

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

March 16, 2020  
Date of Report (date of earliest event reported)

OpGen, Inc.  
(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation  
or organization)

001-37367  
(Commission  
File Number)

06-1614015  
(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

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.**

On March 16, 2020, OpGen, Inc. (the “Company”) issued a press release reporting an update on the business of Curetis GmbH, the other party to the Company’s planned business combination. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

Exhibit	Document
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No.	
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99.1	<a href="#">Press Release issued by OpGen, Inc. dated March 16, 2020</a>
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## 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: March 16, 2020

**OpGen, Inc.**

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer



## **OpGen Provides Update on Curetis Now Offering BGI's CE-IVD Rapid Test Kit for Coronavirus in Europe**

- *Rapid real-time PCR test allows testing for SARS-CoV2 in only a few hours*
- *Test kit to be made available via Curetis' European sales channels*
- *Synergies with Curetis Unyvero HPN panel for pneumonia testing for bacterial co-infections in Covid-19 patients*

GAITHERSBURG, Md. – March 16, 2020 – OpGen, Inc. (Nasdaq: OPGN) reported an update on the business of Curetis GmbH (“Curetis”), the other party to the planned business combination with OpGen. Today, Curetis announced that it started offering a CE-IVD certified real-time PCR test kit for SARS-CoV2 (also known as 2019-nCov), the causal pathogen of Corona Virus Disease 2019 (Covid-19). The test kit was developed and is manufactured by Curetis’ strategic partner BGI (Shenzhen, China) and was cleared by Chinese authorities in January 2020. In compliance with European regulations for in-vitro-diagnostics (IVD) tests, the test kit was CE-IVD certified on February 28, 2020.

The BGI 2019-nCoV RT-qPCR Kit enables diagnostic laboratories to perform SARS-CoV2 testing of nasopharyngeal swabs and bronchoalveolar lavage fluid of patients suspected to suffer from Covid-19. The test kit is compatible with standard methods for extracting the virus’ nucleic acid from the sample such as the QIAamp Viral RNA Mini Kit (QIAGEN) and can be performed on standard real-time PCR instruments such as the Applied Biosystems 7500 Real-Time PCR System (ThermoFisher Scientific) that are available in many molecular diagnostic laboratories in Europe. The test kit includes all necessary reagents and controls to test up to 48 patients in just a few hours.

The test will be made available to diagnostic laboratories in Europe through Curetis network of distribution partners but - owing to the special circumstances of the global SARS-CoV2 outbreak - also directly by Curetis in countries where Curetis’ distribution partners are not set up to supply the test kit themselves at short notices.

Offering the BGI 2019-nCoV RT-qPCR Kit is highly synergistic with Curetis’ Unyvero product line as patients hospitalized with Covid-19 are at risk of co-infections with bacterial pathogens that are often resistant to one or more antibiotics. The Unyvero HPN Panel for pneumonia allows for rapid testing of a broad spectrum of bacterial or fungal pathogens commonly involved in lower respiratory tract infections such as severe and life-threatening cases of pneumonia. It also provides key information on genetic resistance markers often carried by such pathogens and thereby allows for earlier and better-informed treatment decisions for hospitalized patients suffering from severe pneumonia.

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“We commend both Curetis and BGI Group for swiftly bringing this important product to market in a time of greatest need. As Covid-19 spreads across the globe, rapid testing technologies will be critical to the containment and ultimate treatment of the outbreak in Europe and beyond,” said Evan Jones, Chairman & CEO of OpGen.

OpGen and Curetis entered into a definitive agreement to combine businesses on September 4, 2019. The closing of the transaction under such definitive agreement has not yet occurred and is subject to a number of significant closing conditions, including receipt of approval from the stockholders of OpGen, Inc. Until the closing occurs, each of OpGen and Curetis are operating as stand-alone businesses.

## **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 proprietary DNA tests and informatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize care decisions for patients with acute infections.

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. Currently we offer our Acuitas AMR Gene Panel tests for research use only. For more information, please visit [www.opgen.com](http://www.opgen.com).

OpGen, Acuitas, and Acuitas Lighthouse are registered trademarks of OpGen, Inc.

## **Forward-Looking Statements**

This press release includes statements relating to the proposed business combination transaction between OpGen and Curetis and a planned collaboration between Curetis Group company, Ares Genetics, and BGI Group for next-generation sequencing and PCR-based coronavirus testing in Europe. 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 and timely seek approval of, and obtain approval of our stockholders for the transaction, satisfy the closing conditions under the implementation agreement between OpGen and Curetis, successfully combine the businesses of OpGen and Curetis, comply with the complexities of a global business, achieve the synergies we expect, successfully implement the combined company’s strategic and business goals and objectives, and advance our current and planned 510(k) clearance submissions with the FDA, 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.

## **No Offer or Solicitation**

This press release is neither an offer to purchase, nor a solicitation of an offer to sell, any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transactions or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

## **Additional Information and Where to Find It**

In connection with the transactions contemplated by the Implementation Agreement (the definitive agreement related to the proposed business combination between the Company and Curetis GmbH), a Registration Statement on Form S-4 (File No. 333-234657) has been filed with and declared effective by the Securities and Exchange Commission (the “SEC”). Investors and security holders are encouraged to read the registration statement and any other relevant documents filed with the SEC, including the proxy statement/prospectus that forms a part of the registration statement. Such documents contain important information about the proposed transaction. The definitive proxy statement/prospectus was first mailed to stockholders of the Company on or about January 27, 2020. This communication is not a substitute for the registration statement, the proxy statement/prospectus or any other document that OpGen may send to its stockholders in connection with the proposed transaction. Investors and security holders will be able to obtain the documents free of charge at the SEC’s website, [www.sec.gov](http://www.sec.gov), or from the Company at its website, [www.opgen.com](http://www.opgen.com).

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