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

May 14, 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)

(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. [_]

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OPGN	The Nasdaq Capital Market
Common Stock Warrants (IPO)	OPGNW	The Nasdaq Capital Market

Item 2.02 Results of Operations and Financial Condition.

On May 14, 2019, OpGen, Inc. issued a press release announcing its first quarter financial results for the quarter ended March 31, 2019. 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 May 14, 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.

Date: May 14, 2019

/s/ Timothy C. Dec

Timothy C. Dec
Chief Financial Officer

OpGen Reports First Quarter 2019 Financial Results and Provides Business Update

Submission of 510(k) application to the FDA for clearance of the Acuitas® AMR Gene Panel test for bacterial isolates

Revenue up 21% Quarter-over-Quarter

Conference call to be held at 4:30 p.m. Eastern time today

GAITHERSBURG, Md., May 14, 2019 -- OpGen, Inc. (NASDAQ: OPGN) today reported financial and operating results for the three months ended March 31, 2019 and provided a business update. Total revenue for the first quarter of 2019 was $1.0 million, compared with $0.85 million for the first quarter of 2018. Recent business highlights include:

- Submission, on May 13, 2019, of 510(k) application to the U.S. Food and Drug Administration ("FDA") for clearance of the Acuitas® AMR Gene Panel test for the detection of antimicrobial resistance genes in bacterial isolates;
- Advancement of the 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, LLC;
- Achievement of first program milestone of $500,000 for New York State Infectious Disease Digital Health Initiative demonstration project, following installation of Acuitas systems at New York City metro area health systems and the Wadsworth Laboratories;
- Publication of data supporting prediction of antibiotic resistance using the company's Acuitas® AMR Gene Panel and Acuitas Lighthouse Software in the April issue of *Antimicrobial Agents and Chemotherapy*, a peer-reviewed scientific journal of the American Society for Microbiology;
- Presentation of OpGen rapid diagnostic ID products to key opinion leaders during an event co-hosted with ILÚM at the VIII International Symposium on Hospital Acquired Infections and Antimicrobial Stewardship, held in Cali, Colombia;
- Completion of public offering of common stock with gross proceeds of $5.4 million in March 2019.

"We have achieved several critical milestones to start the year, led by the submission of our first FDA 510(k) application for testing of antimicrobial resistance genes in bacterial isolates. We expect the process with the FDA to be completed in 2019 and have already started preparing for this key product launch," said Evan Jones, Chairman and CEO of OpGen.

"Simultaneously, we are working to complete two additional 510(k) submissions for our lead rapid molecular diagnostic test, the Acuitas AMR Gene Panel (Urine) and the Acuitas Lighthouse Software. The clinical trials to support these submissions are anticipated to begin by the end of the second quarter. We plan to complete these trials in the third quarter of 2019 and will prepare the 510(k) submissions shortly thereafter."

“To support the anticipated launch of these tests and informatics, we have established a robust network of hospitals and strategic industry players. We are particularly pleased with the advancement of the New York State Digital Health Initiative and continue to work closely with ILUM and the New York State DOH to expand the impact of this important project. We are confident that we are well-positioned to execute on a successful commercial launch, as we aim to bring these products to more hospitals around the world,” Evan Jones concluded.

First Quarter 2019 Financial Results

- Total revenue for the first quarter of 2019 was $1.0 million, compared with $0.85 million for the first quarter of 2018;
- Operating expenses for the first quarter 2019 were $4.8 million, compared with $3.9 million for the first quarter of 2018. The increase was primarily due to an increase in research and development expense associated with the Acuitas AMR Gene Panel clinical trials and $0.5 million of non-cash impairment expense related to the Company’s Woburn, Massachusetts office right-of-use asset;
- The net loss for the first quarter of 2019 was $3.9 million or $0.41 per share, compared with a net loss of $3.0 million or $0.75 per share for the first quarter of 2018;
- Cash and cash equivalents were $6.0 million as of March 31, 2019.

Business and Operations Outlook

- Complete clinical evaluations and file *De Novo* 510(k) applications 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;
- 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 AMR Gene Panel products;
- Present clinical verification study results for the Acuitas AMR Gene Panel (Urine) at the ASM Microbe conference in June 2019; and
- Commercialize rapid testing products in South America, using Colombia as a springboard.

Conference Call Information

OpGen management will hold a conference call today, May 14, 2019 at 4:30 p.m. ET to discuss first quarter 2019 financial results and other business activities, and answer questions.

Dial-in Information
U.S. Dial-In Number: (844)-420-8185
International Dial-In Number: (216)-562-0481
Conference ID: 6190299
Webcast URL: **https://edge.media-server.com/m6/p/yxqz4fc4**

Replay Dial-in Information
U.S. Dial-In Number: (855)-859-2056
International Dial-In Number: (404)-537-3406
Conference ID: 6190299

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.

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 outlook for 2019. 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, our ability 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, including our Annual Report on Form 10-K for the year ended December 31, 2018, and subsequent filings. 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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OpGen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	March 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 6,011,508	$ 4,572,487
Accounts receivable, net	813,260	373,858
Inventory, net	498,852	543,747
Prepaid expenses and other current assets	162,178	292,918
Total current assets	**7,485,798**	**5,783,010**
Property and equipment, net	248,167	1,221,827
Finance lease right-of-use assets, net	961,418	—
Operating lease right-of-use assets	1,546,155	—
Goodwill	600,814	600,814
Intangible assets, net	1,018,412	1,085,366
Other noncurrent assets	230,310	259,346
Total assets	**$ 12,091,074**	**$ 8,950,363**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,528,814	$ 1,623,751
Accrued compensation and benefits	1,223,083	1,041,573
Accrued liabilities	950,156	902,019
Deferred revenue	9,993	15,824
Short-term notes payable	347,778	398,595
Short-term finance lease liabilities	492,300	399,345
Short-term operating lease liabilities	930,887	—
Total current liabilities	**5,483,011**	**4,381,107**
Deferred rent	—	162,919
Note payable	494,285	660,340
Warrant liability	—	67
Long-term finance lease liabilities	452,089	437,189
Long-term operating lease liabilities	1,322,696	—
Total liabilities	**7,752,081**	**5,641,622**
Commitments		
Stockholders' equity		
Common stock, $0.01 par value; 50,000,000 shares authorized; 17,645,720 and 8,645,720 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	176,457	86,457
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at March 31, 2019 and December 31, 2018, respectively	—	—
Additional paid-in capital	170,104,444	165,313,902
Accumulated other comprehensive loss	(10,267)	(13,093)
Accumulated deficit	(165,931,641)	(162,078,525)
Total stockholders' equity	**4,338,993**	**3,308,741**
Total liabilities and stockholders' equity	**$ 12,091,074**	**$ 8,950,363**

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

	Three Months Ended March 31,	
	2019	**2018**
Revenue		
Product sales	$ 520,177	$ 633,496
Laboratory services	—	8,690
Collaboration revenue	500,000	204,040
Total revenue	**1,020,177**	**846,226**
Operating expenses		
Cost of products sold	220,702	342,832
Cost of services	144,482	168,553
Research and development	1,776,382	1,230,429
General and administrative	1,747,585	1,790,522
Sales and marketing	372,233	329,773
Impairment of right-of-use asset	520,759	—
Total operating expenses	**4,782,143**	**3,862,109**
Operating loss	**(3,761,966)**	**(3,015,883)**
Other (expense) income		
Other (expense) income	(24,422)	5,298
Interest expense	(56,444)	(57,846)
Foreign currency transaction (losses) gains	(10,351)	12,181
Change in fair value of derivative financial instruments	67	8,166
Total other expense	**(91,150)**	**(32,201)**
Loss before income taxes	**(3,853,116)**	**(3,048,084)**
Provision for income taxes	—	—
Net loss	**(3,853,116)**	**(3,048,084)**
Net loss available to common stockholders	**$ (3,853,116)**	**$ (3,048,084)**
Net loss per common share - basic and diluted	**$ (0.41)**	**$ (0.75)**
Weighted average shares outstanding - basic and diluted	9,345,720	4,055,715
Net loss	$ (3,853,116)	$ (3,048,084)
Other comprehensive gain (loss) - foreign currency translations	2,826	(12,579)
Comprehensive loss	**$ (3,850,290)**	**$ (3,060,663)**