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

May 8, 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 May 8, 2018, OpGen, Inc. issued a press release announcing its financial results for the quarter ended March 31, 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 May 8, 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: May 8, 2018

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

OPGEN REPORTS FIRST QUARTER 2018 FINANCIAL RESULTS AND PROVIDES A BUSINESS UPDATE

Revenue increases 10% to $0.8 million, net loss decreases 39% to $3.0 million

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

GAITHERSBURG, Md. (May 8, 2018) – OpGen, Inc. (NASDAQ: OPGN) today reported financial and operating results for the three months ended March 31, 2018, and provided a summary of recent business highlights. Total revenue for the first quarter of 2018 was $0.85 million, up 10% from the $0.77 million reported in the first quarter of 2017. The net loss for the first quarter of 2018 was $3.0 million, a 39% decrease compared with the net loss of $5.0 million for the first quarter of 2017.

“During the quarter our development efforts advanced for our Acuitas® AMR Gene Panel u5.47 for Research Use Only (RUO) test for infection control purposes and pharmaceutical surveillance studies,” said Evan Jones, Chairman and CEO of OpGen. “The test detects 5 pathogens and 47 gene targets that convey resistance to nine classes of antibiotics directly from urine and bacterial isolates. We were pleased to introduce the Acuitas AMR Gene Panel u5.47 (RUO) during the quarter, and the clinical verification studies begun during the quarter are encouraging. Following discussion with the U.S. Food and Drug Administration in recent weeks, we are finalizing the clinical trial protocols for our Acuitas AMR Gene Panel u5.47 *in vitro* diagnostic (IVD) 510(k) submissions. We continue to anticipate initial filings during the fourth quarter of 2018.

“At last month’s European Congress of Clinical Microbiology and Infectious Diseases, we presented the Acuitas AMR Gene Panel (RUO) analytical verification results for detecting multidrug-resistant pathogens and antibiotic resistance genes and the use of test results to predict antibiotic resistance using the bioinformatics capabilities of the Acuitas Lighthouse® Software,” he added. “Results were used with the Acuitas Lighthouse Software to predict phenotypic resistance for 35 isolates from the CDC & FDA Antibiotic Resistance Isolate Bank. The gene panel accurately semi-quantitated the organisms and resistance genes in our test with agreement to conventional microbiology ranging between 88% and 100%. Importantly, we were also able to reduce the time to result to two hours from sample, down from three hours previously and versus current standards that require up to two days.”

Mr. Jones continued, “During the quarter, 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. We continue to pursue additional collaborations with prestigious health centers to evaluate potential diagnostic and antibiotic decision-making improvements that could be possible using rapid molecular testing and bioinformatics.

“In April, we announced successful completion of a prospective clinical trial evaluating the impact of using rapid diagnostic testing for identification and treatment of bacteremia and fungemia in hospital intensive care units in Colombia. The study showed significant improvement in survival and reductions in antibiotic usage for patients receiving the OpGen rapid diagnostic test. Results will be presented at the American Society for Microbiology ASM Microbe 2018 meeting this June.”

2018 First Quarter Financial Results

- **Revenue**: Total revenue for the first quarter of 2018 was $0.85 million, compared with $0.77 million for the first quarter of 2017.
- **Operating Expenses**: Operating expenses for the first quarter of 2018 were $3.9 million, compared with $5.7 million for the first quarter of 2017.
- **Net Loss**: The net loss available to common stockholders for the first quarter of 2018 was $3.0 million or $0.75 per share, compared with a net loss available to common stockholders of $5.0 million or $4.77 per share for the first quarter of 2017.
- **Cash Position**: Cash and cash equivalents were $10.3 million as of March 31, 2018, compared with $1.8 million as of December 31, 2017. During the first quarter, the Company raised net proceeds of $10.7 million in a public offering.

First Quarter 2018 Enterprise Highlights and Recent Developments:

Additional highlights from the first quarter and recent weeks included:

- Reported successful analytical validation and clinical verification results for the Acuitas AMR Gene Panel u5.47 (RUO).
- Entered into a second global supply agreement to incorporate Thermo Fisher Scientific’s real-time PCR technology in our Acuitas AMR Gene Panel tests. 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.
- 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 33% reduction compared with the first quarter of 2017.

“We made solid progress with our research and development, operations, and financial activities during the quarter. We are encouraged by the progress to date with our Acuitas AMR Gene Panel for complicated urinary tract infections and we anticipate continuing progress towards accomplishment of our strategic objectives during 2018,” concluded Mr. Jones.

2018 Outlook

OpGen expects to advance the following business objectives during the remainder of 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, pharmaceutical companies and clinical research organizations.
- Complete third-party 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 first 510(k) application with the FDA in the fourth quarter for the Acuitas AMR Gene Panel u5.47 (IVD) 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 anti-microbial stewardship 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 extend operating cash runway.

Conference Call Information

OpGen management will hold a conference call today beginning at 4:30 p.m. Eastern time to discuss first 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 1082196. 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 for 90 days.

A telephone replay of the conference call will be available from 7:30 p.m. Eastern time today through May 14, 2018 and can be accessed by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international). All listeners should provide the conference ID: 1082196.

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.

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 first quarter 2018 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. 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)

	March 31, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 10,291,532	$ 1,847,171
Accounts receivable, net	591,492	809,540
Inventory, net	509,057	533,425
Prepaid expenses and other current assets	237,997	311,644
Total current assets	**11,630,078**	**3,501,780**
Property and equipment, net	828,120	835,537
Goodwill	600,814	600,814
Intangible assets, net	1,286,228	1,353,182
Other noncurrent assets	266,112	328,601
Total assets	**$ 14,611,352**	**$ 6,619,914**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	1,443,857	$ 1,691,712
Accrued compensation and benefits	1,003,418	746,924
Accrued liabilities	1,098,986	1,160,714
Deferred revenue	23,040	24,442
Short-term notes payable	983,131	1,010,961
Current maturities of long-term capital lease obligation	191,755	154,839
Total current liabilities	**4,744,187**	**4,789,592**
Deferred rent	261,791	290,719
Warrant liability	287	8,453
Long-term capital lease obligation and other noncurrent liabilities	305,163	130,153
Total liabilities	**5,311,428**	**5,218,917**
Commitments		
Stockholders' equity		
Common stock, $0.01 par value; 50,000,000 shares authorized; 5,289,919 and 2,265,320 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	52,899	22,653
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at March 31, 2018 and December 31, 2017, respectively	—	—
Additional paid-in capital	161,044,016	150,114,671
Accumulated other comprehensive loss	(38,479)	(25,900)
Accumulated deficit	(151,758,512)	(148,710,427)
Total stockholders' equity	**9,299,924**	**1,400,997**
Total liabilities and stockholders' equity	**$ 14,611,352**	**$ 6,619,914**

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

	Three Months Ended March 31,	
	2018	**2017**
Revenue		
Product sales	$ 633,496	$ 734,502
Laboratory services	8,690	16,105
Collaboration revenue	204,040	21,164
Total revenue	**846,226**	**771,771**
Operating expenses		
Cost of products sold	342,832	424,950
Cost of services	168,553	100,233
Research and development	1,230,429	2,122,515
General and administrative	1,790,522	1,969,216
Sales and marketing	329,773	1,105,586
Total operating expenses	**3,862,109**	**5,722,500**
Operating loss	**(3,015,883)**	**(4,950,729)**
Other (expense)/income		
Interest and other expense	5,298	21
Interest expense	(57,846)	(29,844)
Foreign currency transaction losses	12,181	2,620
Change in fair value of derivative financial instruments	8,166	—
Total other expense	**(32,201)**	**(27,203)**
Loss before income taxes	**(3,048,084)**	**(4,977,932)**
Provision for income taxes	—	—
Net loss	**(3,048,084)**	**(4,977,932)**
Net loss available to common stockholders	**$ (3,048,084)**	**$ (4,977,932)**
Net loss per common share - basic and diluted	**$ (0.75)**	**$ (4.77)**
Weighted average shares outstanding - basic and diluted	4,055,715	1,043,178
Net loss	$ (3,048,084)	$ (4,977,932)
Other comprehensive loss - foreign currency translation	(12,579)	(3,757)
Comprehensive loss	**$ (3,060,663)**	**$ (4,981,689)**

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