

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

July 15, 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)(Zip code)

(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

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 2.02 Results of Operations and Financial Condition.

On July 15, 2020, OpGen, Inc. issued a press release announcing preliminary financial results for the quarter ended June 30, 2020. 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

[99.1 Press Release, dated July 15, 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: July 15, 2020

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer



OpGen Provides Business Update and Announces Preliminary Unaudited Revenue and Cash Position for Second Quarter 2020

- Preliminary Total Revenue for Q2 2020 was approximately \$1.2 million dollars
- Balance sheet strengthened significantly with \$6.1 million cash raised in Q2 2020

GAITHERSBURG, Md., July 15, 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 preliminary unaudited revenue for the second quarter of 2020 was approximately \$1.2 million up from \$1.0 million in the second quarter of 2019. The preliminary financial results for the three months ended June 30, 2020 reflect the consummation of our business combination with Curetis GmbH on April 1, 2020. The results for the six months ended June 30, 2020 will be included in the Company's Quarterly Report on Form 10-Q and earnings release for the second quarter of 2020. Cash as of June 30, 2020 was approximately \$12.8 million, an increase from the \$11.5 million as of March 31, 2020.

The company also announced accomplishment of the following key milestones in the second quarter of 2020 and year to date:

- OpGen announced a strategic co-promotion partnership with Menarini Silicon Biosystems to market and sell Menarini's CELLSEARCH system, CELLSEARCH CEC kit and COVID-19 related products to infectious disease healthcare providers and researchers in North America;
 - OpGen's subsidiary Curetis GmbH secured access to an additional EUR 5 million tranche in non-dilutive debt financing for COVID-19 related research and development. Subject to certain conditions, Curetis can draw down the tranche at its sole discretion during a nine-month period and the tranche will have a five-year maturity and is interest-only until then;
 - Preliminary data was released from an investigator-initiated collaboration with Karolinska Institutet, Stockholm, Sweden, to identify bacterial co-infections in hospitalized patients with COVID-19 pneumonia. OpGen's Unyvero HPN Panel for Pneumonia identifies life-threatening bacterial co-infections in COVID-19 patients in just five hours, and Unyvero LRT and LRT BAL panels are FDA-cleared in the U.S. for rapid detection of lower respiratory tract infections such as pneumonia. Furthermore, performance of the Unyvero system was highlighted in several posters and abstracts in ASM Microbe 2020 online;
 - OpGen expanded their partnership with the New York State Department of Health and IDC (Infectious Disease Connect), to continue the collaborative program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions statewide. In response to the COVID-19 pandemic in New York State, testing under the program was put on hold by the Wadsworth Center and participating hospitals during Q2 with sites expecting to begin running tests again in Q3;
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- OpGen announced results from a study on the feasibility and potential of antibiotic susceptibility testing and bacterial pathogen identification using next-generation sequencing (NGS) have been pre-published in the Journal of Clinical Microbiology. The study was performed by OpGen's recently acquired subsidiaries Ares Genetics GmbH and Curetis GmbH;
- OpGen expects that its submission to the U.S. Food and Drug Administration ("FDA") for clearance of the Acuitas® AMR Gene Panel (Isolates) for the detection of antimicrobial resistance genes in bacterial isolates is nearing completion. OpGen has responded, and is continuing to respond, to the FDA's additional information requests and anticipates approaching a clearance decision for the Acuitas® AMR Gene Panel for isolates; exact timing cannot be projected due to the COVID-19 pandemic. As a result of the COVID-19 pandemic, the FDA has granted a 90-day extension to marketing submissions and applications on hold as of June 2020, which resulted in OpGen's original submission deadline of July 15, 2020 being extended to October 13, 2020;
- Clinical trials were initiated during the first quarter of 2020 at nine participating sites for the Company's Acuitas AMR Gene Panel (Urine) test. Testing and the trial have been suspended during most of the second quarter of 2020 due to hospitals focusing resources on the COVID-19 pandemic, however, a number of sites have re-initiated enrollment at the end of the second quarter;
- OpGen significantly improved its working capital position in the second quarter of 2020 through the sale of approximately 2.7 million shares of common stock for gross proceeds of \$6.1 million under the company's ATM program during the second quarter. During the six months ended June 30, 2020, the Company sold approximately 5.6 million shares of common stock for gross proceeds of \$11.9 million under the company's ATM program; and
- The German Federal Ministry for Economic Affairs and Energy (BMWi) initiated an investigation of the OpGen business combination with Curetis with regards to its impact on the public order and security of the Federal Republic of Germany as well as national healthcare interests in the light of the current COVID-19 pandemic. OpGen has already responded to all questions currently raised by the BMWi and will remain in constructive dialogue with the BMWi with a view to completing the process as swiftly as possible.

Oliver Schacht, President & CEO of OpGen commented, "While the current pandemic and subsequent economic disruptions have continued to affect our business, we are pleased with our robust second quarter 2020 initial results and have taken decisive action in re-prioritizing our R&D efforts to ensure the long-term durability of our business. We continue to expect an FDA clearance for the Acuitas® AMR Gene Panel albeit somewhat delayed due to the FDA's unilateral decision to extend submission deadlines and thereby extending their review timelines."

Mr. Schacht continued, "We also anticipate final clinical data with our Unyvero HPN Panel for Pneumonia as it relates to rapid testing for bacterial co-infections in COVID-19 patients. With Q2 being the first quarter of operating as a combined company, our business has grown year-over-year during these challenging and unprecedented times. We have successfully integrated our R&D portfolios, operations and teams, allowing us to develop and commercialize industry-leading, data-driven solutions in infectious disease diagnostics. I am especially pleased with the swift combination of our U.S. sales and marketing teams that have been operating as a single integrated team since the 1st of May."

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

About OpGen, Inc.

OpGen, Inc. (Gaithersburg, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with subsidiaries, Curetis GmbH and Ares Genetics GmbH, we are developing and commercializing molecular microbiology solutions helping to guide clinicians with more rapid and actionable information about life threatening infections to improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. OpGen's product portfolio includes Unyvero, Acuitas AMR Gene Panel and Acuitas® Lighthouse, and the ARES Technology Platform including ARESdb, using NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction.

For more information, please visit www.opgen.com.

Forward-Looking Statements

This press release includes statements regarding OpGen's second quarter 2020 results, the integration of OpGen with its acquired subsidiaries, Curetis GmbH and Ares Genetics GmbH, the pursuit of FDA clearance for the Acuitas® AMR Gene Panel for use with bacterial isolates, the current business and strategic initiatives of OpGen, and the impact of COVID-19 on the company and general market conditions. 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, 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 realization of expected benefits of our business combination transaction with Curetis GmbH, the success of our commercialization efforts, the impact of COVID-19 on the Company's operations, financial results, and commercialization efforts as well as on capital markets and general economic conditions, 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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