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

January 17, 2020
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))

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

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 8.01 Other Events.

In May 2019, OpGen, Inc. (the “Company”) filed a 510(k) submission with the U.S. Food and Drug Administration, or the FDA, seeking clearance of its Acuitas AMR Gene Panel (Isolates) diagnostic test. In July 2019, the Company received an Additional Information, or AI, Request from the FDA detailing a number of questions related to the submission. At the time, questions from the FDA focused on the intended use of the test including the correlation between marker detection and antibiotic resistance, the level of evidence to support resistance marker/organism claims, whole genome sequencing, or WGS, test validation and use as a comparator method, clinical performance of the test compared to WGS and further analysis of individual study results, *in silico* analysis to support test evaluations, further analysis of analytical study results, additional information regarding instrumentation for use with the test, and test reporting and labeling. On January 6, 2020, OpGen filed a formal response to the FDA’s July 2019 AI Request. Subsequently, the FDA issued a second AI Request on January 17, 2020 to formalize additional questions and remaining requests for information from the earlier July 2019 AI Request. OpGen will continue to work interactively with the FDA to provide responses necessary to address questions related to the submission as well as additional questions that may arise through this second interactive response review process.

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.

Date: January 23, 2020

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer