

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 10, 2022
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)

9717 Key West Ave, Suite 100
Rockville, MD 20850
(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 10, 2022, OpGen, Inc. issued a press release announcing preliminary financial results for the year and quarter ended December 31, 2021. 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 10, 2022.](#)
104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 10, 2022

OpGen, Inc.

By: /s/ Oliver Schacht PhD

Name: Oliver Schacht PhD

Title: Chief Executive Officer



OpGen Announces Preliminary Unaudited Revenue for Fiscal 2021 and Provides Business Update

- Preliminary unaudited revenue for 2021 was approximately \$4.3 million
- Maintained strong balance sheet with \$36.1 million cash as of December 31, 2021 and total capital raised in 2021 of \$51.2 million
- Conversion of all 150,000 preferred shares into 7.5 million common shares completed by investor in December 2021

Rockville, Md., Jan. 10, 2022 -- 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 preliminary unaudited revenue for OpGen in 2021 was approximately \$4.3 million, compared to approximately \$4.2 million in 2020. Preliminary revenue for the fourth quarter of 2021 was approximately \$1.4 million compared to approximately \$1.4 million in the fourth quarter of 2020. Fourth quarter revenues in 2021 were achieved despite exiting the FISH business at the beginning of 2021 which had contributed approximately \$0.7 million to fourth quarter 2020 revenue. Growing revenue from Unyvero product sales in the U.S. and globally as well as growth of the Ares Genetics services and data access business were key drivers of the 2021 revenue generation. The company expects to provide fourth quarter 2021 and full year 2021 financial results during its earnings call in March 2022. OpGen's cash position as of December 31, 2021 was approximately \$36.1 million, a significant increase from \$13.3 million as of December 31, 2020.

The company also announced accomplishment of the following key milestones and recent developments in the fourth quarter 2021 as well as 2022 to date:

- On January 1, 2022, Albert Weber joined as CFO of OpGen and Theo deVos joined as Senior Vice President of Corporate Development and Operations for Ares Genetics in the U.S.
 - Ares and Sandoz have extended their services frame agreement to continue collaboration in addressing AMR until January 2025
 - OpGen subsidiary Ares Genetics had total fourth quarter 2021 revenue of approximately \$0.8 million with about 80% of such revenues being derived from its recent strategic database access transaction providing for non-exclusive access to 1.1% of the ARESdb content
 - Special stockholder meeting held in December 2021 where stockholders approved all agenda items, including an increase in the company's authorized shares of common stock
 - Closed a \$15 million registered direct preferred stock financing transaction with a single U.S. healthcare institutional investor
 - Following the increase in the company's authorized shares of common stock, the institutional investor in the company's recent preferred stock financing converted all of its 150,000 shares of preferred stock into 7.5 million shares of common stock in December 2021. This resulted in total shares outstanding, as of December 31, 2021, of approximately 46.5 million shares of common stock with no preferred stock remaining outstanding
 - The company's Chinese partner BCB has informed us that all three clinical trial sites required for the supplementary clinical study in China for the Unyvero pneumonia cartridge have recently received their respective IRB approvals. The company expects the study, which is entirely managed and executed under the control of its partners at BCB, to start in due course
 - Received full regulatory clearance for Unyvero system and several cartridges (including HPN, ITI and IAI) in Colombia and recognized the first commercial sale to Annar Dx
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Oliver Schacht, President & CEO of OpGen, commented, “We are pleased with our fourth quarter and full year 2021 preliminary results and are off to a solid start in 2022. With our much improved cash position and existing network of global partnerships, we are convinced that across our portfolio of products and services we have the potential to see them contribute significantly to our growth in the year ahead. I am especially excited about upcoming key milestones such as Chinese clinical study data and pending NMPA approval decision, our Unyvero UTI clinical trial and anticipated FDA submission, the Unyvero A30 platform development and partnering milestones and Ares Genetics’ commercial expansion in Europe as well as here in the U.S. with the recent addition of our SVP Corporate Development and Operations for Ares.” He added: “We continue our dialog with the European Investment Bank regarding the various options to structure a repayment – either in cash or in equity or a combination thereof - of the loan outstanding. The first tranche matures and is due for repayment in April 2022.”

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. (Rockville, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with our 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 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 preliminary fourth quarter 2021 and full year results as well as certain business updates. 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 fact that we may not effectively use proceeds from recent financings, the continued realization of expected benefits of our business combination transaction with Curetis GmbH, the success of our commercialization efforts, the continued 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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