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 June 30, 2019

or

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

For the transition period from _____ to _____

Commission File Number 001-37367

OPGEN, INC.

(Exact name of registrant as specified in its charter)

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

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

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

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock	OPGN	Nasdaq Capital Market
Common Warrants	OPGNW	Nasdaq Capital Market

17,645,720 shares of the Company's common stock, par value $0.01 per share, were outstanding as of August 10, 2019.

OPGEN, INC.

TABLE OF CONTENTS FOR FORM 10-Q

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our 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;
- receipt of regulatory clearance of our submitted 510(k) application for our Acuitas AMR Gene Panel (Isolates) test;
- the completion of our development efforts for the Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software, and the timing of regulatory submissions;
- our ability to sustain or grow our customer base for our current research use only and rapid pathogen ID testing products;
- regulations and changes in laws or regulations applicable to our business, including regulation by the FDA;
- 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;
- 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®, AdvanDx®, QuickFISH®, and PNA FISH®. All other trademarks, servicemarks or trade names referred to in this quarterly report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this quarterly report are sometimes referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies, products or services.

Part I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

OpGen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	June 30, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 3,055,894	$ 4,572,487
Accounts receivable, net	772,914	373,858
Inventory, net	567,422	543,747
Prepaid expenses and other current assets	178,356	292,918
Total current assets	**4,574,586**	**5,783,010**
Property and equipment, net	197,502	1,221,827
Finance lease right-of-use assets, net	984,742	—
Operating lease right-of-use assets	1,381,830	—
Goodwill	600,814	600,814
Intangible assets, net	951,458	1,085,366
Other noncurrent assets	241,182	259,346
Total assets	**$ 8,932,114**	**$ 8,950,363**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,258,908	$ 1,623,751
Accrued compensation and benefits	1,190,500	1,041,573
Accrued liabilities	820,667	902,019
Deferred revenue	9,993	15,824
Short-term notes payable	343,330	398,595
Short-term finance lease liabilities	576,322	399,345
Short-term operating lease liabilities	958,992	—
Total current liabilities	**5,158,712**	**4,381,107**
Deferred rent	—	162,919
Note payable	494,897	660,340
Warrant liability	—	67
Long-term finance lease liabilities	379,825	437,189
Long-term operating lease liabilities	1,071,677	—
Total liabilities	**7,105,111**	**5,641,622**
Commitments (Note 9)		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at June 30, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.01 par value; 50,000,000 shares authorized; 17,645,720 and 8,645,720 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	176,457	86,457
Additional paid-in capital	170,190,415	165,313,902
Accumulated deficit	(168,524,652)	(162,078,525)
Accumulated other comprehensive loss	(15,217)	(13,093)
Total stockholders' equity	**1,827,003**	**3,308,741**
Total liabilities and stockholders' equity	**$ 8,932,114**	**$ 8,950,363**

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30, 2019	2018	Six Months Ended June 30, 2019	2018
Revenue				
Product sales	$ 504,293	$ 632,525	$ 1,024,470	$ 1,266,021
Laboratory services	5,250	1,100	5,250	9,790
Collaboration revenue	500,000	155,276	1,000,000	359,316
Total revenue	**1,009,543**	**788,901**	**2,029,720**	**1,635,127**
Operating expenses				
Cost of products sold	198,493	303,663	419,195	646,495
Cost of services	251,981	179,402	396,463	347,955
Research and development	1,153,584	1,304,388	2,929,966	2,534,817
General and administrative	1,592,845	1,831,063	3,340,430	3,621,585
Sales and marketing	393,567	426,297	765,800	756,070
Impairment of right-of-use asset	—	—	520,759	—
Total operating expenses	**3,590,470**	**4,044,813**	**8,372,613**	**7,906,922**
Operating loss	**(2,580,927)**	**(3,255,912)**	**(6,342,893)**	**(6,271,795)**
Other (expense) income				
Other income (expense)	15,166	5	(9,256)	5,303
Interest expense	(37,129)	(54,533)	(93,573)	(112,379)
Foreign currency transaction gains (losses)	9,879	(21,762)	(472)	(9,581)
Change in fair value of derivative financial instruments	—	(11)	67	8,155
Total other expense	**(12,084)**	**(76,301)**	**(103,234)**	**(108,502)**
Loss before income taxes	**(2,593,011)**	**(3,332,213)**	**(6,446,127)**	**(6,380,297)**
Provision for income taxes	—	—	—	—
Net loss	**(2,593,011)**	**(3,332,213)**	**(6,446,127)**	**(6,380,297)**
Net loss available to common stockholders	**$ (2,593,011)**	**$ (3,332,213)**	**$ (6,446,127)**	**$ (6,380,297)**
Net loss per common share - basic and diluted	**$ (0.15)**	**$ (0.57)**	**$ (0.48)**	**$ (1.29)**
Weighted average shares outstanding - basic and diluted	17,645,720	5,826,947	13,518,648	4,950,517
Net loss	$ (2,593,011)	$ (3,332,213)	$ (6,446,127)	$ (6,380,297)
Other comprehensive (loss) gain - foreign currency translations	(4,950)	18,113	(2,124)	5,534
Comprehensive loss	**$ (2,597,961)**	**$ (3,314,100)**	**$ (6,448,251)**	**$ (6,374,763)**

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(unaudited)

	Common Stock		Preferred Stock		Additional	Accumulated Other		
	Number of Shares	Amount	Number of Shares	Amount	Paid-in Capital	Comprehensive Loss	Accumulated Deficit	Total
Balances at December 31, 2017	**2,265,320**	**$ 22,653**	—	—	**$ 150,114,671**	**$ (25,900)**	**$ (148,710,427)**	**$ 1,400,997**
Public offering of common stock and warrants, net of issuance costs	3,019,230	30,192	—	—	10,691,208	—	—	10,721,400
Issuance of RSUs	5,400	54	—	—	(54)	—	—	—
Stock compensation expense	—	—	—	—	238,190	—	—	238,190
Stock cancellation	(31)	—	—	—	—	—	—	—
Foreign currency translation	—	—	—	—	—	(12,579)	—	(12,579)
Net loss	—	—	—	—	—	—	(3,048,084)	(3,048,084)
Balances at March 31, 2018	**5,289,919**	**$ 52,899**	**—**	**—**	**$ 161,044,015**	**$ (38,479)**	**$ (151,758,511)**	**$ 9,299,924**
Public offering of common stock and warrants, net of issuance costs	673,077	6,731	—	—	—	—	—	6,731
At the market offering, net of offering costs	104,043	1,040	—	—	191,280	—	—	192,320
Stock compensation expense	—	—	—	—	213,890	—	—	213,890
Foreign currency translation	—	—	—	—	—	18,113	—	18,113
Net loss	—	—	—	—	—	—	(3,332,213)	(3,332,213)
Balances at June 30, 2018	**6,067,039**	**$ 60,670**	**—**	**—**	**$ 161,449,185**	**$ (20,366)**	**$ (155,090,724)**	**$ 6,398,765**
Balances at December 31, 2018	**8,645,720**	**$ 86,457**	—	—	**$ 165,313,902**	**$ (13,093)**	**$ (162,078,525)**	**$ 3,308,741**
Public offering of common stock and warrants, net of issuance costs	9,000,000	90,000	—	—	4,692,509	—	—	4,782,509
Stock compensation expense	—	—	—	—	98,033	—	—	98,033
Foreign currency translation	—	—	—	—	—	2,826	—	2,826
Net loss	—	—	—	—	—	—	(3,853,116)	(3,853,116)
Balances at March 31, 2019	**17,645,720**	**$ 176,457**	**—**	**—**	**$ 170,104,444**	**$ (10,267)**	**$ (165,931,641)**	**$ 4,338,993**
Stock compensation expense	—	—	—	—	85,971	—	—	85,971
Foreign currency translation	—	—	—	—	—	(4,950)	—	(4,950)
Net loss	—	—	—	—	—	—	(2,593,011)	(2,593,011)
Balances at June 30, 2019	**17,645,720**	**$ 176,457**	**—**	**—**	**$ 170,190,415**	**$ (15,217)**	**$ (168,524,652)**	**$ 1,827,003**

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Six Months Ended June 30, 2019	2018
Cash flows from operating activities		
Net loss	$ (6,446,127)	$ (6,380,297)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	450,952	317,652
Noncash interest expense	43,371	94,594
Stock compensation expense	184,004	452,080
Loss (gain) on sale of equipment	9,904	(5,253)
Change in fair value of warrant liability	(67)	(8,155)
Impairment of right-of-use asset	520,759	—
Changes in operating assets and liabilities:		
Accounts receivable	(399,528)	291,273
Inventory	(23,824)	(81,321)
Other assets	429,558	(235,835)
Accounts payable	(301,376)	(219,565)
Accrued compensation and other liabilities	(285,953)	226,611
Deferred revenue	(5,831)	(10,320)
Net cash used in operating activities	**(5,824,158)**	**(5,558,536)**
Cash flows from investing activities		
Purchases of property and equipment	(24,680)	(4,457)
Proceeds from sale of equipment	29,250	10,440
Net cash provided by investing activities	**4,570**	**5,983**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	4,782,509	192,320
Proceeds from issuance of units, net of selling costs	—	10,728,131
Proceeds from debt, net of issuance costs	15,481	309,900
Payments on debt	(237,414)	(55,582)
Payments on finance leases	(235,600)	(107,871)
Net cash provided by financing activities	**4,324,976**	**11,066,898**
Effects of exchange rates on cash	(1,321)	5,587
Net (decrease) increase in cash, cash equivalents and restricted cash	(1,495,933)	5,519,932
Cash, cash equivalents and restricted cash at beginning of period	4,737,207	2,090,551
Cash, cash equivalents and restricted cash at end of period	**$ 3,241,274**	**$ 7,610,483**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 97,599	$ 17,785
Supplemental disclosures of noncash investing and financing activities:		
Right-of-use assets acquired through finance leases	$ 291,936	$ 281,153
Conversion of accounts payable to finance lease	$ 63,600	$ 174,968

See accompanying notes to unaudited condensed consolidated financial statements.

Note 1 – Organization

OpGen, Inc. ("OpGen" or the "Company") was incorporated in Delaware in 2001. References in this report to the "Company" include OpGen and its wholly-owned subsidiaries. The Company's headquarters and its principal operations are in Gaithersburg, Maryland. The Company also has operations in Copenhagen, Denmark, and Bogota, Colombia. The Company operates in one business segment.

OpGen is a precision medicine company harnessing the power of 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 products, product candidates and services combine its Acuitas molecular diagnostics 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 molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include its Acuitas antimicrobial resistance, or AMR, Gene Panel (Urine) test in development for patients at risk for complicated urinary tract infection, or cUTI, and its Acuitas AMR Gene Panel (Isolates) test in development for testing bacterial isolates, and its QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of the Acuitas AMR Gene Panel tests is available for sale for research use only, or RUO.
- 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. Components of the 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 Acuitas Lighthouse Software is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

The Company's operations are subject to certain risks and uncertainties. The risks include the risk that the Company will not receive 510(k) clearance for its Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software on a timely basis, or at all, rapid technology changes, 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, obtain regulatory approval for 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 transactions, including the following in 2018 and 2019 to date:

- On March 29, 2019, the Company closed a public offering (the "March 2019 Public Offering") of 9,000,000 shares of its common stock at a public offering price of $0.60 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million.
- 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 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 Promissory 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. The 851,155 pre-funded warrants issued in the February 2018 Public Offering were exercised during the year ended December 31, 2018.
- 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 could 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. During the year ended December 31, 2018, the Company 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. The at the market offering was terminated in connection with the October 2018 Public 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 will be sufficient to fund operations into the third 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 end of the third 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 accounting principles generally accepted in the United States of America ("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 unaudited condensed consolidated financial statements be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company's 2018 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, 2018 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.

Foreign currency

The Company has subsidiaries located in Copenhagen, Denmark, and Bogota, Colombia, both of 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 June 30, 2019 and December 31, 2018.

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, stock-based compensation, allowances for doubtful accounts and inventory obsolescence, discount rates used to discount unpaid lease payments to present values, valuation of derivative financial instruments measured at fair value on a recurring basis, deferred tax assets and liabilities and related valuation allowance, the estimated useful lives of long-lived assets, and the recoverability of long-lived assets. Actual results could differ from those estimates.

Fair value of financial instruments

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 June 30, 2019, 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, 2018, the Company had funds totaling $164,720, 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.

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

	June 30, 2019	December 31, 2018	June 30, 2018	December 31, 2017
Cash and cash equivalents	$ 3,055,894	$ 4,572,487	$ 7,428,993	$ 1,847,171
Restricted cash	185,380	164,720	181,490	243,380
Total cash, cash equivalents and restricted cash in the condensed consolidated statement of cash flows	$ 3,241,274	$ 4,737,207	$ 7,610,483	$ 2,090,551

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 $22,309 and $18,332 as of June 30, 2019 and December 31, 2018, respectively.

One individual customer represented 50% and 19% of revenues for the three months ended June 30, 2019 and 2018, respectively. One individual customer represented 49% and 21% of revenues for the six months ended June 30, 2019 and 2018, respectively. At June 30, 2019, one individual customer represented 65% of total accounts receivable. At December 31, 2018, one individual customer represented 12% 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:

	June 30, 2019	December 31, 2018
Raw materials and supplies	$ 237,500	$ 368,438
Work-in-process	135,916	58,402
Finished goods	194,006	116,907
Total	$ 567,422	$ 543,747

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 $114,327 and $71,270 at June 30, 2019 and December 31, 2018, 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 six months ended June 30, 2019 and 2018, the Company determined that its property and equipment was not impaired.

Leases

The Company determines if an arrangement is a lease at inception. For leases where the Company is the lessee, right-of-use ("ROU") assets represent the Company's right to use the underlying asset for the term of the lease and the lease liabilities represent an obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of the future lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at the commencement date of the underlying lease arrangement to determine the present value of lease payments. The ROU asset also includes any prepaid lease payments and any lease incentives received. The lease term to calculate the ROU asset and related lease liability includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise the option. The Company's lease agreements generally do not contain any material variable lease payments, residual value guarantees or restrictive covenants.

Lease expense for operating leases is recognized on a straight-line basis over the lease term as an operating expense while expense for financing leases is recognized as depreciation expense and interest expense using the accelerated interest method of recognition. The Company has made certain accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12 months or less) and (ii) combines lease and non-lease elements of our operating leases.

ROU assets

ROU assets 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 the Company 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. In

conjunction with adoption of Accounting Standards Update ("ASU") 2016-02, *Leases* (Topic 842) ("ASC 842"), the Company determined that the ROU asset associated with its Woburn, Massachusetts office lease may not be recoverable. As a result, the Company recorded an impairment charge of $520,759 during the six months ended June 30, 2019.

Intangible assets and goodwill

Intangible assets and goodwill as of June 30, 2019 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 June 30, 2019 and December 31, 2018:

		June 30, 2019		December 31, 2018	
	Cost	Accumulated Amortization	Net Balance	Accumulated Amortization	Net Balance
Trademarks and trade names	$ 461,000	$ (182,835)	$ 278,165	$ (159,783)	$ 301,217
Developed technology	458,000	(259,458)	198,542	(226,746)	231,254
Customer relationships	1,094,000	(619,249)	474,751	(541,105)	552,895
	$ 2,013,000	$ (1,061,542)	$ 951,458	$ (927,634)	$ 1,085,366

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 June 30, 2019 and 2018. Total amortization expense of intangible assets was $133,908 for each of the six months ended June 30, 2019 and 2018.

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 six months ended June 30, 2019 and 2018, 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 2018, 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 June 30, 2019 and December 31, 2018 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 six months ended June 30, 2019 and 2018, the Company determined that its goodwill was not impaired.

Revenue recognition

The Company derives revenues from (i) the sale of QuickFISH and PNA FISH diagnostic test products and Acuitas AMR Gene Panel 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.

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.

Stock-based compensation

Stock-based compensation expense is recognized at fair value. The fair value of stock-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 $178.2 million at December 31, 2018. Despite the NOL carryforwards, which begin to expire in 2022, the Company may have future tax liability due to alternative minimum tax or state tax requirements. Also, use of the NOL carryforwards may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”). To date, the Company has not performed a formal study to determine if any of its remaining NOL and credit attributes might be further limited due to the ownership change rules of Section 382 or Section 383 of the Code. The Company will continue to monitor this matter going forward. There can be no assurance that the NOL carryforwards will ever be fully utilized.

Loss per share

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

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

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The number of anti-dilutive shares, consisting of (i) common stock options, (ii) stock purchase warrants, and (iii) restricted stock units representing the right to acquire shares of common stock which have been excluded from the computation of diluted loss per share, was 4.0 million shares and 3.8 million shares as of June 30, 2019 and 2018, respectively.

Adopted 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, 2018, including the expected dates of adoption and estimated effects on the Company's condensed consolidated financial statements, except for the following:

In February 2016, the FASB issued ASC 842, which amends the existing accounting standards for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The Company adopted this guidance effective January 1, 2019 using the modified retrospective transition method and the following practical expedients:

- The Company did not reassess if any expired or existing contracts are or contain leases.
- The Company did not reassess the classification of any expired or existing leases.

Additionally, the Company made ongoing accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12 months or less) and (ii) combines lease and non-lease elements of our operating leases.

Upon adoption of the new guidance on January 1, 2019, the Company recorded an operating lease right of use asset of approximately $2.2 million (net of existing deferred rent) and recognized a lease liability of approximately $2.5 million.

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 adoption of this new guidance did not have a material impact on the Company's condensed consolidated financial statements.

In August 2018, the SEC issued a final rule that amends certain disclosure requirements that were duplicative, outdated or superseded. In addition, the final rule expanded the financial reporting requirements for changes in stockholders' equity for interim reporting periods. The Company adopted the new guidance on January 1, 2019 with no material impact to the condensed consolidated financial statements.

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

Note 4 – 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Product sales	$ 504,293	$ 632,525	$ 1,024,470	$ 1,266,021
Laboratory services	5,250	1,100	5,250	9,790
Collaboration revenue	500,000	155,276	1,000,000	359,316
Total revenue	$ 1,009,543	$ 788,901	$ 2,029,720	$ 1,635,127

Deferred revenue

Changes in deferred revenue for the period were as follows:

Balance at December 31, 2018	$ 15,824
Revenue recognized in the current period from the amounts in the beginning balance	(5,831)
New deferrals, net of amounts recognized in the current period	—
Balance at June 30, 2019	$ 9,993

Contract assets

The Company had no contract assets as of June 30, 2019, 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 $575,000 at June 30, 2019, which the Company expects to recognize over the next six 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. The Company's obligations under the MGHIF Note are secured by a lien on all of the Company's assets.

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 $7,000 as of June 11, 2018 are 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 six months ended June 30, 2019, 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 six months ended June 30, 2019:

Description	Balance at December 31, 2018	Change in Fair Value	Balance at June 30, 2019
Warrant liability	$ 67	$ (67)	$ —

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 six months ended June 30, 2019 and 2018.

Note 7 – Debt

As of June 30, 2019, the Company's outstanding short-term debt consisted of approximately $333,000 due under the MGHIF Note, as well as the financing arrangements for the Company's insurance with note balances of approximately $10,000 with a final payment scheduled for February 2020. The Company's outstanding long-term debt as of June 30, 2019 consisted of approximately $495,000 due under the MGHIF Note (see Note 5 "MGHIF financing"). As of December 31, 2018, the Company's outstanding short-term debt consisted of $333,000 due under the MGHIF Note, net of discounts and financing costs, as well as the financing arrangements for the Company's insurance with note balances of approximately $65,000. The Company's outstanding long-term debt as of December 31, 2018 consisted of approximately $660,000 due under the MGHIF Note, net of discounts and financing costs. Total principal payments of approximately $333,000 are due annually in 2019, 2020, and 2021.

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $37,129 and $54,533 for the three months ended June 30, 2019 and 2018, respectively. Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $93,573 and $112,379 for the six months ended June 30, 2019 and 2018, respectively.

Note 8 – Stockholders' equity

As of June 30, 2019, the Company has 50,000,000 authorized shares of common stock and 17,645,720 shares issued and outstanding, and 10,000,000 authorized shares of preferred stock, of which none were issued or outstanding.

In September 2016, the Company entered into the Sales Agreement with Cowen pursuant to which the Company could 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. During the year ended December 31, 2018, the Company 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.

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 were exercisable immediately and have a five-year term from the date of issuance. The 851,155 pre-funded warrants issued in the February 2018 Public Offering were exercised during the year ended December 31, 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.

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 offering raised gross proceeds of approximately $3.2 million and net proceeds of approximately $2.8 million.

On March 29, 2019, the Company closed the March 2019 Public Offering of 9,000,000 shares of its common stock at a public offering price of $0.60 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million.

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 June 30, 2019, 84,412 shares remain available for issuance under the 2015 Plan, which includes 345,828 shares automatically added to the 2015 Plan on January 1, 2019.

For the three and six months ended June 30, 2019 and 2018, the Company recognized stock-based compensation expense as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cost of services	$ 524	$ 1,341	$ 562	$ 3,731
Research and development	18,333	61,080	35,460	130,551
General and administrative	61,365	140,158	137,378	292,340
Sales and marketing	5,749	11,311	10,604	25,458
	$ 85,971	$ 213,890	$ 184,004	$ 452,080

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

The Company did not grant any stock options during the three months ended June 30, 2019. During the three months ended June 30, 2019, 720 options were forfeited and no options expired. The Company did not grant any stock options during the six months ended June 30, 2019. During the six months ended June 30, 2019, 720 options were forfeited and 5 options expired. The Company had total stock options to acquire 210,834 shares of common stock outstanding at June 30, 2019.

Restricted stock units

During the six months ended June 30, 2019, 313,000 restricted stock units were granted, no restricted stock units vested and no restricted stock units were forfeited. The Company had 313,250 total restricted stock units outstanding at June 30, 2019.

Stock purchase warrants

At June 30, 2019 and December 31, 2018, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at June 30, 2019	Outstanding at December 31, 2018
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
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	184,615
February 2018	$ 3.25	February 2023	1,846,153	1,846,153
			3,525,632	3,525,797

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

Note 9 – Commitments

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.

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 June 30, 2019, the Company has acquired twenty-one QuantStudio 5s including six in the six months ended June 30, 2019. As of June 30, 2019, the Company has committed to acquiring an additional three QuantStudio 5s at a total cost of approximately $135,000 in the next three months.

Note 10 – Leases

The following table presents the Company's ROU assets and lease liabilities as of June 30, 2019:

Lease Classification	June 30, 2019
ROU Assets:	
Operating	$ 1,381,830
Financing	984,742
Total ROU assets	$ 2,366,572
Liabilities	
Current:	
Operating	$ 958,992
Finance	576,322
Noncurrent:	
Operating	1,071,677
Finance	379,825
Total lease liabilities	$ 2,986,816

Maturities of lease liabilities as of June 30, 2019 by fiscal year are as follows:

Maturity of Lease Liabilities	Operating	Finance	Total
2019	$ 558,109	$ 332,786	$ 890,895
2020	1,128,138	520,947	1,649,085
2021	536,819	166,318	703,137
2022	40,080	11,240	51,320
2023	—	3,644	3,644
Thereafter	—	—	—
Total lease payments	2,263,146	1,034,935	3,298,081
Less: Interest	(232,477)	(78,788)	(311,265)
Present value of lease liabilities	$ 2,030,669	$ 956,147	$ 2,986,816

Statement of operations classification of lease costs are as follows:

		June 30, 2019	
Lease Cost	Classification	Three months ended	Six months ended
Operating	Operating expenses	$ 218,673	$ 439,595
Finance:			
Amortization	Operating expenses	107,496	204,689
Interest expense	Other expenses	19,297	41,778
Total lease costs		$ 345,466	$ 686,062

Other Information	Total
Weighted average remaining lease term (in years)	
Operating leases	2.1
Finance leases	1.8
Weighted average discount rate:	
Operating leases	10.0%
Finance leases	9.2%

Supplemental Cash Flow Information	Total
Cash paid for amounts included in the measurement of lease liabilities	
Cash used in operating activities	
Operating leases	$ 439,595
Finance leases	$ 41,778
Cash used in financing activities	
Finance leases	$ 235,600
ROU assets obtained in exchange for lease obligations:	
Finance leases	$ 355,536

Lease Commitments as of December 31, 2018

Minimum lease payments for future years as of December 31, 2018 were as follows:

Year ending December 31,	Total
2019	$ 1,615,679
2020	1,534,204
2021	639,829
2022	40,080
2023 and thereafter	—
Total	$ 3,829,792

Note 11 – License agreements, research collaborations and development agreements

In 2018, the Company announced a collaboration with the New York State Department of Health ("DOH") and ILÚM Health Solutions, LLC ("ILÚM"), a wholly-owned subsidiary of Merck's Healthcare Services and Solutions division, to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions statewide. The Company is working together with DOH's Wadsworth Center and ILÚM to develop an infectious disease digital health and precision medicine platform that connects healthcare institutions to DOH and uses genomic microbiology for statewide surveillance and control of antimicrobial resistance. As part of the collaboration, the Company will receive $1.6 million over the 12 month demonstration portion of the project. The demonstration project began in early 2019. During the three and six months ended June 30, 2019, the Company recognized $500,000 and $1.0 million of revenue related to the contract, respectively.

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 for each of the three months ended June 30, 2019 and 2018. The Company recognized net royalty expense of $125,000 for each of the six months ended June 30, 2019 and 2018. Annual future minimum royalty fees are $250,000 under this agreement.

Note 12 – 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 recognized research and development expense of $0 and $22,604 related to the agreement in the three months ended June 30, 2019 and 2018, respectively. The Company recognized research and development expense of $0 and $22,604 related to the agreement in the six months ended June 30, 2019 and 2018, respectively.

In December 2017, the Company entered into a subcontractor agreement with ILÚM, whereby ILÚM 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 $84,853 of cost of services expense related to the contract in the three months ended June 30, 2019 and 2018, respectively. The Company recognized $0 and $198,665 of cost of services expense related to the contract in the six months ended June 30, 2019 and 2018, respectively.

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, 2018.

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 and 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 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. 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 products, product candidates and services combine its Acuitas molecular diagnostics 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 molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include its Acuitas antimicrobial resistance, or AMR, Gene Panel (Urine) test in development for patients at risk for complicated urinary tract infections, or cUTI, its Acuitas AMR Gene Panel (Isolates) test in development for testing bacterial isolates, and its QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of its Acuitas AMR Gene Panel tests is available for sale for research use only, or RUO.
- 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. Components of the 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 Acuitas Lighthouse Software is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

In May 2019, the Company filed a 510(k) application with the FDA seeking clearance of its Acuitas AMR Gene Panel (Isolates) diagnostic test. In July 2019, the Company received correspondence from the FDA detailing a number of questions related to this filing. The Company is currently evaluating the FDA correspondence and preparing its responses.

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. During 2018, the Company raised net proceeds of approximately $14.1 million, and renegotiated the payment terms of 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"). On March 29, 2019, the Company closed a public offering (the "March 2019 Public Offering") of 9,000,000 shares of its common stock at a public offering price of $0.60 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million. For more information regarding the public offerings during 2018 and the amendments to the MGHIF Note, see Note 2 ("Liquidity and management's plan") to the Notes to Unaudited Condensed Consolidated Financial Statements elsewhere in this quarterly report on Form 10-Q.

Results of operations for the three months ended June 30, 2019 and 2018

Revenue

	Three Months Ended June 30,	
	2019	2018
Product sales	$ 504,293	$ 632,525
Laboratory services	5,250	1,100
Collaboration revenue	500,000	155,276
Total revenue	$ 1,009,543	$ 788,901

Total revenue for the three months ended June 30, 2019 increased approximately 28%, with a change in the mix of revenue, as follows:

- Product sales: a decrease in revenue of approximately 20% in the 2019 period compared to the 2018 period is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products;
- Laboratory services: an increase in revenue of approximately 377% in the 2019 period compared to the 2018 period is a result of Acuitas whole genome sequencing performed in 2019; and
- Collaboration revenue: an increase in revenue of approximately 222% in the 2019 period compared to the 2018 period is primarily the result of revenue from our contract with the New York State Department of Health.

Operating expenses

	Three Months Ended June 30,	
	2019	2018
Cost of products sold	$ 198,493	$ 303,663
Cost of services	251,981	179,402
Research and development	1,153,584	1,304,388
General and administrative	1,592,845	1,831,063
Sales and marketing	393,567	426,297
Impairment of right-of-use asset	—	—
Total operating expenses	$ 3,590,470	$ 4,044,813

The Company's total operating expenses for the three months ended June 30, 2019 decreased approximately 11% when compared to the same period in 2018. This decrease is primarily attributable to:

- Cost of products sold: cost of products sold for the three months ended June 30, 2019 decreased approximately 35% when compared to the same period in 2018. The change in costs of products sold is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products;
- Cost of services: cost of services for the three months ended June 30, 2019 increased approximately 40% when compared to the same period in 2018. The change in costs of services is primarily attributable to an increase in costs associated with our collaboration contracts;

- Research and development: research and development expenses for the three months ended June 30, 2019 decreased approximately 12% when compared to the same period in 2018, primarily due to expenses related to our 510(k) submission for the Acuitas AMR Gene Panel (Isolates) incurred in 2018;
- General and administrative: general and administrative expenses for the three months ended June 30, 2019 decreased approximately 13% when compared to the same period in 2018, primarily due to decreased payroll related costs; and
- Sales and marketing: sales and marketing expenses for the three months ended June 30, 2019 decreased approximately 8% when compared to the same period in 2018, primarily due to a reduction in marketing expenses.

Other income (expense)

	Three Months Ended June 30,	
	2019	2018
Interest expense	$ (37,129)	$ (54,533)
Foreign currency transaction gains (losses)	9,879	(21,762)
Other income (expense)	15,166	5
Change in fair value of derivative financial instruments	—	(11)
Total other expense	$ (12,084)	$ (76,301)

The Company's total other expense for the three months ended June 30, 2019 decreased primarily due to a decrease in interest expense and an increase in other income.

Results of operations for the six months ended June 30, 2019 and 2018

Revenue

	Six Months Ended June 30,	
	2019	2018
Product sales	$ 1,024,470	$ 1,266,021
Laboratory services	5,250	9,790
Collaboration revenue	1,000,000	359,316
Total revenue	$ 2,029,720	$ 1,635,127

Total revenue for the six months ended June 30, 2019 increased approximately 24%, with a change in the mix of revenue, as follows:

- Product sales: a decrease in revenue of approximately 19% in the 2019 period compared to the 2018 period is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products;
- Laboratory services: a decrease in revenue of approximately 46% in the 2019 period compared to the 2018 period is a result of our ceasing sales of our Acuitas MDRO test products in 2019; and
- Collaboration revenue: an increase in revenue of approximately 178% in the 2019 period compared to the 2018 period is primarily the result of revenue from our contract with the New York State Department of Health.

Operating expenses

	Six Months Ended June 30,	
	2019	2018
Cost of products sold	$ 419,195	$ 646,495
Cost of services	396,463	347,955
Research and development	2,929,966	2,534,817
General and administrative	3,340,430	3,621,585
Sales and marketing	765,800	756,070
Impairment of right-of-use asset	520,759	—
Total operating expenses	$ 8,372,613	$ 7,906,922

The Company's total operating expenses for the six months ended June 30, 2019 increased approximately 6% when compared to the same period in 2018. This increase is primarily attributable to the impairment of our Woburn, Massachusetts ROU asset for the six months ended June 30, 2019 recorded as part of the Company's adoption of ASU 2016-02, *Leases (Topic 842)*. In addition, operating expenses changed as follows:

- Cost of products sold: cost of products sold for the six months ended June 30, 2019 decreased approximately 35% when compared to the same period in 2018. The change in costs of products sold is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products;
- Cost of services: cost of services for the six months ended June 30, 2019 increased approximately 14% when compared to the same period in 2018. The change in costs of services is primarily attributable to an increase in costs associated with our collaboration contracts;
- Research and development: research and development expenses for the six months ended June 30, 2019 increased approximately 16% when compared to the same period in 2018, primarily due to R&D related costs associated with our contract with the New York State Department of Health that were allocated to cost of services;
- General and administrative: general and administrative expenses for the six months ended June 30, 2019 decreased approximately 8% when compared to the same period in 2018, primarily due to decreased payroll related costs; and
- Sales and marketing: sales and marketing expenses for the six months ended June 30, 2019 increased approximately 1% when compared to the same period in 2018, primarily due to the increased headcount of our marketing team.

Other income (expense)

	Six Months Ended June 30,	
	2019	2018
Interest expense	$ (93,573)	$ (112,379)
Foreign currency transaction gains (losses)	(472)	(9,581)
Other income (expense)	(9,256)	5,303
Change in fair value of derivative financial instruments	67	8,155
Total other expense	$ (103,234)	$ (108,502)

The Company's total other expense for the six months ended June 30, 2019 decreased primarily due to a decrease in interest expense and an increase in other expenses.

Liquidity and capital resources

As of June 30, 2019, the Company had cash and cash equivalents of $3.1 million compared to $4.6 million at December 31, 2018. The Company has funded its operations primarily through external investor financing arrangements and has raised funds in 2019 and 2018, including:

On March 29, 2019, the Company closed the March 2019 Public Offering of 9,000,000 shares of its common stock at a public offering price of $0.60 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million.

On October 22, 2018, the Company closed its October 2018 Public Offering of 2,220,000 shares of its common stock at a public offering price of $1.45 per share. The offering raised gross proceeds of approximately $3.2 million and net proceeds of approximately $2.8 million.

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.

During the year ended December 31, 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.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements and business combination transactions. There

can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. The Company believes that current cash on hand will be sufficient to fund operations into the third 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 end of the third 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:

	Six Months Ended June 30,	
	2019	**2018**
Net cash used in operating activities	$ (5,824,158)	$ (5,558,536)
Net cash provided by investing activities	4,570	5,983
Net cash provided by financing activities	4,324,976	11,066,901

Net cash used in operating activities

Net cash used in operating activities for the six months ended June 30, 2019 consists primarily of our net loss of $6.4 million, reduced by certain noncash items, including impairment of ROU asset of $0.5 million, depreciation and amortization expense of $0.5 million, and stock-based compensation expense of $0.2 million. Net cash used in operating activities for the six months ended June 30, 2018 consists primarily of our net loss of $6.4 million, reduced by certain noncash items, including depreciation and amortization expense of $0.3 million and stock-based compensation expense of $0.5 million.

Net cash provided by investing activities

Net cash provided by investing activities in the six months ended June 30, 2019 and 2018 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 six months ended June 30, 2019 of $4.3 million consisted primarily of the net proceeds from the March 2019 Public Offering. Net cash provided by financing activities for the six months ended June 30, 2018 of $11.1 million consisted primarily of net proceeds from the February 2018 Public 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 audited consolidated financial statements, estimates are used for, but not limited to, liquidity assumptions, revenue recognition, stock-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, estimated useful lives of long-lived assets, and the recoverability 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, 2018.

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 June 30, 2019 and December 31, 2018, 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 $1.07 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 June 30, 2019. 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 June 30, 2019 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, 2018, as supplemented by the following:

We have a history of losses, and we expect to incur losses for the next several years. Substantial doubt exists about our ability to continue as a going concern. If we cannot raise additional capital prior to the end of the third quarter 2019, we will not have sufficient cash and liquidity to fund our business as currently contemplated.

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the six months ended June 30, 2019, we had a net loss of $6.4 million and for the year ended December 31, 2018, we had a net loss of $13.4 million. From our inception through June 30, 2019, we had an accumulated deficit of $168.5 million. Substantial doubt exists about our ability to continue as a going concern. We believe that current cash will be sufficient to fund our operations into the third quarter of 2019. If we are not able to successfully raise additional capital during or before the end of the third quarter of 2019, we will not have sufficient cash and liquidity to fund our business 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 a material adverse effect on our business, financial condition and results of operations.

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

On May 6, 2019, we received notice from NASDAQ that we had failed to maintain a bid price of at least $1.00 per share for 30 successive trading days. We have six months to regain compliance with the listing standard. We have submitted a proposal to our stockholders to be considered at our 2019 annual meeting of stockholders to be held on August 22, 2019 to provide the Board of Directors with the authority to effect a reverse stock split of our common stock. However, there can be no assurance that our stockholders will approve the proposal or that we will be able to maintain the NASDAQ Capital Market listing of our common stock in the future.

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

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

The process to obtain and maintain FDA clearances or approvals for our products is complex and time-consuming. If we fail to obtain such clearances or approvals, our business and results of operations will be materially adversely impacted.

The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In May 2019, we filed a 510(k) submission with the FDA seeking clearance of our Acuitas AMR Gene Panel (Isolates) diagnostic test. In July 2019, we received correspondence from the FDA requesting additional information related to this filing. The Company is currently evaluating the FDA correspondence and preparing its responses. If we cannot successfully address the questions posed by the FDA, our receipt of clearance for this product will be delayed. In addition, the time and expense needed to respond to the FDA's request for additional information may divert time and attention from our other regulatory submissions in process, which may adversely affect our strategy and ability to commercialize our diagnostic tests and bioinformatics products and services.

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
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to Unaudited Condensed Consolidated Financial Statements.

* Filed or furnished herewith

SIGNATURES

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

OPGEN, INC.

By: /s/ Timothy C. Dec
Timothy C. Dec
Chief Financial Officer

Date: August 14, 2019

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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

I, Evan Jones, certify that:

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

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

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

4. The registrant's other certifying officer(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: August 14, 2019

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

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

I, Timothy C. Dec, certify that:

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

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

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

4. The registrant's other certifying officer(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: August 14, 2019

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

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of OpGen, Inc. (the "Company") for the quarterly period ended June 30, 2019 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

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

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

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

Date: August 14, 2019

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

Date: August 14, 2019

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.