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 13, 2021
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)(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 [_]

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 January 13, 2021, OpGen, Inc. issued a press release announcing preliminary financial results for the year and quarter ended December 31, 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 January 13, 2021.

The information included in Item 2.02 herein and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 ("Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

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 13, 2021

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer

OpGen Announces Preliminary Unaudited Revenue for Fiscal 2020 and Provides Business Update

- *Preliminary total pro-forma combined revenue for 2020 was approximately $5.2 million*
- *Maintained strong balance sheet with $13.3 million cash as of December 31, 2020 and total capital raised in 2020 of $35.3 million*
- *OpGen subsidiary Ares Genetics to explore multiple collaboration opportunities with several parties*

GAITHERSBURG, Md., January 13, 2020 -- OpGen, Inc. (Nasdaq: OPGN, "OpGen"), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, announced today that total pro-forma preliminary unaudited revenue (including revenue from discontinued operations) for OpGen in 2020 was approximately $5.2 million, compared to about $6.0 million in 2019. Fourth quarter 2020 revenue for OpGen was approximately $1.3 million compared to $ 0.8 million in Q4-2019. The company expects to provide fourth quarter 2020 and full year 2020 financial results during its upcoming earnings call in March 2021. OpGen's cash position as of December 31, 2020 was approximately $13.3 million, an increase from $2.7 million in 2019.

The company also announced accomplishment of the following key milestones and recent developments in the fourth quarter and full year 2020 as well as 2021 to date:

- Following the announced delay in FDA review of the Acuitas AMR Gene Panel 510(k) submission due to the agency's prioritization of COVID-19 related EUAs, OpGen anticipates the re-allocation of FDA staff towards the review of non-COVID-19 related submissions and a near term clearance decision for the Acuitas AMR Gene Panel in Q1-2021.
- The 90-day exclusive negotiation period with a global leading IVD corporation partner towards a potential collaboration and licensing deal recently expired. While a larger strategic deal and licensing agreement is not expected to materialize with such partner in the near term, the parties continue to discuss on a non-exclusive basis potential targeted and focused R&D collaboration as well as possible licensing opportunities. Ares Genetics expects to engage in multiple further partnering and licensing discussions with additional IVD partners that expressed interest in collaborating in the coming months.
- OpGen subsidiary Curetis entered into exclusive distribution partnership in Colombia with Annar Health Technologies for Curetis' Unyvero A50 platform.
- OpGen announced the release of a new peer-reviewed publication that demonstrates that the Unyvero LRT BAL panel accurately detects 19 bacteria alongside *Pneumocystis jirovecii* and 10 antibiotic resistance genes directly from bronchoalveolar lavage fluid, allowing enhanced diagnosis of lower respiratory tract infections.
- OpGen completed a $ 10 million private placement priced at the market with one healthcare-focused U.S. institutional investor, bringing the total amount of capital raised in 2020 to $35.3 million, including the proceeds of the company's ATM facility and warrant exercises.
- Ares Genetics extended its collaboration with Sandoz within its pharma partnering program. Ares Genetics presented advances of its research use only (RUO) based ares-genetics.cloud platform for predictive antibiotic susceptibility testing (AST) at various scientific conferences and expects granting of key patent on genetic resistance prediction.

- OpGen's wholly owned subsidiary, Ares Genetics GmbH, completed the transition of leadership to Dr. Arne Materna, who was appointed as Managing Director and CEO of Ares Genetics effective January 1, 2021.
- OpGen's subsidiary, Curetis GmbH, obtained CE mark certification in the European Union for its own SARS-CoV-2 Kit with PULB for the detection of SARS-CoV-2, the virus that causes COVID-19.
- Streamlined portfolio of platforms and products with focus going forward on Unyvero UTI and IJI for upcoming clinical trials in 2021 and subsequent FDA submissions.
- Exiting FISH business by mid 2021 and ended Acuitas AMR Gene Panel urine trial in fall of 2020.

Oliver Schacht, President & CEO of OpGen, commented, "We are pleased with our fourth quarter and full year 2020 preliminary results and are off to a strong start into 2021. With our new corporate strategy defined and portfolio consolidation successfully completed, a robust cash position and strong global partnerships, there is no doubt that our business has the potential to grow significantly in the coming years. I am especially excited about upcoming key milestones such as an FDA clearance decision on the Acuitas AMR Gene Panel for isolates."

Mr. Schacht continued, "We have strong lines of communication open with the FDA regarding the Acuitas AMR Gene Panel for Isolates. Based on the most recent feedback from the FDA, we expect them to resume review activities following a COVID-19 related staffing surge, and we reiterate anticipation of a near term clearance decision in Q1-2021 and are fully prepared to follow with a swift commercial launch once FDA cleared. While a strategic collaboration and licensing deal did not materialize during the 90-day exclusive negotiation period between Ares Genetics and our IVD partner, conversations to explore further potential collaboration opportunities continue. In addition, we are looking forward to being able to re-engage and continue our dialog with several additional parties based on recent inbound expressions of interest, on a non-exclusive basis over the coming months. In closing, we finished the year strong with a solid balance sheet, access to additional capital and a pipeline and R&D portfolio that allow us to develop and commercialize industry-leading, data-driven solutions in infectious disease diagnostics."

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 fourth quarter 2020 and full year results, expected FDA review and clearance decision regarding the Acuitas AMR Gene Panel for isolates, potential strategic partnering and licensing opportunities for Ares Genetics, and the impact of COVID-19 on the company and general market conditions. These statements and other statements regarding OpGen's Unyvero products, their commercialization and launch, 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 fact that we may not effectively use proceeds from recent financings, including our November 2020 private placement, 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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