

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 11, 2021  
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 11, 2021, OpGen, Inc. (the “Company”) issued a press release announcing its third quarter financial results for the quarter ended September 30, 2021. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01 — Financial Statements and Exhibits.**

(d) Exhibits

99.1 [Press release dated November 11, 2021.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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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 12, 2021

**OpGen, Inc.**

By: /s/ Oliver Schacht PhD

Name: Oliver Schacht PhD

Title: Chief Executive Officer



## OpGen Reports Third Quarter 2021 Financial Results and Provides Business Update

- *Total Revenue for Q3 2021 was approximately \$1.2 million*
- *Cash as of September 30, 2021, was approximately \$25.4 million, up significantly from the \$13.4 million at year-end 2020*
- *Cash balance was further strengthened significantly by \$15 million financing completed in October*

*Conference call to be held at 4:30 p.m. Eastern Standard Time today*

ROCKVILLE, Md., November 11, 2021 (GLOBE NEWSWIRE) – OpGen, Inc. (Nasdaq: OPGN, “OpGen”), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, reported today its financial and operating results for the three and nine months ended September 30, 2021, and provided a business update. Total OpGen revenue for the third quarter of 2021 was approximately \$1.24 million, up 17% from \$1.06 million in the third quarter of 2020. Cash as of September 30, 2021, was approximately \$25.4 million, up significantly from the \$13.4 million at year-end 2020, and the Company’s cash balance was approximately \$40 million in October following the closing of a \$15 million registered direct financing.

Oliver Schacht, President & CEO of OpGen, commented, “We were able to reach major milestone developments in the third quarter, one of which is the FDA 510(k) clearance of our Acuitas AMR Gene Panel. This clearance has allowed us to begin commercializing the Acuitas AMR Gene Panel right away. During this quarter, we also launched AREScld, our first own software suite which allows us to further monetize the value of the ARESdb data asset. OpGen has made major progress this quarter, transforming from an R&D-driven company further into a commercial-stage enterprise, and we are on the right path to continued growth and future success.”

### Third Quarter 2021 Financial Results of OpGen, Inc.

- Total revenue for the third quarter of 2021 was approximately \$1.24 million, up 17% from \$1.06 million in the third quarter of 2020. This increase is primarily attributed to the stronger Unyvero sales that are beginning to counteract the loss of the FISH product line. Total revenue for the nine months ended September 30, 2021 was approximately \$2.9 million, which was in line with revenue for the nine months ended September 30, 2020. This seemingly unchanged revenue is primarily attributed to the discontinuation of the FISH product line and lower Ares R&D collaboration and New York State DOH project revenues, which were offset by significantly increased revenues from Unyvero sales, Curetis COVID testing, and Ares services.
  - Operating expenses for the third quarter of 2021 were approximately \$6.3 million compared with \$7.2 million in the third quarter of 2020. Operating expenses for the nine months ended September 30, 2021 were approximately \$20.4 million, as compared to \$19.6 million for the nine months ended September 30, 2020.
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- The net loss for the third quarter of 2021 was \$6.1 million, or \$0.16 per share, compared with \$7.7 million, or \$0.40 per share, in the third quarter of 2020. The net loss for the nine months ended September 30, 2021 was \$28.0 million, or \$0.79 per share, as compared with a net loss of \$19.1 million, or \$1.36 per share, for the nine months ended September 30, 2020. The increase in net loss is attributable to a \$7.8 million non-cash warrant inducement charge in 2021.
- Cash and cash equivalents were \$25.4 million as of September 30, 2021, compared to \$13.4 million as of December 31, 2020.
- All numbers pertaining to nine months ended September 30, 2020 only include two quarters of combined financials following the business combination between OpGen and Curetis on April 1, 2020.

The company announced accomplishment of the following key milestones and recent developments in the third quarter as well as 2021 to date:

- OpGen received FDA clearance for Acuitas® AMR Gene Panel, which allows testing for a comprehensive panel of 28 AMR markers in isolated bacterial colonies from 26 different pathogens. The panel expands clinicians' ability to diagnose and rapidly test for potential antibiotic resistance to select drugs in 9 classes of antibiotics. Immediately upon receiving the FDA clearance, OpGen began a major marketing and sales campaign across hundreds of institutions in the U.S.
  - Ares Genetics, an OpGen subsidiary, launched AREScloud, a commercial web application designed to expedite the analysis of sequenced clinical isolates. The software fully automates data processes and allows for comparative and outbreak analysis. Ares Genetics is actively engaged in discussion with clinical experts on the usage of AREScloud, in addition to collaborating with two prominent U.S. hospitals on independent studies to assess the platform for clinical routine use and outbreak analysis.
  - OpGen recently announced the appointment of Albert Weber as its Chief Financial Officer, effective January 1, 2022. Mr. Weber joins OpGen from U.S.-German molecular diagnostics company Epigenomics, where he was most recently Epigenomics' Executive Officer, Executive Board member, and EVP Finance. In addition to more than 20 years of running the finance, accounting and controlling functions in a Frankfurt Stock Exchange-listed molecular diagnostics company, Mr. Weber brings a variety of experience in closing commercial agreements, such as R&D collaborations, licensing, distribution, and manufacturing deals, with international partners as well as strategic M&A processes.
  - OpGen announced data from a large investigator-initiated and driven prospective controlled multicenter study using the Unyvero HPN Panel for hospitalized patients with suspicion of pneumonia. The study found that the Unyvero HPN Panel not only significantly reduced inappropriate antibiotic therapy by 45.1%, but it also reduced the overall antibiotic therapy duration by 22.5%.
  - OpGen initiated a clinical trial for its Unyvero Urinary Tract Infection (UTI) Panel. The trial is expected to enroll more than 1,500 prospective patient samples and will be conducted at multiple sites in the U.S. The data from this study will be used to support the ensuing submission to the FDA for OpGen to seek clearance in the U.S.
  - OpGen announced and closed a \$15 million registered direct offering with a single healthcare-focused institutional investor for the issuance and sale of an aggregate of 150,000 shares of convertible preferred stock and warrants to purchase up to an aggregate of 7,500,000 shares of common stock.
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Mr. Schacht commented, "As we continue to progress into the fourth quarter and the remainder of 2021, we are very excited about the future of OpGen. Albert Weber joins OpGen at a great time and will bring transatlantic CFO experience and a long-standing track record in the molecular diagnostics industry. I have been fortunate enough to have known Albert for the past two decades and know the wealth of experience he brings to the team here at OpGen. We enter the fourth quarter in a strong position from the direct offering of \$15 million. We plan to use the proceeds to continue our commercial launch of Acuitas AMR, further growing the Unyvero business in the U.S. and abroad and to fund future clinical trials, as well as potential repayment of debt obligations to EIB as we evaluate potential options to restructure and maybe convert into equity that debt. We look forward to the continued growth and corporate development of OpGen."

### **Conference Call Information**

OpGen's management will host a conference call today, November 11<sup>th</sup> at 4:30 p.m. EST to discuss the third quarter financial results and other business activities, as well as answer questions. Dial-in information is below:

#### **Dial-in Information**

U.S. Dial-in Number: +1-877-705-6003

International Dial-in Number: +1-201-493-6725

Webcast: <http://public.viavid.com/index.php?id=146838>

Conference ID: 13723808

Following the conclusion of the conference call, a replay will be available through November 25, 2021. 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 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: 13723808

### **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 Acuitas® Lighthouse, 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](http://www.opgen.com).

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## Forward-Looking Statements

This press release includes statements regarding OpGen's third quarter 2021 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, 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 our financings, our ability to obtain stockholder approval for an increase in the company's authorized shares of common stock or otherwise pursue alternative means for continued financing, the realization of expected benefits of our business combination transaction with Curetis GmbH, the success of our commercialization efforts, the impact of COVID-19 on the Company's operations, financial results, and commercialization efforts as well as on capital markets and general economic conditions, 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.

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 25,352,337	\$ 13,360,463
Accounts receivable, net	751,065	653,104
Inventory, net	1,356,912	1,485,986
Prepaid expenses and other current assets	2,319,939	1,388,090
<b>Total current assets</b>	<b>29,780,253</b>	<b>16,887,643</b>
Property and equipment, net	4,290,204	3,259,487
Finance lease right-of-use assets, net	141,387	449,628
Operating lease right-of-use assets	1,885,025	2,082,300
Goodwill	7,606,071	8,024,729
Intangible assets, net	15,050,387	16,580,963
Strategic inventory	2,974,992	1,686,342
Other noncurrent assets	560,599	779,953
<b>Total assets</b>	<b>\$ 62,288,918</b>	<b>\$ 49,751,045</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 1,146,895	\$ 1,868,666
Accrued compensation and benefits	1,342,013	2,126,511
Accrued liabilities	1,329,983	1,437,141
Deferred revenue	—	9,808
Current maturities of long-term debt	14,668,424	699,000
Short-term finance lease liabilities	68,831	266,470
Short-term operating lease liabilities	610,336	964,434
<b>Total current liabilities</b>	<b>19,166,482</b>	<b>7,372,030</b>
Long-term debt, net	6,484,300	19,378,935
Derivative liabilities	225,395	112,852
Long-term finance lease liabilities	7,869	46,794
Long-term operating lease liabilities	2,953,615	1,492,544
Other long term liabilities	152,405	156,635
<b>Total liabilities</b>	<b>28,990,066</b>	<b>28,559,790</b>
<b>Stockholders' equity</b>		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.01 par value; 50,000,000 shares authorized; 38,270,250 and 25,085,534 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	382,703	250,855
Additional paid-in capital	260,244,997	219,129,045
Accumulated deficit	(228,729,675)	(200,735,827)
Accumulated other comprehensive income	1,400,827	2,547,182
<b>Total stockholders' equity</b>	<b>33,298,852</b>	<b>21,191,255</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 62,288,918</b>	<b>\$ 49,751,045</b>



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Revenue</b>				
Product sales	\$ 643,887	\$ 601,562	\$ 1,479,270	\$ 1,569,799
Laboratory services	192,753	112,892	643,602	138,884
Collaboration revenue	402,492	342,311	757,591	1,153,400
<b>Total revenue</b>	<b>1,239,132</b>	<b>1,056,765</b>	<b>2,880,463</b>	<b>2,862,083</b>
<b>Operating expenses</b>				
Cost of products sold	648,298	1,350,296	1,544,932	2,340,766
Cost of services	203,314	159,794	446,232	550,115
Research and development	2,382,303	2,433,553	8,055,384	6,630,134
General and administrative	2,088,226	2,356,413	7,444,138	6,549,432
Sales and marketing	1,003,577	932,671	2,705,378	2,258,980
Transaction costs	—	—	—	470,322
Impairment of intangibles assets	—	—	—	750,596
Impairment of right-of-use asset	—	—	170,714	—
<b>Total operating expenses</b>	<b>6,325,718</b>	<b>7,232,727</b>	<b>20,366,778</b>	<b>19,550,345</b>
<b>Operating loss</b>	<b>(5,086,586)</b>	<b>(6,175,962)</b>	<b>(17,486,315)</b>	<b>(16,688,262)</b>
<b>Other (expense) income</b>				
Gain on extinguishment of debt	—	—	259,353	—
Warrant inducement expense	—	—	(7,755,541)	—
Interest and other income, net	31,844	19,965	41,471	101,644
Interest expense	(1,222,867)	(1,183,927)	(3,586,018)	(2,267,085)
Foreign currency transaction gains/(losses)	229,074	(501,168)	655,774	(794,832)
Change in fair value of derivative financial instruments	(8,161)	165,497	(122,572)	548,008
<b>Total other expense</b>	<b>(970,110)</b>	<b>(1,499,633)</b>	<b>(10,507,533)</b>	<b>(2,412,265)</b>
<b>Loss before income taxes</b>	<b>(6,056,696)#</b>	<b>(7,675,595)</b>	<b>(27,993,848)</b>	<b>(19,100,527)</b>
<b>Provision for income taxes</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Net loss</b>	<b>\$ (6,056,696)</b>	<b>\$ (7,675,595)</b>	<b>\$ (27,993,848)</b>	<b>\$ (19,100,527)</b>
<b>Net loss available to common stockholders</b>	<b>\$ (6,056,696)</b>	<b>\$ (7,675,595)</b>	<b>\$ (27,993,848)</b>	<b>\$ (19,100,527)</b>
Net loss per common share - basic and diluted	<b>\$ (0.16)</b>	<b>\$ (0.40)</b>	<b>\$ (0.79)</b>	<b>\$ (1.36)</b>
Weighted average shares outstanding - basic and diluted	38,270,250	19,116,864	35,373,397	14,016,896
Net loss	\$ (6,056,696)	\$ (7,675,595)	\$ (27,993,848)	\$ (19,100,527)
Other comprehensive (loss)/income - foreign currency translation	(597,527)	1,266,901	(1,146,355)	1,631,317
<b>Comprehensive loss</b>	<b>\$ (6,654,223)</b>	<b>\$ (6,408,694)</b>	<b>\$ (29,140,203)</b>	<b>\$ (17,469,210)</b>

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