

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

March 25, 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)

708 Quince Orchard Road, Suite 220  
Gaithersburg, MD 20878  
(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 March 25, 2021, the Company issued a press release announcing its fourth quarter and full year financial results for the year ended December 31, 2020. 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 March 25, 2021.](#)

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: March 25, 2021

**OpGen, Inc.**

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer



## OpGen Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

- Total combined pro-forma revenue for 2020 was approximately \$5.2 million
- Maintained strong balance sheet with \$13.4 million cash as of December 31, 2020
- Raised an additional \$34.7 million of capital in the first quarter of 2021

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

GAITHERSBURG, Md., March 25, 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 financial and operating results for the three and twelve months ended December 31, 2020 and provided a business update. Total pro-forma combined revenue for OpGen in 2020 was approximately \$5.2 million, compared to approximately \$6.1 million in 2019. Fourth quarter 2020 revenue for OpGen was approximately \$1.4 million compared to approximately \$0.8 million in the fourth quarter of 2019. OpGen’s cash position as of December 31, 2020 was approximately \$13.4 million. During the first quarter of 2021 to date, OpGen successfully raised an additional \$34.7 million of capital from equity financings.

Mr. Schacht, OpGen's Chief Executive Officer, commented, "We are pleased with our execution throughout the year and ended 2020 on a strong note with a solid quarter and strong cash position following our recent capital raises. We made substantial progress across our key products and showed investors that our diversified product portfolio has the potential to support an attractive combination of revenue and partnership growth driven by recent awards and publications. The strength of our core business and the anticipated FDA clearance decision for the Acuitas AMR Gene Panel for Isolates gives us confidence in our ability to maintain momentum throughout 2021. This will support our vision to be the global leaders in molecular microbiology focusing on AMR diagnostics and bioinformatics."

### **Fourth Quarter and Full Year 2020 Audited Financial Results of OpGen, Inc.**

Results in 2020 reflect the consummation of the company's business combination with Curetis GmbH on April 1, 2020. Figures for 2019 are for the OpGen on a stand-alone basis only.

- Total revenue for the fourth quarter of 2020 was approximately \$1.4 million, compared with approximately \$0.8 million in the fourth quarter of 2019. Total revenue for the twelve months ended December 31, 2020 was \$4.2 million, compared to \$3.5 million for the twelve months ended December 31, 2019. Total proforma revenue, i.e. revenue shown as if the businesses had been combined for the respective full years, for the twelve months ended December 31, 2020 was approximately \$5.2 million, compared to approximately \$6.1 million for the twelve months ended December 31, 2019.
  - Operating expenses for the fourth quarter of 2020 were \$7.4 million, compared with \$3.3 million in the fourth quarter of 2019. Total operating expenses for the twelve months ended December 31, 2020 were \$26.9 million, compared to \$15.8 million for the twelve months ended December 31, 2019.
  - The net loss for the fourth quarter of 2020 was \$7.1 million, or \$0.34 per share, compared with \$2.5 million, or \$0.61 per share, in the fourth quarter of 2019. The net loss for the twelve months ended December 31, 2020 was \$26.2 million, or \$1.66 per share, compared to \$12.4 million, or \$7.70 per share, for the twelve months ended December 31, 2019.
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The company also announced the completion of the following key milestones and recent developments in the fourth quarter and full year 2020 as well as 2021 to date, all of which it achieved despite the challenges posed by the global COVID-19 pandemic:

- OpGen completed, with one healthcare focused U.S. institutional investor, the following gross capital raises:
    - o \$10 million private placement priced at the market in November 2020
    - o \$25 million registered direct offering in February 2021 priced at the market
    - o \$ 9.7 million warrant exercise and exchange in March 2021
  - OpGen announced the publication of the final study results of the Unyvero HPN Panel for diagnosis of bacterial co-infections in ICU patients with COVID-19 pneumonia demonstrating that the panel would enable crucially important rapid diagnosis of pathogens of concern in these patients, as well as a high negative predictive value of 99.8% for pathogen detection.
  - OpGen announced the release of two new peer-reviewed publications, the first demonstrating that the Unyvero LRT BAL panel accurately detects 19 bacteria alongside *Pneumocystis jirovecii* and 10 antibiotic resistance genes directly from bronchoalveolar lavage fluid, allowing enhanced diagnosis of lower respiratory tract infections, and the second publication highlighting Ares Genetics in best practice techniques for AI-powered prediction of antibiotic susceptibility testing by next-generation sequencing.
  - The Chinese regulatory authority NMPA approved the Curetis Unyvero instrument system as IVD for Chinese market with the application of Unyvero cartridge for pneumonia currently under review and pending NMPA approval.
  - OpGen subsidiary Curetis entered into an exclusive distribution partnership in Colombia with Annar Health Technologies for Curetis' Unyvero A50 platform.
  - Curetis, obtained CE mark certification in the European Union for its own SARS-CoV-2 Kit with PULB for the detection of SARS-CoV-2, the virus that causes COVID-19. These kits were sold to some of Curetis' European distributors as well as used by Curetis for the SARS-CoV-2 testing service offered to regional German customers.
  - OpGen's subsidiary, Ares Genetics GmbH, completed the transition of leadership to Dr. Arne Materna, who was appointed as Managing Director and CEO of Ares Genetics effective January 1, 2021. Ares Genetics extended its collaboration with Sandoz within its pharma partnering program and added another project with Sandoz in 2021 to assess the potential of molecular surveillance for better informed therapeutic guidance and antibiotic stewardship.
  - Ares Genetics presented advances of its research use only (RUO) based ares-genetics.cloud platform for predictive antibiotic susceptibility testing (pAST) at various scientific conferences.
  - Ares Genetics was granted a key patent on antimicrobial resistance prediction from genomic data, supporting the company's vision to improve guidance for antimicrobial therapy through AI-powered prediction of AMR and the discovery of diagnostic biomarkers.
  - Ares Genetics joined the JPIAMR Network for Integrating Microbial Sequencing and Platforms for Antimicrobial Resistance (Seq4AMR). The network will provide guidelines and solutions to microbial sequencing for the detection, surveillance and management of difficult-to-treat infections caused by AMR microorganisms.
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- After a three-month delay in FDA review of the Acuitas AMR Gene Panel 510(k) submission due to the FDA's prioritization of COVID-19 and influenza related EUAs, OpGen has received confirmation that the FDA has resumed its review of the submission. Currently, OpGen is actively engaged in receiving and responding to feedback from the FDA to facilitate a final clearance decision for the Acuitas AMR Gene Panel as soon as practicable.
- OpGen plans to exit its FISH business by the end of the first quarter of 2021 and in the fall of 2020 ended the Acuitas AMR Gene Panel urine trial in favor of two new upcoming U.S. clinical trials towards a future FDA submission for the Unyvero UTI (complicated urinary tract infections) and IJI (invasive joint infections) applications, respectively.
- The 90-day exclusive negotiation period that Ares Genetics had agreed to with a global leading IVD corporation partner towards a potential collaboration and licensing deal recently expired. Ares Genetics has since engaged in and continues to have multiple parallel, non-exclusive partnering and licensing discussions with potential corporate partners.

Mr. Schacht continued: "Despite the unprecedented and industry wide delays in FDA review of non COVID-19 related submissions, we are confident in our anticipation of a clearance decision as soon as practicable for the FDA's staff for the Acuitas AMR Gene Panel with the FDA actively engaged in the review of the submission. Our Unyvero business remains our core focus for the near-term. Following the most recent capital raises, OpGen maintains a strong cash position of almost \$40 million, despite the ongoing challenges presented to the business. The Company continues to see strong growth potential across our portfolio and additional partnership opportunities that further demonstrate the strength of our model."

### **Conference Call Information**

OpGen's management will host a conference call today, March 25 at 4:30 p.m. ET to discuss the fourth quarter and full year 2020 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=143832>

Conference ID: 13717232

Following the conclusion of the conference call, a replay will be available through April 8, 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 under *Financials & Filings*. 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: 13717232

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## About OpGen, Inc.

OpGen, Inc. (Gaithersburg, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with 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).

## Forward-Looking Statements

This press release includes statements regarding OpGen's fourth quarter and full year 2020 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 recent financings, including our November 2020 private placement, February 2021 Registered Direct and March 2021 warrant exercise and exchange, 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>December 31, 2020</u>	<u>December 31, 2019</u>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 13,360,463	\$ 2,708,223
Accounts receivable, net	653,104	567,811
Inventory, net	1,485,986	473,030
Note receivable	—	2,521,479
Prepaid expenses and other current assets	1,388,090	396,760
<b>Total current assets</b>	<b>16,887,643</b>	<b>6,667,303</b>
Property and equipment, net	3,259,487	130,759
Finance lease right-of-use assets, net	449,628	958,590
Operating lease right-of-use assets	2,082,300	1,043,537
Goodwill	8,024,729	600,814
Intangible assets, net	16,580,963	817,550
Strategic Inventory	1,686,342	—
Other noncurrent assets	779,953	203,271
<b>Total assets</b>	<b>\$ 49,751,045</b>	<b>\$ 10,421,824</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 1,868,666	\$ 1,056,035
Accrued compensation and benefits	2,126,511	855,994
Accrued liabilities	1,437,141	1,046,661
Deferred revenue	9,808	9,808
Short-term notes payable	699,000	373,599
Short-term finance lease liabilities	266,470	579,030
Short-term operating lease liabilities	964,434	1,017,414
<b>Total current liabilities</b>	<b>7,372,030</b>	<b>4,938,541</b>
Note payable	19,378,935	329,456
Derivative liabilities	112,852	—
Long-term finance lease liabilities	46,794	313,263
Long-term operating lease liabilities	1,492,544	547,225
Other long term liabilities	156,635	—
<b>Total liabilities</b>	<b>28,559,790</b>	<b>6,128,485</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2020 and 2019, respectively	—	—
Common stock, \$0.01 par value; 50,000,000 shares authorized; 25,085,534 and 5,582,280 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	250,855	55,823
Additional paid-in capital	219,129,045	178,779,814
Accumulated deficit	(200,735,827)	(174,524,983)
Accumulated other comprehensive income/(loss)	2,547,182	(17,315)
<b>Total stockholders' equity</b>	<b>21,191,255</b>	<b>4,293,339</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 49,751,045</b>	<b>\$ 10,421,824</b>



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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
<b>Revenue</b>				
Product sales	\$ 1,134,566	\$ 570,674	\$ 2,704,364	\$ 2,168,179
Laboratory services	28,852	—	167,736	\$ 5,435
Collaboration revenue	188,941	250,000	1,342,341	1,325,000
<b>Total revenue</b>	<b>1,352,359</b>	<b>820,674</b>	<b>4,214,441</b>	<b>3,498,614</b>
<b>Operating expenses</b>				
Cost of products sold	1,019,514	229,997	3,360,280	911,565
Cost of services	(61,904)	127,509	488,211	720,156
Research and development	3,334,581	1,051,833	9,964,720	5,121,168
General and administrative	2,252,233	1,351,306	8,801,661	6,252,442
Sales and marketing	835,112	321,966	3,094,092	1,464,721
Transaction costs	1,200	240,987	471,522	779,048
Impairment of intangible assets	—	—	750,596	—
Impairment of right-of-use asset	101,838	—	101,838	520,759
Gain on sale of equipment	(100,000)	—	(100,000)	—
<b>Total operating expenses</b>	<b>7,382,574</b>	<b>3,323,598</b>	<b>26,932,920</b>	<b>15,769,859</b>
<b>Operating loss</b>	<b>(6,030,215)</b>	<b>(2,502,924)</b>	<b>(22,718,479)</b>	<b>(12,271,245)</b>
<b>Other expense</b>				
Gain on extinguishment of debt	884,970	—	884,970	—
Interest and other income, net	3,982	18,071	105,627	9,859
Interest expense	(1,132,299)	(44,877)	(3,399,384)	(187,549)
Foreign currency transaction (losses)/gains	(674,023)	11,836	(1,468,855)	2,410
Change in fair value of derivative financial instruments	(30,328)	—	517,680	67
<b>Total other expense</b>	<b>(947,698)</b>	<b>(14,970)</b>	<b>(3,359,962)</b>	<b>(175,213)</b>
<b>Loss before income taxes</b>	<b>(6,977,913)</b>	<b>(2,517,894)</b>	<b>(26,078,441)</b>	<b>(12,446,458)</b>
<b>Provision for income taxes</b>	132,403	—	132,403	—
<b>Net loss</b>	<b>\$ (7,110,316)</b>	<b>\$ (2,517,894)</b>	<b>\$ (26,210,844)</b>	<b>\$ (12,446,458)</b>
Net loss per common share - basic and diluted	<b>\$ (0.34)</b>	<b>\$ (0.61)</b>	<b>\$ (1.66)</b>	<b>\$ (7.70)</b>
Weighted average shares outstanding - basic and diluted	21,056,199	4,151,840	15,800,781	1,616,939
Net loss	\$ (7,110,316)	\$ (2,517,894)	\$ (26,210,844)	\$ (12,446,458)
Other comprehensive income/(loss) - foreign currency translation	933,180	(9,396)	2,564,497	(4,222)
<b>Comprehensive loss</b>	<b>\$ (6,177,136)</b>	<b>\$ (2,527,290)</b>	<b>\$ (23,646,347)</b>	<b>\$ (12,450,680)</b>