

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

November 6, 2019
Date of Report (date of earliest event reported)

OpGen, Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-37367
(Commission
File Number)

06-1614015
(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))

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

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock	OPGN	The Nasdaq Capital Market
Common Warrants	OPGNW	The Nasdaq Capital Market

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

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 November 6, 2019, OpGen, Inc. issued a press release announcing its financial results for the quarter ended September 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 6, 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: November 6, 2019

OpGen, Inc.

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



OpGen Reports Third Quarter 2019 Financial Results and Provides Business Update

22% Revenue Increase Year-to-Date

Update on Announced Agreement to Combine Business with Curetis

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

GAITHERSBURG, Md., Nov. 6, 2019 (GLOBE NEWSWIRE) – OpGen, Inc. (NASDAQ: OPGN) today reported financial and operating results for the three and nine months ended September 30, 2019 and provided a business update. Total nine-month revenue was \$2.7 million compared with \$2.2 million in 2018, a 22.4% increase. Total revenue for the third quarter of 2019 was \$648 thousand, compared with \$552 thousand for the third quarter of 2018, a 17.4% increase. Recent business highlights include:

- OpGen and Curetis N.V. entered into the Implementation Agreement to combine the businesses of OpGen and Curetis GmbH that will lead to, when closed, a commercial-stage, transatlantic diagnostics company focused on data-driven solutions for molecular microbiology;
- Ongoing activities to support the 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 filed in May 2019;
- Initiation during November of clinical trials to support *De Novo* submission for our lead rapid molecular diagnostic test, the Acuitas AMR Gene Panel Urine;
- Achievement of planned program milestones under the New York State Infectious Disease Digital Health Initiative demonstration project;
- The allowance by the U.S. Patent and Trademark Office (USPTO) for a key OpGen patent covering the Acuitas Lighthouse® Profiling technology used in the Company’s software for tracking AMR pathogens;
- The presentation of preliminary Acuitas® AMR Gene Panel data for detecting urinary tract infections (UTI) at IDWeek 2019. The data demonstrate the concordance of Acuitas AMR Gene Panel results with conventional urine culture results and prediction of antimicrobial resistance using the Acuitas® Lighthouse Software;
- Completion of a public offering with gross proceeds of \$9.4 million. The Company intends to use a portion of the proceeds to complete the business combination with Curetis GmbH along with other planned business activities.

Evan Jones, Chairman and CEO of OpGen, stated, “The third quarter of 2019 saw a number of highlights for OpGen, most notably the transformative announcement of the planned business combination with Curetis. We believe combining the two companies will be a win for shareholders of both companies, with an expanded and proprietary product portfolio and a solid growth profile.”

Mr. Jones continued, “OpGen’s business had continued success during the third quarter with the achievement of key business milestones and significant progress towards gaining the first FDA clearance for our Acuitas products. We are encouraged by the positive preliminary data presented at IDWeek 2019 and the recent favorable actions by the USPTO.”

“We look forward to the completion of the business combination with Curetis, expected in early 2020. The outlook for OpGen’s products continues to improve and we look forward to further strengthening of our combined businesses through the planned business combination,” concluded Mr. Jones.

Third Quarter and Nine Month 2019 Financial Results

- Total revenue for the third quarter of 2019 was \$648 thousand, compared with \$552 thousand in the third quarter of 2018. Total revenue for the nine months ended September 30, 2019 was \$2.7 million, compared to \$2.2 million for the nine months ended September 30, 2018;
- Operating expenses for the third quarter of 2019 were \$4.1 million, compared with \$3.8 million in the third quarter of 2018. Total operating expenses for the nine months ended September 30, 2019 were \$12.4 million, compared to \$11.7 million for the nine months ended September 30, 2018;
- The net loss for the third quarter of 2019 was \$3.5 million or \$3.95 per share, compared with \$3.3 million or \$10.67 per share in the third quarter of 2018. The net loss for the nine months ended September 30, 2019 was \$9.9 million or \$13.32 per share, compared to \$9.6 million or \$36.09 per share for the period ending September 30, 2018.

Business and Operations Outlook

We anticipate achieving the following:

- Complete planned business combination with Curetis in the first quarter of 2020;
- 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; and
- Complete data collection phase for New York State Infectious Disease Digital Health Initiative demonstration project.

Conference Call Information

OpGen’s management will host a conference call today, November 6 at 4:30 p.m. ET to discuss third quarter 2019 financial results and other business activities, as well as answer questions. Dial-in information is below:

Dial-in Information

U.S. Dial-in Number: (844) 420-8185

International Dial-in Number: +1 (216) 562-0481

Webcast: <https://edge.media-server.com/mmc/p/p64ma2dv>

Conference ID: 2899666

Following the conclusion of the conference call, a replay will be available through November 13, 2019. The live, listen-only webcast of the conference call may also be accessed by visiting the Investors section of the Company's website at ir.opgen.com. A replay of the webcast will be available following the conclusion of the call and will be archived on the Company's website for 90 days. Replay access information is below:

Replay Information

U.S. Dial-in Number: (855) 859-2056
International Dial-in Number: +1 (404) 537-3406
Conference ID: 2899666

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.

OpGen, Acuitas, and Acuitas Lighthouse are registered trademarks of OpGen, Inc.

Forward-Looking Statements

This press release includes statements relating to the completion of the business combination with Curetis N.V., pursuit of FDA clearance for the Acuitas AMR Gene Panel for use with bacterial Isolates, the use of proceeds from the October 2019 public offering and the activities related to the Company's products and services. 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, the fact that we have broad discretion as to the use of proceeds from the October 2019 public offering and that we may not use the proceeds effectively; risks and uncertainties associated with market conditions, OpGen's ability to successfully and timely seek approval of, and obtain approval of its stockholders for the business combination with Curetis N.V., satisfy the closing conditions under the Implementation Agreement, successfully combine the businesses of OpGen and Curetis GmbH, comply with the complexities of a global business, achieve the synergies we expect, successfully implement the combined company's strategic and business goals and objectives, advance our current and planned 510(k) clearance submissions with the FDA, and continue our activities under the New York State Infectious Disease Digital Health Initiative. 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 (SEC). 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

	September 30, 2019 (Unaudited)	December 31, 2018
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		
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

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
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 translations	7,298	1,528	5,174	7,062
Comprehensive loss	\$ (3,475,140)	\$ (3,253,897)	\$ (9,923,391)	\$ (9,628,660)

