

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 18, 2023
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)

(301) 869-9683
(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 18, 2023, OpGen, Inc. issued a press release announcing its preliminary financial results for the year ended December 31, 2022. 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 18, 2023.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 18, 2023

OpGen, Inc.

By: /s/ Oliver Schacht

Name: Oliver Schacht

Title: Chief Executive Officer



OpGen Provides Preliminary Unaudited Revenue for FY 2022 and Business Update

- Preliminary full year revenue for 2022 of approximately \$2.7 million is within most recent guidance range
- Cash position as of December 31, 2022 was approximately \$7.4 million
- Balance sheet strengthened by recently closed public offering with gross proceeds of \$7.5 million

ROCKVILLE, MD., January 18, 2023 (GLOBE NEWSWIRE) – OpGen, Inc. (Nasdaq: OPGN, “OpGen” or “the Company”), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, today announced preliminary unaudited revenue for 2022. Preliminary revenue for full year 2022 was approximately \$2.7 million, which falls within the most recent guidance range the Company had provided in its Q3 earnings call. The year-end cash position as of December 31, 2022 amounted to approximately \$7.4 million. On January 11, 2023, the Company successfully closed a public offering of securities raising gross proceeds of \$7.5 million and net proceeds of approximately \$6.8 million after deduction of placement agent commission and transaction related expenses.

OpGen also provides the following updates on important aspects of its business and reported on the accomplishment of key milestones in Q4-2022 and early 2023:

- Closed a \$7.5 million public offering of approximately 2.6 million shares of common stock, or pre-funded warrants in lieu thereof, at \$2.90 each, along with accompanying Series A-1 and Series A-2 warrants with an exercise price of \$2.65 per share.
 - Implemented a 1 for 20 reverse stock split to regain compliance with Nasdaq’s minimum bid price rule in advance of the February 2023 deadline.
 - Achieved several key milestones and deliverables under the collaboration with the Foundation for Innovative New Diagnostics (FIND), which triggered a milestone payment in early 2023.
 - Following successful completion of patient sample enrollment into the Unyvero Urinary Tract Infection (UTI) clinical trial in the U.S., OpGen completed its initial analysis and published strong top-line data with an overall weighted average sensitivity of 96.4% and an overall weighted average specificity of 97.4%. The Company also initiated the full data analysis and began preparation of its FDA submission package which is expected to be submitted in the coming months. Furthermore, OpGen began next generation sequencing of over 1,000 bacterial isolates from its UTI clinical trial.
 - OpGen initiated a collaboration with Swiss-based BioVersys by training their internal team, as well as members of the clinical research organization (CRO) that will be supporting the BioVersys phase II clinical trial, on the Unyvero platform and use of the Unyvero HPN pneumonia panel.
 - Signed second Acuitas AMR Gene Panel customer contract and successfully installed first two Acuitas systems.
 - Progressed multiple potential commercial agreements and contracts for Acuitas as well as Unyvero LRT BAL and UTI in the U.S. and intend to obtain signatures subject to customer approval. First commercial purchase orders from new customer accounts were already received and processed in Q4-2022.
 - Launched ARESiss next generation sequencing service from OpGen’s Rockville, Maryland lab and successfully executed large pilot project on isolates from the UTI trial.
 - Ares added several new commercial customer accounts for ARES services globally.
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Oliver Schacht, President and Chief Executive Officer of OpGen, commented: “Despite the many challenges during 2022, we delivered on several key milestones that were planned for the year. The successful completion of our UTI clinical trial with excellent top-line data which we will now prepare for submission to the FDA, the FIND collaboration and its several milestones successfully achieved already, the launch of our ARES next generation sequencing service offerings in the U.S., and most recently, the implementation of a reverse stock split to regain compliance with Nasdaq’s minimum bid price rule followed by a successful financing transaction in very challenging market conditions provide us with all of the ingredients for a strong start into 2023. The funnel of new commercial customer contracts and new accounts having begun ordering products and services from OpGen globally provide a solid foundation for revenue growth in 2023.”

About OpGen, Inc.

OpGen, Inc. (Rockville, MD, U.S.A.) 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 current product portfolio includes Unyvero, Acuitas AMR Gene Panel, and the ARES Technology Platform including ARESdb, NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction including ARESiss, ARESid, and AREScloud, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit.

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

Forward-Looking Statements

This press release includes statements regarding the Company’s preliminary unaudited revenue and business update. 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 success of our commercialization efforts, 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 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, our ability to satisfy debt obligations under our loan with the European Investment Bank, the effect of the military action in Russia and Ukraine on our distributors, collaborators and service providers, our liquidity and working capital requirements, the effect on our business of existing and new regulatory requirements, our ability to realize any anticipated benefits from the reverse stock split, including maintaining its listing on the Nasdaq Capital Market and attracting new investors, 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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