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 13, 2019
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. [_]

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OPGN	The Nasdaq Capital Market
Common Stock Warrants (IPO)	OPGNW	The Nasdaq Capital Market

Item 8.01 Other Matters.

On May 13, 2019, OpGen, Inc. (the "Company") filed a 510(k) submission with the U.S. Food and Drug Administration (FDA) for clearance for its Acuitas® AMR Gene Panel test for the detection of antimicrobial resistance genes in bacterial isolates. The Acuitas AMR Gene Panel is a new molecular test developed the Company and is designed to detect 47 antibiotic-resistance genes in less than three hours from bacterial isolates. The test is currently available for research use only ("RUO"). The Company issued a press release announcing this first 510(k) submission on May 14, 2019. 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 May 14, 2019, 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 14, 2019

/s/ Timothy C. Dec

Timothy C. Dec
Chief Financial Officer

OpGen Completes Initial FDA 510(k) Submission for its Acuitas® AMR Gene Panel Test to Identify Presence of Antibiotic Resistance

New molecular test designed to detect 47 antibiotic-resistance genes with high sensitivity and specificity in less than three hours, empowering healthcare facilities to make more informed infection control decisions

GAITHERSBURG, Md. – May, 14, 2019 – OpGen, Inc. (Nasdaq: OPGN) announced today that it has filed its 510(k) submission with the U.S. Food and Drug Administration (FDA) for clearance for its Acuitas AMR Gene Panel test for the detection of antimicrobial resistance genes in bacterial isolates.

The Acuitas AMR Gene Panel is a new molecular test developed by OpGen and is designed to detect 47 antibiotic-resistance genes in less than three hours from bacterial isolates. The test is currently available for research use only (RUO). In addition to the isolate 510(k) submission, OpGen is conducting clinical trials during 2019 to support a submission for its direct-from-urine Acuitas AMR Gene Panel test and its Acuitas Lighthouse® Software for antibiotic resistance prediction direct from clinical samples and management of antimicrobial resistance data in healthcare institutions. These trials will test samples collected from patients with urinary tract infections (UTI).

“We are excited to have completed the first 510(k) submission to the FDA for clearance of one of our Acuitas AMR Gene Panel products, and to take the next step toward bringing our innovative technology to the U.S. market,” said Evan Jones, Chairman and CEO of OpGen, Inc. “The Acuitas AMR Gene Panel test for isolates provides actionable information to help guide physician decision making for critical care patients with acute infections. Our Acuitas AMR Gene Panel tests are designed to help integrate real-time epidemiologic surveillance with rapid delivery of resistance results to care-givers via web-based and mobile platforms. In combination with the Acuitas Lighthouse Software, these products are intended to help rapidly identify and locate antibiotic resistance threats in healthcare institutions and networks.”

The performance of the Acuitas AMR Gene Panel established in the FDA 510(k) submission is based on clinical trials where more than 1,000 clinical isolates were tested at The Johns Hopkins University School of Medicine; Wadsworth Center, New York State Department of Health; University Hospitals Cleveland Medical Center; and IHMA, Inc.

About OpGen

OpGen, Inc. is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. We are developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs.

Our molecular diagnostics and informatics products, product candidates and services combine our Acuitas molecular diagnostics and Acuitas Lighthouse informatics platform for use with our proprietary, curated MDRO knowledgebase. We are working to deliver our products and services, some in development, to a global network of customers and partners. The Acuitas AMR Gene Panel (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. For more information, please visit **www.opgen.com**.

Forward-Looking Statements

The statements in this press release regarding OpGen’s future regulatory submission and clearance 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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