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 13, 2018
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. [_]

Item 2.02 — Results of Operations and Financial Condition.

On November 13, 2018, OpGen, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2018. 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 November 13, 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: November 21, 2018

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

Exhibit 99.1

OPGEN REPORTS THIRD QUARTER 2018 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

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

GAITHERSBURG, Md. (November 13, 2018) – OpGen, Inc. (NASDAQ: OPGN) today reported financial and operating results for the three and nine months ended September 30, 2018 and provided a business update. Total revenue for the third quarter of 2018 was $0.6 million, compared with $0.7 million for the third quarter of 2017. Total revenue for the first nine months of 2018 was $2.2 million, consistent with the $2.2 million reported for the comparable 2017 period. Recent business highlights include:

- Announcement of groundbreaking 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, to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions statewide;
- Entry into collaboration with QIAGEN N.V. to advance rapid diagnostics for antimicrobial resistance based on QIAGEN's EZ1 instrumentation and reagent kits in the U.S.;
- Completion of specimen accrual and testing in Acuitas® clinical verification study with Beth Israel Deaconess Medical Center, Geisinger, and Intermountain Healthcare for initial verification of our Acuitas AMR Gene Panel tests and Acuitas Lighthouse software;
- Starting testing of stock bacterial isolates and analytical validation testing of IUO product to support the Acuitas AMR Gene Panel (Isolates) 510(k) FDA submission to be submitted in early 2019:
- Successful completion of Centers for Disease Control and Prevention (CDC) funded program for development of smartphone-based clinical decision support software with hospital testing in Colombia. Final reporting and fourth milestone payment expected during the fourth quarter of 2018;
- Increased installed base of Acuitas AMR Gene Panel instruments at clinical evaluation sites and commercial customers to ten systems;
- Completed public offering of common stock with gross proceeds of $3.2 million in October 2018;
- Reduced Net Loss by 22.6%, or $2.8 million, compared to the prior year period for the first nine months of 2018 to $9.6 million.

"OpGen's achievements during the third quarter position the company for continued success during 2018 and beyond. We are proud to be a part of the groundbreaking initiative throughout the State of New York, and to collaborate with Wadsworth and ILÚM to help develop the blueprint for how governments and healthcare facilities can detect, track, and manage antimicrobial-resistant infections," said Evan Jones, Chairman and CEO. "We are very pleased with progress to date in developing our lead rapid test, the Acuitas® AMR Gene Panel u5.47 (RUO). Last week we announced the completion of specimen accrual and testing of 670 urine specimens for the clinical verification study with this test and the Acuitas Lighthouse® Software. The preliminary results of the clinical verification study support our plans to introduce our Acuitas AMR Gene Panel and Acuitas Lighthouse Software for under three-hour detection of urinary tract infections with concurrent prediction of resistance to front-line antibiotics. Results are expected to be published in a peer-reviewed journal in the first half of 2019.

“The New York State DOH infectious disease digital health and precision medicine platform will monitor results in real time across healthcare organizations to help identify patients with antimicrobial resistant infections. This program has potential to be truly transformative for OpGen. We are providing the Acuitas AMR Gene Panel u5.47 and customized Acuitas Lighthouse Software. The initial contract is for $1.5 million for 12 months during 2019, with potential for much greater funding should certain milestones be achieved. In addition, we are hopeful that following the success of this program, other states will follow suit in efforts to identify and combat antibiotic-resistant organisms.

“While our Acuitas AMR Gene Panel u5.47 is being marketed for research use only, we are preparing for broader commercialization upon receipt of FDA clearance. We recently announced a supply agreement with QIAGEN to resell their EZ1 Advanced XL automated nucleic acid purification instrumentation (EZ1) and reagent kits in the U.S. The EZ1 will be utilized in the test workflow for our Acuitas AMR Gene Panel u5.47 products. This family of rapid diagnostics has been designed to detect and identify multidrug-resistant bacterial pathogens in urine and bacterial isolates in less than three hours. The test was developed for use with the Acuitas Lighthouse Software for predicting antibiotic resistance and high-resolution pathogen tracking. This agreement with QIAGEN builds on our agreement with Thermo Fisher Scientific to use their real-time PCR technology in our Acuitas AMR Gene Panel Tests, which was signed in early 2018.”

Third Quarter and Nine Month 2018 Financial Results

- Total revenue for the third quarter of 2018 was $0.6 million, compared with $0.7 million for the third quarter of 2017. The decrease was due to a decline in revenue from legacy QuickFISH® rapid diagnostic testing products. Total revenue for the nine months ended September 30, 2018 was $2.2 million, consistent with the $2.2 million reported for the nine months ended September 30, 2017.
- Operating expenses for the third quarter of 2018 were $3.8 million, compared with $3.9 million for the third quarter of 2017. Operating expenses for the first nine months of 2018 were $11.7 million, compared with $14.6 million for the first nine months of 2017.
- The net loss for the third quarter of 2018 was $3.3 million or $0.53 per share, compared with a net loss of $3.3 million or $1.74 per share for the third quarter of 2017. The net loss for the nine months ended September 30, 2018 was $9.6 million or $1.80 per share, compared with a net loss of $12.5 million or $9.17 per share for the nine months ended September 30, 2017.
- Cash Position: Cash and cash equivalents were $4.7 million as of September 30, 2018, compared with $1.8 million as of December 31, 2017. The company closed a public offering with $2.8 million net proceeds on October 22, 2018.

Business and Operations Outlook

- File a 510(k) submission with the FDA in early 2019 for the Acuitas AMR Gene Panel u5.47 (IVD) to support full commercial launch for clinical use for testing of bacterial isolates;
- Complete clinical evaluations and file 510(k) submissions with the FDA for the Acuitas AMR Gene Panel u5.47 (IVD) and the Acuitas Lighthouse Software for rapid testing of urine specimens and prediction of antibiotic resistance to front-line antibiotics;
- Achieve program milestones for New York State Infectious Disease Digital Health initiative including installation of Acuitas systems at New York City metro area health systems and the Wadsworth Laboratories and completion of development of customized Acuitas Lighthouse Software to support ILÚM real-time monitoring data from Regional Health Information Organizations (RHIO) and incorporation of whole genome sequencing data;
- Complete registration process with Colombia regulatory authorities to allow OpGen to commence commercial operations in the country and expand sales of rapid test products and software products in South America;
- Complete CDC contract final report for development of smartphone-based clinical decision support solutions for anti-microbial stewardship and infection control in low- and middle-income countries and associated contracting activities to allow commercialization of the software developed during the project;
- Continue to install Acuitas AMR Gene Panel systems in support of Research Use Only sales and full launch following first FDA clearance.

Conference Call Information

OpGen management will hold a conference call today beginning at 4:30 p.m. Eastern time to discuss third quarter 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: 9163687. 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.

A telephone replay of the conference call will be available from 7:30 p.m. Eastern time today through November 19, 2018 and can be accessed by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international). All listeners should provide the conference ID: 9163687.

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. Its Acuitas AMR Gene Panel and Acuitas Lighthouse software are expected to play a role in the identification of multi-drug resistant organisms. For more information, please visit www.opgen.com.

OpGen, Acuitas, and Acuitas Lighthouse are registered trademarks of OpGen, Inc. EZ1 is a registered trademark of QIAGEN.

The Acuitas AMR Gene Panel u5.47 (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.

Forward-Looking Statements

This press release includes statements relating to OpGen's third quarter 2018 and nine months 2018 results. 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 complete the demonstration project portion of the New York State surveillance contract, successfully, timely and cost-effectively 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. 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.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 4,735,506	$ 1,847,171
Accounts receivable, net	315,612	809,540
Inventory, net	529,815	533,425
Prepaid expenses and other current assets	457,929	311,644
Total current assets	**6,038,862**	**3,501,780**
Property and equipment, net	1,150,238	835,537
Goodwill	600,814	600,814
Intangible assets, net	1,152,320	1,353,182
Other noncurrent assets	280,652	328,601
Total assets	**$ 9,222,886**	**$ 6,619,914**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,036,005	$ 1,691,712
Accrued compensation and benefits	1,023,577	746,924
Accrued liabilities	965,178	1,160,714
Deferred revenue	10,323	24,442
Short-term notes payable	470,911	1,010,961
Current maturities of long-term capital lease obligations	358,604	154,839
Total current liabilities	**3,864,598**	**4,789,592**
Deferred rent	196,558	290,719
Note payable	659,728	—
Warrant liability	383	8,453
Long-term capital lease obligations and other noncurrent liabilities	472,068	130,153
Total liabilities	**5,193,335**	**5,218,917**
Stockholders' equity		
Common stock, $0.01 par value; 50,000,000 shares authorized; 6,425,470 and 2,265,320 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	64,255	22,653
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at September 30, 2018 and December 31, 2017, respectively	—	—
Additional paid-in capital	162,330,283	150,114,671
Accumulated other comprehensive loss	(18,838)	(25,900)
Accumulated deficit	(158,346,149)	(148,710,427)
Total stockholders' equity	**4,029,551**	**1,400,997**
Total liabilities and stockholders' equity	**$ 9,222,886**	**$ 6,619,914**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenue				
Product sales	$ 539,856	$ 729,742	$ 1,805,877	$ 2,145,371
Laboratory services	12,365	9,070	22,155	41,025
Collaboration revenue	—	6,302	359,316	33,699
Total revenue	**552,221**	**745,114**	**2,187,348**	**2,220,095**
Operating expenses				
Cost of products sold	292,984	448,407	939,479	1,266,148
Cost of services	98,189	49,119	446,144	228,115
Research and development	1,286,300	1,513,157	3,821,117	5,397,906
General and administrative	1,743,636	1,600,577	5,365,221	5,319,811
Sales and marketing	361,310	330,305	1,117,380	2,345,293
Total operating expenses	**3,782,419**	**3,941,565**	**11,689,341**	**14,557,273**
Operating loss	**(3,230,198)**	**(3,196,451)**	**(9,501,993)**	**(12,337,178)**
Other (expense) income				
Other (expense) income	(93)	(87,292)	5,210	(87,270)
Interest expense	(28,074)	(90,317)	(140,453)	(173,974)
Foreign currency transaction gains (losses)	3,025	8,018	(6,556)	19,636
Change in fair value of derivative financial instruments	(85)	97,395	8,070	124,139
Total other expense	**(25,227)**	**(72,196)**	**(133,729)**	**(117,469)**
Loss before income taxes	**(3,255,425)**	**(3,268,647)**	**(9,635,722)**	**(12,454,647)**
Provision for income taxes	—	—	—	—
Net loss	**(3,255,425)**	**(3,268,647)**	**(9,635,722)**	**(12,454,647)**
Net loss available to common stockholders	**$ (3,255,425)**	**$ (3,268,647)**	**$ (9,635,722)**	**$ (12,454,647)**
Net loss per common share - basic and diluted	**$ (0.53)**	**$ (1.74)**	**$ (1.80)**	**$ (9.17)**
Weighted average shares outstanding - basic and diluted	6,103,746	1,883,137	5,339,936	1,358,260
Net loss	$ (3,255,425)	$ (3,268,647)	$ (9,635,722)	$ (12,454,647)
Other comprehensive gain (loss) - foreign currency translation	1,528	(6,234)	7,062	(13,825)
Comprehensive loss	**$ (3,253,897)**	**$ (3,274,881)**	**$ (9,628,660)**	**$ (12,468,472)**