

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

February 20, 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 February 20, 2020, OpGen, Inc. (the “Company”) issued a press release announcing certain preliminary unaudited financial results of Curetis GmbH, the other party to the Company’s proposed business combination transaction, for the year ended December 31, 2019. 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

No. Document

99.1 [Press Release issued by OpGen, Inc. dated February 20, 2020](#)

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: February 20, 2020

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer



OpGen Provides Update on Curetis Preliminary, Unaudited 2019 Condensed Combined Key Financials and Business Update

Revenue increases by 64% to EUR 2.3 million, up from 1.4 million in 2018

More than tripled total contract order volume received year-over-year to about EUR 3.4 million 2019

Combined revenue for both companies (had the business combination taken place at the start of 2019) would have been approximately \$6 million, a 31% increase from the prior year

GAITHERSBURG, Md., Feb. 20, 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 preliminary, unaudited 2019 condensed combined key financials and provided a business update.

Revenue of the Curetis business in 2019 amounted to EUR 2.3 million, up by 64% compared to EUR 1.4 million in 2018. This revenue was realized from a total contract order volume of about EUR 3.4 million received in 2019, up by a factor of more than three compared to contract order volume in 2018 (EUR 1.1 million). Revenue growth in 2019 was primarily driven by partnering projects of Curetis Group Company Ares Genetics as well as increasing uptake of Curetis’ Unyvero product line. Preliminary, unaudited operating loss of the condensed combined business for fiscal year 2019 was approximately EUR 17.2 million compared to EUR 21.6 million in 2018, an improvement of about 21%. This improvement is mainly driven by significant reductions in operating costs for R&D as well as distribution (marketing and sales) and comes despite significantly increased G&A costs that were driven by one-off transaction-related expenses for the preparation and implementation of the proposed business combination.

Key accomplishments of the Curetis business in 2020 year-to-date include:

- Curetis’ launch of the Unyvero LRT Panel for BAL specimens in the U.S. following receipt of 510(k) clearance by the U.S. FDA in December 2019. The panel includes atypical pathogens such as *Pneumocystis jirovecii* important for immunocompromised patients and is commercially available to Curetis’ U.S. customers since end of January 2020. The LRT BAL panel is expected to substantially increase the total addressable market for the Unyvero System in the U.S.
 - Curetis GmbH’s subsidiary Ares Genetics’ collaboration with BGI Group to offer Next-Generation Sequencing (NGS) and PCR-based Coronavirus (2019-nCoV) testing in Europe.
 - Curetis GmbH and Quaphaco entered into an exclusive distribution partnership for Vietnam for an initial term of three years with Quaphaco committing to a minimum purchase totaling approximately EUR 1.9 million during such initial term.
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Had the business combination with OpGen taken place at the start of 2019, combined revenue for both companies would have been approximately \$6 million, a 31% increase from 2018 (approximately \$4.6 million).

“We are pleased with the progress Curetis has made in both product development and revenue generation over the past year, and believe those results, along with our own, provide a positive outlook of the combined companies moving forward,” said Evan Jones, CEO, OpGen. “We are looking forward to closing the business combination in the near future and to continue the growth of both companies as one moving forward.”

The preliminary financial results of Curetis and OpGen are estimates prior to the completion of the companies’ financial closing procedures and audit procedures by its external auditors and therefore may be subject to adjustment when the actual results are available.

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. and the shareholders of Curetis, N.V. To this end, OpGen filed and furnished to its stockholders a proxy statement/prospectus and a notice of special meeting of OpGen stockholders to be held on March 10, 2020 to approve the business combination with Curetis. On the same day at 1:00pm CET, Curetis will host its extraordinary shareholder meeting with the objective of seeking approval from its shareholders for the planned business combination with OpGen.

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 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.

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

Forward-Looking Statements

This press release includes statements relating to the completion of the business combination with Curetis N.V., pursuit of FDA clearance for the Acuitas AMR Gene Panel for use with bacterial Isolates, the use of proceeds from the October 2019 public offering and the activities related to the Company's products and services. 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, the fact that we have broad discretion as to the use of proceeds from the October 2019 public offering and that we may not use the proceeds effectively; risks and uncertainties associated with market conditions, OpGen's ability to successfully and timely seek approval of, and obtain approval of its stockholders for the business combination with Curetis N.V., satisfy the closing conditions under the Implementation Agreement, successfully combine the businesses of OpGen and Curetis GmbH, 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, advance our current and planned 510(k) clearance submissions with the FDA, and continue our activities under the New York State Infectious Disease Digital Health Initiative. 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 (SEC). 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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