UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

February 26, 2019
Date of Report (date of earliest event reported)

OpGen, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**001-37367**	**06-1614015**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878
(Address of principal executive offices, including zip code)

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

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[_] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[_] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[_] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[_] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company [X]

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. [_]

Item 2.02 Results of Operations and Financial Condition.

On February 26, 2019, OpGen, Inc. issued a press release announcing its fourth quarter and full year financial results for the year ended December 31, 2018. The full text of such press release is furnished as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release, dated February 26, 2019, issued by OpGen, Inc.

The information included herein and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 ("Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

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
Name: Timothy C. Dec
Title: Chief Financial Officer

Date: February 26, 2019

OPGEN REPORTS FOURTH QUARTER AND 2018 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

Conference call begins at 4:30 p.m. Eastern time today

GAITHERSBURG, Md. (February 26, 2019) – OpGen, Inc. (NASDAQ: OPGN) today reported financial and operating results for the three and 12 months ended December 31, 2018 and provided a business update. Total revenue for the fourth quarter of 2018 was $0.8 million, compared with $1.0 million for the fourth quarter of 2017. Total revenue for 2018 was $2.9 million, compared with the $3.2 million reported for 2017. Recent business highlights include:

- Completion of the clinical trials needed to support the 510(k) submission to the U.S. Food and Drug Administration ("FDA") for clearance of the Acuitas® AMR Gene Panel product for the detection of antimicrobial resistance genes in bacterial isolates;
- Announcement of a groundbreaking 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, to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions statewide;
- Completion of specimen accrual and testing in Acuitas clinical verification study with Beth Israel Deaconess Medical Center, Geisinger, and Intermountain Healthcare which confirmed the performance of our Acuitas AMR Gene Panel tests and Acuitas Lighthouse® Software;
- Entry into a collaboration with QIAGEN N.V. to advance rapid diagnostics for antimicrobial resistance based on QIAGEN's EZ1 instrumentation and reagent kits in the U.S.;
- Completion of the contract from the Centers for Disease Control and Prevention (CDC) to develop smartphone-based clinical decision support solutions for antimicrobial stewardship (AMS) and infection control in low- and middle-income countries, and receipt of final milestone payment under the award;
- Receipt of approval to market its rapid pathogen identification products in Colombia; and
- Completion of public offering of common stock with gross proceeds of $3.2 million in October 2018;

"After several years of research and development for our groundbreaking Acuitas tests and software, we anticipate 2019 will be a year of transition toward commercialization for these new products. We are completing the final steps necessary to file our first 510(k) submission for testing of antimicrobial resistance genes in bacterial isolates in March. Subsequently we anticipate filing submissions with the FDA for clearance for direct testing from urine samples and for the Acuitas Lighthouse® Software for prediction of antimicrobial resistance in acute care patients in under three hours," said Evan Jones, Chairman and CEO.

“In recent weeks we announced the completion of the clinical trial for the detection of antimicrobial resistance genes in bacterial isolates, having tested more than 1,000 clinical isolates at four participating clinical sites. We are also continuing the development to support direct-from-urine testing for the Acuitas AMR Gene Panel (Urine) and for the Acuitas Lighthouse Software. We expect to complete these trials during the summer of 2019 for submission to the FDA in the second half of 2019.

“We are proud to be a part of the initiative with the New York State DOH Wadsworth Laboratories and ILÚM to help develop the blueprint for how governments and healthcare facilities can detect, track, and manage antimicrobial-resistant infections. As part of the collaboration, OpGen will receive a $1.6 million contract for the 12-month demonstration portion of the project, with the potential for full implementation during the next five years, should certain milestones be achieved by all parties involved. We have been hard at work on this initiative, which, if successful, could provide meaningful revenues, beyond the initial revenue associated with the demonstration project while serving as a springboard to initiatives to identify and combat antibiotic resistant organisms in additional states,”

“With the anticipated FDA clearance of our Acuitas products and software, and the contribution to revenues from the New York State Digital Health Initiative, we expect to transition to a period of top line revenue growth for the company during 2019. Our financial performance reflects the investments we are making to successfully complete the FDA submissions for our new Acuitas products and software, and the preparations for the transition to commercial sales for these products post FDA clearance,” Mr. Jones added.

“We are pleased that R. Don Elsey has joined the company’s board of directors and audit committee. Mr. Elsey is a biotechnology, life sciences and high technology industries veteran with more than three decades of experience in international financial management and operations with both large and small companies. Most recently he served as chief financial officer of Senseonics, Inc., a position he held from February 2015 to January 2019,” Evan Jones concluded.

Fourth Quarter and Full Year 2018 Financial Results

- Total revenue for the fourth quarter of 2018 was $0.8 million, compared with $1.0 million for the fourth quarter of 2017. Total revenue for the 12 months ended December 31, 2018 was $2.9 million, compared with the $3.2 million reported for the 12 months ended December 31, 2017.
- Operating expenses for the fourth quarter of 2018 were $4.4 million, compared with $3.9 million for the fourth quarter of 2017. The increase was primarily due to an increase in research and development expense associated with the AMR Gene Panel clinical trial. Operating expenses for the 12 months ended December 31, 2018 were $16.1 million, compared with $18.5 million for the 12 months ended December 31, 2017.
- The net loss for the fourth quarter of 2018 was $3.7 million or $0.47 per share, compared with a net loss of $3.0 million or $1.34 per share for the fourth quarter of 2017. The net loss for the 12 months ended December 31, 2018 was $13.4 million or $2.22 per share, compared with a net loss of $15.4 million or $9.80 per share for the 12 months ended December 31, 2017.
- Cash Position: Cash and cash equivalents were $4.6 million as of December 31, 2018, compared with $1.8 million as of December 31, 2017.

Business and Operations Outlook

- File a 510(k) submission with the FDA for the Acuitas AMR Gene Panel (Isolates) in Q1 2019 to support full commercial launch for clinical use for testing of bacterial isolates;
- Complete clinical evaluations and file De Novo 510(k) submissions with the FDA for the Acuitas AMR Gene Panel (Urine) and the Acuitas Lighthouse Software for rapid testing of urine specimens and prediction of antibiotic resistance to front-line antibiotics;
- Achieve program milestones for New York State Infectious Disease Digital Health Initiative demonstration project, including installation of Acuitas systems at New York City metro area health systems and the Wadsworth Laboratories during Q1 2019 and complete development of customized Acuitas Lighthouse Software to support ILÚM real-time monitoring data and incorporation of whole genome sequencing data;
- Continue to install Acuitas AMR Gene Panel systems in support of Research Use Only sales and full launch following first FDA clearance;
- Expand commercial activities to support FDA clearance and launch of the Acuitas products;
- Publish results in a peer-reviewed journals for the Acuitas Lighthouse Software antibiotic resistance prediction training panel verification study, Acuitas AMR Gene Panel urine specimen clinical verification and clinical validation studies for isolate testing; and
- Commercialize rapid testing products in South America, using Colombia as a springboard.

Conference Call Information

OpGen management will hold a conference call today beginning at 4:30 p.m. Eastern time to discuss fourth quarter and 2018 financial results and other business activities, and answer questions. The call can be accessed by dialing (888) 883-4599 (domestic) or (484) 653-6821 (international) and providing conference ID: 7268038. A live webcast of the conference call can be accessed by visiting the Investor Relations section of the company's website at www.ir.opgen.com. A replay of the webcast will be available shortly after the conclusion of the call for 90 days.

A telephone replay of the conference call will be available from 7:30 p.m. Eastern time today through March 4, 2019, and can be accessed by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international). All listeners should provide the conference ID: 7268038.

About OpGen

OpGen, Inc. is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. We are 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.

Our molecular diagnostics and informatics products, product candidates and services combine our Acuitas molecular diagnostics and Acuitas Lighthouse informatics platform for use with our proprietary, curated MDRO knowledgebase. We are working to deliver our products and services, some in development, to a global network of customers and partners. The Acuitas AMR Gene Panel (RUO) is intended for Research Use Only and is not for use in diagnostic procedures. The Acuitas Lighthouse Software is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures. For more information, please visit www.opgen.com.

Forward-Looking Statements

This press release includes statements relating to OpGen’s fourth quarter and full year 2018 results. These statements and other statements regarding OpGen’s future plans and goals constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control, and which may cause results to differ materially from expectations. Factors that could cause our results to differ materially from those described include, but are not limited to, timely and cost-effectively seek and obtain regulatory clearance for and commercialize our product and services offerings, our ability to successfully complete the demonstration project portion of the New York State Infectious Disease Digital Health Initiative, the rate of adoption of our products and services by hospitals and other healthcare providers, the success of our commercialization efforts, the effect on our business of existing and new regulatory requirements, and other economic and competitive factors. For a discussion of the most significant risks and uncertainties associated with OpGen's business, please review our filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which are based on our expectations as of the date of this press release and speak only as of the date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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(Tables follow)

OpGen, Inc.
Consolidated Balance Sheets
(unaudited)

	2018	2017
Assets		
Current assets		
Cash and cash equivalents	$ 4,572,487	$ 1,847,171
Accounts receivable, net	373,858	809,540
Inventory, net	543,747	533,425
Prepaid expenses and other current assets	292,918	311,644
Total current assets	**5,783,010**	**3,501,780**
Property and equipment, net	1,221,827	835,537
Goodwill	600,814	600,814
Intangible assets, net	1,085,366	1,353,182
Other noncurrent assets	259,346	328,601
Total assets	**$ 8,950,363**	**$ 6,619,914**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,623,751	$ 1,691,712
Accrued compensation and benefits	1,041,573	746,924
Accrued liabilities	902,019	1,160,714
Deferred revenue	15,824	24,442
Short-term notes payable	398,595	1,010,961
Current maturities of long-term capital lease obligation	399,345	154,839
Total current liabilities	**4,381,107**	**4,789,592**
Deferred rent	162,919	290,719
Note payable	660,340	—
Warrant liability	67	8,453
Long-term capital lease obligation and other noncurrent liabilities	437,189	130,153
Total liabilities	**5,641,622**	**5,218,917**
Stockholders' equity		
Common stock, $0.01 par value; 50,000,000 shares authorized; 8,645,720 and 2,265,320 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	86,457	22,653
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2018 and December 31, 2017, respectively	—	—
Additional paid-in capital	165,313,902	150,114,671
Accumulated other comprehensive loss	(13,093)	(25,900)
Accumulated deficit	(162,078,525)	(148,710,427)
Total stockholders' equity	**3,308,741**	**1,400,997**
Total liabilities and stockholders' equity	**$ 8,950,363**	**$ 6,619,914**

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	**2017**	**2018**	**2017**
Revenue				
Product sales	$ 589,749	$ 626,498	$ 2,395,626	$ 2,771,869
Laboratory services	12,510	935	34,665	41,960
Collaboration revenue	156,700	363,479	516,016	397,178
Total revenue	**758,959**	**990,912**	**2,946,307**	**3,211,007**
Operating expenses				
Cost of products sold	283,440	346,690	1,222,919	1,612,838
Cost of services	179,372	292,223	625,516	520,338
Research and development	1,856,126	1,485,387	5,677,243	6,883,293
General and administrative	1,704,094	1,372,848	7,069,315	6,692,659
Sales and marketing	414,176	422,377	1,531,556	2,767,670
Total operating expenses	**4,437,208**	**3,919,525**	**16,126,549**	**18,476,798**
Operating loss	**(3,678,249)**	**(2,928,613)**	**(13,180,242)**	**(15,265,791)**
Other (expense) income				
Other (expense) income	174	15	5,384	(87,255)
Interest expense	(50,742)	(59,531)	(191,195)	(233,505)
Foreign currency transaction gains (losses)	(3,875)	3,543	(10,431)	23,179
Change in fair value of derivative financial instruments	316	19,925	8,386	144,064
Total other expense	**(54,127)**	**(36,048)**	**(187,856)**	**(153,517)**
Loss before income taxes	**(3,732,376)**	**(2,964,661)**	**(13,368,098)**	**(15,419,308)**
Provision for income taxes	—	—	—	—
Net loss	**(3,732,376)**	**(2,964,661)**	**(13,368,098)**	**(15,419,308)**
Net loss available to common stockholders	**$ (3,732,376)**	**$ (2,964,661)**	**$ (13,368,098)**	**$ (15,419,308)**
Net loss per common share - basic and diluted	**$ (0.47)**	**$ (1.34)**	**$ (2.22)**	**$ (9.80)**
Weighted average shares outstanding - basic and diluted	7,970,501	2,211,290	6,009,065	1,573,769
Net loss	$ (3,732,376)	$ (2,964,661)	$ (13,368,098)	$ (15,419,308)
Other comprehensive gain (loss) - foreign currency translation	5,745	(18,251)	12,807	(32,076)
Comprehensive loss	**$ (3,726,631)**	**$ (2,982,912)**	**$ (13,355,291)**	**$ (15,451,384)**