

**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, 2018

or

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

For the transition period from _____ to _____

Commission File Number 001-37367

OPGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

06-1614015
(I.R.S. employer
identification no.)

708 Quince Orchard Road, Suite 205, Gaithersburg, MD
(Address of principal executive offices)

20878
(Zip code)

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

8,645,470 shares of the Company's common stock, par value \$0.01 per share, were outstanding as of November 9, 2018.

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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:

- the completion of our development efforts for the AMR Gene Panel for patients at risk for cUTI and Acuitas Lighthouse Software, and the timing of commercialization;
- 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;
- our ability to maintain compliance with the ongoing listing requirements for the Nasdaq Capital Market;
- anticipated trends and challenges in our business and the competition that we face;
- the execution of our business plan and our growth strategy;
- our expectations regarding the size of and growth in potential markets;
- our opportunity to successfully enter into new collaborative or strategic agreements;
- regulations and changes in laws or regulations applicable to our business, including regulation by the FDA;
- compliance with the U.S. and international regulations applicable to our business; and
- our expectations regarding future revenue and expenses.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. 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)

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 4,735,506	\$ 1,847,171
Accounts receivable, net	315,612	809,540
Inventory, net	529,815	533,425
Prepaid expenses and other current assets	457,929	311,644
Total current assets	6,038,862	3,501,780
Property and equipment, net	1,150,238	835,537
Goodwill	600,814	600,814
Intangible assets, net	1,152,320	1,353,182
Other noncurrent assets	280,652	328,601
Total assets	\$ 9,222,886	\$ 6,619,914
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,036,005	\$ 1,691,712
Accrued compensation and benefits	1,023,577	746,924
Accrued liabilities	965,178	1,160,714
Deferred revenue	10,323	24,442
Short-term notes payable	470,911	1,010,961
Current maturities of long-term capital lease obligations	358,604	154,839
Total current liabilities	3,864,598	4,789,592
Deferred rent	196,558	290,719
Note payable	659,728	—
Warrant liability	383	8,453
Long-term capital lease obligations and other noncurrent liabilities	472,068	130,153
Total liabilities	5,193,335	5,218,917
Commitments (Note 9)		
Stockholders' equity		
Common stock, \$0.01 par value; 50,000,000 shares authorized; 6,425,470 and 2,265,320 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	64,255	22,653
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at September 30, 2018 and December 31, 2017, respectively	—	—
Additional paid-in capital	162,330,283	150,114,671
Accumulated other comprehensive loss	(18,838)	(25,900)
Accumulated deficit	(158,346,149)	(148,710,427)
Total stockholders' equity	4,029,551	1,400,997
Total liabilities and stockholders' equity	\$ 9,222,886	\$ 6,619,914

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,	
	2018	2017	2018	2017
Revenue				
Product sales	\$ 539,856	\$ 729,742	\$ 1,805,877	\$ 2,145,371
Laboratory services	12,365	9,070	22,155	41,025
Collaboration revenue	—	6,302	359,316	33,699
Total revenue	552,221	745,114	2,187,348	2,220,095
Operating expenses				
Cost of products sold	292,984	448,407	939,479	1,266,148
Cost of services	98,189	49,119	446,144	228,115
Research and development	1,286,300	1,513,157	3,821,117	5,397,906
General and administrative	1,743,636	1,600,577	5,365,221	5,319,811
Sales and marketing	361,310	330,305	1,117,380	2,345,293
Total operating expenses	3,782,419	3,941,565	11,689,341	14,557,273
Operating loss	(3,230,198)	(3,196,451)	(9,501,993)	(12,337,178)
Other (expense) income				
Other (expense) income	(93)	(87,292)	5,210	(87,270)
Interest expense	(28,074)	(90,317)	(140,453)	(173,974)
Foreign currency transaction gains (losses)	3,025	8,018	(6,556)	19,636
Change in fair value of derivative financial instruments	(85)	97,395	8,070	124,139
Total other expense	(25,227)	(72,196)	(133,729)	(117,469)
Loss before income taxes	(3,255,425)	(3,268,647)	(9,635,722)	(12,454,647)
Provision for income taxes	—	—	—	—
Net loss	(3,255,425)	(3,268,647)	(9,635,722)	(12,454,647)
Net loss available to common stockholders	\$ (3,255,425)	\$ (3,268,647)	\$ (9,635,722)	\$ (12,454,647)
Net loss per common share - basic and diluted	\$ (0.53)	\$ (1.74)	\$ (1.80)	\$ (9.17)
Weighted average shares outstanding - basic and diluted	6,103,746	1,883,137	5,339,936	1,358,260
Net loss	\$ (3,255,425)	\$ (3,268,647)	\$ (9,635,722)	\$ (12,454,647)
Other comprehensive gain (loss) - foreign currency translation	1,528	(6,234)	7,062	(13,825)
Comprehensive loss	\$ (3,253,897)	\$ (3,274,881)	\$ (9,628,660)	\$ (12,468,472)

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,	
	2018	2017
Cash flows from operating activities		
Net loss	\$ (9,635,722)	\$ (12,454,647)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	508,162	499,651
Noncash interest expense	108,011	65,511
Share-based compensation	658,731	722,304
Gain on sale of equipment	(5,253)	—
Change in fair value of warrant liabilities	(8,070)	(124,139)
Unamortized discount on bridge loan at repayment	—	85,932
Changes in operating assets and liabilities:		
Accounts receivable	492,444	72,466
Inventory	3,179	231,239
Other assets	(164,346)	(337,999)
Accounts payable	(493,971)	(293,388)
Accrued compensation and other liabilities	174,560	337,562
Deferred revenue	(14,119)	(6,158)
Net cash used in operating activities	(8,376,394)	(11,201,666)
Cash flows from investing activities		
Purchases of property and equipment	(41,910)	(142,687)
Proceeds from sale of equipment	10,440	—
Net cash used in investing activities	(31,470)	(142,687)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	597,743	3,426,050
Proceeds from issuance of units, net of selling costs	10,728,132	8,754,882
Proceeds from debt, net of issuance costs	381,253	1,168,222
Proceeds from exercise of stock options	—	48,179
Payments on debt	(299,256)	(1,146,287)
Payments on capital lease obligations	(177,092)	(156,161)
Net cash provided by financing activities	11,230,780	12,094,885
Effects of exchange rates on cash	7,419	(13,825)
Net increase in cash, cash equivalents and restricted cash	2,830,335	736,707
Cash, cash equivalents and restricted cash at beginning of period	2,090,551	4,360,704
Cash, cash equivalents and restricted cash at end of period	\$ 4,920,886	\$ 5,097,411
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 32,442	\$ 108,463
Supplemental disclosures of noncash investing and financing activities:		
Shares issued to settle obligations	\$ 272,610	\$ 110,000
Issuance of placement agent warrant	\$ —	\$ 93,677
Property and equipment acquired through capital lease	\$ 585,278	\$ —
Conversion of accounts payable to capital lease	\$ 156,775	\$ —
Unpaid deferred offering costs	\$ —	\$ 48,398

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
September 30, 2018

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 and its principal operations are in Gaithersburg, Maryland. The Company also has operations in Woburn, Massachusetts, Copenhagen, Denmark, and Bogota, Colombia. 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 its 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 its Acuitas antimicrobial resistance (“AMR”) Gene Panel u5.47 for complicated urinary tract infections in development as a clinical diagnostic test and available for Research Use Only (“RUO”), the QuickFISH and PNA FISH 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, which 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 the Company’s informatics systems include the Acuitas Lighthouse Knowledgebase and the Acuitas Lighthouse Software. The Acuitas Lighthouse Knowledgebase is a relational database management system and a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens. The Acuitas Lighthouse Software system includes the Acuitas Lighthouse Portal, a suite of web applications and dashboards, the Acuitas Lighthouse Prediction Engine, which is a data analysis software, and other supporting software components. The Acuitas Lighthouse Software can be customized and made 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 significant actions taken by the Company to reduce costs, including:

- On October 22, 2018, the Company closed a public offering (the “October 2018 Public Offering”) of 2,220,000 shares of its common stock at a public offering price of \$1.45 per share. The Company also granted to the underwriters a 45-day option to acquire an additional 330,751 shares to cover overallocments in connection with the offering. The offering raised gross proceeds of approximately \$3.2 million and net proceeds of approximately \$2.8 million.
- On June 11, 2018, the Company executed an Allonge (the “Allonge”) to its Second Amended and Restated Senior Secured Promissory Note, dated June 28, 2017, with a principal amount of \$1,000,000 issued to Merck Global Health Innovation Fund, LLC (“MGHIF”). The Allonge provided that accrued and unpaid interest of \$285,512 due as of July 14, 2018, the original maturity date, be paid through the issuance of shares of OpGen’s common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Note to six semi-annual payments of \$166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021. On July 30, 2018, the Company issued 144,238 shares of common stock to MGHIF in a private placement transaction for \$285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

- On February 6, 2018, the Company closed a public offering (the “February 2018 Public Offering”) of 2,841,152 units at \$3.25 per unit, and 851,155 pre-funded units at \$3.24 per pre-funded unit, raising gross proceeds of approximately \$12 million and net proceeds of approximately \$10.7 million. Each unit included one share of common stock and one common warrant to purchase 0.5 share of common stock at an exercise price of \$3.25 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 0.5 share of common stock at an exercise price of \$3.25 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. As of April 19, 2018, all 851,155 pre-funded warrants issued in the February 2018 Public Offering have been exercised.
- On July 18, 2017, the Company closed a public offering (the “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, LLC (“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 twenty-fifth of a share of common stock and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of \$10.63 per share. Each pre-funded unit included one pre-funded warrant to purchase one twenty-fifth of a share of common stock for an exercise price of \$0.25 per share, and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of \$10.63 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.
- In early June 2017, the Company commenced a restructuring of its operations to improve efficiency and reduce its cost structure. Under the restructuring plan the Company is consolidating its operations, including manufacturing, for its FDA-cleared and CE marked QuickFISH and PNA FISH families of products and research and development activities for the Acuitas AMR Gene Panel products and services, in Gaithersburg, Maryland, and reducing the size of its commercial organization while the Company works to complete the development of its Acuitas AMR Gene Panel 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 5,634 shares with an exercise price of \$19.50 per share, and warrants to acquire 6,350 shares with an exercise price of \$17.25 per share. The Company drew down on two of three Bridge Financing Notes during June and July 2017, and repaid such outstanding Bridge Financing Notes in full upon the closing of the July 2017 Public Offering.
- On September 13, 2016, the Company entered into the 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. As of September 30, 2018, the Company sold an aggregate of 690,247 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$8.8 million, and gross proceeds of \$9.4 million. During the three months ended September 30, 2018, the Company has sold 214,193 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$0.4 million, and gross proceeds of \$0.4 million. During the nine months ended September 30, 2018, the Company has sold 318,236 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$0.6 million, and gross proceeds of \$0.6 million. In connection with the October 2018 Public Offering, the Company terminated the at the market offering.

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, including the October 2018 Public Offering will be sufficient to fund operations into the second quarter of 2019. 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 second quarter of 2019, 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, 2017 consolidated balance sheet included herein was derived from the audited consolidated financial statements, but does 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

The Company has subsidiaries located in Copenhagen, Denmark, and Bogota, Colombia both which use currencies other than the U.S. dollar as their functional currency. As a result, all assets and liabilities are translated into U.S. dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the average exchange rates prevailing during the reporting period. Translation adjustments are reported in accumulated other comprehensive loss, a component of stockholders’ equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive loss at September 30, 2018 and December 31, 2017.

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, liquidity assumptions, revenue recognition, share-based compensation, allowances for doubtful accounts and inventory obsolescence, and valuation of derivative financial instruments 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, cash equivalents and restricted cash

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 limit 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, 2018, the Company has funds totaling \$185,380, which are required as collateral for letters of credit benefiting its landlords and for credit card processors. At December 31, 2017, the Company had 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 yet 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 \$29,607 and \$31,278 as of September 30, 2018 and December 31, 2017, respectively.

No individual customer represented in excess of 10% of revenues for the three months ended September 30, 2018 and 2017. One individual customer represented in excess of 10% of revenues for the nine months ended September 30, 2018. No individual customer represented in excess of 10% of revenues for the nine months ended September 30, 2017. At September 30, 2018, no individual customer represented in excess of 10% of total accounts receivable. At December 31, 2017, one individual customer represented in excess of 10% of total accounts receivable.

Inventory

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

	September 30, 2018	December 31, 2017
Raw materials and supplies	\$ 321,651	\$ 360,134
Work-in process	101,835	51,233
Finished goods	106,329	122,058
Total	<u>\$ 529,815</u>	<u>\$ 533,425</u>

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 \$116,173 and \$155,507 at September 30, 2018 and December 31, 2017, respectively.

Long-lived assets

Property and equipment

Property and equipment are 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, 2018 and 2017, the Company determined that its property and equipment was not impaired.

Intangible assets and goodwill

Intangible assets and goodwill as of September 30, 2018 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, 2018 and December 31, 2017:

	September 30, 2018			December 31, 2017	
	Cost	Accumulated Amortization	Net Balance	Accumulated Amortization	Net Balance
Trademarks and tradenames	\$ 461,000	\$ (148,257)	\$ 312,743	\$ (113,679)	\$ 347,321
Developed technology	458,000	(210,390)	247,610	(161,322)	296,678
Customer relationships	1,094,000	(502,033)	591,967	(384,817)	709,183
	<u>\$ 2,013,000</u>	<u>\$ (860,680)</u>	<u>\$ 1,152,320</u>	<u>\$ (659,818)</u>	<u>\$ 1,353,182</u>

Finite-lived intangible assets are amortized over their estimated useful lives. The estimated useful life of trademarks is 10 years, developed technology is 7 years, and customer relationships is 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, 2018 and 2017. Total amortization expense of intangible assets was \$200,862 for each of the nine months ended September 30, 2018 and 2017.

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, 2018 and 2017, 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 2017, 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 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, 2018 and December 31, 2017 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. During the three and nine months ended September 30, 2018 and 2017, the Company determined that its goodwill was not impaired.

Revenue recognition

Subsequent to the Adoption of Accounting Standards Codification Revenue from Contracts with Customers ("ASC 606") on January 1, 2018

The Company derives revenues from (i) the sale of QuickFISH and PNA FISH diagnostic test products and Acuitas AMR Gene Panel u5.47 RUO test products, (ii) providing laboratory services, and (iii) providing collaboration services including funded software arrangements, and license arrangements.

The Company analyzes contracts to determine the appropriate revenue recognition using the following steps: (i) identification of contracts with customers, (ii) identification of distinct performance obligations in the contract, (iii) determination of contract transaction price, (iv) allocation of contract transaction price to the performance obligations and (v) determination of revenue recognition based on timing of satisfaction of the performance obligation.

The Company recognizes revenues upon the satisfaction of its performance obligation (upon transfer of control of promised goods or services to our customers) in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services.

The Company defers incremental costs of obtaining a customer contract and amortizes the deferred costs over the period that the goods and services are transferred to the customer. The Company had no material incremental costs to obtain customer contracts in any period presented.

Deferred revenue results from amounts billed in advance to customers or cash received from customers in advance of services being provided.

For details about the Company's revenue recognition policy prior to the adoption of ASC 606, refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Research and development costs

Research and development costs are expensed as incurred. Research and development costs primarily consist of salaries and related expenses for personnel, other resources, laboratory supplies, and fees paid to consultants and outside service partners.

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 \$165.5 million at December 31, 2017. 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.

On December 22, 2017, the Tax Cuts and Jobs Act ("Tax Legislation") was enacted into law, which reduced the US federal corporate income tax rate to 21% for tax years beginning after December 31, 2017. As a result of the newly enacted tax rate, the Company adjusted its U.S. deferred tax assets as of December 31, 2017, by applying the new 21% rate, which resulted in a decrease to the deferred tax assets and a corresponding decrease to the valuation allowance of approximately \$14.6 million.

The Tax Legislation also implements a territorial tax system. Under the territorial tax system, in general, the Company's foreign earnings will no longer be subject to tax in the U.S. As part of the transition to the territorial tax system the Tax Legislation includes a mandatory deemed repatriation of all undistributed foreign earnings that are subject to a U.S. income tax. The Company estimates that the deemed repatriation will not result in any additional U.S. income tax liability as it estimates it currently has no undistributed foreign earnings.

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 3.7 million shares and 1.8 million shares as of September 30, 2018 and 2017, respectively.

Recent accounting pronouncements

There have been no developments to the Recent Accounting Pronouncements discussion included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, including the expected dates of adoption and estimated effects on the Company's condensed consolidated financial statements, except for the following:

In May 2014, the Financial Accounting Standards Board ("FASB") and International Accounting Standards Board ("IASB") jointly issued a new revenue recognition standard, Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASC 606") that is designed to improve financial reporting by creating common recognition guidance for GAAP and International Financial Reporting Standards ("IFRS"). This guidance provides a robust framework for addressing revenue issues, improves the comparability of revenue recognition practices across industries, provides useful information to users of financial statements through improved disclosure requirements and simplifies the presentation of financial statements. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. From March to December 2016, amendments to the new revenue recognition standard were issued to clarify numerous accounting topics, including, but not limited to (i) the implementation guidance on principal versus agent considerations, (ii) the identification of performance obligations, (iii) the licensing implementation guidance, (iv) the objective of the collectability criterion, (v) the application of the variable consideration guidance and modified retrospective transition method, (vi) the way in which impairment testing is performed and (vii) the disclosure requirements for revenue recognized from performance obligations. This guidance permits the use of either a full retrospective method or a modified retrospective approach. The modified retrospective approach is applied only to the most current period presented along with a cumulative-effect adjustment at the date of adoption. This guidance is effective for annual reporting periods beginning after December 15, 2017.

On January 1, 2018, the Company adopted ASC 606, using the modified retrospective method. Results for reporting periods beginning subsequent to December 31, 2017 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting policies prior to adoption. In adopting the guidance, the Company applied the guidance to all contracts and used available practical expedients including assessing contracts with similar terms and conditions on a "portfolio" basis. The adoption of this new guidance did not have a material impact on the Company's unaudited condensed consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows: Restricted Cash*, which addresses classification and presentation of changes in restricted cash on the statement of cash flows. The standard requires that restricted cash and restricted cash equivalents be included as components of total cash and cash equivalents as presented on the statement of cash flows. The Company adopted ASU 2016-18 using a retrospective transition method effective January 1, 2018 and applied to the periods presented on the condensed consolidated statements of cash flows. Restricted cash includes cash and cash equivalents that is restricted through legal contracts, regulations or the Company's intention to use the cash for a specific purpose. The Company's restricted cash primarily related to funds held as collateral for letters of credit.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the unaudited condensed consolidated balance sheets that sum to the total of the same amounts shown in the unaudited statements of cash flows:

	September 30, 2018	December 31, 2017	September 30, 2017	December 31, 2016
Cash and cash equivalents	\$ 4,735,506	\$ 1,847,171	\$ 4,854,031	\$ 4,117,324
Restricted cash	185,380	243,380	243,380	243,380
Total cash, cash equivalents and restricted cash in the condensed consolidated statement of cash flows	<u>\$ 4,920,886</u>	<u>\$ 2,090,551</u>	<u>\$ 5,097,411</u>	<u>\$ 4,360,704</u>

In February 2016, the FASB issued ASU 2016-02, *Leases*. This 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 has hired an external consultant to assist in evaluating the impact, if any, that this new accounting pronouncement will have on its unaudited condensed consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07: *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, early adoption is permitted but no earlier than an entity's adoption date of ASC 606. The Company is currently evaluating the impact this new guidance will have on its financial statements and related disclosures.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, *Disclosure Update and Simplification*, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018 for filings beginning in 2019. The Company is currently evaluating the changes it will make under such final rule.

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 – Revenue from Contracts with Customers

Disaggregated Revenue

The Company provides diagnostic test products, laboratory services to hospitals, clinical laboratories and other healthcare provider customers, and enters into collaboration agreements with government agencies and healthcare providers. The revenues by type of service consist of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Product sales	\$ 539,856	\$ 729,742	\$ 1,805,877	\$ 2,145,371
Laboratory services	12,365	9,070	22,155	41,025
Collaboration revenue	—	6,302	359,316	33,699
Total revenue	<u>\$ 552,221</u>	<u>\$ 745,114</u>	<u>\$ 2,187,348</u>	<u>\$ 2,220,095</u>

Deferred Revenue

Changes in deferred revenue for the period were as follows:

Balance at December 31, 2017	\$	24,442
Revenue recognized in the current period from the amounts in the beginning balance		(14,119)
New deferrals, net of amounts recognized in the current period		—
Balance at September 30, 2018	\$	<u>10,323</u>

Contract Assets

The Company had contract assets of \$51,575 as of September 30, 2018, which are generated when contractual billing schedules differ from revenue recognition timing. Contract assets represent a conditional right to consideration for satisfied performance obligations that becomes a billed receivable when the conditions are satisfied.

Unsatisfied Performance Obligations

Remaining contract consideration for which revenue has not been recognized due to unsatisfied performance obligations was \$156,700 at September 30, 2018, which the Company expects to recognize over the next three months.

Note 5 – MGHIF Financing

In July 2015, in connection with the Merger, the Company entered into a Purchase Agreement with MGHIF, pursuant to which MGHIF purchased 45,454 shares of common stock of the Company at \$110.00 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. 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.

On June 28, 2017, the MGHIF Note was amended and restated, and the maturity date of the 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 13,120 shares of its common stock to MGHIF.

On June 11, 2018, the Company executed an Allonge to the MGHIF Note. The Allonge provided that accrued and unpaid interest of \$285,512 due as of July 14, 2018, the original maturity date, be paid through the issuance of shares of OpGen’s common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Note to six semi-annual payments of \$166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021.

On July 30, 2018, the Company issued 144,238 shares of common stock to MGHIF in a private placement transaction for \$285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

The Allonge to the MGHIF Note, was treated as a debt modification and as such the unamortized issuance costs of approximately \$7 thousand as of June 11, 2018 is deferred and amortized as incremental expense over the term of the MGHIF Note.

Note 6 – Fair value measurements

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

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

For the nine months ended September 30, 2018, 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 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 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 nine months ended September 30, 2018:

Description	Balance at December 31, 2017	Change in Fair Value	Balance at September 30, 2018
Warrant liability	\$ 8,453	\$ (8,070)	\$ 383

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, 2018 and 2017.

Note 7 – Debt

As of September 30, 2018, the Company's outstanding short-term debt consisted of approximately \$333 thousand due under the MGHIF Note, as well as, the financing arrangements for the Company's insurance with note balances of approximately \$138 thousand with a final payment scheduled for December 2018. The Company's outstanding long-term debt as of September 30, 2018 consisted of approximately \$660 thousand due under the MGHIF Note, net of discounts and financing costs (see Note 5 "MGHIF Financing"). As of December 31, 2017, the Company's outstanding short-term debt consisted of the \$1.0 million MGHIF Note, net of discounts and financing costs, as well as the financing arrangements for the Company's insurance with note balances of approximately \$56 thousand. The Company did not have any long-term debt as of December 31, 2017. Total principal payments of approximately \$333 thousand are due annually in 2019, 2020, and 2021.

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 were 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 \$28,074 and \$90,317 for the three months ended September 30, 2018 and 2017, respectively. Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was \$140,453 and \$173,974 for the nine months ended September 30, 2018 and 2017, respectively.

Note 8 – Stockholders’ equity

As of September 30, 2018, the Company has 50,000,000 shares of authorized common stock and 6,425,470 shares issued and outstanding, and 10,000,000 authorized preferred shares, of which none were issued or outstanding.

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, 2018, the Company has sold an aggregate of 690,247 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$8.8 million, and gross proceeds of \$9.4 million. During the three months ended September 30, 2018, the Company has sold 214,193 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$0.4 million, and gross proceeds of \$0.4 million. During the nine months ended September 30, 2018, the Company has sold 318,236 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$0.6 million, and gross proceeds of \$0.6 million. In connection with the October 2018 Public Offering (see Note 12 “Subsequent events”), the Company terminated the at the market offering, leaving \$2,075,318 unsold under such terminated at the market offering.

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 twenty-fifth of a share of common stock and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of \$10.63 per share. Each pre-funded unit included one pre-funded warrant to purchase one twenty-fifth of a share of common stock for an exercise price of \$0.25 per share, and one common warrant to purchase one twenty-fifth of a share of common stock at an exercise price of \$10.63 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. All pre-funded warrants issued in the July 2017 Public Offering were exercised during the year ended December 31, 2017.

In connection with the July 2017 Public Offering, the Company issued to its placement agent warrants to purchase 50,000 shares of common stock. The warrants issued to the Placement Agent have an exercise price of \$12.50 per share and are exercisable for five years.

In September 2017, the Company issued 15,842 shares of its common stock with an aggregate value of \$110,000 to settle a dispute related to pre-Merger AdvanDx activities. In October 2017, the Company issued 2,898 shares of its common stock with an aggregate value of \$23,245 to a vendor in exchange for consulting services.

Following receipt of approval from stockholders at a special meeting of stockholders held on January 17, 2018, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to effect a reverse stock split of the issued and outstanding shares of common stock, at a ratio of one share for twenty-five shares, and to reduce the authorized shares of common stock from 200,000,000 to 50,000,000 shares. All share amounts and per share prices in this quarterly report have been adjusted to reflect the reverse stock split.

In the February 2018 Public Offering, the Company issued 2,841,152 units at \$3.25 per unit, and 851,155 pre-funded units at \$3.24 per pre-funded unit, raising gross proceeds of approximately \$12 million and net proceeds of approximately \$10.7 million. Each unit included one share of common stock and one common warrant to purchase 0.5 share of common stock at an exercise price of \$3.25 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 0.5 share of common stock at an exercise price of \$3.25 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. All 851,155 pre-funded warrants issued in the February 2018 Public Offering were exercised during the nine months ended September 30, 2018.

In connection with the February 2018 Public Offering, the Company issued to its placement agent warrants to purchase 184,615 shares of common stock. The warrants issued to the Placement Agent have an exercise price of \$4.0625 per share and are exercisable for five years.

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) 54,200 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, 2018, 43,658 shares remain available for issuance under the 2015 Plan, which includes 90,612 shares automatically added to the 2015 Plan on January 1, 2018.

For the three and nine months ended September 30, 2018 and 2017, the Company recognized share-based compensation expense as follows:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Cost of services	\$ (2,807)	\$ 2,306	\$ 924	\$ 6,274
Research and development	56,961	61,097	187,512	171,652
General and administrative	141,974	187,357	434,314	500,252
Sales and marketing	10,523	16,832	35,981	44,126
	<u>\$ 206,651</u>	<u>\$ 267,592</u>	<u>\$ 658,731</u>	<u>\$ 722,304</u>

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

The Company did not grant any stock options during the three months ended September 30, 2018. During the three months ended September 30, 2018, 7,120 options were forfeited at a weighted average exercise price of \$5.61 per share.

During the nine months ended September 30, 2018, the Company granted stock options to acquire 95,800 shares of common stock at a weighted average exercise price of \$3.84 per share and a weighted average grant date fair value of \$1.93 per share. During the nine months ended September 30, 2018, 13,336 options were forfeited at a weighted average exercise price of \$13.36 per share. The Company had total stock options to acquire 218,759 shares of common stock outstanding at September 30, 2018.

Restricted stock units

During the nine months ended September 30, 2018, 5,400 restricted stock units vested and no restricted stock units were forfeited. The Company had 500 total restricted stock units outstanding at September 30, 2018.

Stock purchase warrants

At September 30, 2018 and December 31, 2017, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at	
			September 30, 2018 (1)	December 31, 2017 (1)
March 2008	\$ 19,763.50	March 2018	—	2
November 2009	\$ 197.75	November 2019	270	270
January 2010	\$ 197.75	January 2020	270	270
March 2010	\$ 197.75	March 2020	55	55
November 2011	\$ 197.75	November 2021	212	212
December 2011	\$ 197.75	December 2021	27	27
March 2012	\$ 2,747.50	March 2019	165	165
February 2015	\$ 165.00	February 2025	9,001	9,001
May 2015	\$ 165.00	May 2020	138,310	138,310
May 2016	\$ 32.81	May 2021	189,577	189,577
June 2016	\$ 32.81	May 2021	82,035	82,035
June 2017	\$ 19.50	June 2022	18,754	18,754
July 2017	\$ 17.25	July 2022	6,350	6,350
July 2017	\$ 12.50	July 2022	50,000	50,000
July 2017	\$ 10.63	July 2022	1,000,003	1,000,003
February 2018	\$ 4.06	February 2023	184,615	—
February 2018	\$ 3.25	February 2023	1,846,153	—
			<u>3,525,797</u>	<u>1,495,031</u>

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

- (1) Warrants to purchase fractional shares of common stock resulting from the reverse stock split on January 17, 2018 were rounded up to the next whole share of common stock on a holder by holder basis.

Note 9 – Commitments

Operating leases

The Company 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. The Company also leases a facility in Woburn, Massachusetts under an operating lease that expires January 30, 2022. 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, 2018 and 2017 was \$248,580 and \$238,791, respectively. Rent expense under the Company's facility operating leases for the nine months ended September 30, 2018 and 2017 was \$750,872 and \$710,330, 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. Under the restructuring plan, the Company is consolidating its operations for FDA-cleared and CE marked QuickFISH and PNA FISH products and research and development activities for the Acuitas AMR Gene Panel in Gaithersburg, Maryland, and reducing the size of its commercial organization while the Company works to complete the development of its Acuitas AMR Gene Panel and Acuitas Lighthouse Knowledgebase products and services in development.

There were approximately \$121,000 of one-time termination benefits that were recognized during the year ended December 31, 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 ended in December 2017. The Company incurred total retention expense of approximately \$68,000 during the year ended December 31, 2017. The future minimum lease payments for the Woburn facility were approximately \$1.5 million as of September 30, 2018. 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 next six months. We have not estimated the contract termination costs associated with this lease given that we have not yet reached the cease-use date. We do not believe there will be significant additional costs related to restructuring outside of what is described herein.

Supply Agreements

In June 2017, the Company entered into an agreement with Life Technologies Corporation (“LTC”) to supply the Company with QuantStudio 5 Real-Time PCR Systems (“QuantStudio 5”) to be used to run OpGen’s Acuitas AMR Gene Panel tests. Under the terms of the agreement the Company must notify LTC of the number of QuantStudio 5s that it commits to purchase in the following quarter. As of September 30, 2018 the Company has acquired thirteen QuantStudio 5s including nine in the nine months ended September 30, 2018. As of September 30, 2018 the Company has committed to acquiring an additional two QuantStudio 5s at a total cost of approximately \$90 thousand in the next three months.

Note 10 – 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 \$62,500 for the three months ended September 30, 2018 and 2017, respectively. The Company recognized net royalty expense of \$187,500 and \$194,686 for the nine months ended September 30, 2018 and 2017, respectively. Annual future minimum royalty fees are \$250,000 under this agreement.

Note 11 – Related party transactions

In October 2016, the Company entered into an agreement with Merck Sharp & Dohme Corp. (“MSD”), a wholly-owned subsidiary of Merck, and an affiliate of MGHIF, a principal stockholder of the Company and a related party to the Company. Under the agreement, MSD 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. MSD 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 \$171,646 of procurement costs which have been recognized as research and development expense. The Company did not recognize any research and development expense related to the agreement in the three months ended September 30, 2018 and 2017. The Company recognized research and development expense of \$22,604 and \$113,907 related to the agreement in the nine months ended September 30, 2018 and 2017, respectively.

In December 2017, the Company entered into a subcontractor agreement with ILÚM Health Solutions, LLC, an entity created by Merck’s Healthcare Services and Solutions division, whereby ILÚM Health Solutions will provide services to the Company in the performance of the Company’s CDC contract to deploy ILÚM’s commercially-available cloud- and mobile-based software platform for infectious disease management in up to three medical sites in Colombia with the aim of improving antibiotic use in resource-limited settings. The Company recognized \$0 and \$198,665 of cost of services expense related to the contract in the three and nine months ended September 30, 2018, respectively.

Note 12 – Subsequent events

On October 22, 2018, the Company closed the October 2018 Public Offering of 2,220,000 shares of its common stock at a public offering price of \$1.45 per share. The Company also granted to the underwriters a 45-day option to acquire an additional 330,751 shares to cover overallotments in connection with the offering. The offering raised gross proceeds of approximately \$3.2 million and net proceeds of approximately \$2.8 million.

In connection with the October 2018 Public Offering, the Company terminated the at the market offering.

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, 2017.

Overview

OpGen was incorporated in Delaware in 2001. On July 14, 2015, OpGen completed the Merger with AdvanDx. Pursuant to the terms of a Merger Agreement, Velox Acquisition Corp., OpGen’s wholly owned subsidiary formed for the express purpose of effecting the Merger, merged with and into AdvanDx with AdvanDx surviving as OpGen’s wholly-owned subsidiary. OpGen, AdvanDx are collectively referred to hereinafter as the “Company.” The Company’s headquarters and principal operations are in Gaithersburg, Maryland. The Company also has operations in Woburn, Massachusetts, Copenhagen, Denmark, and Bogota, Colombia. 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 (“MDRO”). The Company’s 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 products and services, some in development, to a global network of customers and partners.

- The Company’s Acuitas DNA tests provide rapid microbial identification and antibiotic resistance gene information. These products include the Acuitas AMR Gene Panel u5.47 for complicated urinary tract infections in development as a clinical diagnostic test and available for Research Use Only, the QuickFISH® and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures, and the Acuitas Resistome Tests for genetic analysis of hospital surveillance isolates.
- The Company’s 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.

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 and 2018:

- On October 22, 2018, the Company closed a public offering (the “October 2018 Public Offering”) of 2,220,000 shares of its common stock at a public offering price of \$1.45 per share. The Company also granted to the underwriters a 45-day option to acquire an additional 330,751 shares to cover overallotments in connection with the offering. The offering raised gross proceeds of approximately \$3.2 million and net proceeds of approximately \$2.8 million.
- On June 11, 2018, the Company executed an Allonge (the “Allonge”) to its Second Amended and Restated Senior Secured Promissory Note, dated June 28, 2017, with a principal amount of \$1,000,000 issued to Merck Global Health Innovation Fund, LLC (“MGHIF”). The Allonge provided that accrued and unpaid interest of \$285,512 due as of July 14, 2018, the original maturity date, will be paid through the issuance of shares of OpGen’s common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the Note to six semi-annual payments of \$166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021. On July 30, 2018, the Company issued 144,238 shares of common stock to MGHIF in a private placement transaction for \$285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

- On February 6, 2018, the Company closed its February 2018 Public Offering of 2,841,152 units at \$3.25 per unit, and 851,155 pre-funded units at \$3.24 per pre-funded unit, raising gross proceeds of approximately \$12 million and net proceeds of approximately \$10.7 million. Each unit included one share of common stock and one common warrant to purchase 0.5 share of common stock at an exercise price of \$3.25 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 0.5 share of common stock at an exercise price of \$3.25 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance.
- 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 5,634 shares with an exercise price of \$19.50 per share, and stock purchase warrants to acquire 6,350 shares at an exercise price of \$17.25 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 year ended December 31, 2017, the Company sold 227,216 shares of its common stock under its at the market offering resulting in aggregate net proceeds to the Company of approximately \$3.8 million, and gross proceeds of \$4.0 million. During the nine months ended September 30, 2018, the Company sold 318,236 shares of its common stock under its at the market offering resulting in aggregate net proceeds to the Company of approximately \$0.6 million, and gross proceeds of \$0.6 million.

On January 17, 2018, at a special meeting of stockholders, our stockholders approved an amendment to our Amended and Restated Certificate of Incorporation, authorizing a reverse stock split of the issued and outstanding shares of our common stock, at a ratio within a range of two-to-one and not more than twenty-five-to-one, such ratio and the implementation and timing of such reverse stock split to be determined in the discretion of our Board of Directors, and to reduce the authorized shares of common stock to 50,000,000 shares. On January 17, 2018, our Board of Directors approved a reverse stock split of one share for twenty-five outstanding shares, or the Reverse Stock Split, and we filed an Amendment to our Amended and Restated Certificate of Incorporation to effect the Reverse Stock Split and reduce our authorized shares of common stock to 50,000,000.

In early June 2017, the Company commenced a restructuring of its operations to improve efficiency and reduce its cost structure. Under the restructuring plan, the Company is consolidating its operations for FDA-cleared and CE marked QuickFISH and PNA FISH products and research and development activities for the Acuitas AMR Gene Panel in Gaithersburg, Maryland, and reducing the size of its commercial organization while the Company works to complete the development of its Acuitas AMR Gene Panel and Acuitas Lighthouse Knowledgebase products and services in development. As part of this restructuring, the Company decommissioned its CLIA laboratory operations in the third quarter of 2018 to provide incremental resources in support of efforts to gain FDA clearance for the Company's Acuitas AMR Gene Panel products in development.

There were approximately \$121,000 of one-time termination benefits that were recognized during the year ended December 31, 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 ended in December 2017. The Company incurred total retention expense of approximately \$68,000 during the year ended December 31, 2017. The future minimum lease payments for the Woburn facility were approximately \$1.5 million as of September 30, 2018. 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 next six months. We have not estimated the contract termination costs associated with this lease given that we have not yet reached the cease use date. 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, 2018 and 2017

Revenues

	<u>Three Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>
Product sales	\$ 539,856	\$ 729,742
Laboratory services	12,365	9,070
Collaboration revenue	-	6,302
Total revenue	<u>\$ 552,221</u>	<u>\$ 745,114</u>

Total revenue for the three months ended September 30, 2018 decreased approximately 26%. This decrease is primarily attributable to:

- Product Sales: the decrease in revenue of approximately 26% in the 2018 period compared to the 2017 period is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products;
- Laboratory Services: the increase in revenue of approximately 36% in the 2018 period compared to the 2017 period is a result of increases in sales of our Acuitas MDRO test products; and
- Collaboration Revenue: the decrease in revenue in the 2018 period compared to the 2017 period is primarily the result of decreased revenue associated with our license agreement with Hitachi.

Operating expenses

	<u>Three Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>
Cost of products sold	\$ 292,984	\$ 448,407
Cost of services	98,189	49,119
Research and development	1,286,300	1,513,157
General and administrative	1,743,636	1,600,577
Sales and marketing	361,310	330,305
Total operating expenses	<u>\$ 3,782,419</u>	<u>\$ 3,941,565</u>

The Company's total operating expenses for the three months ended September 30, 2018 decreased approximately 4% when compared to the same period in 2017. This decrease is primarily attributable to:

- Costs of products sold: cost of products sold for the three months ended September 30, 2018 decreased approximately 35% when compared to the same period in 2017. The change in costs of products sold is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products;
- Costs of services: cost of services for the three months ended September 30, 2018 increased approximately 100% when compared to the same period in 2017. The change in costs of services is primarily attributable to an increase in our CLIA lab inventory reserve;

- Research and development: research and development expenses for the three months ended September 30, 2018 decreased approximately 15% when compared to the same period in 2017, primarily due to the consolidation of our Woburn and Gaithersburg R&D activities in 2017;
- General and administrative: general and administrative expenses for the three months ended September 30, 2018 increased approximately 9% when compared to the same period in 2017, primarily due to increased outside service costs; and
- Sales and marketing: sales and marketing expenses for the three months ended September 30, 2018 increased approximately 9% when compared to the same period in 2017, primarily due to the increased headcount of our marketing team.

Other income (expense)

	Three Months Ended September 30,	
	2018	2017
Interest expense	\$ (28,074)	\$ (90,317)
Foreign currency transaction gains	3,025	8,018
Other expense	(93)	(87,292)
Change in fair value of derivative financial instruments	(85)	97,395
Total other expense	\$ (25,227)	\$ (72,196)

The Company's total other expense for the three months ended September 30, 2018 decreased primarily as a decrease in interest expense and the expense of the unamortized discount on the outstanding Bridge Financing Notes at repayment in the prior year. These decreases were offset by decreased gains due to changes in the fair value of warrant liabilities.

Results of operations for the nine months ended September 30, 2018 and 2017

Revenues

	Nine Months Ended September 30,	
	2018	2017
Product sales	\$ 1,805,877	\$ 2,145,371
Laboratory services	22,155	41,025
Collaboration revenue	359,316	33,699
Total revenue	\$ 2,187,348	\$ 2,220,095

Total revenue for the nine months ended September 30, 2018 decreased approximately 1%. This decrease is primarily attributable to:

- Product Sales: the decrease in revenue of approximately 16% in the 2018 period compared to the 2017 period is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products and the discontinuance of our legacy whole genome mapping business;
- Laboratory Services: the decrease in revenue of approximately 46% in the 2018 period compared to the 2017 period is a result of decreases in sales of our Acuitas MDRO test products; and
- Collaboration Revenue: the increase in revenue in the 2018 period compared to the 2017 period is primarily the result of increased revenue associated with our CDC contract.

Operating expenses

	Nine Months Ended September 30,	
	2018	2017
Cost of products sold	\$ 939,479	\$ 1,266,148
Cost of services	446,144	228,115
Research and development	3,821,117	5,397,906
General and administrative	5,365,221	5,319,811
Sales and marketing	1,117,380	2,345,293
Total operating expenses	\$ 11,689,341	\$ 14,557,273

The Company's total operating expenses for the nine months ended September 30, 2018 decreased approximately 20% to \$11.7 million from \$14.6 million, when compared to the same period in 2017. This decrease is primarily attributable to:

- Costs of products sold: cost of products sold for the nine months ended September 30, 2018 decreased approximately 26% when compared to the same period in 2017. The change in costs of products sold is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products;
- Costs of services: cost of services for the nine months ended September 30, 2018 increased approximately 96% when compared to the same period in 2017. The change in costs of services is primarily attributable to increased costs of services associated with our CDC contract;
- Research and development: research and development expenses for the nine months ended September 30, 2018 decreased approximately 29% when compared to the same period in 2017, primarily due to a decrease in costs related to the automated rapid pathogen identification project that was suspended in the first half of 2017;
- General and administrative: general and administrative expenses for the nine months ended September 30, 2018 increased approximately 1% when compared to the same period in 2017, primarily due to increased payroll costs; and
- Sales and marketing: sales and marketing expenses for the nine months ended September 30, 2018 decreased approximately 52% when compared to the same period in 2017, primarily due to the reductions in the size of our commercial organization in 2017.

Other income (expense)

	Nine Months Ended September 30,	
	2018	2017
Interest expense	\$ (140,453)	\$ (173,974)
Foreign currency transaction gains (losses)	(6,556)	19,636
Other (expense) income	5,210	(87,270)
Change in fair value of derivative financial instruments	8,070	124,139
Total other expense	\$ (133,729)	\$ (117,469)

The Company's total other expense for the nine months ended September 30, 2018 increased primarily as a result of decreased gains due to the change in fair value of warrant liabilities offset by the expense of the unamortized discount on the outstanding Bridge Financing Notes at repayment in the prior year .

Liquidity and capital resources

As of September 30, 2018, the Company had cash and cash equivalents of \$4.7 million compared to \$1.8 million at December 31, 2017. The Company has funded its operations primarily through external investor financing arrangements and has raised funds in 2018 and 2017, including:

- On February 6, 2018, the Company closed a public offering, or the February 2018 Public Offering, of 2,841,152 units at \$3.25 per unit, and 851,155 pre-funded units at \$3.24 per pre-funded unit, raising gross proceeds of approximately \$12 million and net proceeds of approximately \$10.7 million as described above under "Recent Developments."
- 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 as described above under "Recent Developments."
- 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 MGHIF Note from July 14, 2017 to July 14, 2018. In return for MGHIF's consent to such extension, the Company issued the amended and restated 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 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. 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, 2018, the Company sold an aggregate of 690,247 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$8.8 million, and gross proceeds of \$9.4 million. During the year ended December 31, 2017, the Company sold 227,216 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$3.8 million, and gross proceeds of \$4.0 million. During the three months ended September 30, 2018, the Company has sold 214,193 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$0.4 million, and gross proceeds of \$0.4 million. During the nine months ended September 30, 2018, the Company has sold 318,236 shares of its common stock under this at the market offering resulting in aggregate net proceeds to the Company of approximately \$0.6 million, and gross proceeds of \$0.6 million. In connection with the October 2018 Public Offering, the Company terminated the at the market offering, leaving \$2,075,318 unsold under such terminated at the market offering.

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 including the October 2018 Public Offering, will be sufficient to fund operations into the second quarter of 2019. 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 second quarter of 2019, 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.

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:

	<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>
Net cash used in operating activities	\$ (8,376,394)	\$ (11,201,666)
Net cash used in investing activities	(31,470)	(142,687)
Net cash provided by financing activities	11,230,780	12,094,885

Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2018 consists primarily of our net loss of \$9.6 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, 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 investing activities

Net cash used in investing activities in the nine months ended September 30, 2018 and 2017 consisted solely of purchases of property and equipment offset by proceeds from the sale of equipment.

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2018 of \$11.2 million consisted primarily of the net proceeds from the February 2018 Public Offering and net proceeds from the at the market offering. Net cash provided by financing activities for the nine months ended September 30, 2017 of \$12.1 million consisted primarily of net proceeds from the July 2017 Public Offering and net proceeds from the at the market offering.

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, 2017.

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.

Off-balance sheet arrangements

As of September 30, 2018 and December 31, 2017, 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 it 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, 2018. 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, 2018 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

Reference is made to the Risk Factors included in our Annual Report on Form 10-K for the year ended December 31, 2017, which are supplemented and updated by the following risk factors.

Risks Related to Our Business

We have a history of losses, and we expect to incur losses for the next several years. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2017 and 2016 contains explanatory language that substantial doubt exists about our ability to continue as a going concern.

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the nine months ended September 30, 2018 and 2017, we had net losses of \$9.6 million and \$12.5 million, respectively. From our inception through September 30, 2018, we had an accumulated deficit of \$158.3 million. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2017 and 2016 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. We completed a number of financings in 2018 and 2017, including the October 2018 Public Offering, the February 2018 Public Offering, the July 2017 Public Offering, and an at-the-market, or ATM, public offering commenced in September 2016. The net proceeds from such financings were approximately \$26.7 million.

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

- developing our Acuitas AMR Gene Panel 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;
- development of collaborative arrangements during 2018;

- 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 believe that current cash on hand including the October 2018 Public Offering, will be sufficient to fund operations into the second quarter of 2019. In the event we are unable to successfully raise additional capital during or before the second quarter of 2019, 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 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 AMR Gene Panel tests in development, Acuitas MDRO tests and Acuitas Lighthouse bioinformatics 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. 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.

We believe that current cash on hand including the October 2018 Public Offering, will be sufficient to fund operations into the second quarter of 2019. In the event we are unable to successfully raise additional capital during or before the second quarter of 2019, 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 MGHIF Note, secured by a security interest in substantially all of our assets, including our intellectual property assets. The debt is due to be paid in six semi-annual payments of \$166,667 beginning on January 2, 2019 and ending on July 1, 2021. Such secured creditor rights could negatively impact our ability to raise money in the future. If we default on payments under the 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 future success is dependent upon our ability to expand our customer base.

The current customers we are targeting for our Acuitas AMR Gene Panel and Acuitas Lighthouse Software RUO products are hospital systems, pharmaceutical companies and clinical research organizations, and the customers we will target for our Acuitas AMR Gene Panel and Acuitas Lighthouse Software test products and services will be 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 and PNA FISH 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 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. We have identified approximately 47 antibiotic resistance genes to help guide clinician antibiotic therapy decisions when test results are evaluated using the Acuitas Lighthouse Software. 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, 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.

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 bioMérieux Cepheid, Becton-Dickinson, Curetis, Accelerate Diagnostics, T2 Biosystems, GenMark and Luminex, and sequencing CLIA laboratories.

We also face competition from commercial laboratories, such as 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.

We may enter into collaborations or strategic partnering transactions 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, antibiotic resistance 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 have been awarded a contract by the 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 September 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 AMR Gene Panel and Acuitas Lighthouse Software is 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 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 products 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 AMR Gene Panel and Acuitas Lighthouse Software, our QuickFISH and PNA FISH products, and our Acuitas Lighthouse 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 AMR Gene Panel and Acuitas Lighthouse Software 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.

If our sole laboratory and manufacturing facility becomes inoperable, we will be unable to manufacture our Acuitas AMR Gene Panel products, QuickFISH and PNA Fish products or other products, and our business will be harmed.

We are near completing the process of re-locating the manufacturing our QuickFISH and PNA FISH products from our leased facility located in Woburn, Massachusetts 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 obtained all necessary FDA certifications with respect to such relocation. As we look to increase the manufacturing of our Acuitas AMR Gene Panel tests for RUO and in vitro diagnostic customers, we may need to obtain additional regulatory approvals.

In order to establish a redundant 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.

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 Thermo Fisher, Qiagen, and 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 online 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 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 offerings 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.

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 products may 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.

Risks Related to Our Securities and 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 Capital 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.

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 November 9, 2018, the market price of our common stock fluctuated from a high of \$136.00 per share to a low of \$1.18 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.

In the past the Company has failed to meet the minimum bid price and stockholders' equity requirements for continued listing on the Nasdaq Capital Market. The Company has regained its compliance with those continued listing requirements. If the Company does not remain in compliance with those continued listing requirements, Nasdaq could delist the common stock from the Nasdaq Capital Market.

During 2017, we received notices from the Listing Qualifications Staff of the Nasdaq Stock Market LLC, or Nasdaq, notifying us that we no longer met the requirement to maintain a minimum closing bid price of \$1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2) and failed to meet The Nasdaq Capital Market's minimum stockholders' equity requirement of \$2,500,000 to be relisted. As a result, the Staff commenced delisting proceeding on January 2, 2018. We were able to achieve compliance with the minimum bid price as a result of the reverse stock split, and compliance with the minimum stockholders' equity component following the February 2018 Public Offering. If we do not remain in compliance with those continued listing requirements in the future, Nasdaq could delist the common stock from the Nasdaq Capital Market, which would have a material impact on our ability to raise funds in the future, and would make it more difficult for investors to trade shares of our common stock.

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 7% of our common stock, on a fully diluted basis, is held by officers, directors and their affiliates, each of whom is subject to certain restrictions with regard to trading our common stock. This ownership 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, following the reverse stock split, 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.

The exercise of outstanding common stock purchase warrants and stock options will have a dilutive effect on the percentage ownership of our capital stock by existing stockholders.

As of November 9, 2018, we had outstanding warrants to acquire 3,525,797 shares of our common stock, and stock options to purchase 218,759 shares of our common stock. The expiration of the term of such options and warrants range from March 2019 to February 2025. A significant number of such warrants are out of the money, but the holders have the right to effect a cashless exercise of such warrants. If a significant number of such warrants and stock options are exercised by the holders, the percentage of our common stock owned by our existing stockholders will be diluted.

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, an amended and restated promissory note issued in June 2017 to MGHIF, and the related security agreement restricts our ability to pay cash dividends on our common stock. 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.

We issued warrants to purchase an aggregate of 25,102 shares of 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 warrants to purchase an aggregate 25,102 shares of common stock to jVen Capital and MGHIF in connection with the bridge financing transactions. Each of these warrants has a put feature that allows 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 estimates, 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. In addition, as these warrants will be valued based upon the Black-Scholes value, which assesses a value to the warrants even if the exercise price is below the current fair market value of the underlying security, warrant holders could get a disproportionate amount of the consideration upon a change of control or fundamental transaction under certain circumstances.

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.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
10.1!	OpGen, Inc. Retention Plan for Executives (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 25, 2018).
10.2!	Executive Change In Control and Severance Benefits Agreement, dated September 24, 2018 between OpGen, Inc. and Evan Jones (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on September 25, 2018).
10.3!	Executive Change In Control and Severance Benefits Agreement, dated September 24, 2018 between OpGen, Inc. and Timothy C. Dec (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed on September 25, 2018).
10.4!	Executive Change In Control and Severance Benefits Agreement, dated September 24, 2018 between OpGen, Inc. and Vadim Sapiro (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed on September 25, 2018).
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

! Denotes management compensation plan or contract

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 14, 2018

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(s) 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 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, including its consolidated subsidiaries, 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(s) 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 14, 2018

/s/ Evan Jones

Evan Jones

Chief Executive Officer (principal executive officer)

CERTIFICATION OF CHIEF FINANCIAL OFFICER

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

I, Timothy C. Dec, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OpGen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) 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 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, including its consolidated subsidiaries, 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(s) 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 14, 2018

/s/ Timothy C. Dec

Timothy C. Dec

Chief Financial Officer (principal financial officer and
principal accounting officer)

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

In connection with the quarterly report on Form 10-Q of OpGen, Inc. (the "Company") for the quarterly period ended September 30, 2018 (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 14, 2018

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

Date: November 14, 2018

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.