

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 8, 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)

(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 November 10, 2022, OpGen, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 2022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 8, 2022, the Board of Directors of the Company (the “Board”) elected Yvonne Schlaeppli as a member of its Board of Directors. The Board also confirmed that Ms. Schlaeppli is an independent director under applicable standards, including Nasdaq corporate governance standards. Her term as a director began on November 8, 2022.

Since 2011, Ms. Schlaeppli has served as a Managing Partner of Stratevise LLC, an international strategic advisory firm that she cofounded. From 2016 through its going private in 2019, Ms. Schlaeppli served on the board of directors of Stallergenes Greer plc, a pharmaceutical company traded on the Euronext Paris exchange. From 2014 to 2015, Ms. Schlaeppli served on the boards of directors of allergy immunotherapy companies, Ares Allergy Holdings Inc. and Greer Laboratories, Inc. Since 2018, Ms. Schlaeppli has been a director of AstroNova, Inc., a Nasdaq-listed industrial company, which applies data visualization technologies to its hardware and software products for the aerospace and defense, packaging and product identification, and electronic signal data test and measurement sectors, as well as Chair of its Nominating and Governance Committee and a member of its Audit Committee. Since 2015, Ms. Schlaeppli has been a member of the External Advisory Council to the Channing Division of Network Medicine of Brigham and Women’s Hospital in Boston. Ms. Schlaeppli has been recognized as Directorship Certified by the National Association of Corporate Directors (“NACD”) in 2022 and, from 2017 to 2022, has been recognized annually as a Board Leadership Fellow by the NACD. Prior to founding Stratevise, Ms. Schlaeppli served as General Counsel at Global Enterprise Technologies, Passport & ID, a high-security document printing solutions provider and systems integrator from 2007 to 2011 and as Executive Vice President, General Counsel and Corporate IP Officer at Organon BioSciences, a global pharmaceutical, animal health and biotech group based in the Netherlands, from 2006 until its sale in 2007. From 1999 to 2006, Ms. Schlaeppli was a partner at the Boston-based law firm of Palmer & Dodge LLP, where she served as Chairperson of that firm’s International Practice Group. From 1995 to 1998 Ms. Schlaeppli served in senior positions at Johnson Controls, Inc., a NYSE-listed diversified industrial company, including as General Counsel Europe. The Company believes that Ms. Schlaeppli’s extensive experience in life sciences, as well as international business and corporate governance, qualify her to serve on the Company’s Board of Directors.

In light of her prior experience with audit-, risk- and governance-related matters, the Board also appointed Ms. Schlaeppli to the Company’s Audit Committee.

The Company entered into an indemnification agreement with Ms. Schlaeppli in the form previously approved by the Board.

Item 9.01 — Financial Statements and Exhibits.

(d) Exhibits

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|------|---|
| 10.1 | Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.2 of Form S-1, File No. 333-202478, filed on March 3, 2015). |
| 99.1 | Press release dated November 10, 2022. |
| 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: November 10, 2022

OpGen, Inc.

By: /s/ Albert Weber

Name: Albert Weber

Title: Chief Financial Officer



OpGen Reports Third Quarter 2022 Financial Results and Provides Business Update

- *Completes first two commercial customer installations for Acuitas AMR Gene Panel*
- *OpGen subsidiary, Curetis, signed collaboration agreement with BioVersys AG and R&D collaboration agreement with FIND for the Unyvero A30 RQ platform*
- *Elects Yvonne Schlaeppli as new, independent non-executive director to the board*
- *Management conference call scheduled for November 10, 2022, at 4:30 p.m. EST*

ROCKVILLE, MD., November 10, 2022 (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 2022 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, “During the third quarter we reached multiple agreements and entered into collaborations with various partners. These include our research collaboration agreement with the Belgian National Reference Center (BNRC), an R&D collaboration with FIND, our second commercial installation of the Acuitas AMR Gene Panel, a new commercial contract for Unyvero in the U.S., and a collaboration agreement with BioVersys. We are seeing progress on both the R&D and commercial fronts and look forward to the upcoming progress.”

Mr. Schacht continued, “As we proceed through 2022 and move into the calendar year of 2023, we have several upcoming catalysts and milestones to look forward to, including our UTI clinical trial data read-out and anticipated subsequent FDA submission, proceeds from the FIND collaboration as well as its potential future extension and expansion, and several potential new commercial contracts with U.S. customers across Unyvero and Acuitas products. We look forward to announcing these potential milestones as we continue to focus on building shareholder value.”

Third Quarter 2022 Financial Results of OpGen, Inc.

- Total revenue for the third quarter of 2022 was approximately \$0.4 million, compared with approximately \$1.2 million in the third quarter of 2021. Total revenue for the nine months ended September 30, 2022 was approximately \$1.9 million, compared with approximately \$2.9 million for the nine months ended September 30, 2021.
 - Operating expenses for the third quarter of 2022 were approximately \$14.0 million, compared with approximately \$6.3 million in the third quarter of 2021. Operating expenses for the nine months ended September 30, 2022 were approximately \$26.5 million, compared with approximately \$20.4 million for the nine months ended September 30, 2021.
 - The net loss available to common stockholders for the third quarter of 2022 was approximately \$14.1 million, or \$0.30 per share, compared with approximately \$6.1 million, or \$0.16 per share, in the third quarter of 2021. Net loss for the nine months ended September 30, 2022 was approximately \$26.7 million, compared with approximately \$28.0 million for the nine months ended September 30, 2021.
 - Cash and cash equivalents were approximately \$10.3 million as of September 30, 2022, compared with \$36.1 million as of December 31, 2021.
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In the third quarter and year to date, the Company reached the following key milestones:

- OpGen subsidiary, Ares Genetics, signed a research collaboration agreement with the Belgian National Reference Center (BNRC) for invasive *Streptococcus pneumoniae* at the University Hospital Leuven.
 - OpGen subsidiary, Ares Genetics, launched the ARESiss isolate sequencing service in the U.S.
 - OpGen completed enrollment of over 1,800 patient samples for the prospective multicenter clinical trial in the U.S. for the Unyvero UTI Panel on the Unyvero A50 platform.
 - OpGen subsidiary, Curetis, signed an R&D collaboration agreement with FIND for the Unyvero A30 RQ platform.
 - OpGen signed an additional commercial contract for the Acuitas AMR Gene Panel and initiated the first two customer sites in the U.S. with installations, trainings and delivery of Acuitas kits.
 - OpGen subsidiary, Curetis, signed a collaboration agreement with BioVersys AG from Switzerland to use the Unyvero platform in BioVersys' upcoming Phase II clinical trial.
 - OpGen received an update from Beijing Clear Biotech's regulatory advisors about feedback from China's NMPA regarding the Unyvero A50 pneumonia product and the need to resubmit our filing under a new electronic filing regime that NMPA has recently implemented.
 - Nasdaq granted OpGen an extension until February 27, 2023 to meet Nasdaq's minimum bid price requirement.
 - This week, OpGen's board elected Yvonne Schlaeppli as a new, independent non-executive member of the Company's board of directors. Ms. Schlaeppli brings legal, governance, life sciences and international experience to the board. Since 2011, Ms. Schlaeppli has served as a Managing Partner of Stratevise LLC, an international strategic advisory firm that she co-founded. Prior to founding Stratevise, Ms. Schlaeppli served as General Counsel at Global Enterprise Technologies, Passport & ID, a high-security document printing solutions provider and systems integrator, from 2007 to 2011, and as Executive Vice President, General Counsel and Corporate IP Officer at Organon BioSciences, a global pharmaceutical, animal health and biotech group based in the Netherlands, from 2006 until its sale in 2007. Prior to that, Ms. Schlaeppli was a partner at the Boston-based law firm of Palmer & Dodge LLP, where she served as Chairperson of that firm's International Practice Group. Ms. Schlaeppli has been recognized by the National Association of Corporate Directors as Directorship Certified[®], has served on the board of directors of several public companies and currently is a member of the board of AstroNova, Inc.
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In terms of guidance, the Company anticipates:

- The unblinding of data from the Unyvero UTI trial around year-end and subsequent FDA submission in 2023;
- To enter into new commercial contracts in the coming months across Unyvero and Acuitas products, which contracts could have the potential to drive revenue growth for 2023;
- Further developing ARES services and progressing strategic collaborations and partnerships with U.S. key accounts and leading organizations; and
- Overall, 2022 revenue in a range of approximately \$2.5 to \$3 million from products and services as well as collaboration business globally.
- OpGen will be holding a special meeting of stockholders on November 30, 2022 to vote on the proposal for a potential reverse stock split.
- The Company will continue to explore additional strategic and tactical equity and debt financing opportunities as well as potential strategic alternative options throughout the remainder of the year and into 2023 to possibly further strengthen its cash position.

Conference Call Information

OpGen's management will host a conference call today, November 10, at 4:30 p.m. EST, to discuss the third quarter 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
Webcast: https://viaavid.webcasts.com/starthere.jsp?ei=1569725&tp_key=91a31a2b1f	
Conference ID:	13732787

Following the conclusion of the conference call, a replay will be available through November 24th, 2022.

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 for 90 days. 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:	13732787

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 AMR surveillance, outbreak analysis, and 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 OpGen's third quarter 2022 financial results 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, 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, 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, Inc.
Consolidated Balance Sheets
(unaudited)

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 10,275,654	\$ 36,080,392
Accounts receivable, net	665,313	1,172,396
Inventory, net	771,864	1,239,456
Prepaid expenses and other current assets	1,678,729	1,250,331
Total current assets	13,391,560	39,742,575
Property and equipment, net	3,054,990	4,011,748
Finance lease right-of-use assets, net	4,347	90,467
Operating lease right-of-use assets	1,472,934	1,814,396
Goodwill	—	7,453,007
Intangible assets, net	12,001,036	14,530,209
Strategic inventory	2,614,805	3,472,337
Other noncurrent assets	419,495	551,794
Total assets	\$ 32,959,167	\$ 71,666,533
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 682,592	\$ 1,307,081
Accrued compensation and benefits	1,391,145	1,621,788
Accrued liabilities	1,046,865	1,965,845
Deferred revenue	194,960	—
Short-term notes payable	8,342,715	14,519,113
Short-term finance lease liabilities	6,748	43,150
Short-term operating lease liabilities	346,629	459,792
Total current liabilities	12,011,654	19,916,769
Note payable	4,108,421	7,176,251
Derivative liabilities	146,207	228,589
Long-term finance lease liabilities	1,121	3,644
Long-term operating lease liabilities	2,631,957	2,977,402
Other long term liabilities	121,496	146,798
Total liabilities	19,020,856	30,449,453
Stockholders' equity		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at September 30, 2022 and December 31, 2021, respectively	—	—
Common stock, \$0.01 par value; 100,000,000 shares authorized; 48,338,500 and 46,450,250 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	483,386	464,503
Additional paid-in capital	277,406,700	275,708,490
Accumulated deficit	(262,289,652)	(235,541,539)
Accumulated other comprehensive (loss)/income	(1,662,123)	585,626
Total stockholders' equity	13,938,311	41,217,080
Total liabilities and stockholders' equity	\$ 32,959,167	\$ 71,666,533

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue				
Product sales	\$ 359,112	\$ 643,887	\$ 1,614,435	\$ 1,479,270
Laboratory services	31,016	192,753	94,515	643,602
Collaboration revenue	58,585	402,492	176,713	757,591
Total revenue	448,713	1,239,132	1,885,663	2,880,463
Operating expenses				
Cost of products sold	1,886,191	648,298	2,824,577	1,544,932
Cost of services	17,239	203,314	63,450	446,232
Research and development, net	2,031,113	2,382,303	6,621,310	8,055,384
General and administrative	2,020,452	2,088,226	6,779,773	7,444,138
Sales and marketing	1,031,496	1,003,577	3,252,277	2,705,378
Impairment of right-of-use asset	—	—	—	170,714
Goodwill impairment charge	6,975,520	—	6,975,520	—
Total operating expenses	13,962,011	6,325,718	26,516,907	20,366,778
Operating loss	(13,513,298)	(5,086,586)	(24,631,244)	(17,486,315)
Other expense				
Gain on extinguishment of debt	—	—	—	259,353
Warrant inducement expense	—	—	—	(7,755,541)
Interest and other income, net	11,174	31,844	28,147	41,471
Interest expense	(569,306)	(1,222,867)	(2,618,799)	(3,586,018)
Foreign currency transaction gains	(51,547)	229,074	419,160	655,774
Change in fair value of derivative financial instruments	18,995	(8,161)	54,623	(122,572)
Total other expense	(590,684)	(970,110)	(2,116,869)	(10,507,533)
Loss before income taxes	(14,103,982)	(6,056,696)	(26,748,113)	(27,993,848)
Provision for income taxes	—	—	—	—
Net loss	\$ (14,103,982)	\$ (6,056,696)	\$ (26,748,113)	\$ (27,993,848)
Net loss available to common stockholders	\$ (14,103,982)	\$ (6,056,696)	\$ (26,748,113)	\$ (27,993,848)
Basic and diluted net loss per share attributable to common stockholders	\$ (0.30)	\$ (0.16)	\$ (0.57)	\$ (0.79)
Weighted average shares outstanding - basic and diluted	47,656,972	38,270,250	46,915,880	35,373,397
Net loss	\$ (14,103,982)	\$ (6,056,696)	\$ (26,748,113)	\$ (27,993,848)
Other comprehensive loss - foreign currency translation	(536,758)	(597,527)	(2,247,749)	(1,146,355)
Comprehensive loss	\$ (14,640,740)	\$ (6,654,223)	\$ (28,995,862)	\$ (29,140,203)