

**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**

**March 15, 2018
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))

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 March 15, 2018, OpGen, Inc. issued a press release announcing its financial results for the fourth quarter and full fiscal year ended December 31, 2017. The full text of such press release is furnished as Exhibit 99.1 to this report.

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.

Item 9.01 — Financial Statements and Exhibits.

(d) Exhibits.

[99.1 Press Release, dated March 15, 2018 issued by OpGen, Inc.](#)

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: March 15, 2018

By: /s/ Timothy C. Dec

Timothy C. Dec
Chief Financial Officer



OPGEN REPORTS FOURTH QUARTER AND FULL YEAR 2017 FINANCIAL RESULTS AND PROVIDES A BUSINESS UPDATE

Acuitas® AMR Gene Panel u5.47 introduced for Research Use Only

Fourth quarter revenue consistent with previous year; net loss decreases 38% year over year

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

GAITHERSBURG, Md. (March 15, 2018) – OpGen, Inc. (NASDAQ: OPGN) today reported financial and operating results for the three and 12 months ended December 31, 2017, and provided a summary of recent business highlights. Total revenue for the fourth quarter of 2017 was \$1.0 million, compared with \$1.0 million for the fourth quarter of 2016. Total revenue for 2017 was \$3.2 million, compared with \$4.0 million for 2016. The net loss for the fourth quarter of 2017 was \$2.9 million, compared with a net loss of \$4.8 million for the fourth quarter of 2016. Net loss for 2017 was \$15.4 million, compared with a net loss of \$19.2 million for 2016.

"During 2017 we completed the initial development of our Acuitas® AMR Gene Panel and the Acuitas Lighthouse® Software for management of patients with complicated urinary tract infections (cUTI). The new Acuitas AMR Gene Panel u5.47 test for Research Use Only (RUO) was released for commercial sale in the first quarter of 2018 for infection control purposes and for pharmaceutical surveillance studies," said Evan Jones, Chairman and CEO of OpGen. "The test detects 5 pathogens and 47 gene targets that span 600 subtypes and convey resistance to nine classes of antibiotics directly from urine. Clinical verification studies are underway, and we anticipate beginning clinical trials in the second quarter in support of a 510(k) filing for clinical use of the test with the U.S. Food and Drug Administration by the end of the year."

Mr. Jones continued, "Earlier this week, we announced a collaboration with Beth Israel Deaconess Medical Center in Boston on a clinical verification study for the Acuitas AMR Gene Panel u5.47 test and Acuitas Lighthouse Software. This prospective verification study is among the first to evaluate potential diagnostic and antibiotic decision-making improvements that could be possible using rapid molecular testing and bioinformatics.

"During the fourth quarter we were awarded a one-year, \$860,000 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. Our work with partners ILÚM Health Solutions, LLC, created by Merck's Healthcare Services and Solutions (HSS) division, and Universidad El Bosque, in Colombia is ongoing."

2017 Fourth Quarter and Year-end Financial Results

- **Revenue:** Total revenue for the fourth quarter of 2017 was \$1.0 million, compared with \$1.0 million for the fourth quarter of 2016. Total revenue for 2017 was \$3.2 million, compared with \$4.0 million for 2016.
- **Operating Expenses:** Operating expenses for the fourth quarter of 2017 were \$3.9 million, compared with \$5.7 million for the fourth quarter of 2016. Operating expenses for 2017 were \$18.5 million, compared with \$23.0 million for 2016.
- **Net Loss:** The net loss available to common stockholders for the fourth quarter of 2017 was \$2.9 million or \$1.33 per share, compared with a net loss available to common stockholders of \$4.8 million or \$5.28 per share for the fourth quarter of 2016. Net loss available to common stockholders for 2017 was \$15.4 million or \$9.78 per share, compared with a net loss available to common stockholders of \$19.5 million or \$27.59 per share for 2016.
- **Cash Position:** Cash and cash equivalents were \$1.8 million as of December 31, 2017, compared with \$4.1 million as of December 31, 2016. Subsequent to the close of the year, the Company raised net proceeds of \$10.7 million in a public offering.

2017 Enterprise Highlights and Recent Developments:

Highlights for recent weeks, the fourth quarter and full year included:

- Acuitas AMR Gene Panel development program accomplishments include: production of first RUO test kits; successful completion of analytical verification studies; and initiation of clinical verification studies with flagship IDN hospitals.
- Curated Acuitas Lighthouse Knowledgebase of 10,000 bacterial isolates tested from the Merck SMART Study surveillance network.
- In January 2018, the Company entered into a second global supply agreement to incorporate Thermo Fisher Scientific's real-time PCR technology in the company's Acuitas® AMR Gene Panel tests. Specific products covered under these agreements include the QuantStudio 5 Real-Time PCR System, TaqMan® Fast Advanced Master Mix and TaqMan® Probes for quick, multiplexed gene detection.
- Developed and presented data on rapid antibiotic prediction capabilities.
- Completed a \$12.0 million public offering with net proceeds to OpGen of \$10.7 million.
- Regained compliance with Nasdaq listing requirements for both minimum stockholders' equity and minimum bid price.
- Continued to achieve stated operating expense reduction during the quarter, with a 32% reduction compared with the fourth quarter of 2016.

"Our Acuitas Rapid Test for cUTI is expected to be the first of a series of OpGen tests that will help address the global antibiotic-resistance crisis by identifying antibiotic-resistant pathogens in less than three hours. Along with the Acuitas Lighthouse Knowledgebase, a dynamic cloud-based information store that is continuously updated for new resistance genes, results will help inform patient treatment," added Mr. Jones. "Importantly, with our recent public financing, OpGen is on the firmest financial footing since our initial public offering."

2018 Outlook

OpGen expects to advance the following business objectives during 2018 as it transitions to the commercial phase of its molecular informatics business:

- Derive revenues from the sale of the RUO Acuitas AMR Gene Panel u5.47 to large hospitals and pharmaceutical clinical research organizations.
- Complete third-party RUO clinical verification studies and FDA clinical trials to support clearance for *in vitro diagnostic* use of the Acuitas AMR Gene Panel u5.47 test and the Acuitas Lighthouse Software.
- File a 510(k) application with the FDA in the fourth quarter of 2018 for the Acuitas AMR Gene Panel u5.47 and Acuitas Lighthouse Software to support full commercial launch for clinical use.
- Add QuantStudio™ 5 System and Qiagen EZ1 Advanced XL revenue-generating system placements.
- Enter into additional supply and cooperation agreements in support of the new Acuitas product family under development.
- Complete CDC Contract demonstration project in Colombia for development of smartphone-based clinical decision support solutions for AMS and infection control in low- and middle-income countries.
- Continue to seek third-party funding for development programs.
- Maintain cost reductions and overall cash burn rate to help provide extended operating cash runway.

Conference Call Information

OpGen management will hold a conference call today beginning at 4:30 p.m. Eastern time to discuss fourth quarter and full year 2017 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 8899787. A live webcast of the conference call can be accessed by visiting the Investor Relations section of the company's website at <http://ir.opgen.com>. A replay of the webcast will be available shortly after the conclusion of the call on the company's website for 90 days.

A telephone replay of the conference call will be available from 7:30 p.m. Eastern time today through March 22, 2018 and can be accessed by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international). All listeners should provide the conference ID: 8899787.

About OpGen

OpGen, Inc. is harnessing the power of informatics and genomic analysis to provide complete solutions for patient, hospital and network-wide infection prevention and treatment. For more information, please visit www.opgen.com.

OpGen, Acuitas, and Acuitas Lighthouse are registered trademarks of OpGen, Inc. QuantStudio 5 Real-Time PCR System is a registered trademark of Thermo Fisher Scientific.

Forward-Looking Statements

This press release includes statements relating to the Company's 2017 financial results and 2018 outlook. 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 successfully, timely and cost-effectively develop, seek and obtain regulatory clearance for and commercialize our product and services offerings, 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 (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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(Tables to follow)

OpGen, Inc.
Consolidated Balance Sheets

	<u>2017</u>	<u>2016</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 1,847,171	\$ 4,117,324
Accounts receivable, net	809,540	542,420
Inventory, net	533,425	692,368
Prepaid expenses and other current assets	311,644	329,646
Total current assets	3,501,780	5,681,758
Property and equipment, net	835,537	800,723
Goodwill	600,814	600,814
Intangible assets, net	1,353,182	1,620,998
Other noncurrent assets	328,600	279,752
Total assets	\$ 6,619,913	\$ 8,984,045
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,691,712	\$ 2,232,563
Accrued compensation and benefits	746,924	578,480
Accrued liabilities	1,160,714	1,215,283
Deferred revenue	24,442	37,397
Short-term notes payable	1,010,961	1,023,815
Current maturities of long-term capital lease obligation	154,839	184,399
Total current liabilities	4,789,592	5,271,937
Deferred rent	290,719	398,084
Warrant liability	8,453	—
Long-term capital lease obligation and other noncurrent liabilities	130,153	146,543
Total liabilities	5,218,917	5,816,564
Commitments		
Stockholders' equity		
Common stock, \$0.01 par value; 200,000,000 shares authorized; 2,265,320 and 1,012,171 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	22,653	10,122
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2017 and December 31, 2016, respectively	—	—
Additional paid-in capital	150,114,669	136,442,302
Accumulated other comprehensive (loss)/income	(52,367)	6,176
Accumulated deficit	(148,683,959)	(133,291,119)
Total stockholders' equity	1,400,996	3,167,481
Total liabilities and stockholders' equity	\$ 6,619,913	\$ 8,984,045

OpGen, Inc.
Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
Revenue				
Product sales	\$ 626,498	\$ 818,488	\$ 2,771,869	\$ 3,524,178
Laboratory services	935	46,774	41,960	228,904
Collaboration revenue	363,479	141,301	397,178	272,603
Total revenue	990,912	1,006,563	3,211,007	4,025,685
Operating expenses				
Cost of products sold	346,690	388,581	1,612,838	1,658,571
Cost of services	292,223	102,600	520,338	631,333
Research and development	1,485,387	2,334,407	6,883,293	8,613,236
General and administrative	1,366,469	1,647,512	6,686,280	6,602,608
Sales and marketing	402,289	1,246,646	2,747,582	5,529,274
Total operating expenses	3,893,058	5,719,746	18,450,331	23,035,022
Operating loss	(2,902,146)	(4,713,183)	(15,239,324)	(19,009,337)
Other expense				
Other income/(expense)	15	(2,889)	(87,255)	(5,967)
Interest expense	(59,531)	(33,541)	(233,505)	(143,347)
Foreign currency transaction gains/(losses)	3,543	(10,395)	23,179	(8,102)
Changes in fair value of warrant liabilities	19,925	-	144,064	-
Total other expense	(36,048)	(46,825)	(153,517)	(157,416)
Loss before income taxes	(2,938,194)	(4,760,008)	(15,392,841)	(19,166,753)
Provision for income taxes	—	—	—	—
Net loss	(2,938,194)	(4,760,008)	(15,392,841)	(19,166,753)
Preferred stock dividends and beneficial conversion	—	—	—	(332,550)
Net loss available to common stockholders	\$ (2,938,194)	\$ (4,760,008)	\$ (15,392,841)	\$ (19,499,303)
Net loss per common share - basic and diluted	\$ (1.33)	\$ (5.28)	\$ (9.78)	\$ (27.59)
Weighted average shares outstanding - basic and diluted	2,211,290	901,991	1,573,769	706,702
Net loss	\$ (2,938,194)	\$ (4,760,008)	\$ (15,392,841)	\$ (19,166,753)
Other comprehensive (loss)/income - foreign currency translation	(44,718)	6,176	(58,543)	7,235
Comprehensive loss	\$ (2,982,912)	\$ (4,753,832)	\$ (15,451,384)	\$ (19,159,518)

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