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

October 15, 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, including zip code)

(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 October 15, 2018, OpGen, Inc. issued a press release announcing preliminary financial results for the quarter ended September 30, 2018. The full text of such press release is filed as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release, dated October 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.

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

Date: October 16, 2018

OPGEN PROVIDES BUSINESS AND PRELIMINARY FINANCIAL UPDATE

GAITHERSBURG, Md. (October 15, 2018) – OpGen, Inc. (NASDAQ: OPGN) today provided an update on its commercial activities and clinical trials for its Acuitas® AMR Gene Panel tests and the Acuitas Lighthouse® Software. Preliminary unaudited results for the third quarter of 2018 were also reported.

OpGen continues to make commercial progress with the Acuitas AMR Gene Panel and the Acuitas Lighthouse Software Research Use Only (RUO) products. During the third quarter we were selected to participate in a ground-breaking antimicrobial resistance surveillance initiative across New York State. As part of the collaboration, OpGen will receive a $1.5 million contract for the 12-month demonstration portion of the project, with the potential for full implementation during the next four years, should certain milestones be achieved by all parties involved. The demonstration project revenue includes Acuitas AMR Gene Panel u5.47 (RUO) revenue and use of the Acuitas Lighthouse Software. Revenue is expected to be recognized during 2019. During the third quarter of 2018, the Company sold its first Acuitas AMR Gene Panel u5.47 RUO tests. Ten AMR Gene Panel (RUO) systems are in use in the field with both current customers as well as prospective customers evaluating the products for potential commercial use.

The Company's 2017 contract with 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, has progressed successfully. The software is in use at three healthcare institutions in Colombia as part of the final evaluation stage of the contract, which has been extended into the fourth quarter of 2018 to allow for more extensive data collection and evaluation of the system's impact on antimicrobial stewardship and infection control. Consequently, the final payment from the one-year award that was originally anticipated to occur in the third quarter of 2018 is now anticipated to be recognized during the fourth quarter of 2018.

The Company has commenced performance testing for its Investigational Use Only (IUO) Acuitas AMR Gene Panel u5.47 (Isolates) test to support a 510(k) submission to the U.S. Food and Drug Administration (FDA). Interactions with the FDA continue under the Agency's Q-Sub process to continue to clarify specific requirements for clinical validation and clinical trials for the Acuitas AMR Gene Panel Tests and the Acuitas Lighthouse Software. The Company is targeting its first 510(k) submission for the end of the fourth quarter of 2018 or in the first quarter of 2019. The overall performance testing schedules at OpGen and at third-party sites have been impacted by expanded FDA clinical validation testing requirements and delays in sourcing scale-up quantities of a key reagent for AMR Gene Panel test kits.

Total preliminary unaudited revenue for the third quarter of 2018 was approximately $550,000 compared with approximately $750,000 in the third quarter of 2017. The decrease was due to a decline in revenue from the Company's legacy QuickFISH rapid diagnostic testing products. In the third quarter of 2018 the company anticipated a fourth payment under the CDC smartphone-based clinical decision support solutions contract; this payment is now expected in the fourth quarter of 2018. Total preliminary unaudited revenue for the first nine months of 2018 was approximately $2.2 million, compared with approximately $2.2 million for the first nine months of 2017. Cash as of September 30, 2018 was approximately $4.7 million.

“We achieved key milestones in the development of our Acuitas AMR Gene Panel rapid testing and informatics business during the quarter,” said Evan Jones, CEO, OpGen. “We were selected as a partner by New York State to work collaboratively with the Department of Health’s Wadsworth Center and ILÚM Health Solutions, LLC, a wholly owned subsidiary of Merck’s Healthcare Services and Solutions, to build a sustainable, flexible infectious diseases reporting, tracking and surveillance tool for antimicrobial resistance that can be applied across New York State. We also began performance evaluations for the Acuitas AMR Gene Panel u5.47 Investigational Use Only (IUO) product to support FDA clearance of the AMR Gene Panel u5.47 (Isolates) while beginning commercial sales of the RUO product.”

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) and the Acuitas Lighthouse Software (RUO) are intended for Research Use Only and are 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 financial and business expectations. 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, our ability to successfully complete the pilot portion of the NY State project, the rate of adoption of our products and services by hospitals and other healthcare providers, 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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