

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 11, 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)

(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 11, 2022, OpGen, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 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 August 11, 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: August 11, 2022

OpGen, Inc.

By: /s/ Albert Weber

Name: Albert Weber

Title: Chief Financial Officer



OpGen Reports Second Quarter 2022 Financial Results and Provides Business Update

- Total Q2 2022 revenues of \$1.0 million with product sales a key growth driver
- First two commercial customer contracts for Acuitas AMR Gene Panel signed in June and July 2022
- Requested additional 180-day period to regain compliance with Nasdaq minimum bid price rule
- Management conference call scheduled for August 11th, 2022, at 4:30 p.m. EDT

ROCKVILLE, Md., August 11th, 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 second 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, “We are pleased with the progress we’ve made in the first half of 2022, which includes signing two commercial contracts for our Acuitas AMR Gene Panel with two major U.S. hospitals. Additionally, we have added a fourth trial site and continued enrollment towards our 1,500th patient sample for the clinical trial for Unyvero Urinary Tract Infection (UTI) Panel. We anticipate completing the enrollment and expect final data read out in the second half of this year towards an FDA submission.”

Dr. Schacht continued, “Overall we are tracking well against our R&D milestones and continue to progress on the commercial front with significant growth in direct product sales year over year. We look forward to continuing to update on our progress and continue the fight against antimicrobial resistance.”

Second Quarter and First Half 2022 Financial Results of OpGen, Inc.

- Total revenue for the second quarter of 2022 was approximately \$1.0 million, compared with approximately \$0.8 million in the second quarter of 2021. Total revenue for the first half of 2022 was approximately \$1.4 million, as compared to approximately \$1.6 million for the first half of 2021.
- Operating expenses for the second quarter of 2022 were approximately \$6.2 million, compared with approximately \$7.0 million in the second quarter of 2021. Operating expenses for the first half of 2022 were approximately \$12.6 million, compared with approximately \$14.0 million in the first half of 2021.
- The net loss available to common stockholders for the second quarter of 2022 was approximately \$5.8 million, or \$0.13 per share, compared with approximately \$7.1 million, or \$0.19 per share, in the second quarter of 2021. The net loss available to common stockholders for the first half of 2022 was approximately \$12.6 million, or \$0.27 per share, compared with approximately \$21.9 million, or \$0.65 per share, in the first half of 2021.
- Cash and cash equivalents were approximately \$16.6 million as of June 30, 2022, compared with \$36.1 million as of December 31, 2021.

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

- OpGen signed its first two commercial customer contracts for the Acuitas AMR Gene Panel in June and July 2022 with a major 1,000+ bed teaching hospital in the Northeast and a renowned 400+ bed children’s hospital in the Midwest
 - OpGen subsidiary Ares Genetics extended its collaboration agreement with Sandoz until 2025, to drive cutting-edge digital solutions in the global fight against antimicrobial resistance (AMR)
 - OpGen subsidiary Ares Genetics also commercially launched new sequencing and analysis services globally, which includes ARESid and ARESiss Express
-

- OpGen announced interim analysis results from its clinical trial for Unyvero UTI Panel and added a fourth trial site
- OpGen to date has enrolled over 1,300 patient samples in the clinical trial for Unyvero UTI Panel and is on track towards the enrollment goal of 1,500 prospective patient samples
- OpGen subsidiary Curetis and Leader Life Sciences entered into a Unyvero distribution partnership within the United Arab Emirates and Qatar for a total value of approximately \$1 million in revenue during the initial three-year term
- OpGen subsidiary Curetis and Keis Group entered into a three-year exclusive Unyvero distribution partnership in Kosovo based on Keis' successfully won tender for Unyvero products
- OpGen and Menarini expanded their distribution agreement to increase the annual minimum revenue commitment by Menarini in the next two years, in addition to the sale of around 70 installed Unyvero systems across nine European countries at residual fair market value from OpGen's subsidiary Curetis to Menarini
- OpGen announced publication of results from a major prospective, multi center, randomized and interventional clinical study using Unyvero Hospitalized Pneumonia (HPN) Panel in The Lancet Respiratory Medicine that demonstrated Unyvero decreases the duration of inappropriate antibiotic therapy in hospitalized patients with pneumonia
- OpGen announced publication of results of Unyvero HPN Panel for detection of bacterial respiratory tract pathogens from serial specimens collected from hospitalized COVID-19 patients at Karolinska University Hospital (Sweden), confirming the ability of Unyvero in detecting potential pneumonia pathogens earlier than culture
- OpGen commenced a new At The Market (ATM) sales facility for up to approximately \$10.7 million, pursuant to which the Company may sell, from time to time, in an "at the market" offering shares of its common stock. While no shares were sold under this new ATM in H1 2022, in July and August to date the Company has sold approximately 1.7 million new shares of its common stock for gross proceeds of approximately \$1 million.
- OpGen requested an additional 180-day period from Nasdaq to regain compliance with the \$1.00 minimum bid price rule and expects their decision by the end of August.

In terms of fiscal 2022 guidance, OpGen expects:

- U.S. direct product sales of Unyvero and Acuitas are anticipated to contribute to growth
- Continuous increase in its European and international distribution business for Unyvero products
- Expand Ares Genetics strategic collaborations and partnerships and launch U.S. Next Generation Sequencing lab services in Q3 2022
- Overall, 2022 revenue growth of approximately 25% year over year from the products and services business globally

Conference Call Information

OpGen's management will host a conference call today, August 11th at 4:30 p.m. EDT, to go over the second quarter and first half of 2022 financial results and business activities, as well as answer analyst questions.

Dial-in Information

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=1556114&tp_key=e1546ec0f5

Conference ID: 13730742

Following the conclusion of the conference call, a replay will be available through August 25th, 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 Information

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

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

Replay PIN: 13730742

About OpGen, Inc. OpGen, Inc. (Rockville, MD, USA) 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 product portfolio includes Unyvero®, Acuitas® AMR Gene Panel and the ARES Technology Platform including ARESdb®, using NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction.

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

Forward-Looking Statements

This press release includes statements regarding the second quarter and first half 2022 financials of OpGen 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. and Subsidiaries
Condensed Consolidated Balance Sheets
(unaudited)

	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 16,586,577	\$ 36,080,392
Accounts receivable, net	738,148	1,172,396
Inventory, net	1,196,956	1,239,456
Prepaid expenses and other current assets	1,687,564	1,250,331
Total current assets	20,209,245	39,742,575
Property and equipment, net	3,209,311	4,011,748
Finance lease right-of-use assets, net	19,660	90,467
Operating lease right-of-use assets	1,582,325	1,814,396
Goodwill	6,884,915	7,453,007
Intangible assets, net	12,969,215	14,530,209
Strategic inventory	3,492,602	3,472,337
Other noncurrent assets	441,320	551,794
Total assets	\$ 48,808,593	\$ 71,666,533
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 731,845	\$ 1,307,081
Accrued compensation and benefits	1,575,299	1,621,788
Accrued liabilities	788,153	1,965,845
Current maturities of long-term debt	10,887,469	14,519,113
Short-term finance lease liabilities	16,731	43,150
Short-term operating lease liabilities	394,027	459,792
Total current liabilities	14,393,524	19,916,769
Long-term debt, net	4,024,413	7,176,251
Long-term finance lease liabilities	1,962	3,644
Long-term operating lease liabilities	2,721,233	2,977,402
Derivative liabilities	175,498	228,589
Other long-term liabilities	130,983	146,798
Total liabilities	21,447,613	30,449,453
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, \$0.01 par value; 100,000,000 shares authorized; 46,623,618 and 46,450,250 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	466,237	464,503
Additional paid-in capital	276,205,778	275,708,490
Accumulated deficit	(248,185,670)	(235,541,539)
Accumulated other comprehensive (loss) income	(1,125,365)	585,626
Total stockholders' equity	27,360,980	41,217,080
Total liabilities and stockholders' equity	\$ 48,808,593	\$ 71,666,533

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

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Revenue				
Product sales	\$ 889,271	\$ 307,804	\$ 1,255,323	\$ 835,383
Laboratory services	20,570	266,784	63,499	450,849
Collaboration revenue	57,364	237,027	118,128	355,099
Total revenue	967,205	811,615	1,436,950	1,641,331
Operating expenses				
Cost of products sold	646,389	342,580	938,386	896,634
Cost of services	15,650	137,934	46,212	242,918
Research and development	2,273,756	2,859,590	4,590,197	5,673,081
General and administrative	2,134,266	2,692,255	4,759,319	5,355,912
Sales and marketing	1,169,349	802,549	2,220,781	1,701,801
Impairment of right-of-use asset	—	115,218	—	170,714
Total operating expenses	6,239,410	6,950,126	12,554,895	14,041,060
Operating loss	(5,272,205)	(6,138,511)	(11,117,945)	(12,399,729)
Other (expense) income				
Gain on extinguishment of debt	—	259,353	—	259,353
Warrant inducement expense	—	—	—	(7,755,541)
Interest and other income	13,851	4,702	16,972	9,627
Interest expense	(779,912)	(1,198,169)	(2,049,493)	(2,363,151)
Foreign currency transaction gains (losses)	271,967	(915)	470,707	426,700
Change in fair value of derivative financial instruments	(74,116)	(13,021)	35,628	(114,411)
Total other expense	(568,210)	(948,050)	(1,526,186)	(9,537,423)
Loss before income taxes	(5,840,415)	(7,086,561)	(12,644,131)	(21,937,152)
Provision for income taxes	—	—	—	—
Net loss	\$ (5,840,415)	\$ (7,086,561)	\$ (12,644,131)	\$ (21,937,152)
Net loss available to common stockholders	\$ (5,840,415)	\$ (7,086,561)	\$ (12,644,131)	\$ (21,937,152)
Net loss per common share - basic and diluted	\$ (0.13)	\$ (0.19)	\$ (0.27)	\$ (0.65)
Weighted average shares outstanding - basic and diluted	46,574,512	38,268,293	46,529,718	33,900,964
Net loss	\$ (5,840,415)	\$ (7,086,561)	\$ (12,644,131)	\$ (21,937,152)
Other comprehensive income (loss) - foreign currency translation	(1,227,142)	529,651	(1,710,991)	(548,828)
Comprehensive loss	\$ (7,067,557)	\$ (6,556,910)	\$ (14,355,122)	\$ (22,485,980)