

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

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**FORM 8-K**

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**CURRENT REPORT**

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

**November 8, 2017  
Date of Report (date of earliest event reported)**

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

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**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)

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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.

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**Item 2.02 — Results of Operations and Financial Condition.**

On November 8, 2017, OpGen, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2017. 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 November 8, 2017, issued by OpGen, Inc.](#)

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**EXHIBIT INDEX**

Exhibit No.	Document
99.1	Press Release, dated November 8, 2017, issued by OpGen, Inc.

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**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: November 9, 2017

By: /s/ Timothy C. Dec

Timothy C. Dec  
Chief Financial Officer



## OPGEN REPORTS 2017 THIRD QUARTER FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

*Affirms plans to release Acuitas® AMR Gene Panel in the first quarter of 2018*

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

**GAITHERSBURG, Md. (November 7, 2017)** – OpGen, Inc. (NASDAQ: OPGN) reports financial and operational results for the three and nine months ended September 30, 2017, and provides a summary of recent business highlights.

“During the third quarter and recent weeks, we continued to achieve important corporate milestones in the development of our new Acuitas gene tests and informatics for multi-drug resistant organisms” said Evan Jones, Chairman and CEO of OpGen. “We continued to advance development of our first Acuitas® AMR Gene Panel u5.47 test and the Acuitas Lighthouse® Knowledgebase and are planning to begin clinical validation studies during the fourth quarter of 2017. Consistent with our corporate initiative to obtain third party funding for priority development programs, 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.”

Additional developments during the third quarter and recent weeks include:

- Advanced development of the Acuitas AMR Gene Panel u5.47 for complicated urinary tract infections (cUTI) for release in the first half of 2018 for research and investigational use
  - Produced the first AMR Gene Panel test kits for cUTI and clinical isolate testing
  - Began analytical validation studies for the cUTI panel
  - Advanced plans to begin clinical validation studies for the cUTI panel in the fourth quarter of 2017
  - Continued development of genotype/phenotype predictive algorithms based on the testing of 7,400 clinical isolates from the Merck SMART surveillance network and clinical collaborators, contributing to the 15,800 isolates contained in the Acuitas Lighthouse Knowledgebase
  - Achieved stated operating expense reduction during the quarter, with a 29% reduction compared with the third quarter of 2016
  - Completed a \$10.0 million public offering with net proceeds to OpGen of \$8.8 million
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## 2017 Third Quarter and Year-to-Date Financial Results

- **Revenue:** Total revenue for the three months ended September 30, 2017 was \$745,000, compared with \$760,000 for the three months ended September 30, 2016. Total revenue for the nine months ended September 30, 2017 was \$2.2 million, compared with \$3.0 million for the nine months ended September 30, 2016.
- **Operating Expenses:** Operating expenses for the three months ended September 30, 2017 were \$3.9 million, compared with \$5.6 million for the three months ended September 30, 2016. Operating expenses for the nine months ended September 30, 2017 were \$14.6 million, compared with \$17.3 million for the nine months ended September 30, 2016.
- **Net Loss Available to Common Stockholders:** Net loss for the three months ended September 30, 2017 was \$3.3 million or \$0.07 per share, compared with \$4.8 million or \$0.23 per share for the three months ended September 30, 2016. Net loss for the nine months ended September 30, 2017 was \$12.5 million or \$0.37 per share, compared with \$14.7 million or \$0.92 per share for the nine months ended September 30, 2016.
- **Cash Position:** Cash and cash equivalents were \$4.9 million as of September 30, 2017, compared with \$4.1 million as of December 31, 2016.

## 2017 Third Quarter Enterprise Highlights and Recent Developments

- Awarded \$860,000 CDC Contract funding development and evaluation of cloud- and mobile-based software integrating electronic patient data and local empiric treatment guidelines to support antimicrobial stewardship and infection control for low- and middle-income countries. OpGen will work with partners TEQQA, LLC and Universidad El Bosque of Bogota, Colombia led by Maria Virginia Villegas, M.D., M.Sc. and will work to establish connectivity to WHONET, an information system developed to support the World Health Organization's goal of global surveillance of bacterial resistance to antimicrobial agents. WHONET analyzes the data of over 4,000 laboratories worldwide and is used in more than 120 countries.
- Presented study results on the company's new rapid test in development, the Acuitas AMR Gene Panel u5.47, and the Acuitas Lighthouse Knowledgebase for the prediction of antibiotic susceptibility at the 2017 ASM/ESCMID Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance. The semi-quantitative PCR test detects 5 bacterial pathogens in clinical isolates and urine specimens and detects 47 antimicrobial resistance genes.

“We were pleased with our financial performance during the third quarter with the significant narrowing of our net loss,” continued Mr. Jones. “We maintained product sales and collaboration revenue at \$736,000, which was comparable to levels from Q3 2016. We set out to reduce operating expenses by 25% to 30% in the second half of 2017 compared with the first half, or a reduction of \$4.0 million to \$5.0 million of annualized operating expenses and a marked improvement in our cash burn. The 29% reduction in operating expenses compared with the third quarter of 2016, or a reduction of \$1.6 million during the third quarter, was consistent with these objectives.”

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“Our Acuitas Rapid Test for cUTI is on track to be evaluated at third-party clinical sites in the fourth quarter and released for research use only in the first quarter of 2018,” added Mr. Jones. “This antimicrobial resistance test 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 proper patient treatments.”

## 2017 Outlook

OpGen expects to advance the following business objectives through the remainder of 2017:

- Finalize initial Acuitas Lighthouse Knowledgebase antibiotic resistance prediction algorithms and begin clinical validation studies for Acuitas AMR Gene Panel u5.47 at major academic medical centers and health systems.
- Complete analytical validation studies for the AMR Gene Panel u5.47 to allow commercial release in Q1 2018 and FDA clinical trials during 2018.
- Enter into additional supply and cooperation agreements in support of the new Acuitas product family under development.
- Complete first program milestones in CDC contract, with our collaboration partners, for development of smartphone-based clinical decision support solutions for antimicrobial stewardship (AMS) and infection control in low- and middle-income countries.
- Continue to reduce costs 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 third quarter 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 the conference ID: 2498769. 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 November 13, 2017 and can be accessed by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international). All listeners should provide the conference ID: 2498769.

## 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](http://www.opgen.com).

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

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## Forward-Looking Statements

This press release includes statements relating to the proceeds from the Company's public offering and its 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, 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)

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**OpGen, Inc.**  
**Condensed Consolidated Balance Sheets**  
(unaudited)

	<u>September 30, 2017</u>	<u>December 31, 2016</u>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 4,854,031	\$ 4,117,324
Accounts receivable, net	469,954	542,420
Inventory, net	461,129	692,368
Prepaid expenses and other current assets	340,923	329,646
<b>Total current assets</b>	<b>6,126,037</b>	<b>5,681,758</b>
Property and equipment, net	750,090	800,723
Goodwill	600,814	600,814
Intangible assets, net	1,420,136	1,620,998
Other noncurrent assets	321,592	279,752
<b>Total assets</b>	<b>\$ 9,218,669</b>	<b>\$ 8,984,045</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 1,939,175	\$ 2,232,563
Accrued compensation and benefits	902,892	578,480
Accrued liabilities	857,024	1,215,283
Deferred revenue	31,239	37,397
Short-term notes payable	1,100,012	1,023,815
Current maturities of long-term capital lease obligation	160,485	184,399
<b>Total current liabilities</b>	<b>4,990,827</b>	<b>5,271,937</b>
Deferred rent	319,273	398,084
Warrant liability	28,378	—
Long-term capital lease obligation and other noncurrent liabilities	119,764	146,543
<b>Total liabilities</b>	<b>5,458,242</b>	<b>5,816,564</b>
<b>Commitments</b>		
<b>Stockholders' equity</b>		
Common stock, \$0.01 par value; 200,000,000 shares authorized; 51,964,878 and 25,304,270 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	519,648	253,042
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at September 30, 2017 and December 31, 2016, respectively	—	—
Additional paid-in capital	148,994,194	136,199,382
Accumulated other comprehensive (loss)/income	(7,649)	6,176
Accumulated deficit	(145,745,766)	(133,291,119)
<b>Total stockholders' equity</b>	<b>3,760,427</b>	<b>3,167,481</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 9,218,669</b>	<b>\$ 8,984,045</b>

**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>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
<b>Revenue</b>				
Product sales	\$ 729,742	\$ 730,325	\$ 2,145,371	\$ 2,705,690
Laboratory services	9,070	23,036	41,025	182,130
Collaboration revenue	6,302	6,302	33,699	131,302
<b>Total revenue</b>	<b>745,114</b>	<b>759,663</b>	<b>2,220,095</b>	<b>3,019,122</b>
<b>Operating expenses</b>				
Cost of products sold	448,407	400,001	1,266,148	1,269,990
Cost of services	49,119	51,802	228,115	528,733
Research and development	1,513,157	2,178,818	5,397,906	6,278,829
General and administrative	1,600,577	1,639,996	5,319,811	4,955,096
Sales and marketing	330,305	1,294,640	2,345,293	4,282,628
<b>Total operating expenses</b>	<b>3,941,565</b>	<b>5,565,257</b>	<b>14,557,273</b>	<b>17,315,276</b>
<b>Operating loss</b>	<b>(3,196,451)</b>	<b>(4,805,594)</b>	<b>(12,337,178)</b>	<b>(14,296,154)</b>
<b>Other expense</b>				
Other (expense)/income	(87,292)	623	(87,270)	(3,078)
Interest expense	(90,317)	(41,423)	(173,974)	(109,806)
Foreign currency transaction gains/(losses)	8,018	(1,269)	19,636	2,293
Changes in fair value of warrant liabilities	97,395	-	124,139	-
<b>Total other expense</b>	<b>(72,196)</b>	<b>(42,069)</b>	<b>(117,469)</b>	<b>(110,591)</b>
<b>Loss before income taxes</b>	<b>(3,268,647)</b>	<b>(4,847,663)</b>	<b>(12,454,647)</b>	<b>(14,406,745)</b>
<b>Provision for income taxes</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Net loss</b>	<b>(3,268,647)</b>	<b>(4,847,663)</b>	<b>(12,454,647)</b>	<b>(14,406,745)</b>
Preferred stock dividends and beneficial conversion	—	—	—	(332,550)
<b>Net loss available to common stockholders</b>	<b>\$ (3,268,647)</b>	<b>\$ (4,847,663)</b>	<b>\$ (12,454,647)</b>	<b>\$ (14,739,295)</b>
Net loss per common share - basic and diluted	<b>\$ (0.07)</b>	<b>\$ (0.23)</b>	<b>\$ (0.37)</b>	<b>\$ (0.92)</b>
Weighted average shares outstanding - basic and diluted	47,078,415	20,938,700	33,956,494	16,028,047
Net loss	\$ (3,268,647)	\$ (4,847,663)	\$ (12,454,647)	\$ (14,406,745)
Other comprehensive (loss)/income - foreign currency translation	(6,234)	672	(13,825)	1,059
<b>Comprehensive loss</b>	<b>\$ (3,274,881)</b>	<b>\$ (4,846,991)</b>	<b>\$ (12,468,472)</b>	<b>\$ (14,405,686)</b>

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