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

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 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

5,582,268 shares of the Company's common stock, par value $0.01 per share, were outstanding as of November 14, 2019.

OPGEN, INC.

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our ability to complete the business combination of OpGen and Curetis;
- 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) pre-market submission for our Acuitas AMR Gene Panel test for use with bacterial isolates;
- the completion of our development efforts for the Acuitas AMR Gene Panel Urine test 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

	September 30, 2019 (Unaudited)	December 31, 2018 (See Note 3)
Assets		
Current assets		
Cash and cash equivalents	$ 626,420	$ 4,572,487
Accounts receivable, net	377,284	373,858
Inventory, net	468,374	543,747
Prepaid expenses and other current assets	533,411	292,918
Total current assets	**2,005,489**	**5,783,010**
Property and equipment, net	201,762	1,221,827
Finance lease right-of-use assets, net	1,096,472	—
Operating lease right-of-use assets	1,214,482	—
Goodwill	600,814	600,814
Intangible assets, net	884,504	1,085,366
Other noncurrent assets	426,629	259,346
Total assets	**$ 6,430,152**	**$ 8,950,363**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 1,872,762	$ 1,623,751
Accrued compensation and benefits	1,387,498	1,041,573
Accrued liabilities	1,040,562	902,019
Deferred revenue	9,808	15,824
Short-term notes payable	508,292	398,595
Short-term finance lease liabilities	627,620	399,345
Short-term operating lease liabilities	987,833	—
Total current liabilities	**6,434,375**	**4,381,107**
Deferred rent	—	162,919
Note payable	328,843	660,340
Warrant liability	—	67
Long-term finance lease liabilities	411,103	437,189
Long-term operating lease liabilities	812,801	—
Total liabilities	**7,987,122**	**5,641,622**
Commitments (Note 9)		
Stockholders' equity (deficit)		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.01 par value; 50,000,000 shares authorized; 882,268 and 432,286 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively*	8,823	4,323
Additional paid-in capital	170,449,216	165,396,036
Accumulated deficit	(172,007,090)	(162,078,525)
Accumulated other comprehensive loss	(7,919)	(13,093)
Total stockholders' equity (deficit)	**(1,556,970)**	**3,308,741**
Total liabilities and stockholders' equity (deficit)	**$ 6,430,152**	**$ 8,950,363**

*Reflects the 1-for-20 reverse stock split that became effective on August 29, 2019. Refer to Note 8 – Stockholders' equity for further information.

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30, 2019	2018	Nine Months Ended September 30, 2019	2018
Revenue				
Product sales	$ 573,035	$ 539,856	$ 1,597,505	$ 1,805,877
Laboratory services	185	12,365	5,435	22,155
Collaboration revenue	75,000	—	1,075,000	359,316
Total revenue	**648,220**	**552,221**	**2,677,940**	**2,187,348**
Operating expenses				
Cost of products sold	262,373	292,984	681,568	939,479
Cost of services	196,184	98,189	592,647	446,144
Research and development	1,139,369	1,286,300	4,069,335	3,821,117
General and administrative	1,560,706	1,743,636	4,901,136	5,365,221
Sales and marketing	376,955	361,310	1,142,755	1,117,380
Transaction costs	538,061	—	538,061	—
Impairment of right-of-use asset	—	—	520,759	—
Total operating expenses	**4,073,648**	**3,782,419**	**12,446,261**	**11,689,341**
Operating loss	**(3,425,428)**	**(3,230,198)**	**(9,768,321)**	**(9,501,993)**
Other (expense) income				
Other income (expense)	1,043	(93)	(8,213)	5,210
Interest expense	(49,099)	(28,074)	(142,672)	(140,453)
Foreign currency transaction gains (losses)	(8,954)	3,025	(9,426)	(6,556)
Change in fair value of derivative financial instruments	—	(85)	67	8,070
Total other expense	**(57,010)**	**(25,227)**	**(160,244)**	**(133,729)**
Loss before income taxes	**(3,482,438)**	**(3,255,425)**	**(9,928,565)**	**(9,635,722)**
Provision for income taxes	—	—	—	—
Net loss	**(3,482,438)**	**(3,255,425)**	**(9,928,565)**	**(9,635,722)**
Net loss available to common stockholders*	**$ (3,482,438)**	**$ (3,255,425)**	**$ (9,928,565)**	**$ (9,635,722)**
Net loss per common share - basic and diluted*	**$ (3.95)**	**$ (10.67)**	**$ (13.32)**	**$ (36.09)**
Weighted average shares outstanding - basic and diluted*	882,280	305,187	745,471	266,997
Net loss	$ (3,482,438)	$ (3,255,425)	$ (9,928,565)	$ (9,635,722)
Other comprehensive gain foreign currency translation adjustment	7,298	1,528	5,174	7,062
Comprehensive loss	**$ (3,475,140)**	**$ (3,253,897)**	**$ (9,923,391)**	**$ (9,628,660)**

* Reflects the 1-for-20 reverse stock split that became effective on August 29, 2019. Refer to Note 8 – Stockholders' equity for further information.

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(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	**113,266**	**$ 1,133**	—	—	**$ 150,136,191**	**$ (25,900)**	**$ (148,710,427)**	**$ 1,400,997**
Public offering of common stock and warrants, net of issuance costs	150,962	1,510	—	—	10,719,890	—	—	10,721,400
Issuance of RSUs	270	3	—	—	(3)	—	—	—
Stock compensation expense	—	—	—	—	238,190	—	—	238,190
Stock cancellation	(2)	—	—	—	—	—	—	—
Foreign currency translation	—	—	—	—	—	(12,579)	—	(12,579)
Net loss	—	—	—	—	—	—	(3,048,084)	(3,048,084)
Balances at March 31, 2018	**264,496**	**$ 2,646**	**—**	**—**	**$ 161,094,268**	**$ (38,479)**	**$ (151,758,511)**	**$ 9,299,924**
Public offering of common stock and warrants, net of issuance costs	33,654	337	—	—	6,394	—	—	6,731
At the market offering, net of offering costs	5,202	52	—	—	192,268	—	—	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	**303,352**	**$ 3,035**	**—**	**—**	**$ 161,506,820**	**$ (20,366)**	**$ (155,090,724)**	**$ 6,398,765**
At the market offering, net of offering costs	10,710	107	—	—	405,316	—	—	405,423
Stock compensation expense	—	—	—	—	206,651	—	—	206,651
Interest settlement in common stock	7,212	72	—	—	272,537	—	—	272,609
Foreign currency translation	—	—	—	—	—	1,528	—	1,528
Net loss	—	—	—	—	—	—	(3,255,425)	(3,255,425)
Balances at September 30, 2018	**321,274**	**$ 3,214**	**—**	**—**	**$ 162,391,324**	**$ (18,838)**	**$ (158,346,149)**	**$ 4,029,551**
Balances at December 31, 2018	**432,286**	**$ 4,323**	—	—	**$ 165,396,036**	**$ (13,093)**	**$ (162,078,525)**	**$ 3,308,741**
Public offering of common stock and warrants, net of issuance costs	450,000	4,500	—	—	4,778,009	—	—	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	**882,286**	**$ 8,823**	**—**	**—**	**$ 170,272,078**	**$ (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	**882,286**	**$ 8,823**	**—**	**—**	**$ 170,358,049**	**$ (15,217)**	**$ (168,524,652)**	**$ 1,827,003**
Stock compensation expense	—	—	—	—	91,167	—	—	91,167
Share cancellation	(18)	—	—	—	—	—	—	—
Foreign currency translation	—	—	—	—	—	7,298	—	7,298
Net loss	—	—	—	—	—	—	(3,482,438)	(3,482,438)
Balances at September 30, 2019	**882,268**	**$ 8,823**	**—**	**—**	**$ 170,449,216**	**$ (7,919)**	**$ (172,007,090)**	**$ (1,556,970)**

*Reflects the 1-for-20 reverse stock split that became effective on August 29, 2019. Refer to Note 8 – Stockholders' equity for further information.

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30, 2019	2018
Cash flows from operating activities		
Net loss	$ (9,928,565)	$ (9,635,722)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	687,107	508,162
Noncash interest expense	2,659	108,011
Stock compensation expense	275,171	658,731
Loss (gain) on sale of equipment	9,904	(5,253)
Change in fair value of warrant liability	(67)	(8,070)
Impairment of right-of-use asset	520,759	—
Changes in operating assets and liabilities:		
Accounts receivable	(5,173)	492,444
Inventory	74,449	3,179
Other assets	55,122	(164,346)
Accounts payable	314,559	(493,971)
Accrued compensation and other liabilities	(55,871)	174,560
Deferred revenue	(6,016)	(14,119)
Net cash used in operating activities	**(8,055,962)**	**(8,376,394)**
Cash flows from investing activities		
Purchases of property and equipment	(72,607)	(41,910)
Proceeds from sale of equipment	29,250	10,440
Net cash used in investing activities	**(43,357)**	**(31,470)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	4,782,509	597,743
Proceeds from issuance of units, net of selling costs	—	10,728,132
Proceeds from debt, net of issuance costs	470,519	381,253
Payments on debt	(694,156)	(299,256)
Payments on finance leases	(389,501)	(177,092)
Net cash provided by financing activities	**4,169,371**	**11,230,780**
Effects of exchange rates on cash	4,541	7,419
Net (decrease) increase in cash, cash equivalents and restricted cash	(3,925,407)	2,830,335
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	**$ 811,800**	**$ 4,920,886**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 170,608	$ 32,442
Supplemental disclosures of noncash investing and financing activities:		
Right-of-use assets acquired through finance leases	$ 528,413	$ 585,278
Shares issued to settle obligations	$ —	$ 272,610
Conversion of accounts payable to finance lease	$ 63,600	$ 156,775

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 test for use with bacterial isolates 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 and is not for use in diagnostic procedures.
- 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 test for use with bacterial isolates on a timely basis, or at all, the timing and ultimate success of future 510(k) clearance submissions for additional Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software, 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.

Implementation Agreement with Curetis N.V.

As announced on September 4, 2019, OpGen has entered into an Implementation Agreement with Curetis N.V., a Dutch publicly-listed company on Euronext under ticker CURE, or the Implementation Agreement. Under the Implementation Agreement, OpGen has agreed to purchase, through Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and a wholly-owned subsidiary of OpGen, all of the outstanding shares and acquire all of the related business assets of Curetis GmbH, or Curetis, a private limited liability company organized under the laws of the Federal Republic of Germany and a wholly-owned subsidiary of Curetis N.V., to create a combined business within OpGen, which we refer to as "Newco" herein.

Pursuant to the Implementation Agreement, we have agreed to acquire (i) all of the issued and outstanding capital stock of Curetis, or the Transferred Shares, and (ii) all of the assets of Curetis N.V. that are solely and exclusively related to the business of Curetis, or the Transferred Assets. The Company has also agreed to assume (1) the Curetis N.V. 2016 Stock Option Plan, as amended, or the 2016 Stock Option Plan, and the outstanding awards thereunder, (2) the obligation to issue equity to the holders of awards under the Curetis AG Phantom Stock Option Incentive Plan of 2010, as amended, or the PSOP, and (3) the outstanding indebtedness of Curetis N.V. under certain convertible notes, or the Curetis Convertible Notes, including providing for conversion of such notes into shares of the Company's common stock. We will also assume all of the liabilities of Curetis N.V. that are solely and exclusively related to the business being acquired.

Under the Implementation Agreement, the Company has agreed to issue, as the sole consideration, 2,662,564 shares of common stock, less the number of shares of common stock the issuance of which shall be reserved by the Company in connection with (a) its assumption of the 2016 Stock Option Plan, (b) any future issuance of shares of common stock under the PSOP, and (c) shares of common stock reserved for future issuance upon the conversion, if any, of the Curetis Convertible Notes, or together, the Consideration. The number of shares of common stock to be reserved for the deductions described above are based on a conversion ratio of 0.0959, which is the ratio of the Consideration as contrasted with the number of ordinary shares of Curetis N.V. on a fully diluted basis. The number of shares of OpGen common stock to be issued to Curetis N.V. is fixed, therefore, the percentage ownership of the Company owned by Curetis will not be known until the closing occurs.

On November 12, 2019 the Company filed a Registration Statement on Form S-4 to register the Consideration. The transactions under the Implementation Agreement are subject to approval by the stockholders of the Company and the shareholders and debt holders of Curetis N.V and Curetis GmbH. The Company plans to call a special meeting of its stockholders as soon as practicable and deliver a proxy statement to its stockholders in advance of such special meeting.

The Implementation Agreement contains customary representations and warranties of the parties and the parties have agreed to use their commercially reasonable efforts to take all actions necessary to consummate the closing of the transactions contemplated by the Implementation Agreement. Pursuant to the Implementation Agreement, the Company committed to raise at least $10,000,000 of gross interim equity financing to support the continuing operations of both the Company and the Curetis Group, and to lend funds to the Curetis Group following such offering (See Note 13 – Subsequent Events).

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 450,000 shares of its common stock at a public offering price of $12.00 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 111,000 shares of its common stock at a public offering price of $29.00 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 7,212 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 twentieth of a share of common stock and one common warrant to purchase one fortieth of a share of common stock at an exercise price of $65.00 per share. Each pre-funded unit included one pre-funded warrant to purchase one twentieth of a share of common stock for an exercise price of $0.20 per share, and one common warrant to purchase one fortieth of a share of common stock at an exercise price of $65.00 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 15,912 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 plus the cash generated from the October 2019 Public Offering (See Note 13 – Subsequent Events) will be sufficient to fund operations into the first quarter of 2020 and to meet the Company's obligations under the Interim Facility. 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 first quarter of 2020, 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 (deficit). Foreign currency translation adjustments are the sole component of accumulated other comprehensive loss at September 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 September 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:

	September 30, 2019	December 31, 2018	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 626,420	$ 4,572,487	$ 4,735,506	$ 1,847,171
Restricted cash	185,380	164,720	185,380	243,380
Total cash, cash equivalents and restricted cash in the condensed consolidated statement of cash flows	$ 811,800	$ 4,737,207	$ 4,920,886	$ 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 $18,309 and $18,332 as of September 30, 2019 and December 31, 2018, respectively.

One individual customer represented 12% of revenues for the three months ended September 30, 2019. No individual customer represented in excess of 10% of revenues for the three months ended September 30, 2018. One individual customer represented 40% and 16% of revenues for the nine months ended September 30, 2019 and 2018, respectively. At September 30, 2019, one individual customer represented 20% 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:

	September 30, 2019	December 31, 2018
Raw materials and supplies	$ 292,271	$ 368,438
Work-in-process	14,676	58,402
Finished goods	161,427	116,907
Total	$ 468,374	$ 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 $129,345 and $71,270 at September 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 nine months ended September 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 nine months ended September 30, 2019.

Intangible assets and goodwill

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

		September 30, 2019		December 31, 2018	
	Cost	Accumulated Amortization	Net Balance	Accumulated Amortization	Net Balance
Trademarks and trade names	$ 461,000	$ (194,361)	$ 266,639	$ (159,783)	$ 301,217
Developed technology	458,000	(275,814)	182,186	(226,746)	231,254
Customer relationships	1,094,000	(658,321)	435,679	(541,105)	552,895
	$ 2,013,000	$ (1,128,496)	$ 884,504	$ (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 September 30, 2019 and 2018. Total amortization expense of intangible assets was $200,862 for each of the nine months ended September 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 nine months ended September 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 September 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 nine months ended September 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.

Transaction costs

Transaction costs include expenses associated with legal, accounting, and regulatory services rendered in connection with business combinations. Transaction costs are expensed as incurred in support of the business combination.

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 0.2 million shares and 0.2 million shares as of September 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Product sales	$ 573,035	$ 539,856	$ 1,597,505	$ 1,805,877
Laboratory services	185	12,365	5,435	22,155
Collaboration revenue	75,000	—	1,075,000	359,316
Total revenue	$ 648,220	$ 552,221	$ 2,677,940	$ 2,187,348

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	(6,016)
New deferrals, net of amounts recognized in the current period	—
Balance at September 30, 2019	$ 9,808

Contract assets

The Company had no contract assets as of September 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 $500,000 at September 30, 2019, which the Company expects to recognize over the next six months.

Note 5 – MGHIF financing

In July 2015, the Company entered into a Purchase Agreement with MGHIF, pursuant to which MGHIF purchased 2,273 shares of common stock of the Company at $2,200 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 656 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 7,212 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 nine months ended September 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 nine months ended September 30, 2019:

Description	Balance at December 31, 2018	Change in Fair Value	Balance at September 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 nine months ended September 30, 2019 and 2018.

Note 7 – Debt

As of September 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 $175,000 with a final payment scheduled for May 2020. The Company's outstanding long-term debt as of September 30, 2019 consisted of approximately $329,000 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 2020 and 2021.

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $49,099 and $28,074 for the three months ended September 30, 2019 and 2018, respectively. Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $142,672 and $140,453 for the nine months ended September 30, 2019 and 2018, respectively.

Note 8 – Stockholders' equity (deficit)

As of September 30, 2019, the Company has 50,000,000 authorized shares of common stock and 882,268 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 15,912 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 twentieth of a share of common stock and one common warrant to purchase one fortieth of a share of common stock at an exercise price of $65.00 per share. Each pre-funded unit included one pre-funded warrant to purchase one twentieth of a share of common stock for an exercise price of $0.20 per share, and one common warrant to purchase one fortieth of a share of common stock at an exercise price of $65.00 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 9,231 shares of common stock. The warrants issued to the placement agent have an exercise price of $81.25 per share and are exercisable for five years.

On October 22, 2018, the Company closed the October 2018 Public Offering of 111,000 shares of its common stock at a public offering price of $29.00 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 450,000 shares of its common stock at a public offering price of $12.00 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million.

Following receipt of approval from stockholders at a special meeting of stockholders held on August 22, 2019, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to affect a reverse stock split of the issued and outstanding shares of common stock, at a ratio of one share for twenty shares. All share amounts and per share prices in this Quarterly Report have been adjusted to reflect the reverse stock split.

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) 2,710 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date, that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by the Company's Board of Directors. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. As of September 30, 2019, 3,827 shares remain available for issuance under the 2015 Plan, which includes 17,291 shares automatically added to the 2015 Plan on January 1, 2019.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cost of services	$ 584	$ (2,807)	$ 1,146	$ 924
Research and development	20,175	56,961	55,635	187,512
General and administrative	65,318	141,974	202,696	434,314
Sales and marketing	5,090	10,523	15,694	35,981
	$ 91,167	$ 206,651	$ 275,171	$ 658,731

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 September 30, 2019. During the three months ended September 30, 2019, 107 options were forfeited and 499 options expired. The Company did not grant any stock options during the

nine months ended September 30, 2019. During the nine months ended September 30, 2019, 143 options were forfeited and 499 options expired. The Company had total stock options to acquire 9,936 shares of common stock outstanding at September 30, 2019.

Restricted stock units

During the nine months ended September 30, 2019, 17,150 restricted stock units were granted, no restricted stock units vested and 500 restricted stock units were forfeited. The Company had 16,663 total restricted stock units outstanding at September 30, 2019.

Stock purchase warrants

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

Issuance	Exercise Price	Expiration	Outstanding at September 30, 2019 (1)	Outstanding at December 31, 2018 (1)
November 2009	$ 3,955.00	November 2019	17	17
January 2010	$ 3,955.00	January 2020	17	17
March 2010	$ 3,955.00	March 2020	7	7
November 2011	$ 3,955.00	November 2021	15	15
December 2011	$ 3,955.00	December 2021	2	2
March 2012	$ 54,950.00	March 2019	—	8
February 2015	$ 3,300.00	February 2025	451	451
May 2015	$ 3,300.00	May 2020	6,555	6,555
May 2016	$ 656.00	May 2021	9,483	9,483
June 2016	$ 656.00	May 2021	4,102	4,102
June 2017	$ 390.00	June 2022	938	938
July 2017	$ 345.00	July 2022	318	318
July 2017	$ 250.00	July 2022	2,501	2,501
July 2017	$ 212.60	July 2022	50,006	50,006
February 2018	$ 81.20	February 2023	9,232	9,232
February 2018	$ 65.00	February 2023	92,338	92,338
			175,982	175,990

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

(1) Warrants to purchase fractional shares of common stock resulting from the reverse stock split on August 29, 2019 were rounded up to the next whole share of common stock on a holder by holder basis.

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 September 30, 2019, the Company has acquired twenty-four QuantStudio 5s including nine in the nine months ended September 30, 2019. As of September 30, 2019, the Company has not committed to acquiring additional QuantStudio 5s in the next three months.

Note 10 – Leases

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

Lease Classification	September 30, 2019
ROU Assets:	
Operating	$ 1,214,482
Financing	1,096,472
Total ROU assets	$ 2,310,954
Liabilities	
Current:	
Operating	$ 987,833
Finance	627,620
Noncurrent:	
Operating	812,801
Finance	411,103
Total lease liabilities	$ 2,839,357

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

Maturity of Lease Liabilities	Operating	Finance	Total
2019	$ 279,055	$ 180,753	$ 459,808
2020	1,128,294	633,130	1,761,424
2021	536,819	270,043	806,862
2022	40,080	41,961	82,041
2023	—	3,364	3,364
Thereafter	—	280	280
Total lease payments	1,984,248	1,129,531	3,113,779
Less: Interest	(183,614)	(90,808)	(274,422)
Present value of lease liabilities	$ 1,800,634	$ 1,038,723	$ 2,839,357

Statement of operations classification of lease costs are as follows:

		September 30, 2019	
Lease Cost	Classification	Three months ended	Nine months ended
Operating	Operating expenses	$ 216,368	$ 655,963
Finance:			
Amortization	Operating expenses	124,749	329,438
Interest expense	Other expenses	18,704	60,482
Total lease costs		$ 359,821	$ 1,045,883

Other Information	Total
Weighted average remaining lease term (in years)	
Operating leases	1.9
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	$ 655,963
Finance leases	$ 60,482
Cash used in financing activities	
Finance leases	$ 389,501
ROU assets obtained in exchange for lease obligations:	
Finance leases	$ 592,014

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 15 month demonstration portion of the project. The demonstration project began in early 2019. During the three and nine months ended September 30, 2019, the Company recognized $75,000 and $1.1 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 September 30, 2019 and 2018. The Company recognized net royalty expense of $187,500 for each of the nine months ended September 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 informatics, and to speed development of its rapid diagnostic products. MSD gains access to the high-resolution genotype data for the isolates as well as access to the Acuitas Lighthouse informatics to support internal research and development programs. The Company is required to expend up to $175,000 for the procurement of materials related to the activities contemplated by the agreement. Contract life-to-date, the Company has incurred $171,646 of procurement costs which have been recognized as research and development expense. The Company did not recognize any research and development expense related to the agreement in the three months ended September 30, 2019 and 2018. The Company recognized research and development expense of $0 and $22,604 related to the agreement in the nine months ended September 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 did not incur any cost of services expense related to the contract in the three months ended September 30, 2019 and 2018. The Company recognized $0 and $198,665 of cost of services expense related to the contract in the nine months ended September 30, 2019 and 2018, respectively.

Note 13 – Subsequent events

On October 28, 2019, the Company closed the October 2019 Public Offering of 2,590,170 units at $2.00 per unit and 2,109,830 pre-funded units at $1.99 per pre-funded unit. The Company also granted the underwriter a 30-day option to purchase up to an additional 705,000 shares of common stock and/or common warrants to purchase up to 705,000 shares of common stock. The offering raised gross proceeds of approximately $9.4 million and net proceeds of approximately $8.3 million.

On October 31, 2019, the Company filed a Form 8-K to report that, following the October 2019 Public Offering, it believed it had regained compliance with the Nasdaq continuing listing requirement for stockholders' equity. Nasdaq confirmed the Company's compliance with all continuing listing requirements in November 2019.

On November 12, 2019, Crystal GmbH, OpGen's subsidiary, as lender, and Curetis GmbH, as borrower, entered into an Interim Facility Agreement, or the Interim Facility. Under the Interim Facility, the lender shall lend to the Borrower, for the benefit of the Curetis Group, committed capital, up to $4 million, between November 18, 2019 and the closing of the transaction contemplated by the Implementation Agreement. Under the Interim Facility, OpGen and Curetis N.V. have confirmed that the October 2019 Public Offering satisfies the closing condition for OpGen to raise at least $10 million, and that the entry into the Interim Facility satisfies an additional closing condition.

On November 12, 2019, the Company filed a Registration Statement on Form S-4 to register the Consideration to be issued under the Implementation Agreement. Such filing was a requirement to closing the transactions contemplated by the Implementation Agreement.

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 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 and is not for use in diagnostic procedures.
- 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) submission with the FDA seeking clearance of its Acuitas AMR Gene Panel diagnostic test for use with bacterial isolates. 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 450,000 shares of its common stock at a public offering price of $12.00 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million. On October 28, 2019, the Company closed a public offering (the "October 2019 Public Offering") of 2,590,170 units at $2.00 per unit and 2,109,830 pre-funded units at $1.99 per pre-funded unit. The Company also granted the underwriter a 30-day option to purchase up to an additional 705,000 shares of common stock and/or common warrants to purchase up to 705,000 shares of common stock. The offering raised gross proceeds of approximately $9.4 million and net proceeds of approximately $8.3 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.

Implementation Agreement with Curetis N.V.

As announced on September 4, 2019, OpGen has entered into an Implementation Agreement with Curetis N.V., a Dutch publicly-listed company on Euronext under ticker CURE, or the Implementation Agreement. Under the Implementation Agreement, OpGen has agreed to purchase, through Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and a wholly-owned subsidiary of OpGen, all of the outstanding shares and acquire all of the related business assets of Curetis GmbH, or Curetis, a private limited liability company organized under the laws of the Federal Republic of Germany and a wholly-owned subsidiary of Curetis N.V., to create a combined business within OpGen, which we refer to as "Newco" herein.

Pursuant to the Implementation Agreement, we have agreed to acquire (i) all of the issued and outstanding capital stock of Curetis, or the Transferred Shares, and (ii) all of the assets of Curetis N.V. that are solely and exclusively related to the business of Curetis, or the Transferred Assets. The Company has also agreed to assume (1) the Curetis N.V. 2016 Stock Option Plan, as amended, or the 2016 Stock Option Plan, and the outstanding awards thereunder, (2) the obligation to issue equity to the holders of awards under the Curetis AG Phantom Stock Option Incentive Plan of 2010, as amended, or the PSOP, and (3) the outstanding indebtedness of Curetis N.V. under certain convertible notes, or the Curetis Convertible Notes, including providing for conversion of such notes into shares of the Company's common stock. We will also assume all of the liabilities of Curetis N.V. that are solely and exclusively related to the business being acquired.

Under the Implementation Agreement, the Company has agreed to issue, as the sole consideration, 2,662,564 shares of common stock, less the number of shares of common stock the issuance of which shall be reserved by the Company in connection with (a) its assumption of the 2016 Stock Option Plan, (b) any future issuance of shares of common stock under the PSOP, and (c) shares of common stock reserved for future issuance upon the conversion, if any, of the Curetis Convertible Notes, or together, the Consideration. The number of shares of common stock to be reserved for the deductions described above are based on a conversion ratio of 0.0959, which is the ratio of the Consideration as contrasted with the number of ordinary shares of Curetis N.V. on a fully diluted basis. The number of shares of OpGen common stock to be issued to Curetis N.V. is fixed, therefore, the percentage ownership of the Company owned by Curetis will not be known until the closing occurs.

On November 12, 2019, the Company filed a Registration Statement on Form S-4 to register the Consideration. The transactions under the Implementation Agreement are subject to approval by the stockholders and debt holder of the Company and the shareholders and debt holders of Curetis N.V and Curetis GmbH. The Company plans to call a special meeting of its stockholders as soon as practicable and deliver a proxy statement to its stockholders in advance of such special meeting.

The Implementation Agreement contains customary representations and warranties of the parties and the parties have agreed to use their commercially reasonable efforts to take all actions necessary to consummate the closing of the transactions contemplated by the Implementation Agreement. Pursuant to the Implementation Agreement, the Company committed to raise at least $10,000,000 of interim equity financing to support the continuing operations of both the Company and the Curetis Group. The October 2019 Public Offering fulfilled this commitment.

Interim Facility

As required under the Implementation Agreement, on November 12, 2019, Crystal GmbH, OpGen's subsidiary, as lender, and Curetis GmbH, as borrower, entered into an Interim Facility Agreement, or the Interim Facility. Under the Interim Facility, the lender shall

lend to the Borrower, for the benefit of the Curetis Group, committed capital, up to $4 million, between November 18, 2019 and the closing of the transaction contemplated by the Implementation Agreement. The purpose of the loans are to provide capital to fund the operations of the Curetis Business, including the discharge of current liabilities when due. Each loan under the Interim Facility bears interest at 10% per annum, and is due to be repaid on the first anniversary of the loan. The loans will be subject to mandatory pre-payment if the Implementation Agreement is terminated. The Interim Facility loans are deeply subordinated to the current and future indebtedness of the borrower. The Interim Facility has identified, customary events of default. Under the Interim Facility, the OpGen and Curetis N.V. have confirmed that the October 2019 Public Offering satisfies the closing condition for OpGen to raise at least $10 million, and that the entry into the Interim Facility satisfies an additional closing condition.

On November 12, 2019, the Company filed a Registration Statement on Form S-4 to register the Consideration to be issued under the Implementation Agreement. Such filing was a requirement to closing the transactions contemplated by the Implementation Agreement.

We believe Newco will be a market leader positioned to capitalize on global opportunities in the infectious disease and antimicrobial resistance testing markets. We believe that Newco will have a unique portfolio of in vitro diagnostic, or IVD premier portfolio of Artificial Intelligence, or AI, powered bioinformatics solutions for multi-drug resistance diagnostics, and a global commercial channel with extensive capabilities and distribution partners.

We anticipate that Newco will achieve significant financial, operational, technical, and commercial synergies through the combination of the OpGen and Curetis businesses. We intend to derive commercial synergy by using a single sales and marketing infrastructure and working to distribute the OpGen products through the Curetis international distribution channels. Financial and operational synergies include the consolidation of the companies' separate infrastructures into one streamlined organization. We envision the technical organizations building off the capabilities of each individual organization and leveraging best practices and common systems.

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

Revenue

	Three Months Ended September 30,	
	2019	2018
Product sales	$ 573,035	$ 539,856
Laboratory services	185	12,365
Collaboration revenue	75,000	-
Total revenue	$ 648,220	$ 552,221

Total revenue for the three months ended September 30, 2019 increased approximately 17%, with a change in the mix of revenue, as follows:

- Product sales: an increase in revenue of approximately 6% in the 2019 period compared to the 2018 period is primarily attributable to an increase in the sales of our Acuitas AMR products;
- Laboratory services: a decrease in revenue of approximately 99% 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 100% 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 September 30,	
	2019	2018
Cost of products sold	$ 262,373	$ 292,984
Cost of services	196,184	98,189
Research and development	1,139,369	1,286,300
General and administrative	1,560,706	1,743,636
Sales and marketing	376,955	361,310
Transaction costs	538,061	—
Impairment of right-of-use asset	—	—
Total operating expenses	$ 4,073,648	$ 3,782,419

The Company's total operating expenses for the three months ended September 30, 2019 increased approximately 8% when compared to the same period in 2018. This increase is primarily attributable to $538 thousand of transaction costs incurred in connection with our business combination with Curetis. In addition, operating expenses changed as follows:

- Cost of products sold: cost of products sold for the three months ended September 30, 2019 decreased approximately 10% when compared to the same period in 2018. The change in costs of products sold is primarily attributable to savings from our manufacturing consolidation to Maryland;
- Cost of services: cost of services for the three months ended September 30, 2019 increased approximately 100% 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 September 30, 2019 decreased approximately 11% when compared to the same period in 2018, 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 three months ended September 30, 2019 decreased approximately 10% 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 September 30, 2019 increased approximately 4% when compared to the same period in 2018, primarily due to an increase in marketing expenses.

Other income (expense)

	Three Months Ended September 30,	
	2019	2018
Interest expense	$ (49,099)	$ (28,074)
Foreign currency transaction gains (losses)	(8,954)	3,025
Other income (expense)	1,043	(93)
Change in fair value of derivative financial instruments	—	(85)
Total other expense	$ (57,010)	$ (25,227)

The Company's total other expense for the three months ended September 30, 2019 increased primarily due to an increase in interest expense and foreign currency transaction losses.

Results of operations for the nine months ended September 30, 2019 and 2018

Revenue

	Nine Months Ended September 30,	
	2019	2018
Product sales	$ 1,597,505	$ 1,805,877
Laboratory services	5,435	22,155
Collaboration revenue	1,075,000	359,316
Total revenue	$ 2,677,940	$ 2,187,348

Total revenue for the nine months ended September 30, 2019 increased approximately 22%, with a change in the mix of revenue, as follows:

- Product sales: a decrease in revenue of approximately 12% 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 partially offset by an increase in the sales of our Acuitas AMR products;
- Laboratory services: a decrease in revenue of approximately 75% 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 199% 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

	Nine Months Ended September 30,	
	2019	2018
Cost of products sold	$ 681,568	$ 939,479
Cost of services	592,647	446,144
Research and development	4,069,335	3,821,117
General and administrative	4,901,136	5,365,221
Sales and marketing	1,142,755	1,117,380
Transaction costs	538,061	—
Impairment of right-of-use asset	520,759	—
Total operating expenses	$ 12,446,261	$ 11,689,341

The Company's total operating expenses for the nine months ended September 30, 2019 increased approximately 6% when compared to the same period in 2018. This increase is primarily attributable to $538 thousand of transaction costs incurred in connection with our business combination with Curetis and the impairment of our Woburn, Massachusetts ROU asset 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 nine months ended September 30, 2019 decreased approximately 27% 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 nine months ended September 30, 2019 increased approximately 33% 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 nine months ended September 30, 2019 increased approximately 6% when compared to the same period in 2018, primarily due to R&D related costs associated with our isolate submission expenses related to our 510(k) submission for the Acuitas AMR Gene Panel for use with bacterial isolates;
- General and administrative: general and administrative expenses for the nine months ended September 30, 2019 decreased approximately 9% when compared to the same period in 2018, primarily due to decreased outside service and payroll related costs; and
- Sales and marketing: sales and marketing expenses for the nine months ended September 30, 2019 increased approximately 2% when compared to the same period in 2018, primarily due to the increased headcount of our marketing team.

Other income (expense)

	Nine Months Ended September 30,	
	2019	2018
Interest expense	$ (142,672)	$ (140,453)
Foreign currency transaction losses	(9,426)	(6,556)
Other income (expense)	(8,213)	5,210
Change in fair value of derivative financial instruments	67	8,070
Total other expense	$ (160,244)	$ (133,729)

The Company's total other expense for the nine months ended September 30, 2019 increased primarily due to an increase in other expenses.

Liquidity and capital resources

As of September 30, 2019, the Company had cash and cash equivalents of $0.6 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 450,000 shares of its common stock at a public offering price of $12.00 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 111,000 shares of its common stock at a public offering price of $29.00 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 15,912 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 plus the cash generated from the October 2019 Public Offering will be sufficient to fund operations into the first quarter of 2020, and to meet the Company's obligations under the Interim Facility. 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 first quarter of 2020, 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:

	Nine Months Ended September 30,	
	2019	2018
Net cash used in operating activities	$ (8,055,962)	$ (8,376,394)
Net cash used in investing activities	(43,357)	(31,470)
Net cash provided by financing activities	4,169,371	11,230,780

Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2019 consists primarily of our net loss of $9.9 million, reduced by certain noncash items, including impairment of ROU asset of $0.5 million, depreciation and amortization expense of $0.7 million, and stock-based compensation expense of $0.3 million. Net cash used in operating activities for the nine months ended September 30, 2018 consists primarily of our net loss of $9.6 million, reduced by certain noncash items, including depreciation and amortization expense of $0.5 million and stock-based compensation expense of $0.7 million.

Net cash used in investing activities

Net cash used in investing activities in the nine months ended September 30, 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 nine months ended September 30, 2019 of $4.2 million consisted primarily of the net proceeds from the March 2019 Public Offering. Net cash provided by financing activities for the nine months ended September 30, 2018 of $11.2 million consisted primarily of the net proceeds from the February 2018 Public Offering and net proceeds from the at the market offering.

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 September 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 September 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 September 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 first quarter of 2020, 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 nine months ended September 30, 2019, we had a net loss of $9.9 million and for the year ended December 31, 2018, we had a net loss of $13.4 million. From our inception through September 30, 2019, we had an accumulated deficit of $172.0 million. Substantial doubt exists about our ability to continue as a going concern. We believe that current cash plus the cash generated from the October 2019 Public Offering will be sufficient to fund our operations into the first quarter of 2020, and to meet the Company's obligations under the Interim Facility. If we are not able to successfully raise additional capital during or before the end of the first quarter of 2020, 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.

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.

We may not be successful in consummating the proposed transaction with Curetis N.V., which failure could have a material adverse effect on us.

The proposed combination with Curetis is subject to the approval of our stockholders and debt holder, and by the shareholders and debt holders of Curetis N.V. and Curetis GmbH, and we cannot provide any assurance that such approvals will be obtained. If the proposed transaction is not approved by our stockholders, we may become liable to reimburse Curetis N.V. for its expenses up to a maximum amount of $250,000. In case of termination of the Implementation Agreement in accordance with its terms, Curetis would also be required to repay us under the Interim Facility, and we would need to re-focus our attention on OpGen as a stand-alone business. Any of these events would have a material adverse impact on our financial condition.

Completion of the proposed transaction with Curetis N.V. is subject to the fulfillment or the waiver, as the case may be, of a number of conditions precedent, which may prevent, delay, hinder or otherwise adversely affect the proposed Transaction.

Completion of the proposed transaction with Curetis N.V. is subject to the fulfillment or the waiver, as the case may be, of a number of conditions precedent as described in the Implementation Agreement. These include, in addition to customary closing conditions, the necessary shareholder approvals by the requisite majority of shareholders of Curetis N.V. and the stockholders of OpGen; the assumption by us of the obligation to under the Curetis Convertible Notes, including the need to provide for the conversion of the Curetis Convertible Notes into shares of OpGen's common stock; the entry into the Interim Facility and the funding thereunder; and the receipt of the applicable consents or waivers to be received or granted by certain debt financing providers of Curetis N.V., Curetis GmbH and OpGen. Failure to satisfy any of the conditions may result in the transaction not being closed.

We have agreed to use a significant portion of the capital raised in the October 2019 Public Offering to support the operations of Curetis in the period prior to the closing. This reduces the proceeds invested in OpGen's operations, which could have a negative impact on us if the proposed transaction is not consummated, or if the approval process takes longer than anticipated.

Pursuant to the Implementation Agreement, on November 12, 2019, we entered into the Interim Facility pursuant to which we have agreed to lend to Curetis GmbH up to $4 million of the proceeds of the October 2019 Public Offering to fund and support the operations, and satisfy the current obligations, of Curetis in the period prior to closing. If such period extends for a longer period than anticipated or the amount loaned to Curetis is higher than expected, such commitment could negatively impact the availability of resources to devote to the OpGen business or to the business of Newco if the closing occurs, and we may be required to raise additional capital.

If the transaction contemplated by the Implementation Agreement does not close, we anticipate that it will be difficult for Curetis to repay us under the Interim Facility, if at all. Any unanticipated loans under the Interim Facility, or failure to be repaid under the Interim Facility would have a material adverse effect on our financial condition.

If the combination with Curetis does not occur, our financial condition will be materially adversely affected.

If we or Curetis N.V. cannot meet all of the conditions to close under the Implementation Agreement, and the business combination does not occur, we will be in a difficult financial position. We will have lent funds to Curetis under the Interim Facility, and there is a real possibility that Curetis would not be able to repay us some or all of such debt. In addition, we would have to refocus our attention on OpGen as a stand-alone business and would likely need to raise additional funds to support that business going forward. We cannot assure you that we would be able to continue OpGen as a stand-alone business or be able to raise sufficient capital to do so. If we are unable to raise equity capital, we may need to incur debt financing, if possible, sell assets, curtail business programs, seek bankruptcy protection or dissolve.

We will incur significant indebtedness as a result of the combination with Curetis, which could have a material adverse effect on our financial condition.

If the combination with Curetis closes, we will assume the indebtedness of Curetis N.V. and Curetis. As of November 1, 2019, Curetis N.V. owed indebtedness of $1.4 million to lenders under the Curetis Convertible Notes and as of September 30, 2019, Curetis owed indebtedness of $20.4 million of principal (plus interest of $1.6 million) under a loan provided by the EIB. In addition, OpGen has secured indebtedness to MGHIF under the MGHIF Note. Pursuant to the Implementation Agreement, OpGen will be required to assume the indebtedness of Curetis N.V. (subject to approval of the holder of the Curetis Convertible Notes) and of Curetis, and Newco will therefore be obligated under substantially more indebtedness than OpGen currently owes. Newco may not be able to generate sufficient cash to service all of its indebtedness and may be forced to take other actions to satisfy its obligations under indebtedness that may not be successful. The inability in the future to repay such indebtedness when due would have a material adverse effect on Newco.

We will incur significant transaction costs as a result of the proposed business combination transaction with Curetis, which could have a material adverse effect on our financial condition.

We will incur significant one-time transaction costs related to the proposed business combination with Curetis. These transaction costs include legal and accounting fees and expenses and filing fees, printing expenses and other related charges. We may also incur additional unanticipated transaction costs in connection with the transaction. A portion of the transaction costs related to the proposed business combination will be incurred regardless of whether the transaction is completed. Additional costs will be incurred in connection with integrating the two companies' businesses. Costs in connection with the transaction and integration may be higher than expected. These costs could adversely affect OpGen's financial condition, operating results or prospects of the combined company.

The proposed business combination transaction with Curetis will significantly change the business and operations of OpGen. We may face challenges integrating the businesses.

Following the consummation of the proposed combination with Curetis, OpGen will continue as the operating entity and both the size and geographic scope of OpGen's business will significantly increase. Most of the Curetis business is currently conducted in Europe, Asia and other countries outside of the United States, and many of the Curetis employees are located outside of the United States. In addition, the majority of the initial board of directors will consist of individuals appointed by Curetis N.V., and we expect that the focus of Newco may shift to Curetis operations. We may face challenges integrating such geographically diverse businesses and implementing a smooth transition of business focus and governance in a timely or efficient manner. In particular, if the effort we devote to the integration of our businesses with that of Curetis diverts more management time or other resources from carrying out our operations than we originally planned, our ability to maintain and increase revenues as well as manage our costs could be impaired. Furthermore, our capacity to expand other parts of our existing businesses may be impaired. We also cannot assure you that the combination of the OpGen and Curetis businesses will function as we anticipate, or that significant synergies will result from the business combination. Any of the above could have a material adverse effect on our business.

Management and the board of directors of OpGen will change upon the consummation of the Transaction. We cannot assure you that this will not have a material impact on the Newco.

The current chief executive officer of Curetis N.V., Oliver Schacht, Ph.D., will be the chief executive officer of Newco, and Timothy C. Dec will continue to serve as chief financial officer. The Implementation Agreement provides that four members of the initial board of directors of Newco following the closing will be appointed by Curetis N.V. and two by the board of directors of OpGen. The parties have agreed to add a seventh director, to be recommended by OpGen, but that process has not started. Most of the current members of the management board of Curetis N.V. have experience serving on the boards of companies listed on Euronext and German prime standard companies, but not on U.S. publicly-listed companies and this could impact the transition of Newco.

The combination of the OpGen and Curetis businesses may not lead to the growth and success of the combined business that we believe will occur.

Although we believe the combination of the OpGen and Curetis businesses provides a significant commercial opportunity for growth, we may not realize all of the synergies that we anticipate and may not be successful in implementing our commercialization strategy. Our combined business will be subject to all of the risks and uncertainties inherent in the pursuit of growth in our industry and we may not be able to successfully sell our products, obtain the regulatory clearances and approvals we apply for or, or realize the anticipated benefits from our distribution, collaboration and other commercial partners. If we are not able to grow the business of Newco as a commercial enterprise, our financial condition will be negatively impacted.

Integrating the businesses of OpGen and Curetis may disrupt or have a negative impact on Newco.

We could have difficulty integrating the assets, personnel and business of OpGen and Curetis. The proposed transaction is complex and we will need to devote significant time and resources to integrating the businesses. Risks that could impact us negatively include:

- the difficulty of integrating the acquired companies, and their concepts and operations;
- the difficulty in combining our financial operations and reporting;
- the potential disruption of the ongoing businesses and distraction of our management;
- changes in our business focus and/or management;
- risks related to international operations;
- the potential impairment of relationships with employees and partners as a result of any integration of new management personnel; and
- the potential inability to manage an increased number of locations and employees.

If we are not successful in addressing these risks effectively, the business of Newco could be severely impaired.

If we or Curetis receive a proposal for an alternative transaction, and one of us accepts such proposal, the Transaction will not close.

We may be liable to pay Curetis N.V. a termination fee of $500,000 if our board of directors changes its recommendation to approve the proposed transaction at the Special Meeting, or if following a refusal by our stockholders to approve the proposed Transaction at the Special Meeting, we enter into a definitive agreement implementing an alternative transaction with a third party. Curetis N.V. has undertaken the same obligations with respect to us if the shareholders of Curetis N.V. do not approve the proposed transaction or if the boards of Curetis N.V. change their recommendation to approve the proposed transaction. Any such alternative transaction could divert the attention of our board of directors and management team, and would, if accepted, cause the termination of the Transaction.

We expect our ability to utilize our net operating loss carryforwards will be limited as a result of an "ownership change," as defined in Section 382 of the Internal Revenue Code triggered by consummation of the transaction with Curetis.

As of December 31, 2018, we had approximately $178.2 million of net operating loss, or NOL, carryforwards for U.S. federal tax purposes. Under U.S. federal income tax law, we generally can use our NOL carryforwards (and certain tax credits) to offset ordinary taxable income, thereby reducing our U.S. federal income tax liability, for up to 20 years from the year in which the losses were generated, after which time they will expire. State NOL carryforwards (and certain tax credits) generally may be used to offset future state taxable income for 20 years from the year in which the losses are generated, depending on the state, after which time they will expire. The rate at which we can utilize our NOL carryforwards is limited (which could result in NOL carryforwards expiring prior to their use) each time we experience an "ownership change," as determined under Section 382 of the Internal Revenue Code. A Section 382 ownership change generally occurs if a shareholder or a group of shareholders who are deemed to own at least 5% of our common stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. If an ownership change occurs, Section 382 generally would impose an annual limit on the amount of post-ownership change taxable income that may be offset with pre-ownership change NOL carryforwards equal to the product of the total value of our outstanding equity immediately prior to the ownership change (reduced by certain items specified in Section 382) and the U.S. federal long-term tax-exempt interest rate in effect at the time of the ownership change. A number of special and complex rules apply in calculating this Section 382 limitation. While the complexity of Section 382 makes it difficult to determine whether and when an ownership change has occurred, and if a portion of our NOLs is subject to an annual limitation under Section 382, we believe that an additional ownership change may occur upon the consummation of the transaction with Curetis. In addition, our ability to use our NOL carryforwards will be limited to the extent we fail to generate enough taxable income in the future before they expire. Existing and future Section 382 limitations and our inability to generate enough taxable income in the future could result in a substantial portion of our NOL carryforwards expiring before they are used. In addition, under the 2017 Tax Cut and Jobs Act, effective for losses arising in taxable years beginning after December 31, 2017, the deduction for NOLs is limited to 80% of taxable income, NOLs can no longer be carried back, and NOLs can be carried forward indefinitely.

Current OpGen stockholders will have a reduced ownership and voting interest after the business combination and will exercise less influence over management.

Current OpGen stockholders have the right to vote in the election of the OpGen board of directors and on other matters affecting OpGen. Immediately after the business combination is completed, it is estimated that then current OpGen stockholders, including

purchasers in this offering, will own approximately 67.7%, and Curetis N.V. will own approximately 32.3% of the outstanding shares of OpGen, in each based on the sale of 2,590,170 units and 2,109,830 pre-funded units in this offering and the exercise of all pre-funded warrants. As a result of the business combination, current OpGen stockholders will have less influence on the management and policies of OpGen post-closing than they currently have.

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

On November 12, 2019, Crystal GmbH, OpGen's subsidiary, as lender, and Curetis GmbH, as borrower, entered into an Interim Facility Agreement, or the Interim Facility. Under the Interim Facility, the lender shall lend to the Borrower, for the benefit of the Curetis Group, committed capital, up to $4 million, between November 18, 2019 and the closing of the transaction contemplated by the Implementation Agreement. The purpose of the loans are to provide capital to fund the operations of the Curetis Business, including the discharge of current liabilities when due. Each loan under the Interim Facility bears interest at 10% per annum, and is due to be repaid on the first anniversary of the loan. The loans will be subject to mandatory pre-payment if the Implementation Agreement is terminated. The Interim Facility loans are deeply subordinated to the current and future indebtedness of the borrower. The Interim Facility has identified, customary events of default. Under the Interim Facility, the OpGen and Curetis N.V. have confirmed that the October 2019 Public Offering satisfies the closing condition for OpGen to raise at least $10 million, and that the entry into the Interim Facility satisfies an additional closing condition. This summary of the Interim Facility is not complete. The Interim Facility is incorporated by reference into this Form 10-Q. You are encouraged to read the Interim Facility for a complete understanding of its terms.

Item 6. Exhibits

Exhibit Number	Description
2.1	Implementation Agreement, dated as of September 4, 2019, by and among Curetis N.V., Crystal GmbH, and OpGen (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on September 4, 2019)
3.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of OpGen, Inc., filed with the Secretary of the State of Delaware on August 28, 2019 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on August 28, 2019
4.1	Form of Pre-funded Warrant (incorporated by reference to Exhibit 4.9 to the Registrant's Registration Statement on Form S-1, Amendment No. 1, File No. 333-233775, filed on October 15, 2019)
4.2	Form of Underwriter's Warrant (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed on October 28, 2019)
4.3	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on October 28, 2019)
10.1	Underwriting Agreement, dated October 23, 2019, by and between OpGen, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K, filed on October 28, 2019)
10.2	Interim Facility Agreement, dated as of November 11, 2019, by and between Curetis GmbH, as Borrower, and Crystal GmbH, a wholly owned subsidiary of the Registrant, as Lender (incorporated by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-4, File No. 333-234657, filed November 12, 2019)
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to Unaudited Condensed Consolidated Financial Statements.

* Filed or furnished herewith

SIGNATURES

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

OPGEN, INC.

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

Date: November 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: November 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: November 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 September 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: November 14, 2019

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

Date: November 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.