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

August 7, 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 August 7, 2019, OpGen, Inc. issued a press release announcing its financial results for the quarter ended June 30, 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 August 7, 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.

Date: August 7, 2019

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer

Exhibit 99.1

OpGen Reports Second Quarter 2019 Financial Results and Provides Business Update

Revenue up 28% Quarter-over-Quarter

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

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

GAITHERSBURG, Md., August 7, 2019 -- OpGen, Inc. (NASDAQ: OPGN) today reported financial and operating results for the three and six months ended June 30, 2019 and provided a business update. Total revenue for the second quarter of 2019 was $1.0 million, compared with $0.8 million for the second quarter of 2018. Recent business highlights include:

- Submission and ongoing review of 510(k) pre-market notification 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;
- Initiation of testing to support *de novo* submission for our lead rapid molecular diagnostic test, the Acuitas AMR Gene Panel Urine;
- Achievement of second $500,000 program milestone under the New York State Infectious Disease Digital Health Initiative demonstration project;
- Presentation of new data demonstrating the potential clinical utility of Acuitas AMR Gene Panel and Acuitas Lighthouse® for antibiotic-resistant urinary tract infection patient management and for rapid carbapenem-resistant bacteria outbreak detection during a podium presentation at ASM Microbe 2019;
- Presentation of data by collaborator, Geisinger, obtained from the first multisite assessment evaluating the potential clinical utility of OpGen's Acuitas AMR Gene Panel using clinical samples presented at ASM Microbe 2019;
- Advancement of South America initiative to commercialize rapid testing products, marked by the closing of OpGen's first customer accounts in Colombia; and
- Launch of new OpGen website and branding to reflect our transformation into an innovative commercial organization and leader in precision medicine.

"During the second quarter, we continued to execute against OpGen's highest priority of bringing our novel Acuitas AMR Gene Panel and Acuitas Lighthouse Software to market. We engaged in ongoing dialogue with the FDA regarding our recent 510(k) submission for the Acuitas AMR Gene Panel for use with bacterial isolates. We are encouraged by our interactions with the Agency and we are continuing to work towards receiving our first FDA clearance during 2019," said Evan Jones, Chairman and CEO of OpGen.

"We are also working to complete two (2) additional FDA pre-market submissions for our lead rapid molecular diagnostic test, the Acuitas AMR Gene Panel Urine, and for the Acuitas Lighthouse Software. We have begun testing to support the AMR Gene Panel Urine submission, and we plan to complete the trials and make an initial FDA submission by year-end or in the first quarter of 2020."

“Finally, we continued to build commercial momentum in preparation of our anticipated receipt of regulatory clearance. To meet our capital needs, which will enable us to pursue the development and regulatory work to complete our additional FDA filings and, once clearance is received, execute a successful commercial launch, we are considering multiple alternatives ranging from strategic financings to other potential transactions. This consideration includes potential partnering arrangements and business combination transactions in order to obtain sufficient financing so we can continue to deliver distinct and differentiated precision medicine capabilities and maximize our shareholder value.” Evan Jones concluded.

2019 Second Quarter and First Half Financial Results

- Total revenue for the second quarter of 2019 was $1.0 million, compared with $0.8 million for the second quarter of 2018. Total revenue for the first half of 2019 was $2.0 million, compared with $1.6 million for the first half of 2018;
- Operating expenses for the second quarter 2019 were $3.6 million, compared with $4.0 million for the second quarter of 2018. Operating expenses for the first half of 2019 were $8.4 million, compared with $7.9 million for the first half of 2018;
- The net loss for the second quarter of 2019 was $2.6 million or $0.15 per share, compared with a net loss of $3.3 million or $0.57 per share for the second quarter of 2018. The net loss for the first half of 2019 was $6.4 million or $0.48 per share, compared with a net loss of $6.4 million or $1.29 per share for the first half of 2018; and
- Cash and cash equivalents were $3.1 million as of June 30, 2019.

Business and Operations Outlook

- Obtain FDA clearance to market the Acuitas AMR Gene Panel for use with bacterial isolates;
- Complete clinical studies and file *de novo* 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;
- Continue to install Acuitas AMR Gene Panel systems in support of Research Use Only (“RUO”) sales and full launch following first FDA clearance;
- Expand commercial activities to support FDA clearance and launch of the Acuitas AMR Gene Panel products;
- Enter data collection phase for New York State Infectious Disease Digital Health Initiative demonstration project; and
- Commercialize rapid testing products in South America, using Colombia as a springboard.

Annual Meeting

We are holding our Annual Meeting of stockholders on August 22, 2019 and are asking our stockholders to approve a reverse stock split proposal to help us maintain our Nasdaq Capital Market listing and position the Company to pursue potential partnering arrangements and business combination transactions.

Conference Call Information

OpGen management will hold a conference call today, August 7, 2019 at 4:30 p.m. ET to discuss second 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: 7288909
Webcast URL: **https://edge.media-server.com/mmc/p/6grvivzp**

Replay Dial-in Information
U.S. Dial-In Number: (855)-859-2056
International Dial-In Number: (404)-537-3406 Conference ID: 7288909

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 and 2020. 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.

OpGen Contact:
Michael Farmer
Vice President, Marketing (240) 813-1284
mfarmer@opgen.com InvestorRelations@opgen.com

Press Contact:
Matthew Bretzius
FischTank Marketing and PR matt@fischtankpr.com

Investor Contacts:
Joe Green
Edison Group
jgreen@edisongroup.com

OpGen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

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

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

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