

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

May 15, 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 May 15, 2023, OpGen, Inc. (the “Company”) issued a press release announcing its first quarter financial results for the quarter ended March 31, 2023. The full text of such press release is furnished as Exhibit 99.1 to this report.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 [Press Release, dated May 15, 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.

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## 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: May 15, 2023

**OpGen, Inc.**

By: /s/ Albert Weber

Name: Albert Weber

Title: Chief Financial Officer



### OpGen Reports First Quarter 2023 Financial Results and Provides Business Update

- Total revenue for the first quarter of 2023 was approximately \$0.91 million, an increase of approximately 94% compared to the first quarter of 2022
- Expanded U.S. growth opportunities with the Unyvero UTI De Novo FDA submission and Unyvero distribution partnership with Fisher Healthcare
- Met all remaining key milestones of the FIND collaboration for Unyvero A30
- Management conference call scheduled for May 15, 2023, at 4:30 p.m. EST

ROCKVILLE, Md., May 15, 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, reported its first quarter 2023 financial and operating results. Management will host an investor call to discuss quarterly results and provide a business update.

Oliver Schacht, President & CEO of OpGen, commented, “The beginning of this year has been a news rich period. It's clear the momentum during the first quarter has carried over to the second quarter. We look forward to our near-term strategic goals and continue to focus on executing on our operational and commercial plans.”

Mr. Schacht continued, “We continue to see revenue growth opportunities for our Unyvero products and Ares Genetics’ services globally and especially here in the U.S. We recently announced our distribution partnership for Unyvero products with Fisher Healthcare, and we believe will create traction and momentum for our Unyvero sales in the U.S. under this distribution partnership in the coming quarters and beyond.”

#### First Quarter 2023 Financial Results of OpGen, Inc.

- Total revenue for the first quarter of 2023 was approximately \$0.91 million, an increase of approximately 94% over the company’s revenue of \$0.47 million in the first quarter of 2022. Compared to the fourth quarter 2022 revenue of \$0.72 million, OpGen achieved a 26% revenue increase in the first quarter of 2023.
- Total operating expenses decreased in the first quarter of 2023 to \$6.0 million compared to \$6.3 million for the same quarter in 2022.
- Cash and cash equivalents were approximately \$7.0 million as of March 31, 2023, compared with \$7.4 million as of December 31, 2022.

During the year to date period, the Company reached the following key milestones:

- OpGen subsidiary, Curetis, met all remaining key milestones in its R&D collaboration project with the Foundation for Innovative New Diagnostics (FIND).
- Signed a short-term expansion of Curetis’ R&D collaboration with FIND. The work already completed under the collaboration was expanded by three work packages, which increased total project volume to up to approximately \$913 thousand in revenue.
- Submitted a *De Novo* classification request to the FDA for the marketing authorization of Unyvero Urinary Tract Infection (UTI) panel. The Company received confirmation from the FDA that the submission is complete, and that they have initiated substantive review. If cleared, the Unyvero UTI would become the first ever rapid multiplex sample-to-answer IVD test for urinary tract infections available in the U.S.
- Entered a non-exclusive distribution agreement with Fisher Healthcare, a part of Thermo Fisher Scientific. This agreement is for the distribution of the Unyvero A50 platform and *in vitro* diagnostic tests for pneumonia and urinary tract infections.
- Entered into a strategic advisory agreement to support Unyvero A30 corporate business development in China and engage in frequent, ongoing dialog with our Chinese partners.
- OpGen subsidiary, Ares Genetics, announced that they were granted a key patent in China. The patent covers the identification and diagnostic use of genomic variants for the diagnosis of antibiotic resistant bacteria infections.
- Closed \$7.5 million and \$3.5 million public offerings with net proceeds to be used, among other things, for the support of commercialization of the Acuitas AMR Gene Panel, products on the Unyvero platform, development of the ARES database, and to support direct sales and marketing as well as repayment of certain indebtedness to the EIB.

The Company reiterates and updates its guidance for 2023 as follows:

- net cash consumption of around \$4.5 to \$5 million per quarter from its current operations;
- continue pursuing significant revenue growth opportunities, especially with Unyvero product sales and ARESiss services, both in the U.S. and internationally;
- actively pursue the commercial opportunities in our funnel;
- expect global revenues from our products, services and collaborations for 2023 to be in the range of approximately \$4 to \$5 million;
- engage in interactive review with the FDA towards a clearance decision on the *De Novo* classification request for the Unyvero UTI panel;
- recognize approximately \$180 thousand in the second quarter for the additional work packages from the FIND collaboration;
- expect continued revenue generation and growth under the collaboration between Curetis and BioVersys during 2023 and 2024 as the BioVersys clinical trial progresses;
- prioritize non-dilutive financing with several multi-million dollar proposals already submitted or currently being prepared for submission, recognizing that the Company needs a strong balance sheet to support and provide co-funding for projects under any such agreements.

### **Conference Call Information**

OpGen's management will host a conference call today, May 15, 2023 at 4:30 p.m. EST, to review the first quarter 2023 financial results and business activities, as well as answer analyst questions.

#### **Conference Call Details**

U.S. Dial-in Number: 1-877-704-4453

International Dial-in Number: 1-201-389-0920

Conference ID: 13738364

Webcast: [https://viaavid.webcasts.com/starthere.jsp?ei=1611539&tp\\_key=76976884dc](https://viaavid.webcasts.com/starthere.jsp?ei=1611539&tp_key=76976884dc)

Following the conclusion of the conference call, a replay will be available through May 29th, 2023. The live, listen-only webcast of the conference call may also be accessed by visiting the Investors section of the Company's website at [www.opgen.com](http://www.opgen.com). A replay of the webcast will be available following the conclusion of the call and will be archived on the Company's website under Financials & Filings. Replay access information is below:

#### **Replay Details**

U.S. Dial-in Number: 1-844-512-2921

International Dial-in Number: 1-412-317-6671

Replay PIN: 13738364

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## **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, ARESasp, 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](http://www.opgen.com)

## **Forward-Looking Statements**

This press release includes statements regarding the first quarter 2023 and the current business of OpGen.

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, 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, 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.

### **OpGen:**

Oliver Schacht  
President and CEO  
[InvestorRelations@opgen.com](mailto:InvestorRelations@opgen.com)

### **OpGen Investor & Press Contact:**

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**OpGen, Inc. and Subsidiaries**  
**Consolidated Balance Sheets**  
(unaudited)

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 7,039,375	\$ 7,440,030
Accounts receivable, net	666,765	514,372
Inventory, net	1,577,762	1,345,137
Prepaid expenses and other current assets	1,455,815	1,355,949
<b>Total current assets</b>	<b>10,739,717</b>	<b>10,655,488</b>
Property and equipment, net	3,666,823	3,457,531
Finance lease right-of-use assets, net	2,671	3,500
Operating lease right-of-use assets	2,139,974	1,459,413
Intangible assets, net	7,398,333	7,440,974
Strategic inventory, net	2,066,795	2,300,614
Other noncurrent assets	497,055	495,629
<b>Total assets</b>	<b>\$ 26,511,368</b>	<b>\$ 25,813,149</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 266,637	\$ 420,821
Accrued compensation and benefits	1,424,602	1,097,654
Accrued liabilities	1,436,014	1,526,204
Deferred revenue	46,003	142,061
Current maturities of long-term debt	4,959,417	7,023,901
Short-term finance lease liabilities	2,803	3,364
Short-term operating lease liabilities	500,994	377,626
<b>Total current liabilities</b>	<b>8,636,470</b>	<b>10,591,631</b>
Long-term debt, net	5,358,433	4,850,686
Long-term finance lease liabilities	—	280
Long-term operating lease liabilities	3,121,433	2,566,138
Derivative liabilities	88,635	99,498
Other long-term liabilities	129,213	129,368
<b>Total liabilities</b>	<b>17,334,184</b>	<b>18,237,601</b>
<b>Stockholders' equity</b>		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, \$0.01 par value; 100,000,000 shares authorized; 5,495,546 and 2,899,911 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	54,955	28,999
Additional paid-in capital	288,326,377	281,167,161
Accumulated deficit	(278,561,375)	(272,824,772)
Accumulated other comprehensive loss	(642,773)	(795,840)
<b>Total stockholders' equity</b>	<b>9,177,184</b>	<b>7,575,548</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 26,511,368</b>	<b>\$ 25,813,149</b>

**OpGen, Inc. and Subsidiaries**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(unaudited)

	Three months ended March 31,	
	2023	2022
<b>Revenue</b>		
Product sales	\$ 410,897	\$ 366,052
Laboratory services	21,673	42,929
Collaboration revenue	480,874	60,764
<b>Total revenue</b>	<b>913,444</b>	<b>469,745</b>
<b>Operating expenses</b>		
Cost of products sold	592,378	291,997
Cost of services	128,306	30,562
Research and development, net	1,812,831	2,316,441
General and administrative	2,423,953	2,625,053
Sales and marketing	1,026,087	1,051,432
<b>Total operating expenses</b>	<b>5,983,555</b>	<b>6,315,485</b>
<b>Operating loss</b>	<b>(5,070,111)</b>	<b>(5,845,740)</b>
<b>Other (expense) income</b>		
Interest and other income	30,106	3,121
Interest expense	(617,298)	(1,269,581)
Foreign currency transaction (losses) gains	(91,994)	198,740
Change in fair value of derivative financial instruments	12,694	109,744
<b>Total other expense</b>	<b>(666,492)</b>	<b>(957,976)</b>
<b>Loss before income taxes</b>	<b>(5,736,603)</b>	<b>(6,803,716)</b>
<b>Provision for income taxes</b>	—	—
<b>Net loss</b>	<b>\$ (5,736,603)</b>	<b>\$ (6,803,716)</b>
<b>Net loss available to common stockholders</b>	<b>\$ (5,736,603)</b>	<b>\$ (6,803,716)</b>
Basic and diluted net loss per share attributable to common stockholders	<b>\$ (1.25)</b>	<b>\$ (2.93)</b>
Weighted average shares outstanding - basic and diluted	4,577,269	2,324,184
Net loss	\$ (5,736,603)	\$ (6,803,716)
Other comprehensive income (loss) - foreign currency translation	153,067	(483,849)
<b>Comprehensive loss</b>	<b>\$ (5,583,536)</b>	<b>\$ (7,287,565)</b>