

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

November 14, 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)

(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 November 14, 2023, OpGen, Inc. (the “Company”) issued a press release announcing its third quarter financial results for the quarter ended September 30, 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 November 14, 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: November 14, 2023

**OpGen, Inc.**

By: /s/ Albert Weber

Name: Albert Weber

Title: Chief Financial Officer



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

- Total revenue for the first nine months of 2023 was approximately \$2.35 million compared to approximately \$1.89 million in the first nine months of 2022
- Implemented certain cash management initiatives, including restructuring U.S. operations by reducing headcount during the third quarter of 2023
- Signed preferred stock purchase agreement with a potential strategic investor in October 2023
- Entered into a warrant inducement agreement with an institutional investor in October 2023
- Subsidiaries Curetis GmbH in Germany and Ares Genetics GmbH in Austria filed for insolvency under German and Austrian laws, respectively, in November 2023

ROCKVILLE, Md., November 14, 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 third quarter 2023 financial and operating results.

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

- Total revenue for the third quarter of 2023 was approximately \$0.70 million compared to the Company’s revenue of approximately \$0.45 million in the third quarter of 2022. Total revenue for the nine months ended September 30, 2023 was approximately \$2.35 million compared to the Company’s revenue of approximately \$1.89 million in the nine months ended September 30, 2022.
- Total operating expenses decreased in the third quarter of 2023 to approximately \$4.26 million compared to approximately \$13.96 million for the third quarter of 2022 primarily due to the Company’s goodwill impairment charge of \$6.98 million recorded in the third quarter of 2022. Total operating expenses decreased by approximately 39% in the nine months ended September 30, 2023 to approximately \$16.14 million compared to approximately \$26.52 million for the same period in 2022.
- Cash and cash equivalents were approximately \$0.29 million as of September 30, 2023, compared with approximately \$7.44 million as of December 31, 2022.

The Company entered into two agreements in October 2023 to improve its cash position consisting of a preferred stock purchase agreement for \$1.0 million in gross proceeds with a potential strategic investor and a warrant inducement agreement with an existing institutional investor that, as of November 14, 2023, resulted in gross proceeds of approximately \$2.06 million. Nevertheless, the Company has concluded that there is substantial doubt about the Company’s ability to continue as a going concern. The Company continues to actively consider multiple alternatives, including, but not limited to, restructuring or refinancing its debt, seeking additional debt or equity capital, reducing or delaying business activities, selling assets, other strategic financings or transactions and other measures, including obtaining relief under applicable bankruptcy laws. There can be no assurance that the Company will be able to identify or execute on any of these alternatives on acceptable terms or that any of these alternatives will be successful.

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In the reporting quarter and year to date, the Company has seen the following key developments:

- OpGen implemented certain cash management initiatives, including restructuring its U.S. operations by reducing headcount from 23 to 6 and scaling down operations at OpGen's U.S. headquarters to the core functions of a U.S. Nasdaq listed company with only minimal marketing and sales support, allowing the Company to conserve cash and focus on the functions needed to pursue potential strategic alternatives.
- In October 2023, OpGen amended its non-exclusive distribution agreement with Fisher Healthcare to allow Fisher Healthcare to sell to existing U.S. Unyvero customers of the Company, which had previously been maintained by the Company's sales force.
- In October 2023, OpGen discontinued its FDA cleared Acuitas AMR Gene Panel diagnostic test.
- In October 2023, OpGen's German subsidiary Curetis GmbH responded to all of the FDA's additional requests with regard to Curetis' *De Novo* request for the Unyvero UTI urinary tract infection test in order to continue the FDA review.
- In October 2023, OpGen entered into a preferred stock purchase agreement with a potential strategic investor for gross proceeds of \$1.0 million in exchange for 1,000 shares of the Company's Series D Preferred Stock. In connection with the ongoing discussions for a transaction with such potential strategic investor, the parties anticipate closing the transaction under the preferred stock purchase agreement as soon as practical.
- On November 6, 2023, following OpGen's unsuccessful efforts to sell the businesses or assets of its wholly owned subsidiaries Curetis GmbH and Ares Genetics GmbH or to access additional capital to continue their operations, Curetis GmbH and Ares Genetics GmbH filed for insolvency under the applicable German and Austrian laws, respectively.

### **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, both of which are subject to insolvency proceedings under German and Austrian laws, respectively, since November 6, 2023, 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 and the ARES Technology Platform including ARESdb, NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction including ARESiss, ARESid, ARESasp, and AREScloud.

For more information, please visit [www.opgen.com](http://www.opgen.com)

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## Forward-Looking Statements

This press release includes statements regarding the third quarter of 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 risks and uncertainties relating to the insolvency proceedings of Curetis GmbH and Ares Genetics GmbH, our ability to continue to finance our business and operations, the result of any alternatives to mitigate the Company's cash position, including restructuring or refinancing of our debt, seeking additional debt or equity capital, reducing or delaying our business activities, selling assets, other strategic transactions or other measures, including obtaining relief under U.S. bankruptcy laws, and the terms, value and timing of any transaction resulting from such alternatives, our ability to satisfy debt obligations under our loan with the European Investment Bank, and our liquidity and working capital requirements. 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

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

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

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 292,642	\$ 7,440,030
Accounts receivable, net	422,725	514,372
Inventory, net	1,198,259	1,345,137
Prepaid expenses and other current assets	1,541,074	1,355,949
<b>Total current assets</b>	<b>3,454,700</b>	<b>10,655,488</b>
Property and equipment, net	3,820,829	3,457,531
Finance lease right-of-use assets, net	986	3,500
Operating lease right-of-use assets	1,915,049	1,459,413
Intangible assets, net	6,842,406	7,440,974
Strategic inventory	1,608,890	2,300,614
Other noncurrent assets	492,022	495,629
<b>Total assets</b>	<b>\$ 18,134,882</b>	<b>\$ 25,813,149</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Current maturities of long-term debt	\$ 9,199,764	\$ 7,023,901
Accounts payable	904,559	420,821
Accrued compensation and benefits	381,807	1,097,654
Accrued liabilities	1,268,723	1,526,204
Deferred revenue	194,687	142,061
Short-term finance lease liabilities	1,121	3,364
Short-term operating lease liabilities	521,424	377,626
<b>Total current liabilities</b>	<b>12,472,085</b>	<b>10,591,631</b>
Long-term debt, net	—	4,850,686
Derivative liabilities	34,364	99,498
Long-term finance lease liabilities	—	280
Long-term operating lease liabilities	2,830,282	2,566,138
Other long-term liabilities	121,428	129,368
<b>Total liabilities</b>	<b>15,458,159</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 September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.01 par value; 100,000,000 shares authorized; 10,013,524 and 2,899,911 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	100,135	28,999
Additional paid-in capital	291,705,905	281,167,161
Accumulated deficit	(288,451,655)	(272,824,772)
Accumulated other comprehensive loss	(677,662)	(795,840)
<b>Total stockholders' equity</b>	<b>2,676,723</b>	<b>7,575,548</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 18,134,882</b>	<b>\$ 25,813,149</b>

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
<b>Revenue</b>				
Product sales	\$ 558,965	\$ 359,112	\$ 1,409,534	\$ 1,614,435
Laboratory services	47,135	31,016	112,810	94,515
Collaboration revenue	92,922	58,585	826,257	176,713
<b>Total revenue</b>	<b>699,022</b>	<b>448,713</b>	<b>2,348,601</b>	<b>1,885,663</b>
<b>Operating expenses</b>				
Cost of products sold	618,796	1,886,191	1,925,566	2,824,577
Cost of services	73,174	17,239	405,582	63,450
Research and development	1,201,865	2,031,113	4,403,488	6,621,310
General and administrative	2,034,628	2,020,452	6,883,588	6,779,773
Sales and marketing	336,184	1,031,496	2,522,471	3,252,277
Goodwill impairment charge	—	6,975,520	—	6,975,520
<b>Total operating expenses</b>	<b>4,264,647</b>	<b>13,962,011</b>	<b>16,140,695</b>	<b>26,516,907</b>
<b>Operating loss</b>	<b>(3,565,625)</b>	<b>(13,513,298)</b>	<b>(13,792,094)</b>	<b>(24,631,244)</b>
<b>Other (expense) income</b>				
Interest and other income	24,977	11,174	86,301	28,147
Interest expense	(396,768)	(569,306)	(1,698,564)	(2,618,799)
Foreign currency transaction (losses) gains	(135,930)	(51,547)	(288,326)	419,160
Change in fair value of derivative financial instruments	10,389	18,995	65,800	54,623
<b>Total other expense</b>	<b>(497,332)</b>	<b>(590,684)</b>	<b>(1,834,789)</b>	<b>(2,116,869)</b>
<b>Loss before income taxes</b>	<b>(4,062,957)</b>	<b>(14,103,982)</b>	<b>(15,626,883)</b>	<b>(26,748,113)</b>
<b>Provision for income taxes</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Net loss</b>	<b>\$ (4,062,957)</b>	<b>\$ (14,103,982)</b>	<b>\$ (15,626,883)</b>	<b>\$ (26,748,113)</b>
<b>Net loss available to common stockholders</b>	<b>\$ (4,062,957)</b>	<b>\$ (14,103,982)</b>	<b>\$ (15,626,883)</b>	<b>\$ (26,748,113)</b>
Net loss per common share – basic and diluted	<b>\$ (0.46)</b>	<b>\$ (5.92)</b>	<b>\$ (2.38)</b>	<b>\$ (11.40)</b>
Weighted average shares outstanding – basic and diluted	8,778,152	2,382,848	6,565,853	2,345,794
Net loss	\$ (4,062,957)	\$ (14,103,982)	\$ (15,626,883)	\$ (26,748,113)
Other comprehensive income (loss) – foreign currency translation	78,815	(536,758)	118,178	(2,247,749)
<b>Comprehensive loss</b>	<b>\$ (3,984,142)</b>	<b>\$ (14,640,740)</b>	<b>\$ (15,508,705)</b>	<b>\$ (28,995,862)</b>