jVen Capital") was one of the investors participating in the offering. jVen Capital is an affiliate of Evan Jones, the Company’s Chairman of the Board and Chief Executive Officer. Each unit included one share of common stock and one common warrant to purchase one share of common stock at an exercise price of $0.425 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one common warrant to purchase one share of common stock at an exercise price of $0.425 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. Approximately $1 million of the gross proceeds was used to repay the outstanding Bridge Financing Notes (as defined below) in July 2017. Four million pre-funded warrants were exercised in July 2017 (see Note 11 “Subsequent events”).
- In early June 2017, the Company commenced a restructuring of its operations to improve efficiency and reduce its cost structure. The Company expects these actions to reduce operating expenses by 25-30 percent by the fourth quarter of 2017. The restructuring plans anticipate that the Company will consolidate operations for FDA-cleared and CE marked products

and research and development activities for the Acuitas Rapid Test in Gaithersburg, Maryland, and reduce the size of its commercial organization while the Company works to complete the development of its Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase products and services in development.

- On May 31, 2017, the Company entered into a Note Purchase Agreement with jVen Capital, under which jVen Capital agreed to provide bridge financing in an aggregate principal amount of up to $1,500,000 to the Company in up to three separate tranches of $500,000 (each, a "Bridge Financing Note" and collectively, the "Bridge Financing Notes"). The interest rate on each Bridge Financing Note was ten percent (10%) per annum (subject to increase upon an event of default). The Bridge Financing Notes were prepayable by the Company at any time without penalty, and had a maturity date of September 30, 2017, which could be accelerated upon the closing of a qualified financing (any equity or debt financing that raised net proceeds of $5 million or more). The Bridge Financing Notes were contingently convertible at the option of the holder upon an event of default into shares of the Company's convertible Series B preferred stock. In connection with the issuance of Bridge Financing Notes, in June and July 2017, the Company issued jVen Capital stock purchase warrants to acquire 140,845 shares with an exercise price of $0.78 per share, and warrants to acquire 158,730 shares with an exercise price of $0.69 per share. The Company drew down on two of three Bridge Financing Notes during June and July, and repaid such outstanding Bridge Financing Notes in full upon the closing of the July 2017 Public Offering.

- As a condition to the receipt of the bridge financing, the Company issued the Second Amended & Restated Senior Secured Promissory Note (the "A&R MGHIF Note") to Merck Global Health Innovation Fund, LLC ("MGHIF"), which extended the maturity date of the promissory note from, July 14, 2017 to July 14, 2018. In return for MGHIF's consent to such extension, the Company increased the interest rate of the A&R MGHIF Note to 10% per annum and issued warrants to purchase shares of common stock to MGHIF equal to 20% of the principal balance of the A&R MGHIF Note, plus interest accrued thereon, as of June 28, 2017.

- In September 2016, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company LLC ("Cowen") pursuant to which the Company may offer and sell from time to time, up to an aggregate of $25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of $11.5 million. Pursuant to the Sales Agreement, Cowen may sell the shares of the Company's common stock by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933, as amended (the "Securities Act"), including, without limitation, sales made by means of ordinary brokers' transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by the Company. The Company pays Cowen compensation equal to 3.0% of the gross proceeds from the sales of common stock pursuant to the terms of the Sales Agreement. As of September 30, 2017, the Company has sold an aggregate of approximately 7.7 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $7.8 million, and gross proceeds of $8.4 million. As of September 30, 2017, remaining availability under the at the market offering is $3.1 million. The Company did not sell any shares of its common stock under this at the market offering during the three months ended September 30, 2017. During the nine months ended September 30, 2017, the Company has sold approximately 4.0 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $3.4 million, and gross proceeds of $3.6 million.

- In May and June 2016, the Company offered and sold units in a private offering to members of management and employees and to accredited investors, including MGHIF and jVen Capital, each unit consisting of either (i) one share of common stock and a detachable stock purchase warrant to purchase an additional 0.75 shares of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.75 shares of common stock, at a price of $1.14 per unit. The total net proceeds to the Company, after deducting offering commissions and expenses were $9.5 million. The Company used the proceeds for working capital and general corporate purposes. Pursuant to the private placement, the Company issued 6,744,127 shares of common stock, 2,309,428 shares of non-voting convertible preferred stock and stock purchase warrants to acquire an additional 6,790,169 shares of common stock. Holders of the non-voting convertible preferred stock subsequently converted all 2,309,428 shares of preferred stock into 2,309,428 shares of common stock. The stock purchase warrants issued as part of the units are exercisable at a price of $1.3125 per share beginning 90 days after closing for five years, expiring on May 18, 2021.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, strategic financings or other transactions, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements and business combination transactions. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. The Company believes that current cash on hand will be sufficient to fund operations into the first quarter of 2018. This has led management to conclude that substantial doubt about the Company's ability to continue as a going concern exists. In the event the Company is unable to successfully raise additional capital during or before the first quarter of 2018, 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 immediately 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. If such sufficient financing is not received on a timely basis, the Company would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

Note 3 - Summary of significant accounting policies

Basis of presentation and consolidation

The Company has prepared the accompanying unaudited condensed, consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") and the standards of accounting measurement set forth in the Interim Reporting Topic of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"). Certain information and note disclosures normally included in annual financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP") have been condensed or omitted, although the Company believes that the disclosures made are adequate to make the information not misleading. The Company recommends that the following unaudited condensed, consolidated financial statements be read in conjunction with the audited condensed, consolidated financial statements and the notes thereto included in the Company's latest Annual Report on Form 10-K. In the opinion of management, all adjustments that are necessary for a fair presentation of the Company's financial position for the periods presented have been reflected. All adjustments are of a normal, recurring nature, unless otherwise stated. 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, 2016 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 condensed consolidated financial statements include the accounts of OpGen and its wholly-owned subsidiaries; all intercompany transactions and balances have been eliminated. The Company operates in one business segment.

Foreign currency

One of the Company's subsidiaries 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)/income, a component of stockholders' equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive (loss)/income at September 30, 2017 and December 31, 2016.

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 unaudited condensed 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 and other liabilities measured at fair value on a recurring basis, deferred tax assets and liabilities and related valuation allowance, depreciation and amortization and estimated useful lives of long-lived assets. Actual results could differ from those estimates.

Fair value of financial instruments

Financial instruments classified as current assets and liabilities (including cash and cash equivalent, receivables, accounts payable, deferred revenue and short-term notes) are carried at cost, which approximates fair value, because of the short-term maturities of those instruments.

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 September 30, 2017 and December 31, 2016, 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 noncurrent assets on the accompanying unaudited 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 $24,783 and $26,716 as of September 30, 2017 and December 31, 2016, respectively.

No individual customer represented in excess of 10% of revenues for the three months ended September 30, 2017. Revenue earned from one customer represented 11% of total revenues for the three months ended September 30, 2016. No individual customer represented in excess of 10% of revenues for the nine months ended September 30, 2017 and 2016. At September 30, 2017, no individual customer represented in excess of 10% of total accounts receivable. At September 30, 2016, accounts receivable from one customer represented 11% of the total accounts receivable.

Inventory

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

	September 30, 2017	December 31, 2016
Raw materials and supplies	$ 279,562	$ 479,479
Work-in process	40,814	27,422
Finished goods	140,753	185,467
Total	$ 461,129	$ 692,368

Inventory includes 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 $157,529 and $704,516 at September 30, 2017 and December 31, 2016, respectively. The primary driver of the decrease in the inventory reserves for obsolescence and expirations is the disposal of legacy Argus Whole Genome Mapping Systems and the portion of the reagents and supplies used for Argus consumable kits. All items disposed in the nine months ended September 30, 2017 related to Argus were fully reserved for as of December 31, 2016.

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 and nine months ended September 30, 2017 and 2016, the Company determined that its property and equipment was not impaired.

Intangible assets and goodwill

Intangible assets and goodwill as of September 30, 2017 consist of finite-lived intangible assets and goodwill.

Finite-lived intangible assets

Finite-lived intangible assets include trademarks, developed technology and customer relationships and consisted of the following as of September 30, 2017 and December 31, 2016:

	September 30, 2017			December 31, 2016	
	Cost	Accumulated Amortization	Net Balance	Accumulated Amortization	Net Balance
Trademarks and tradenames	$ 461,000	$ (102,153)	$ 358,847	$ (67,575)	$ 393,425
Developed technology	458,000	(144,966)	313,034	(95,898)	362,102
Customer relationships	1,094,000	(345,745)	748,255	(228,529)	865,471
	$ 2,013,000	$ (592,864)	$ 1,420,136	$ (392,002)	$ 1,620,998

Finite-lived intangible assets are amortized over their estimated useful lives. The estimated useful life of trademarks was 10 years, developed technology was 7 years, and customer relationships was 7 years. The Company reviews the useful lives of intangible assets when events or changes in circumstances occur which may potentially impact the estimated useful life of the intangible assets.

Total amortization expense of intangible assets was $66,954 for each of the three months ended September 30, 2017 and 2016. Total amortization expense of intangible assets was $200,862 for each of the nine months ended September 30, 2017 and 2016, respectively. The Company estimates amortization expense related to intangible assets will be $268,000 per year for each of the next five years.

Finite-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 and nine months ended September 30, 2017 and 2016, the Company determined that its finite-lived intangible assets were not impaired.

In accordance with ASC 360-10, *Property, Plant and Equipment*, the Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that long-lived assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. During the fourth quarter of 2016, events and circumstances indicated the Company's intangible assets might be impaired. However, management's estimate of undiscounted cash flows indicated that such carrying amounts were expected to be recovered. Nonetheless, it is reasonably possible that the estimate of undiscounted cash flows may change in the near term resulting in the need to write down those assets to fair value. Management's estimate of cash flows might change if the Company's commercial operations are negatively impacted by the consolidation of operations for the FDA-cleared and CE marked products to Gaithersburg, Maryland or if there is an unfavorable development of sales trends.

Goodwill

Goodwill represents the excess of the purchase price paid in a July 2015 merger transaction in which the Company acquired AdvanDx, Inc. and its subsidiary (the "Merger") over the fair values of the acquired tangible or intangible assets and assumed liabilities. Goodwill is not tax deductible in any relevant jurisdictions. The Company's goodwill balance as of September 30, 2017 and December 31, 2016 was $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.

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 products sold.

Revenue from sales of QuickFISH, PNA FISH and XpressFISH diagnostic test products

Revenue is recognized upon shipment to the customer.

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.

Revenue from license arrangements

The Company recognizes revenue from licenses of its technologies over the applicable license term.

Revenue from sales of the reagents and supplies used for Argus consumable kits

Revenue is recognized for sales of the reagents and supplies used for Argus consumable kits upon shipment to the customer.

Share-based compensation

Share-based compensation expense is recognized at fair value. The fair value of share-based compensation 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. The Company accounts for forfeitures as they occur.

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 $151.0 million at December 31, 2016. 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) restricted stock units representing the right to acquire shares of common stock which have been excluded from the computation of diluted loss per share, was 44.0 million shares and 13.5 million shares as of September 30, 2017 and 2016, respectively.

Recent accounting pronouncements

In May 2014, the FASB issued an Accounting Standards Update ("ASU") 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. In April 2016, the FASB issued guidance to clarify the identification of performance obligations and licensing arrangements. In May 2016, the FASB issued guidance addressing the presentation of sales and other similar taxes collected from customers, providing clarification of the collectability criterion assessment, as well as clarifying certain transition requirements. The Company has identified its major revenue streams and it plans on completing formal contract reviews in the fourth quarter of 2017. While the Company continues to assess all of the potential impacts of these ASUs, the Company does not expect the implementation of these ASUs to have a significant impact on the Company's results of operations, financial position or cash flows.

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 adopted this guidance effective January 1, 2017 on a prospective basis. The adoption of this new guidance did not have a material impact on the Company's consolidated 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 consolidated balance sheets 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 consolidated financial statements.

The Company has evaluated all other issued and unadopted ASUs 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 – 2015 MGHIF financing

In July 2015, in connection with the Merger, the Company entered into a Purchase Agreement with MGHIF, pursuant to which MGHIF 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 MGHIF an 8% Senior Secured Promissory Note (the "MGHIF 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 MGHIF Note are secured by a lien on all of the Company's assets. Under the Purchase Agreement, MGHIF has the right to participate in future securities offerings made by the Company. Also in July 2015, the Company entered into a Registration Rights Agreement with MGHIF and certain stockholders, which will require the Company to register for resale by such holders in the future, such shares of Company common stock that cannot be sold under an exemption from such registration.

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

On June 6, 2017, the promissory note was amended and restated, and the maturity date of the A&R MGHIF Note was extended by one year to July 14, 2018. As consideration for the agreement to extend the maturity date, the Company issued an amended and restated secured promissory note to MGHIF that (1) increased the interest rate to ten percent (10%) per annum and (2) provided for the issuance of common stock warrants to purchase 327,995 shares of its common stock to MGHIF . The warrants issued to MGHIF each have a five year term from issuance, are first exercisable on the date that is six months after the date of issuance and have an exercise price equal $0.78 which represents 110% of the closing price of the Company's common stock on the date of issuance.

The A&R MGHIF Note was treated as a debt modification and as such the issuance date fair value of the warrants is deferred and amortized as incremental interest expense over the term of A&R MGHIF Note. The warrants are classified as mark to market liabilities under ASC 480, *Distinguishing Liabilities from Equity*, due to certain put features that allow the holder to put the warrant back to the Company for cash equal to the Black-Scholes value of the warrant upon a change of control or fundamental transaction, as defined in the agreement. The warrants had an issuance date fair value of approximately $0.1 million which was calculated using the Black-Scholes model.

The estimated fair value of the A&R MGHIF Note was $1.0 million as of September 30, 2017 and December 31, 2016 which approximates the carry value given the short time lapse since modification, prevailing interest rates and maturity date

Note 5 - 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.

For the nine months ended September 30, 2017, the Company has not transferred any assets between fair value measurement levels.

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.

As part of the Company's bridge financing and amendment to the A&R MGHIF Note, the Company issued stock purchase warrants that the Company considers to be mark-to-market liabilities due to certain put features that allow the holder to put the warrant back to the Company for cash equal to the Black-Scholes value of the warrant upon a change of control or fundamental transaction. The Company determines the fair value of the warrant liabilities using the Black-Scholes option pricing model. Using this model, level 3 unobservable inputs include the estimated volatility of the Company's common stock, estimated terms of the instruments, and estimated risk-free interest rates.

The Company originally accounted for the conversion option embedded in the Bridge Financing Notes as a mark-to-market derivative financial instrument. The Company determined the fair value of the embedded conversion option liability using a probability-weighted expected return method. Using this method, level 3 unobservable inputs include the probability of default, the probability of

a qualified financing, the probability of conversion, the estimated volatility of the Company's common stock, estimated terms of the instruments, and estimated risk-free interest rates, among other inputs. The fair value of the conversion option was expensed at the time of repayment of the Bridge Financing Notes.

The following table sets forth a summary of changes in the fair value of level 3 liabilities measured at fair value on a recurring basis for the three and nine months ended September 30, 2017:

Description	Balance at December 31, 2016	Established in 2017	Changes in Fair Value	Expensed	Balance at September 30, 2017
Embedded conversion option liability	$ —	$ 4,500	$ —	$ (4,500)	$ —
Warrant liability	$ —	$ 152,517	$ (124,139)	$ —	$ 28,378

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 and nine months ended September 30, 2017 and 2016.

Note 6 - Debt

As of September 30, 2017, the Company's outstanding short-term debt consisted of the $1.0 million MGHIF Note, net of discounts and financing costs (see Note 4 "2015 MGHIF financing") as well as, the financing arrangements for the Company's insurance with note balances of approximately $0.2 million with a final payment scheduled for May 2018. Total principal payments of $0.2 million are due in 2017 and $1.0 million are due in 2018. As of December 31, 2016, the Company's outstanding long-term debt consisted of the $1.0 million MGHIF Note, net of discounts and financing costs.

The Company drew down on two of three Bridge Financing Notes (see discussion in Note 2 "Liquidity and management's plans) during June and July of 2017. The outstanding Bridge Financing Notes were repaid in full subsequent to the closing of the July 2017 Public Offering.

The Company accounted for the embedded conversion option granted to jVen Capital in the Bridge Financing Notes as a mark-to-market derivative financial instrument carried at fair value. Changes in fair value of the embedded conversion option are reflected in earnings during the period of change. The embedded conversion option was expensed along with the remaining unamortized discount at the date of the Bridge Financing Notes repayment. The warrants issued to jVen Capital and MGHIF are classified as mark-to-market liabilities under ASC 480 due to certain put features that allow the holder to put the warrant back to the Company for cash equal to the Black-Scholes value of the warrant upon a change of control or fundamental transaction.

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $90,317 and $41,423 for the three months ended September 30, 2017 and 2016, respectively. Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $173,974 and $109,806 for the nine months ended September 30, 2017 and 2016, respectively.

Note 7 - Stockholders' equity

As of September 30, 2017, the Company has 200,000,000 shares of authorized common stock and 51,964,878 shares issued and outstanding, and 10,000,000 authorized preferred shares, of which none were issued or outstanding.

In the July 2017 Public Offering, the Company issued 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million. jVen Capital

was one of the investors participating in the offering. Each unit included one share of common stock and one common warrant to purchase one share of common stock at an exercise price of $0.425 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one common warrant to purchase one share of common stock at an exercise price of $0.425 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. At closing, the outstanding Bridge Financing Notes issued to jVen Capital, were repaid in the principal amount of $1 million plus accrued interest of $6,438. Four million pre-funded warrants were exercised during the three months ended September 30, 2017 (see Note 11 “Subsequent events”).

In connection with the July 2017 Public Offering, the Company issued to its placement agent 1,250,000 shares of common stock. The warrants issued to the Placement Agent have an exercise price of $0.50 per share and are exercisable for five years.

In September 2016, the Company entered into the Sales Agreement with Cowen pursuant to which the Company may offer and sell from time to time, up to an aggregate of $25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of $11.5 million. Pursuant to the Sales Agreement, Cowen may sell the shares of common stock by any method permitted by law deemed to be an "at the market” offering as defined in Rule 415 of the Securities Act, including, without limitation, sales made by means of ordinary brokers' transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by the Company. The Company pays Cowen compensation equal to 3.0% of the gross proceeds from the sales of common stock pursuant to the terms of the Sales Agreement. As of September 30, 2017, the Company has sold an aggregate of approximately 7.7 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $7.8 million, and gross proceeds of $8.4 million. As of September 30, 2017, remaining availability under the at the market offering is $3.1 million. The Company did not sell any shares of its common stock under this at the market offering during the three months ended September 30, 2017. During the nine months ended September 30, 2017, the Company has sold approximately 4.0 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $3.4 million, and gross proceeds of $3.6 million.

In May and June 2016, the Company offered and sold units in a private offering to members of management and employees and to accredited investors, including MGHIF and jVen Capital, each unit consisting of either (i) one share of common stock and a detachable stock purchase warrant to purchase an additional 0.75 shares of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.75 shares of common stock, at a price of $1.14 per unit. The total net proceeds to the Company, after deducting offering commissions and expenses was $9.5 million. Pursuant to the private placement the Company issued 6,744,127 shares of common stock, 2,309,428 of Series A non-voting convertible preferred stock and stock purchase warrants to acquire an additional 6,790,169 shares of common stock. Under the purchase agreement, the Company granted registration rights to the investors in the private financing.

Each share of Series A non-voting convertible preferred stock was convertible at the option of the holder in whole or in part and from time to time into one share of common stock, was entitled to dividends on an “as converted basis” when and if dividends are issued to common stockholders, and would have participated in liquidation on a *pari passu* basis with common stockholders. The preferred stock was classified as permanent equity. The stock purchase warrants issued as part of the units are exercisable at $1.3125 per share beginning 90 days after closing for five years, expiring on May 18, 2021. The warrants are classified as permanent equity at September 30, 2017. In connection with the issuance of Series A non-voting convertible preferred stock, the Company recognized a beneficial conversion feature of $332,550 as a deemed dividend to the preferred shareholders. Holders of the Series A non-voting convertible preferred stock subsequently converted all 2,309,428 shares of preferred stock into 2,309,428 shares of common stock.

The Company filed a registration statement on Form S-3 on June 13, 2016 to register for resale by the investors, from time to time, of the shares of common stock acquired, or underlying the warrants issued, in the private offering. On July 20, 2016, the registration statement was declared effective by the SEC.

Stock options

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 could 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 initial public offering in May 2015. Following the effectiveness of the 2015 Plan, no further grants will be made under the 2008 Plan. The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for the grants of

restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants.

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 1,355,000 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date, that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan 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 September 30, 2017, 869,194 shares remain available for issuance under the 2015 Plan, which includes 1,012,171 shares automatically added to the 2015 Plan on January 1, 2017.

On April 28, 2016, the Board of Directors of the Company made a stock option award to Evan Jones, the Company's Chief Executive Officer ("CEO") and Chairman of the Board. The non-qualified stock option award to acquire 766,500 shares of common stock represented approximately 6% of outstanding shares of common stock as of the date of the award. The stock option grant has an exercise price of $1.35 per share, 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 plan under which the award was made incorporates by reference the provisions of the Company's 2015 Plan applicable to stock option awards. The stock option award was contingent on receipt of stockholder approval, as the award was made outside of the Company's stockholder-approved incentive plans. The stockholders approved the stock option award at the Company's Annual Meeting of Stockholders held on June 22, 2016.

For the three and nine months ended September 30, 2017 and 2016, the Company recognized stock compensation expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Cost of services	$ 2,306	$ —	$ 6,274	$ 5,008
Research and development	61,097	45,945	171,652	181,367
General and administrative	187,357	98,683	500,252	447,811
Sales and marketing	16,832	34,124	44,126	72,462
	$ 267,592	$ 178,752	$ 722,304	$ 706,648

No income tax benefit for stock-based compensation arrangements was recognized in the condensed consolidated statements of operations and comprehensive loss due to the Company's net loss position.

During the three months ended September 30, 2017, the Company granted stock options to acquire 409,500 shares of common stock at a weighted average exercise price of $0.30 per share and a weighted average grant date fair value of $0.12 per share. 196,288 options were forfeited during the three months ended September 30, 2017 at a weighted average exercise price of $1.11 per share.

During the nine months ended September 30, 2017, the Company granted stock options to acquire 1,279,100 shares of common stock at a weighted average exercise price of $0.76 per share and a weighted average grant date fair value of $0.38 per share. 504,197 options were forfeited during the nine months ended September 30, 2017 at a weighted average exercise price of $1.33 per share. The Company had total stock options to acquire 3,471,729 shares of common stock outstanding at September 30, 2017.

Restricted stock units

During the three and nine months ended September 30, 2017, the Company granted restricted stock units to acquire 289,376 shares of common stock, with a weighted average grant date fair value of $0.28. 26,500 restricted stock units vested and no restricted stock units were forfeited during the three and nine months ended September 30, 2017. The Company had 281,626 total restricted stock units outstanding at September 30, 2017.

Stock purchase warrants

At September 30, 2017 and December 31, 2016, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at September 30, 2017	Outstanding at December 31, 2016
August 2007	$ 7.91	August 2017	—	8,921
March 2008	$ 790.54	March 2018	46	46
November 2009	$ 7.91	November 2019	6,674	6,674
January 2010	$ 7.91	January 2020	6,674	6,674
March 2010	$ 7.91	March 2020	1,277	1,277
November 2011	$ 7.91	November 2021	5,213	5,213
December 2011	$ 7.91	December 2021	664	664
March 2012	$ 109.90	March 2019	4,125	4,125
February 2015	$ 6.60	February 2025	225,011	225,011
May 2015	$ 6.60	May 2020	3,457,750	3,457,750
May 2016	$ 1.31	May 2021	4,739,348	4,739,348
June 2016	$ 1.31	May 2021	2,050,821	2,050,821
June 2017	$ 0.78	June 2022	468,840	—
July 2017	$ 0.69	July 2022	158,730	—
July 2017	$ 0.50	July 2022	1,250,000	—
July 2017 (1)	$ 0.01	July 2022	2,835,805	—
July 2017	$ 0.43	July 2022	25,000,000	—
			40,210,978	10,506,524

The warrants listed above were issued in connection with various debt, equity or development contract agreements.

(1) These July 2017 warrants represent the outstanding pre-funded warrants issued under the July 2017 Public Offering. See Note 7 “Stockholders’ equity” and Note 11 “Subsequent events.”

Note 8 - Commitments

Operating leases

The Company leases a facility in Woburn, Massachusetts under an operating lease that expires January 30, 2022. The Company also leases a facility in Gaithersburg, Maryland under an operating lease that expires January 31, 2021, with one additional five-year renewal at the Company’s election. 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 September 30, 2017 and 2016 was $238,791 and $254,219, respectively. Rent expense under the Company’s facility operating leases for the nine months ended September 30, 2017 and 2016 was $710,330 and $756,608, respectively.

Capital leases

The Company leases computer equipment, office furniture, and equipment under various capital leases. The leases expire at various dates through 2021. The leases require monthly principal and interest payments.

Registration and other stockholder rights

In connection with the various investment transactions, the Company entered into registration rights agreements with stockholders, pursuant to which the investors were granted certain demand registration rights and/or piggyback and/or resale registration rights in connection with subsequent registered offerings of the Company’s common stock.

Restructuring

In early June 2017, the Company commenced a restructuring of its operations to improve efficiency and reduce its cost structure. The Company expects these actions to reduce operating expenses by 25-30 percent by the fourth quarter of 2017. The restructuring plans

anticipate that the Company will consolidate operations for FDA-cleared and CE marked products and research and development activities for the Acuitas Rapid Test in Gaithersburg, Maryland, and reduce the size of its commercial organization while the Company works to complete the development of its Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase products and services in development.

There were approximately $0 and $121,000 of one-time termination benefits that were recognized during the three and nine months ended September 30, 2017 related to the restructuring. The Company does not anticipate any further one-time termination benefits related to the restructuring plan. Retention agreements were issued to certain employees in which retention bonuses are earned and paid upon the completion of a designated service period. The service periods end in December 2017. The Company expects to incur total retention expense of approximately $68,000 of which approximately $34,000 and $47,000 was incurred during the three and nine months ended September 30, 2017. The future minimum lease payments for the Woburn facility were approximately $1.8 million as of September 30, 2017. A liability for costs that will continue to be incurred under a contract for its remaining term without economic benefit to the entity shall be recognized at the cease-use date. If the contract is an operating lease the fair value of the liability at the cease-use date shall be determined based on the remaining lease rentals, adjusted for the effects of any prepaid or deferred items recognized under the lease, and reduced by estimated sublease rentals that could be reasonably obtained for the property. The Company expects the cease-use date for the Woburn facility to be in the first quarter of 2018. We have not estimated the contract termination costs associated with this lease given that we have not yet reached the cease use date and given that we have only begun preliminary sublease pursuit activities. We do not believe there will be significant additional costs related to restructuring outside of what is described herein.

Note 9 - License agreements, research collaborations and development agreements

The Company is a party to one license agreement to acquire certain patent rights and technologies related to its FISH product line. Royalties are incurred upon the sale of a product or service which utilizes the licensed technology. The Company recognized net royalty expense of $62,500 and $71,135 for the three months ended September 30, 2017 and 2016, respectively. Under all license agreements, the Company recognized a net royalty expense of $194,686 and $216,937 for the nine months ended September 30, 2017 and 2016, respectively. Annual future minimum royalty fees are $250,000 under these agreements.

In June 2016, the Company entered into a license agreement with Hitachi High-Technologies Corporation (“Hitachi”), pursuant to which it resolved various matters with respect to previously delivered milestones under the technology development agreement and provided a development license and commercial products license to certain technology. The license agreement contains non-contingent multiple elements (the licenses) that the Company determined did not have stand alone value, and a contingent substantive milestone. The licenses are treated as a single unit of accounting and the Company will recognize the revenue associated with that unit of accounting over the applicable license period. During the three and nine months ended September 30, 2017, the Company recognized $6,301 and $18,698, respectively, of revenue related to the license agreement.

Note 10 - Related party transactions

In March 2014, the Company entered into a supply agreement (the “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 expanded the Supply Agreement, 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 resistance 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 was 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 $30,200 and $0 related to these agreements in the three months ended September 30, 2017 and 2016, respectively. The Company paid $74,921 and $160,089 related to these agreements in the nine months ended September 30, 2017 and 2016, respectively.

Under the Supply Agreement, the Company had inventory purchases of $19,760 and $23,624 in the three months ended September 30, 2017 and 2016, respectively. Under the Supply Agreement, the Company had inventory purchases of $110,239 and $91,399 in the nine months ended September 30, 2017 and 2016, respectively.

In addition, the Company has several capital lease arrangements for laboratory equipment manufactured by Fluidigm. The Company paid $15,683 and $45,106 related to the leased equipment in the three months ended September 30, 2017 and 2016, respectively. The Company paid $76,199 and $135,319 related to the leased equipment in the nine months ended September 30, 2017 and 2016, respectively.

In October 2016, the Company entered into an agreement with Merck Sharp & Dohme Corp., a wholly-owned subsidiary of Merck Co. & Inc. (“Merck”), an affiliate of MGHIF, a principal stockholder of the Company and a related party to the Company. Under the agreement, Merck provided access to its archive of over 200,000 bacterial pathogens. The Company is initially performing molecular analyses on up to 10,000 pathogens to identify markers of resistance to support rapid decision making using the Acuitas Lighthouse, and to speed development of its rapid diagnostic products. Merck gains access to the high-resolution genotype data for the isolates as well as access to the Acuitas Lighthouse informatics to support internal research and development programs. The Company is required to expend up to $175,000 for the procurement of materials related to the activities contemplated by the agreement. Contract life-to-date, the Company has incurred $146,177 of procurement costs which have been recognized as research and development expense, including $0 and $113,907 in the three and nine months ended September 30, 2017, respectively.

Note 11 – Subsequent events

As of October 16, 2017, all of the 6,835,805 pre-funded warrants issued in the July 2017 Public Offering have been exercised.

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 consolidated 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 for the year ended December 31, 2016.

Overview

OpGen was incorporated in Delaware in 2001. 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 help combat infectious disease. The Company is developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. Its proprietary DNA tests and informatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize care decisions for patients with acute infections.

The Company's molecular diagnostics and informatics offerings combine its Acuitas DNA tests and Acuitas Lighthouse informatics platform for use with its proprietary, curated MDRO knowledgebase. The Company is working to deliver our products and services, some in development, to a global network of customers and partners. These include:

- Its Acuitas DNA tests provide rapid microbial identification and antibiotic resistance gene information. These products include our Acuitas Rapid Test for complicated urinary tract infection in development, the QuickFISH family of FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures, and its Acuitas Resistome Tests for genetic analysis of hospital surveillance isolates.
- Its Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that combine clinical lab test results with patient and hospital information to provide analytics and actionable insights to help manage MDROs in the hospital and patient care environment. Components of its informatics systems are the Acuitas Lighthouse Knowledgebase, a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens and its Acuitas Lighthouse informatics, which can be specific to a healthcare facility or collaborator, such as a pharmaceutical company.

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 following financing transactions took place during 2017:

- On July 18, 2017, the Company closed its July 2017 Public Offering of 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million. jVen Capital, an affiliate of Evan Jones, the Company's Chairman of the Board and Chief Executive Officer, and three employees of the Company participated in the July 2017 Public Offering. Each unit included one share of common stock and one common warrant to purchase one share of common stock at an exercise price of $0.425 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one common warrant to purchase one share of common stock at an exercise price of $0.425 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. Approximately $1 million of the gross proceeds was used to repay the outstanding Bridge Financing Notes to jVen Capital in July 2017.
- On May 31, 2017, the Company entered into a Note Purchase Agreement with jVen Capital, under which jVen Capital agreed to provide bridge financing in an aggregate principal amount of up to $1,500,000 to the Company in up to three

separate tranches of Bridge Financing Notes. The interest rate on each Bridge Financing Note was ten percent (10%) per annum (subject to increase upon an event of default). In connection with the Bridge Financing Notes, the Company issued jVen Capital stock purchase warrants to acquire 140,845 shares with an exercise price of $0.78 per share, and stock purchase warrants to acquire 158,730 shares at an exercise price of $0.69 per share. On June 14, 2017, the Company drew down on the first of three Bridge Financing Notes, with $1 million remaining capacity available. The Company drew down on the second Bridge Financing Note on July 5, 2017 and the third Bridge Financing Note was never issued. The outstanding Bridge Financing Notes were repaid in full upon the closing of the July 2017 Public Offering.

- On June 6, 2017, as amended on June 28, 2017, the Company issued the amended and restated MGHIF Note to MGHIF, which extended the maturity date of the MGHIF Note from July 14, 2017 to July 14, 2018. In return for MGHIF's consent to such extension, the Company increased the interest rate of the MGHIF Note to 10% per annum and issued warrants to purchase shares of common stock to MGHIF equal to 20% of the principal balance of the MGHIF Note, plus interest accrued thereon, as of June 28, 2017.
- During the nine months ended September 30, 2017 the Company sold approximately 4.0 million shares of its common stock under its at the market offering resulting in aggregate net proceeds to the Company of approximately $3.4 million, and gross proceeds of $3.6 million.

In early June 2017, the Company commenced a restructuring of its operations to improve efficiency and reduce its cost structure. The Company expects these actions to reduce operating expenses by 25-30 percent by the fourth quarter of 2017. The restructuring plans anticipate that the Company will consolidate operations for FDA-cleared and CE marked products and research and development activities for the Acuitas Rapid Test in Gaithersburg, Maryland, and reduce the size of its commercial organization while the Company works to complete the development of its Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase products and services in development.

There were approximately $0 and $121,000 of one-time termination benefits that were recognized during the three and nine months ended September 30, 2017 related to the restructuring. The Company does not anticipate any further one-time termination benefits related to the restructuring plan. Retention agreements were issued to certain employees in which retention bonuses are earned and paid upon the completion of a designated service period. The service periods end in December 2017. The Company expects to incur total retention expense of approximately $68,000 of which approximately $34,000 and $47,000 were incurred during the three and nine months ended September 30, 2017. The future minimum lease payments for the Woburn facility were approximately $1.8 million as of September 30, 2017. A liability for costs that will continue to be incurred under a contract for its remaining term without economic benefit to the entity shall be recognized at the cease-use date. If the contract is an operating lease the fair value of the liability at the cease-use date shall be determined based on the remaining lease rentals, adjusted for the effects of any prepaid or deferred items recognized under the lease, and reduced by estimated sublease rentals that could be reasonably obtained for the property. The Company expects the cease-use date for the Woburn facility to be in the first quarter of 2018. We have not estimated the contract termination costs associated with this lease given that we have not yet reached the cease use date and given that we have only begun preliminary sublease pursuit activities. We do not believe there will be significant additional costs related to restructuring outside of what is described herein.

Results of operations for the three months ended September 30, 2017 and 2016

Revenues

	Three Months Ended September 30,	
	2017	2016
Revenue		
Product sales	$ 729,742	$ 730,325
Laboratory services	9,070	23,036
Collaboration revenue	6,302	6,302
Total revenue	$ 745,114	$ 759,663

Total revenue for the three months ended September 30, 2017 decreased approximately 2%. This decrease is primarily attributable to:

- Product Sales: product sales for the three months ended September 30, 2017 were relatively consistent with the same period in 2016;

- Laboratory Services: the decrease in revenue of approximately 61% in the 2017 period compared to the 2016 period is a result of decreases in sales of our Acuitas MDRO test services and Acuitas Lighthouse services; and
- Collaboration Revenue: collaboration revenue for the three months ended September 30, 2017 was consistent with the same period in 2016;

Operating expenses

	Three Months Ended September 30,	
	2017	2016
Cost of products sold	$ 448,407	$ 400,001
Cost of services	49,119	51,802
Research and development	1,513,157	2,178,818
General and administrative	1,600,577	1,639,996
Sales and marketing	330,305	1,294,640
Total operating expenses	$ 3,941,565	$ 5,565,257

The Company's total operating expenses for the three months ended September 30, 2017 decreased approximately 29% when compared to the same period in 2016. This decrease is primarily attributable to:

- Costs of products sold: cost of products sold for the three months ended September 30, 2017 increased approximately 12% when compared to the same period in 2016. The change in costs of products sold is primarily attributable to increased payroll and facility costs;
- Costs of services: cost of services for the three months ended September 30, 2017 decreased approximately 5% when compared to the same period in 2016. The change in costs of services is primarily attributable to a decrease in sales of Acuitas Lighthouse services;
- Research and development: research and development expenses for the three months ended September 30, 2017 decreased approximately 31% when compared to the same period in 2016, primarily due to a decrease in costs related to the automated rapid pathogen identification project;
- General and administrative: general and administrative expenses for the three months ended September 30, 2017 were relatively consistent with the same period in 2016;
- Sales and marketing: sales and marketing expenses for the three months ended September 30, 2017 decreased approximately 74% when compared to the same period in 2016, primarily due to costs incurred to conduct marketing studies conducted in 2016 and reductions in the size of our commercial organization that occurred in June 2017.

Other income (expense)

	Three Months Ended September 30,	
	2017	2016
Interest expense	$ (90,317)	$ (41,423)
Foreign currency transaction gains/(losses)	8,018	(1,269)
Other (expense)/income	(87,292)	623
Change in fair value of warrant liabilities	97,395	—
Total other expense	$ (72,196)	$ (42,069)

The Company's total other expense for the three months ended September 30, 2017 increased primarily as a result of an increase in interest expense due to the issuance of a Bridge Financing Note and modification of the MGHIF Note in June 2017 as well as the expense of the unamortized discount on the outstanding Bridge Financing Notes at repayment. The increase in other expense was partially offset by an increase in other income in the three months ended September 30, 2017, due to the change in the fair value of warrant liabilities, as a result of a decline the Company's stock price, and due to foreign currency gains.

Results of operations for the nine months ended September 30, 2017 and 2016

Revenues

	Nine Months Ended September 30,	
	2017	2016
Revenue		
Product sales	$ 2,145,371	$ 2,705,690
Laboratory services	41,025	182,130
Collaboration revenue	33,699	131,302
Total revenue	$ 2,220,095	$ 3,019,122

Total revenue for the nine months ended September 30, 2017 decreased approximately 26% as compared to the six months ended June 30, 2016. This decrease is primarily attributable to:

- Product Sales: the decrease in revenue of approximately 21% in the 2017 period compared to the 2016 period is primarily attributable to a reduction in the sale of our Argus products, as we transitioned from our legacy mapping products to the introduction of Acuitas MDRO products sales, and a reduction in the sale of our rapid pathogen ID testing products;
- Laboratory Services: the decrease in revenue of approximately 77% in the 2017 period compared to the 2016 period is a result of decreases in sales of our Acuitas MDRO test products and Acuitas Lighthouse services; and
- Collaboration Revenue: the decrease in revenue of approximately 74% in the 2017 period compared to the 2016 period is primarily attributable to decreased revenue related to Hitachi contracts.

Operating expenses

	Nine Months Ended September 30,	
	2017	2016
Cost of products sold	$ 1,266,148	$ 1,269,990
Cost of services	228,115	528,733
Research and development	5,397,906	6,278,829
General and administrative	5,319,811	4,955,096
Sales and marketing	2,345,293	4,282,628
Total operating expenses	$ 14,557,273	$ 17,315,276

The Company’s total operating expenses for the nine months ended September 30, 2017 decreased approximately 16% when compared to the same period in 2016. This decrease is primarily attributable to:

- Costs of products sold: cost of products sold for the nine months ended September 30, 2017 were relatively consistent with the same period in 2016;
- Costs of services: cost of services for the nine months ended September 30, 2017 decreased approximately 57% when compared to the same period in 2016. The change in costs of services is primarily attributable to a decrease in sales of Acuitas Lighthouse services;
- Research and development: research and development expenses for the nine months ended September 30, 2017 decreased approximately 14% when compared to the same period in 2016, primarily due to a decrease in costs related to the automated rapid pathogen identification project;
- General and administrative: general and administrative expenses for the nine months ended September 30, 2017 increased approximately 7% when compared to the same period in 2016, primarily due to legal costs;
- Sales and marketing: sales and marketing expenses for the nine months ended September 30, 2017 decreased approximately 45% when compared to the same period in 2016, primarily due to costs associated with marketing studies conducted in the first and second quarter of 2016 and the reductions in the size of our commercial organization that occurred in June through September 2017.

Other income (expense)

	Nine Months Ended September 30,	
	2017	2016
Interest expense	$ (173,974)	$ (109,806)
Foreign currency transaction gains	19,636	2,293
Other expense	(87,270)	(3,078)
Change in fair value of warrant liabilities	124,139	—
Total other expense	$ (117,469)	$ (110,591)

The Company's total other expense for the nine months ended September 30, 2017 increased when compared to the same period of 2016, primarily as a result of an increase in interest expense due to the issuance of a Bridge Financing Note and modification of the MGHIF Note in June 2017 as well as the expense of the unamortized discount on the Bridge Financing Notes at repayment. The increase in other expense was partially offset by an increase in other income in the three months ended September 30, 2017, due to the change in the fair value of warrant liabilities, as a result of a decline the Company's stock price, and due to foreign currency gains.

Liquidity and capital resources

As of September 30, 2017, the Company had cash and cash equivalents of $4.9 million compared to $4.1 million at December 31, 2016. The Company has funded its operations primarily through external investor financing arrangements and has raised funds in 2017 and 2016, including:

On July 18, 2017, the Company closed a public offering of 18,164,195 units at $0.40 per unit, and 6,835,805 pre-funded units at $0.39 per pre-funded unit, raising gross proceeds of approximately $10 million and net proceeds of approximately $8.8 million. Each unit included one share of common stock and one warrant to purchase one share of common stock at an exercise price of $0.425 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one warrant to purchase one share of common stock at an exercise price of $0.425 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. Approximately $1 million of the gross proceeds was used to repay outstanding Bridge Financing Notes.

On May 31, 2017, the Company entered the bridge financing transaction with jVen Capital described above under "Recent Developments."

A condition to the receipt of the bridge financing was an extension of the maturity date of the A&R MGHIF Note from July 14, 2017 to July 14, 2018. In return for MGHIF's consent to such extension, the Company issued the A&R MGHIF Note to increase the interest rate to 10% and issued warrants to purchase shares of common stock to MGHIF equal to 20% of the principal balance of the A&R MGHIF Note, plus interest accrued thereon, as of June 28, 2017.

In September 2016, the Company entered into the Sales Agreement with Cowen pursuant to which the Company may offer and sell from time to time, up to an aggregate of $25 million of shares of its common stock through Cowen, as sales agent, with initial sales limited to an aggregate of $11.5 million. Pursuant to the Sales Agreement, Cowen may sell the shares of common stock by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including, without limitation, sales made by means of ordinary brokers' transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by the Company. The Company pays Cowen compensation equal to 3.0% of the gross proceeds from the sales of common stock pursuant to the terms of the Sales Agreement. As of September 30, 2017, the Company has sold an aggregate of approximately 7.7 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $7.8 million, and gross proceeds of $8.4 million. As of September 30, 2017, remaining availability under the at the market offering is $3.1 million. The Company did not sell any shares of its common stock under this at the market offering during the three months ended September 30, 2017. For the nine months ended September 30, 2017, the Company has sold approximately 4.0 million shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately $3.4 million, and gross proceeds of $3.6 million.

In May and June 2016, the Company offered and sold units in a private offering to members of management and employees and to accredited investors, including MGHIF and jVen Capital, each unit consisting of either (i) one share of common stock and a detachable stock purchase warrant to purchase an additional 0.75 shares of common stock, or (ii) one share of non-voting convertible preferred stock and a detachable stock purchase warrant to purchase an additional 0.75 shares of common stock, at a price of $1.14 per unit. The total net proceeds to the Company, after deducting offering commissions and expenses were $9.5 million. The Company has used the proceeds for working capital and general corporate purposes. Pursuant to the private placement, the Company issued

6,744,127 shares of common stock, 2,309,428 shares of non-voting convertible preferred stock and stock purchase warrants to acquire an additional 6,790,169 shares of common stock.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements and business combination transactions. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. The Company believes that current cash on hand will be sufficient to fund operations into the first quarter of 2018. This has led management to conclude that there is substantial doubt about the Company's ability to continue as a going concern. In the event the Company is unable to successfully raise additional capital during or before the first quarter of 2018, 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 immediately 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. If such sufficient financing is not received on a timely basis, the Company would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection. Furthermore, the $1.0 million MGHIF Note matures in July 2018. If the Company is unable to repay the note, negotiate its conversion or extend its term, the assets of the Company may be seized, as the note is secured by a lien on all the Company's assets.

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:

	Nine Months Ended September 30,	
	2017	2016
Net cash used in operating activities	$ (11,201,666)	$ (12,866,572)
Net cash used in investing activities	(142,687)	(87,533)
Net cash provided by financing activities	12,094,885	9,399,514

Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2017 consists primarily of our net loss of $12.5 million, reduced by certain noncash items, including depreciation and amortization expense of $0.5 million, and share-based compensation expense of $0.7 million. Net cash used in operating activities for the nine months ended September 30, 2016 consists primarily of our net loss of $14.4 million, reduced by certain noncash items, including depreciation and amortization expense of $0.5 million and share-based compensation expense of $0.7 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 nine months ended September 30, 2017 and 2016 consisted solely of purchases of property and equipment, net of proceeds on disposals.

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2017 of $12.1 million consisted primarily of the net proceeds from the July 2017 Public Offering and the at the market offering. Net cash provided by financing activities for the nine months ended September 30, 2016 of $9.4 million consisted primarily of net proceeds from the private offering of common stock, preferred stock and warrants.

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, valuation of derivative financial instruments and other liabilities measured at fair value on a recurring

basis, allowances for doubtful accounts and inventories, deferred tax assets and liabilities and related valuation allowance, depreciation and amortization and estimated useful lives of long-lived assets. Actual results could differ from those estimates.

A summary of our significant accounting policies is included in Note 3 “Summary of significant accounting policies” 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. Our critical policies are summarized in Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our Annual Report on Form 10-K for the year ended December 31, 2016.

Recently issued accounting pronouncements

See Note 3 “Summary of significant accounting policies” in this Form 10-Q for a full description of recent accounting pronouncements, including the respective expected dates of adoption and effects on our unaudited condensed consolidated financial statements.

Contractual obligations and off-balance sheet arrangements

As of September 30, 2017 and December 31, 2016, we did not have any off-balance sheet arrangements.

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. The Company has 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 the Company 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, the Company’s financial statements may not be comparable to companies that comply with public company effective dates.

Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” the Company intends 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. The Company will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which it has total annual gross revenues of $1 billion or more; (ii) December 31, 2019; (iii) the date on which the Company has issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which the Company is 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 September 30, 2017. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure

controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting during the quarter ended September 30, 2017 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

Risks Related to Our Securities

We have a history of losses, and we expect to incur losses for the next several years. 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 nine months ended September 30, 2017, we had a net loss of $12.5 million. From our inception through September 30, 2017, we had an accumulated deficit of $145.7 million. We completed a number of financings in 2017 and 2016, including the July 2017 Public Offering, a private investment in public equity, or PIPE, in May and June 2016 to members of management, employees and accredited investors, including MGHIF and jVen Capital, and an at-the-market, or ATM, public offering commenced in September 2016. The net proceeds from such financings were approximately $25.8 million. As of September 30, 2017, the Company has raised $7.8 million in aggregate gross proceeds through the ATM. We expect to raise additional funds through capital transactions in 2017. We believe that current cash on hand, excluding any additional bridge financings, other financings, or further cash conservation measures will be sufficient to fund operations into the first quarter of 2018. In the event we are unable to successfully raise sufficient capital prior to such time, 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. 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 would have an adverse effect on our business, financial condition and results of operations.

We needed bridge financing from a principal stockholder and an affiliate of our Chairman of the Board and Chief Executive Officer to provide us with financing in order to complete the July 2017 Public Offering and for our operations.

On May 31, 2017, the Company entered into a Note Purchase Agreement (amended and restated on July 10, 2017) with jVen Capital under which jVen Capital agreed to lend up to $1,500,000 to the Company in the form of three $500,000 secured convertible promissory notes to provide bridge financing for the July 2017 Public Offering and fund our operations. A total of $1,000,000 principal amount of Bridge Financing Notes and warrants to purchase 299,575 shares of common stock were issued to jVen Capital. jVen Capital is an affiliate of Evan Jones, the Company's Chairman of the Board and Chief Executive Officer. If we had not been able to secure the bridge financing, we would not have been able to sustain our operations through the July 2017 Public Offering.

There is no public market for the common warrants to purchase shares of our common stock included in the units and the pre-funded units sold by us in the July 2017 Public Offering.

There is no established public trading market for the common warrants included in the units and the pre-funded units being sold in the July 2017 Public Offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the common warrants on any national securities exchange or other nationally recognized trading system, including The NASDAQ Capital Market. Without an active market, the liquidity of the common warrants will be limited.

The common warrants are speculative in nature.

The common warrants do not confer any rights of common stock ownership on its holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time.

Specifically, commencing on the date of issuance, holders of the common warrants may exercise their right to acquire the common stock and pay an exercise price of $0.425 per share, subject to certain adjustments, prior to five years from the date of issuance, after which date any unexercised common warrants will expire and have no further value. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the common warrants, and consequently, whether it will ever be profitable for holders of the common warrants to exercise the common warrants.

Directors, executive officers 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 current officers, directors, their affiliated entities and affiliates collectively own approximately 22% of our outstanding common stock. As a result, if some or all of our directors, executive officers and affiliated entities 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.

The market price of our common stock has been, and may continue to be, highly volatile, and such volatility could cause the market price of our common stock to decrease and could cause you to lose some or all of your investment in our common stock.

During the period from our initial public offering in May 2015 through September 30, 2017, the market price of our common stock fluctuated from a high of $5.43 per share to a low of $0.21 per share, and our stock price continues to fluctuate. The market price of our common stock may continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- our ability to grow our revenue and customer base;
- the announcement of new products or product enhancements by us or our competitors;
- developments concerning regulatory oversight and approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- successes or challenges in our collaborative arrangements or alternative funding sources;
- developments in the health care and life science industries;
- the results of product liability or intellectual property lawsuits;
- future issuances of common stock or other securities;
- the addition or departure of key personnel;
- announcements by us or our competitors of acquisitions, investments or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

Further, the stock market in general, and the market for health care and life science companies in particular, has recently experienced extreme price and volume fluctuations. The volatility of our common stock is further exacerbated due to its low trading volume. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock and the loss of some or all of your investment.

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. Currently, approximately 22% of the issued and outstanding shares of our common stock is held by officers, directors and beneficial owners of at least 10% of our outstanding shares, including jVen Capital and MGHIF, 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.

We issued an aggregate of 627,570 warrants to purchase common stock to jVen Capital and MGHIF in connection with the bridge financing transactions. These warrants must be revalued each reporting period. Such assessments involve the use of estimates that could later be found to differ materially from actual results, which could have an adverse effect on our financial condition.

In June and July 2017, we issued an aggregate of 627,570 warrants to purchase common stock to jVen Capital and MGHIF in the bridge financing transactions. Each of these warrants has a put feature that allow the holder to put the warrants back to the Company for cash equal to the Black-Scholes value upon a change of control or fundamental transaction. The warrants are each recorded as a liability on our financial statements, and we are required to revalue each of the warrants each financial quarter. Such revaluations necessarily involve the use of estimate, assumptions, probabilities and application of complex accounting principles. Actual value at the time the warrants are exercised could vary significantly from the value assigned to such liabilities on a quarterly basis. We cannot assure you that the revaluation of the warrants will equal the value in the future, and know that the actual value could be significantly different, which could have a material adverse effect on our financial condition.

The exercise of our outstanding options and warrants will dilute shareholders and could decrease our stock price.

The existence of our outstanding options and warrants, including the common warrants issued in the July 2017 Public Offering may adversely affect our stock price due to sales of a large number of shares or the perception that such sales could occur. These factors also could make it more difficult to raise funds through future offerings of common stock or warrants, and could adversely impact the terms under which we could obtain additional equity capital. Exercise of outstanding options and warrants, or any future issuance of additional shares of common stock or other equity securities, including but not limited to options, warrants or other derivative securities convertible into our common stock, may result in significant dilution to our stockholders and may decrease our stock price.

We received a bid price deficiency notice from The NASDAQ Capital Market. If we are unable to cure this deficiency and meet the NASDAQ continued listing requirements, we could be delisted from the NASDAQ Capital Market which would negatively impact the trading of our common stock.

On June 20, 2017, we received notice from NASDAQ that we had failed to maintain a bid price of at least $1.00 per share for 30 successive trading days. We have a minimum of six months to regain compliance with the listing standard, and may be able to obtain an additional six-month compliance period. However, there can be no assurance that we will be able to maintain the NASDAQ Capital Market listing of our common stock in the future.

If our common stock is delisted by NASDAQ, our common stock may be eligible for quotation on an over-the-counter quotation system or on the pink sheets. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of shareholders to sell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be eligible for trading or quotation on any alternative exchanges or markets.

Delisting from NASDAQ could adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, the A&R MGHIF Note and related security agreement restrict our ability to pay cash dividends on our common stock and we may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our Board of Directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

Risks Related to Our Business

We have a history of losses, and we expect to incur losses for the next several years. 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 nine months ended September 30, 2017, we had a net loss of $12.5 million. We believe that current cash on hand, will be sufficient to fund operations into the first quarter of 2018. In the event we are unable to successfully raise sufficient capital prior to such time, 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. 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 would have an adverse effect on our business, financial condition and results of operations.

We expect to continue to incur significant operating expenses relating to, among other things:

- developing our Acuitas Rapid Test products and services for antibiotic resistance testing, and our automated rapid molecular diagnostic products;
- commercializing our rapid pathogen identification and Acuitas MDRO and Acuitas Lighthouse informatics services;
- developing, presenting and publishing additional clinical and economic utility data intended to increase clinician adoption of our current and future products and services;
- expansion of our operating capabilities;
- maintenance, expansion and protection of our intellectual property portfolio and trade secrets;
- future clinical trials as we seek regulatory approval for some of our product offerings;
- 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 expect to make significant additional investment in the future related to our diagnostic products and services, which investments will require additional financing transactions through the issuance of equity or debt. If we are unable to make such investments our business will suffer.

We anticipate that we will need to make significant investments in our Acuitas Rapid Test in development, Acuitas MDRO tests, and Acuitas Lighthouse informatics 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.

To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements and business combination transactions. In September 2016, we commenced an “at-the-market,” or ATM, offering under an existing shelf registration statement to raise up to $11.5 million. As of September 30, 2017, we have raised approximately $8.4 million in gross proceeds under the ATM offering. We believe that additional equity financings are the most likely source of capital. There can be no assurance that we will be able to complete any such financing transaction on acceptable terms or otherwise.

In the event we are unable to successfully raise sufficient 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 immediately 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. If such sufficient financing is not received timely, we would then need to pursue a plan to license or sell assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

In July 2015, in connection with our acquisition of our subsidiary, AdvanDx, MGHIF made investments in the Company, including the $1 million A&R MGHIF Note, secured by a security interest in substantially all of our assets, including our intellectual property assets. Such secured creditor rights could negatively impact our ability to raise money in the future. If we default on payments under the A&R MGHIF Note, MGHIF has the rights of a secured creditor. If those rights are exercised, it could have a material adverse effect on our financial condition.

Our restructuring plans may not produce the cost savings we anticipate, and we may encounter difficulties associated with the related organizational change.

In June 2017, we commenced a restructuring of our operations to improve efficiency and reduce our cost structure. We expect these actions to reduce operating expenses by 25-30 percent by the fourth quarter of 2017. The restructuring plans anticipate that we will consolidate operations for our FDA-cleared and CE marked products and research and development activities for the Acuitas Rapid Test in Gaithersburg, Maryland, and reduce the size of our commercial organization while we work to complete the development of our Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase products and services in development.

If we are unable to complete the objectives of the restructuring, our business and results of operations may be materially and adversely affected. We may not fully realize the anticipated benefits from our restructuring plans. Our restructuring plans may not adequately reduce expenses or produce the cost savings we anticipate or in the time frame we expect. Further restructuring activities may also be required in the future beyond what is currently planned, which could enhance the risks associated with these activities.

Moreover, the costs associated with the closing of our facility in Woburn, Massachusetts and consolidating our operations in Gaithersburg, Maryland may be significant. In addition, our Gaithersburg facility may not meet the FDA and CE marked requirements. If we are unable to consolidate our operations, receive the necessary regulatory approvals for our Gaithersburg facility, or sufficiently reduce our cash burn it could have a material adverse effect on our business, operating results and financial condition.

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, including our surveillance services offering, despite the lack of reimbursement for such services;
- our ability to successfully develop automated rapid pathogen identification and antibiotic resistance testing products and services, including informatics, and convince hospitals and other healthcare providers of the patient safety, improved patient outcomes and potential cost savings that could result;
- our ability to grow our microbial isolate and antibiotic resistance genes knowledgebase;
- 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 rapid pathogen identification and Acuitas MDRO test products and services are hospital systems, acute care hospitals, particularly those with advanced care units, such as intensive care units, community-based hospitals and governmental units, such as public health facilities. 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 current product offerings. We may not be successful in developing such automated rapid pathogen identification products, which would materially, adversely affect our business.

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

We are currently developing a new one to three hour antibiotic resistance 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, and confirmed genotype/phenotype predictive algorithms, 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 antibiotic resistance 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 may offer these products in development to the research use only market or for other non-clinical research uses prior to receiving clearance or approval to commercialize these products in development for use in the clinical setting. We will need to comply with the applicable laws and regulations regarding such other uses. Failure to comply with such laws and regulations may have a significant impact on the Company.

We have been awarded a contract by the Center for Disease Control, or CDC, and may enter into additional 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 October 2017, we were awarded a contract by the CDC to assess use of smartphone-based clinical decision support tools for antimicrobial stewardship and infection control in low- and middle-income countries. Receipt of this funding is contingent on our successful implementation of the grant agreement with our collaboration partners. If we fail to meet the obligations under the contract, our financial condition could be adversely affected.

In the future, we may seek to enter into additional agreements with governmental funding sources or contract with government healthcare organizations to sell our products and services. Under such 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.

Our sales cycle for our marketed products and services 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 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 may enter into collaborations related to our MDRO and informatics products and services. Such collaborations may be with pharmaceutical companies, platform companies or other participants in our industry. We would 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.

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 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 services to generate future revenue growth. To date, the Acuitas MDRO test products and Acuitas Lighthouse 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 informatics 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 healthcare 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.

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 and informatics 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 products and services, and adoption by key opinion leaders in the infectious disease market are very important to our commercial success. 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 their clinical benefits. Clinicians may not adopt our current and future products and services 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 products and services 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 products and services would suffer and our business would be harmed.

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 infection, 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 or manufacturing facility becomes inoperable, we will be unable to perform Acuitas MDRO test services, or manufacture our QuickFISH, PNA Fish and XpressFISH products, and our business will be harmed.

We perform all of our Acuitas MDRO and Acuitas Lighthouse testing services in our CLIA-compliant 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. In addition to a CLIA certification, 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 currently have active licenses in Maryland, Florida, New York and Pennsylvania. If we failed to secure any such licenses, we would not be able to process samples from recipients in such states. If we fail to maintain our CLIA certification or if our CLIA certification is suspended, limited or revoked, we would not be able to process human-derived samples from recipients that are not for research purposes. 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.

We currently manufacture our QuickFISH, PNA Fish and XpressFISH products in a leased facility located in Woburn, Massachusetts, however, we are currently in the process of re-locating such manufacturing capability to our Gaithersburg, Maryland facility. If demand for these products increase beyond our current forecasts or, regulatory requirements arise, we may not be able to meet our obligations to produce these products, and backlog or reduced demand for such products could occur. We are in the process of obtaining all necessary FDA certifications with respect to such relocation. If we are not successful in obtaining all necessary FDA certifications, it could delay our ability to manufacture these products. If any of these issues occur, it could have a material adverse effect on our financial condition and results of operations.

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, bioMérieux, Accelerate Diagnostics, T2 Biosystems, GenMark and Nanosphere.

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

Competitors may develop their own versions of competing products 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 product and service offering, or offer products at prices designed to promote market penetration, which could force us to lower the list prices of our product and service offerings 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 product and service offering 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 healthcare 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 healthcare 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 Safety and Health Administration, or OSHA, requirements. The requirements of these laws and regulations are complex, change frequently and could become more stringent in the future. Failure to comply with current or future environmental laws and regulations could result in the imposition of substantial fines, suspension of production, alteration of our production processes, cessation of operations or other actions, which could severely harm our business.

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 services. 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 2017 or for several years thereafter. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. We may be unable to use these net operating loss carryforwards, or NOLs, and certain tax credit carryforwards to offset income before such unused NOLs tax credit carryforwards expire. Under Section 382 of the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation’s ability to use its pre-change NOLs and other pre- change tax attributes to offset its post-change income may be further limited. The AdvanDx Merger 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 AdvanDx 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 AdvanDx 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 $151.0 million and research and development tax credits of $2.6 million as of December 31, 2016, 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 Public Company Status

We 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 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 need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, compliance with these rules and regulations has increased our legal, accounting and financial compliance costs and has made some activities more time-consuming and costly. It is also more expensive for us to obtain director and officer liability insurance.

If we are unable to 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 are 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 provide a management report on 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.

When we are no longer an emerging growth company and a smaller reporting 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.

When we are no longer an emerging growth company and a smaller reporting 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 have elected 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 until May 2020, although if our revenue exceeds $1.07 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 May 2020, we would cease to be an emerging growth company as of December 31 of that year. As an emerging growth company, we 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.

Risks Related to Regulation of Our Business

If we fail to comply with federal, state and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA for our Acuitas MDRO tests, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payors. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories.

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

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

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

We do not have significant experience in complying with the rules and regulations of the FDA and foreign regulatory authorities. The rapid diagnostic products regulated as medical devices, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such products, are subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA's QSR regulations for the manufacture, labeling, distribution and promotion of the QuickFISH products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval, and with ISO regulations. The FDA enforces the QSR and similarly, other regulatory bodies with similar regulations enforce those regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions against us: (1) untitled letters, Form 483 observation letters, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products; (7) operating restrictions; (8) withdrawing 510(k) clearances or PMA approvals that have already been granted; (9) refusal to grant export approval for our products; or (10) criminal prosecution.

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

We and our suppliers are also subject to periodic inspections by the FDA to determine compliance with the FDA's requirements, including primarily the QSR and medical device reporting regulations. The results of these inspections can include inspectional observations on FDA's Form 483, untitled letters, warning letters, or other forms of enforcement. Since 2009, the FDA has significantly increased its oversight of companies subject to its regulations, by hiring new investigators and stepping up inspections of manufacturing facilities. The FDA has recently also significantly increased the number of warning letters issued to companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our FDA-cleared products are ineffective or pose an unreasonable health risk, the FDA could take a number of regulatory actions, including but not limited to, preventing us from manufacturing any or all of our devices or performing laboratory testing on human specimens, which could materially adversely affect our business.

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

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

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

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

Clinical laboratory tests, like our Acuitas MDRO Gene Test, are regulated under CLIA, as well as by applicable state laws. Historically, most LDTs were not subject to FDA regulations applicable to medical devices, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. The FDA defines the term “laboratory developed test” as an IVD test that is intended for clinical use and designed, manufactured and used within a single laboratory. We believe that our Acuitas MDRO test products are LDTs. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug, and Cosmetic Act (the “FDA Act”) with respect to LDTs. In July 2014, due to the increased proliferation of LDTs for complex diagnostic testing and concerns with several high-risk LDTs related to lack of evidentiary support for claims, erroneous results and falsification of data, the FDA issued a Notification to Congress that it intended to issue a draft guidance that, when and if finalized, would likely adopt a risk-based framework that would increase FDA oversight of LDTs. The FDA issued draft guidance in October 2014, informing manufacturers of LDTs of its intent to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. The FDA will use this information to classify LDTs and to prioritize enforcement of premarket review requirements for categories of LDTs based on risk, using a public process. Specifically, the FDA plans to use advisory panels to provide recommendations to the agency on LDT risks, classification and prioritization of enforcement of applicable regulatory requirements on certain categories of LDTs, as appropriate. In November 2016, the FDA announced that a final LDT Policy guidance would not be issued to allow for further public discussion on an appropriate oversight approach, to give the FDA’s congressional authorizing committees the opportunity to develop a legislative solution to LDT regulation. The FDA further elaborated in January 2017, through a discussion paper, the agency’s intended framework for potential regulation while also confirming that the FDA intends to continue to exercise enforcement discretion over LDTs at this time.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. We cannot predict the timing or content of future legislation enacted, regulations promulgated or guidance issued regarding LDTs, or how it will affect our business.

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

allowed to remain on the market but there is uncertainty in the marketplace about our tests, if we are required by the FDA to label them investigational, or if labeling claims the FDA allows us to make are limited, orders may decline. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements.

If we are required to but fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our products or product enhancements, our ability to commercially distribute and market our products could suffer.

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

Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

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

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

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

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

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

The FDA and similar foreign governmental authorities have the authority to require the recall of regulated products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign

governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture.

Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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

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

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

We believe that our Acuitas MDRO test products are LDTs, subject to the FDA's enforcement discretion. To remain within the FDA's enforcement discretion, we are restricted in the ways we can promote and market our products. Furthermore, certain of our future products, including specimen transport containers we may develop such as Grow on the Go, might be regulated as Class I medical devices for which premarket clearance or approval may not be required, subject to certain limitations. We believe that our promotional activities for our products fall within the scope of the FDA's enforcement discretion and applicable premarket exemptions. However, the FDA could disagree and require us to stop promoting our Acuitas MDRO products in certain ways unless and until we obtain FDA clearance or approval for them, or our FDA-cleared products for unapproved or "off-label" uses unless and until we obtain FDA clearance or approval for those uses. In addition, because our Acuitas MDRO products are not currently cleared or approved by the FDA, if the FDA determines that our promotional materials constitute promotion of a use for which premarket clearance or approval is required, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions, including, but not limited to, the issuance of an untitled letter, a Form 483 letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

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

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

- required compliance with existing and changing foreign health care and other regulatory requirements and laws, such as those relating to patient privacy;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act, or FCPA, and U.K. Bribery Act, data privacy requirements, labor laws and anti- competition regulations;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;

- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- foreign exchange controls;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties protecting or procuring intellectual property rights.

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

We face the risk of potential liability under the FCPA for past international distributions of products and to the extent we distribute products or otherwise operate internationally in the future.

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

Risks Related to Compliance with Healthcare and Other Regulations

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

In March 2010, President Obama signed into law both the Patient Protection and Affordable Care Act, or Affordable Care Act, and the reconciliation law known as Health Care and Education Reconciliation Act, with the Affordable Care Act, the 2010 Health Care Reform Legislation. The constitutionality of the 2010 Health Care Reform Legislation was confirmed twice by the Supreme Court of the United States. The 2010 Health Care Reform Legislation has changed the existing state of the health care system by expanding coverage through voluntary state Medicaid expansion, attracting previously uninsured persons through the new health care insurance exchanges and by modifying the methodology for reimbursing medical services, drugs and devices. The U.S. Congress is seeking to replace the 2010 Health Care Reform Legislation. At this time the Company is not certain as to the impact of federal health care legislation on its business.

The 2010 Health Care Reform Legislation subjects manufacturers of medical devices to an excise tax of 2.3% on certain U.S. sales of medical devices beginning in January 2013. This excise tax was suspended in December 2015 for two years, and we anticipate that this may be repealed. If eventually implemented, this excise tax will likely increase our expenses in the future.

Further, the 2010 Health Care Reform Legislation includes the Open Payments Act (formerly referred to as the Physician Payments Sunshine Act), which, in conjunction with its implementing regulations, requires manufacturers of certain drugs, biologics, and devices that are reimbursed by Medicare, Medicaid and the Children’s Health Insurance Program to report annually certain payments or “transfers of value” provided to physicians and teaching hospitals and to report annually ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. We have provided reports under the Open Payments Act to the CMS since 2013. The failure to report appropriate data accurately, timely, and completely could subject us to significant financial penalties. Other countries and several states currently have similar laws and more may enact similar legislation.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the

new federal legislation and the expansion in government's effect on the United States healthcare industry may result in decreased profits to us, which may adversely affect our business, financial condition and results of operations.

Failure in our information technology, storage systems or our digital platform technology could significantly disrupt our operations and our research and development efforts, which could adversely impact our revenues, as well as our research, development and commercialization efforts.

Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology systems, which support our operations and our research and development efforts, as well as our storage systems and our analyzers. Due to the sophisticated nature of the technology we use in our products and service offerings, including our Acuitas Lighthouse services, we are substantially dependent on our information technology systems. information technology systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, and in particular to operate our digital immunoassay platform, could adversely affect our ability to operate our business. Any interruption in the operation of our digital immunoassay platform, due to information technology system failures, part failures or potential disruptions in the event we are required to relocate our instruments within our facility or to another facility, could have an adverse effect on our operations.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including legally protected health information and personally identifiable information about our customers and their patients. We also store sensitive intellectual property and other proprietary business information, including that of our customers. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data center systems. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information.

We face four primary risks relative to protecting this critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of our being unable to identify and audit our controls over the first three risks.

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store this critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions.

A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise our networks, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the federal HIPAA and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill facilities or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare Company financial information, provide information about our current and future solutions and other patient and clinician education and outreach efforts through our website, and manage the administrative aspects of our business and damage our reputation, any of which could adversely

affect our business. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

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

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

If hospital patient volumes drop as a result of severe economic conditions, or other unforeseen changes in healthcare provision or affordability, individual hospitals and health systems may be less willing to invest in our products and services. In addition, state and federal funds that are anticipated to be invested in the National Strategy for Combating Antibiotic- Resistant Bacteria could be reduced. If such funds are reduced, the market for our products would be impacted, which may affect our ability to generate revenues.

We are subject to potential enforcement actions involving false claims, kickbacks, physician self-referral or other federal or state fraud and abuse laws, and we could incur significant civil and criminal sanctions, which would hurt our business.

The government has made enforcement of the false claims, anti-kickback, physician self-referral and various other fraud and abuse laws a major priority. In many instances, private whistleblowers also are authorized to enforce these laws even if government authorities choose not to do so. Several clinical diagnostic laboratories and members of their management have been the subject of this enforcement scrutiny, which has resulted in very significant civil and criminal settlement payments. In most of these cases, private whistleblowers brought the allegations to the attention of federal enforcement agencies. The risk of our being found in violation of these laws and regulations is increased by the fact that some of the laws and regulations have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. We could be subject to enforcement actions under the following laws:

- the federal Anti-Kickback Statute, which constrains certain marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent;
- federal physician self-referral laws, such as the Stark Law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician’s family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third party payor, including commercial insurers, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If we or our operations, are found to be in violation of any of these laws and regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. We have compliance policies and are in the process of adopting a written compliance plan based on the Health and Human Services’ Office of the Inspector General guidance set forth in its model compliance plan for clinical laboratories, and federal and state fraud and abuse laws. We will monitor changes in government enforcement, particularly in these areas, as we grow and expand our business. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management’s attention from the operation of our business and hurt our reputation. If we were excluded from participation in U.S. federal healthcare programs, we would not be able to receive, or to sell our tests to other parties who receive reimbursement from Medicare, Medicaid and other federal programs, and that could have a material adverse effect on our business.

Risks Related to Our Intellectual Property

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.

In the future, we may license third-party technology to develop or commercialize new products. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our solutions. Royalties are a component of cost of services and affect the margins on our products. We may also need to negotiate licenses to patents and patent applications after introducing a commercial product. Our business may suffer if we are unable to enter into the necessary licenses on acceptable terms, or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable.

If we are unable to protect our intellectual property effectively, our business would be harmed.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

In July 2015, we issued a senior secured promissory note, in the principal amount of $1 million to MGHIF. Such promissory note is secured by a lien on our assets, including our intellectual property assets. In May 2017, we entered into a secured bridge financing facility with jVen Capital, which is also secured by a lien on our assets, including our intellectual property assets. If we default on our payment obligations under any of these secured promissory notes, the secured creditors have the right to control the disposition of our assets, including our intellectual property assets. If such default occurs, and our intellectual property assets are sold or licensed, our business could be materially adversely affected.

We apply for patents covering our products and technologies and uses thereof, as we deem appropriate, however we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our current or future patented technologies. We may not be successful in defending any challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation can be uncertain and any attempt by us to enforce our patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA.

In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests, like ours, are particularly uncertain. Various courts, including the U.S. Supreme Court, have recently rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that patent claims that recite laws of nature (for example, the relationship between blood levels of certain metabolites and the likelihood that a dosage of a specific drug will be ineffective or cause harm) are not themselves patentable. What constitutes a law of nature is uncertain, and it is possible that certain aspects of genetic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned and licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We may also be subject to claims that our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and face increased competition to our business. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential products, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Further, competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of our products and technologies. If our intellectual property does not adequately protect us against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We have not yet registered certain of our trademarks in all of our potential markets. If we apply to register these trademarks, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate coverage of our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

We may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect our business, operating results or financial condition.

We may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties' proprietary rights from time to time. Some of these claims may lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us.

We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings, or other post-grant proceedings declared by the United States Patent and Trademark Office that could result in substantial cost to us. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, recent changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require on acceptable terms or at all. Further, we could encounter

delays in product introductions, or interruptions in product sales, as we develop alternative methods or products. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and, in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non- infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that making, having made, using, selling, offering to sell or importing our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses on acceptable terms, if at all. We could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our financial results. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our business and our ability to gain market acceptance for our products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

Item 2. Unregistered Sales of Equity and Use of Proceeds

Unregistered Sales of Equity Securities

In July 2017, the Company issued one Bridge Financing Notes to jVen Capital and warrants to purchase shares of common stock to jVen Capital and MGHIF in a private placement transactions as described in this Quarterly Report on Form 10-Q and in the Form D filed on June 20, 2017.

In September 2017, we issued common stock with an aggregate value of $110,000 to settle a dispute related to pre-Merger AdvanDx activities. A Form D was filed on September 21, 2017.

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.

EXHIBIT INDEX

Exhibit Number	Description
4.1	Form of Common Stock Warrant (issued to jVen Capital, LLC and Merck Global Health Innovation Fund) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K/A, filed on July 10, 2017)
4.2	Form of Pre-Funded Warrant for July 2017 Public Offering (incorporated by reference to Exhibit 4.3 to the Registrants Form S-1/A, File No. 333-218392, filed on July 11, 2017)
4.3	Form of Common Warrant for July 2017 Public Offering (incorporated by reference to Exhibit 4.4 to the Registrants Form S-1/A, File No. 333-218392, filed on July 11, 2017)
4.4	Form of Placement Agent Warrant for July 2017 Public Offering (incorporated by reference to Exhibit 4.5 to the Registrants Form S-1/A, File No. 333-218392, filed on July 11, 2017)
10.1	Amended & Restated Note Purchase Agreement, dated July 10, 2017, by and between the Registrant and jVen Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A, filed on July 10, 2017)
10.2	Form of Secured Convertible Promissory Note #1 to be issued to jVen Capital, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K/A, filed on July 10, 2017)
10.3	Form of Secured Promissory Note #2 and #3 to be issued to jVen Capital, LLC (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K/A, filed on July 10, 2017)
10.4	Second Amended and Restated Senior Secured Convertible Promissory Note, dated June 28, 2017, by and between the Registrant and Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Current Report on Form 8-K/A, filed on June 28, 2017)
10.5	Securities Purchase Agreement, among the Registrant and the purchasers signatory thereto, dated as of July 12, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 14, 2017)
10.6	Engagement Letter with H.C Wainwright & Co., dated as of June 12, 2017 (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-1/A, filed on July 11, 2017)
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 Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to Unaudited Condensed Consolidated Financial Statements.

* Filed or furnished herewith

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: November 9, 2017

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO RULE 13A-14(A)/15D-14(A)

I, Evan Jones, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2017

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO RULE 13A-14(A)/15D-14(A)

I, Timothy C. Dec, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2017

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

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of OpGen, Inc. (the "Company") for the quarterly period ended September 30, 2017 (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: November 9, 2017

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

Date: November 9, 2017

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.