

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 12, 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 12, 2020, OpGen, Inc. (the “Company”) issued a press release announcing certain preliminary unaudited financial results for the year ended December 31, 2019 and providing a business update. 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 12, 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 12, 2020

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer



OpGen Announces Preliminary Unaudited Revenue for Fiscal 2019 and Provides Business Update

- Total Revenue for 2019 increases 18.7% to \$3.5 million, up from \$3.0 million in 2018
- Curetis - OpGen business combination shareholder votes set for March 10, 2020

Gaithersburg, MD – February 12, 2020 - OpGen, Inc. (Nasdaq: OPGN, “OpGen”), a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease, announced today that total revenue for 2019 increased 18.7% to \$3.5 million, up from \$3.0 million in 2018. The company also announced accomplishment of the following key milestones:

- Patient accrual underway since December to support FDA submission for the company’s lead rapid molecular diagnostic test, the Acuitas® AMR Gene Panel Urine for the Acuitas AMR Gene Panel (Urine) FDA *De Novo* clearance clinical trial;
- OpGen working interactively with the FDA to provide final responses to Additional Information Request Letters for the Acuitas AMR Gene Panel (Isolates) pending FDA 510(K) submission. Response process to FDA anticipated to be completed in February to be followed by formal response filings; and
- Achievement of planned program milestone under the New York State Infectious Disease Digital Health Initiative demonstration project.

OpGen revenue growth during 2019 was from Acuitas AMR Gene Panel and Acuitas® Lighthouse revenue which increased 147% to approximately \$1.4 million while revenues from the company’s rapid FISH products decreased approximately 12% to \$2.1 million. Preliminary, unaudited operating loss for fiscal year 2019 was approximately \$12.4 million compared with \$13.4 million in 2018. The company expects to provide full year 2019 financial results during its fourth quarter 2019 earnings call in March 2020.

Evan Jones, Chairman & CEO of OpGen commented, “We were pleased with the initial results from fiscal year 2019 and we look forward to further progress following the expected first FDA clearance of our AMR Gene Panel products. Our teams have been working closely with Curetis to complete the planned business combination of our two companies. Together we have exciting prospects for growth from our combined product portfolios.”



Business combination with Curetis Group

The company also announced the following updates relating to the planned business combination with Curetis:

- Curetis Group Company, Ares Genetics', collaboration with BGI Group to offer Next-Generation Sequencing and PCR-based Coronavirus (2019-nCoV) testing in Europe;
- Curetis launches Unyvero LRT Panel for BAL Specimens in the U.S. following receipt of 510(k) clearance by the U.S. FDA;
- LRT BAL Panel recently FDA cleared with labeling expanded to include atypical pathogens such as *Pneumocystis jirovecii* important for immunocompromised patients;
- LRT BAL panel commercially available to Curetis' U.S. customers beginning at the end of January. Expected to substantially increase total addressable market for Unyvero System;
- 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;
- Curetis will host its shareholder meeting on March 10, 2020 at 1:00pm CET with the same objective.

Oliver Schacht, CEO Curetis, N.V commented, "We are encouraged by the significant progress with our planned business combination with OpGen and the initial launch of the new LRT BAL indication. Several prestigious medical centers, including a major cancer center and a large academic institution, have already committed to evaluate the Unyvero LRT BAL panel for routine use in patients hospitalized for suspected pneumonia. The Unyvero LRT BAL application is the first and only FDA-cleared molecular diagnostic pneumonia panel that includes *Pneumocystis jirovecii*. This difficult to diagnose pathogen is a leading cause of pneumonia in immunocompromised individuals."

The preliminary financial results and product growth rates are estimates prior to the completion of OpGen's 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. Until the closing occurs, each of OpGen and Curetis are operating as stand-alone businesses.



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, or from the Company at its website, www.opgen.com.

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.

About Curetis

Curetis N.V.'s (Euronext: CURE) goal is to become a leading provider of innovative solutions for molecular microbiology diagnostics designed to address the global challenge of detecting severe infectious diseases and identifying antibiotic resistances in hospitalized patients.

Curetis' Unyvero System is a versatile, fast and highly automated molecular diagnostic platform for easy-to-use, cartridge-based solutions for the comprehensive and rapid detection of pathogens and antimicrobial resistance markers in a range of severe infectious disease indications. Results are available within hours, a process that can take days or even weeks if performed with standard diagnostic procedures, thereby facilitating improved patient outcomes, stringent antibiotic stewardship and health-economic benefits. Unyvero in vitro diagnostic (IVD) products are marketed in Europe, the Middle East, Asia and the U.S.

Curetis' wholly-owned subsidiary Ares Genetics GmbH offers next-generation solutions for infectious disease diagnostics and therapeutics. The ARES Technology Platform combines what the Company believes to be the most comprehensive database worldwide on the genetics of antimicrobial resistances, ARESdb, with advanced bioinformatics and artificial intelligence.

For further information, please visit www.curetis.com and www.ares-genetics.com.

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