

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

August 10, 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 August 10, 2023, OpGen, Inc. (the “Company”) issued a press release announcing its second quarter financial results for the quarter ended June 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 August 10, 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: August 10, 2023

OpGen, Inc.

By: /s/ Albert Weber

Name: Albert Weber

Title: Chief Financial Officer



OpGen Reports Second Quarter 2023 Financial Results and Provides Business Update

- Total revenue for the first half of 2023 was approximately \$1.65 million, an increase of approximately 15% compared to approximately \$1.44 million in the first half of 2022
- Signed FIND R&D collaboration contract extension
- Entered distribution agreement with Fisher Healthcare for the distribution of the Unyvero A50 platform in the U.S.
- Management conference call is scheduled for August 10, 2023, at 4:30 p.m. ET

ROCKVILLE, Md., August 10, 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 second quarter and first half of 2023 financial and operating results. Management will host an investor call to discuss quarterly results and provide a business update.

Second Quarter 2023 and First Half 2023 Financial Results of OpGen, Inc.

- Total revenue for the second quarter of 2023 was approximately \$0.7 million compared to the company’s revenue of approximately \$1.0 million in the second quarter of 2022, which was primarily driven by the one-time sale of a pool of Unyvero instrument systems to Menarini in Q2-2022. Total revenue for the first half of 2023 was approximately \$1.65 million, an increase of approximately 15% compared to the company’s revenue of approximately \$1.44 million in the first half of 2022.
- Total operating expenses decreased in the second quarter of 2023 to approximately \$5.9 million compared to approximately \$6.2 million for the second quarter of 2022. Total operating expenses decreased by approximately 6% in the first half of 2023 to approximately \$11.9 million compared to approximately \$12.6 million for the same period in 2022.
- Cash and cash equivalents were approximately \$3.2 million as of June 30, 2023, compared with approximately \$7.4 million as of December 31, 2022.

As previously reported, and in light of the Company’s business performance and current cash position, the Company does not expect that its current cash will be sufficient to fund operations beyond September 2023. Since the end of the second quarter, the Company has pursued options to improve its cash position or mitigate a liquidity shortfall. 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 consider all alternatives, including restructuring or refinancing its debt, seeking additional debt or equity capital, reducing or delaying the Company’s business activities, selling assets, and other strategic transactions or other measures, including obtaining relief under U.S. as well as applicable foreign bankruptcy laws. There is no guarantee that the Company will be able to identify and execute on any of these alternatives or that any of them will be successful.

In the reporting quarter and year to date, the Company reached the following key milestones:

- OpGen subsidiary, Curetis, and FIND signed an extension to their R&D collaboration agreement for the development of an AMR panel on the Unyvero A30 RQ platform for low- and middle-income countries. This next phase covers full development of AMR assay and cartridge, analytical testing and software development.
 - Curetis successfully completed the first phase of its FIND collaboration, including the expanded scope of the FIND project in Q1 and Q2, respectively. The FIND collaboration contributed \$609 thousand to first half 2023 revenue.
 - In June 2023, OpGen received ten Unyvero A30 C-Series instruments which will be used in the next phase of the FIND collaboration.
 - Curetis announced the completion of two interim milestones of its collaboration project with InfectoGnostics under the PREPLEX grant.
 - The Company submitted a *De Novo* classification request to the FDA for marketing authorization of the Unyvero Urinary Tract Infection (UTI) panel. Following the FDA's substantive review of the Company's submission, the Company received a formal communication from the FDA requesting certain additional information on June 30, 2023. The FDA has provided OpGen with 180 days to fully respond to their requests.
 - OpGen entered into a distribution agreement with Fisher Healthcare, a division of Thermo Fisher Scientific, for the distribution of the Unyvero A50 platform and *in vitro* diagnostic tests for pneumonia and urinary tract infections in the U.S. During the second quarter and year-to-date, the Company successfully completed vendor set-up of OpGen under Fisher Healthcare's systems, trained the Fisher Healthcare sales teams across the U.S., created digital marketing campaigns, and identified several hundred potential high priority leads with the Fisher Healthcare team. In several territories, the teams are already working towards commercial customer contract opportunities.
 - With the assistance of a U.S.-Chinese strategic advisory firm, OpGen continues to have an active strategic corporate business development campaign to over 40 Chinese corporate IVD companies potentially interested in the Unyvero A30 RQ.
 - Following a successful feasibility assessment, the Ares team recently signed an annual genomic surveillance contract with a major U.S. healthcare network to sequence and analyze pathogen isolates on a twice weekly basis. In addition, the team has signed multiple new ARESiss contracts for isolate sequencing and new AREScloud subscriptions for web-based sequence analysis.
 - On the IP front, OpGen's subsidiary, Ares Genetics, successfully defended a key patent that was being contested in Europe. In the ruling, the European Patent Office ruled in favor of maintaining the patent, which broadly covers the prediction of AMR in pathogens based on any genetic determinants involving two or more nucleotides.
 - Ares recently announced a new feature release for its AREScloud software designed to enhance genomic surveillance. These features include a Single Nucleotide Polymorphism (SNP) analysis module and interpretation of plasmids with reporting customized for the needs of hospital epidemiologists.
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Conference Call Information

OpGen's management will host a conference call today, August 10, 2023 at 4:30 p.m. ET, to review the second quarter 2023 financial results and business activities, but will not be taking any questions.

Conference Call Details

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

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

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1618010&tp_key=fc7c8907d6

Following the conclusion of the conference call, a replay will be available through August 24, 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. 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 Details

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

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

Replay PIN: 13739109

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.

For more information, please visit www.opgen.com

Forward-Looking Statements

This press release includes statements regarding the second 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, 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

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OpGen, Inc.
Consolidated Balance Sheets
(unaudited)

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 3,237,176	\$ 7,440,030
Accounts receivable, net	619,575	514,372
Inventory, net	1,735,122	1,345,137
Prepaid expenses and other current assets	1,637,593	1,355,949
Total current assets	7,229,466	10,655,488
Property and equipment, net	3,849,734	3,457,531
Finance lease right-of-use assets, net	1,833	3,500
Operating lease right-of-use assets	2,041,010	1,459,413
Intangible assets, net	7,206,382	7,440,974
Strategic inventory	1,609,643	2,300,614
Other noncurrent assets	496,894	495,629
Total assets	\$ 22,434,962	\$ 25,813,149
Liabilities and Stockholders' Equity		
Current liabilities		
Current maturities of long-term debt	\$ 9,191,151	\$ 7,023,901
Accounts payable	195,253	420,821
Accrued compensation and benefits	1,439,181	1,097,654
Accrued liabilities	1,043,123	1,526,204
Deferred revenue	27,279	142,061
Short-term finance lease liabilities	1,962	3,364
Short-term operating lease liabilities	517,602	377,626
Total current liabilities	12,415,551	10,591,631
Long-term debt, net	—	4,850,686
Derivative liabilities	45,656	99,498
Long-term finance lease liabilities	—	280
Long-term operating lease liabilities	2,987,194	2,566,138
Other long-term liabilities	126,671	129,368
Total liabilities	15,575,072	18,237,601
Stockholders' equity		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—
Common stock, \$0.01 par value; 100,000,000 shares authorized; 6,967,699 and 2,899,911 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	69,677	28,999
Additional paid-in capital	291,935,388	281,167,161
Accumulated deficit	(284,388,698)	(272,824,772)
Accumulated other comprehensive loss	(756,477)	(795,840)
Total stockholders' equity	6,859,890	7,575,548
Total liabilities and stockholders' equity	\$ 22,434,962	\$ 25,813,149

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

	Three months ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue				
Product sales	\$ 439,672	\$ 889,271	\$ 850,569	\$ 1,255,323
Laboratory services	44,003	20,570	65,676	63,499
Collaboration revenue	252,462	57,364	733,336	118,128
Total revenue	736,137	967,205	1,649,581	1,436,950
Operating expenses				
Cost of products sold	714,392	646,389	1,306,770	938,386
Cost of services	204,102	15,650	332,408	46,212
Research and development	1,388,792	2,273,756	3,201,624	4,590,197
General and administrative	2,425,007	2,134,266	4,848,960	4,759,319
Sales and marketing	1,160,200	1,169,349	2,186,287	2,220,781
Total operating expenses	5,892,493	6,239,410	11,876,049	12,554,895
Operating loss	(5,156,356)	(5,272,205)	(10,226,468)	(11,117,945)
Other (expense) income				
Interest and other income	31,215	13,851	61,323	16,972
Interest expense	(684,498)	(779,912)	(1,301,796)	(2,049,493)
Foreign currency transaction (losses) gains	(60,401)	271,967	(152,396)	470,707
Change in fair value of derivative financial instruments	42,717	(74,116)	55,411	35,628
Total other expense	(670,967)	(568,210)	(1,337,458)	(1,526,186)
Loss before income taxes	(5,827,323)	(5,840,415)	(11,563,926)	(12,644,131)
Provision for income taxes	—	—	—	—
Net loss	\$ (5,827,323)	\$ (5,840,415)	\$ (11,563,926)	\$ (12,644,131)
Net loss available to common stockholders	\$ (5,827,323)	\$ (5,840,415)	\$ (11,563,926)	\$ (12,644,131)
Net loss per common share - basic and diluted	\$ (0.93)	\$ (2.51)	\$ (2.13)	\$ (5.43)
Weighted average shares outstanding - basic and diluted	6,246,326	2,328,725	5,424,542	2,326,485
Net loss	\$ (5,827,323)	\$ (5,840,415)	\$ (11,563,926)	\$ (12,644,131)
Other comprehensive (loss) income - foreign currency translation	(113,704)	(1,227,142)	39,363	(1,710,991)
Comprehensive loss	\$ (5,941,027)	\$ (7,067,557)	\$ (11,524,563)	\$ (14,355,122)