

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 29, 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 March 29, 2022, OpGen, Inc. issued a press release announcing its fourth quarter and full year financial results for the year ended December 31, 2021. 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 March 29, 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: March 29, 2022

OpGen, Inc.

By: /s/ Oliver Schacht

Name: Oliver Schacht

Title: Chief Executive Officer



OpGen Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

- Total revenue for 2021 was approximately \$4.3 million
- Strong total cash position of approximately \$36.1 million as of December 31, 2021, up significantly from \$13.4 million at year-end 2020
- Conference call to be held March 29, 2022 at 4:30 p.m. EDT

ROCKVILLE, Md., March 29th, 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 today its fourth quarter 2021 and full-year 2021 financial and operating results and provided a business update.

OpGen’s revenue for the fourth quarter of 2021 was approximately \$1.43 million, a 5% increase from \$1.35 million in Q4 2020. Its total revenue for 2021 was approximately \$4.3 million, up 2% from \$4.2 million in 2020.

“We are pleased with our fourth quarter and full-year 2021 financial picture as we look forward to our 2022 commercialization initiatives,” said Oliver Schacht, President & CEO of OpGen. “The Company’s positive 2022 outlook is based on OpGen’s improved cash position, existing network of partnerships, and recent collaborations.”

“We are continuing to execute on our key development milestones, as recently seen with the successful completion of final verification and validation, as well as lifetime testing of the Unyvero A30 RQ platform,” Mr. Schacht continued. “I am pleased with our accomplishments and continue to believe we are putting our Company in a position to succeed.”

Fourth Quarter and Full-Year 2021 Financial Results of OpGen, Inc.

- Total revenue for the fourth quarter of 2021 was approximately \$1.43 million, compared with \$1.35 million in the fourth quarter of 2020. Total revenue for the twelve months ended December 31, 2021 was approximately \$4.3 million, compared to \$4.2 million for the twelve months ended December 31, 2020.
- Operating expenses for the fourth quarter of 2021 were approximately \$7.3 million, compared with \$7.4 million in the fourth quarter of 2020. Total operating expenses for the twelve months ended December 31, 2021 were approximately \$27.6 million, compared to \$26.9 million for the twelve months ended December 31, 2020.
- The net loss available to common stockholders for the fourth quarter of 2021 was approximately \$14.1 million, or \$0.35 per share, compared with \$7.1 million, or \$0.34 per share, in the fourth quarter of 2020. The net loss available to common stockholders for the twelve months ended December 31, 2021, was approximately \$42.0 million, or \$1.14 per share, compared to \$26.2 million, or \$1.66 per share, for the twelve months ended December 31, 2020. The net loss available to common stockholders for the twelve months ended December 31, 2021, included non-cash charges of approximately \$7.8 million and \$7.2 million related to the Company’s 2021 warrant inducement and 2021 preferred stock offering, respectively.
- Cash and cash equivalents were approximately \$36.1 million as of December 31, 2021, compared with \$13.4 million as of December 31, 2020.

In reporting OpGen’s Q4 2021 and full-year financials, Albert Weber, OpGen’s Chief Financial Officer (CFO), said, “As we have entered 2022, we see ourselves in a much better position than a year ago.” Mr. Weber joined OpGen in January 2022. “With existing products picking up sales and with the upcoming product commercialization pipeline, OpGen anticipates revenue growth to be significantly stronger in 2022 than the previous year and expects a steady improvement in gross margins over time. We expect our R&D, G&A and sales and marketing spend will be mostly on par with last year. We have a solid cash position to execute on our business plan.”

“OpGen’s revenue growth is primarily attributed to the strong uptake in Unyvero sales in the U.S. and globally,” said Mr. Weber. “OpGen’s top line was further supported by significant increases in laboratory services, mainly due to COVID testing services performed by OpGen’s subsidiaries Curetis and Ares Genetics’ NGS-based services. Collaboration revenue declined mainly due to conclusion of a non-recurring R&D collaboration project at Ares Genetics and the New York State Department of Health project; however, it was more than offset by higher lab service revenue.”

Mr. Weber reported that OpGen continues to explore restructuring options for the repayment of amounts due under its loan with the European Investment Bank, including through the payment of cash, possible amortization over time, issuance of equity over a period of up to 24 months or a combination of both. The Company is in discussion with the EIB as well as several other parties relating to such repayment options. The first tranche under the loan of approximately \$15 million matures and is due in late April 2022 followed by maturity dates in June 2023 and June 2024 of approximately \$4.4 million and \$7.4 million, respectively. Such options would allow the Company to preserve cash and help avoid conversion of the debt to equity at this time when there are unfavorable market conditions. The Company believes that such changes will also provide greater flexibility and potentially help minimize dilution.

The Company announced reaching the following key milestones, as well as recent developments in the fourth quarter and into 2022 to date:

- OpGen made two strategic hires as of January 1, 2022: Albert Weber joined OpGen as CFO and Managing Director of OpGen’s subsidiary Curetis GmbH, and Theo deVos joined as Senior Vice President of Corporate Development and Operations for Ares Genetics in the U.S.
- OpGen received FDA clearance for Acuitas AMR Gene Panel. Several commercial multi-year contracts have been submitted to hospitals and labs across the U.S. These remain subject to final negotiation. OpGen expects its first commercial sales of the Acuitas AMR Gene Panel in the upcoming quarter(s) of 2022.
- Enrollment for the Unyvero Urinary Tract Infection (UTI) Panel trial is progressing and the Company expects completing an interim data analysis and anticipates to communicate a relevant update early in the second quarter.
- OpGen closed a \$15 million registered direct preferred stock offering with a single, U.S.-based, healthcare-focused institutional investor in October 2021. The investor subsequently converted all of its 150,000 shares of preferred stock into 7.5 million shares of common stock in December 2021, which resulted in total shares outstanding, as of December 31, 2021, of approximately 46.5 million shares of common stock with no preferred stock remaining outstanding.
- OpGen held a Special Meeting of Stockholders in December 2021, where both of its proposals were approved. The first proposal was to reduce the stockholder approval requirement to changes in the Charter to a majority of the outstanding shares entitled to vote. The second proposal was an amendment to the Charter to increase the authorized number of shares of common stock from 50 million to 100 million.
- The Ares database access deal in the fourth quarter 2021 contributed significantly to product revenue for the non-exclusive access to 1.1% of the ARESdb content to a leading global microbiology and In Vitro Diagnostics (IVD) corporation.
- Ares Genetics successfully completed the first part of a collaboration with a leading U.S. clinical research organization (CRO) and reference lab and has entered the next phase. During this next phase, Ares Genetics will gain access to up to 1,000 carefully selected proprietary genome and antibiotic susceptibility testing (AST) datasets. Ares Genetics aims to further increase the value of ARESdb and grow its contents in the future through strategic collaborations and clinical trials conducted by OpGen.
- OpGen completed successful verification and validation (V&V) testing, as well as lifetime testing, of its Unyvero A30RQ instruments.

In outlining OpGen’s 2022 initiatives, Mr. Schacht said, “We look forward to achieving upcoming key milestones in the development and commercialization of our innovative diagnostic test portfolio.” “OpGen’s recent 510(k) approval for its Acuitas AMR Gene Panel, the commercial launch of the AREScloud web application, and Ares Genetics’ strategic non-exclusive database access transaction, have already set the tone for 2022,” Mr. Schacht said. “OpGen is expecting to report results of its Chinese clinical study once completed and pending clearance decision by the China’s National Medical Products Administration (NMPA), its Unyvero UTI clinical trial and anticipated FDA submission, the Unyvero A30 platform development and partnering activities, and Ares Genetics’ commercial expansion in Europe and the U.S.”

In terms of guidance for 2022, OpGen expects to:

- grow its U.S. direct product sales of Unyvero and Acuitas by 50% or greater;
- continue to grow its European and international distribution business for Unyvero products albeit at more moderate growth rates;
- gain significant traction and acceleration in Ares Genetics related services and software solutions business;
- achieve overall revenue growth from the products and services business for 2022 in a range of approximately around 25% to 50% year over year; and
- have significant upside potential from revenue recognition under any potential future strategic partnering or licensing deal for the Unyvero A30 platform or the Ares database assets.

Conference Call Information

OpGen's management will host a conference call today, March 29th at 4:30 p.m. EDT, to discuss the fourth quarter and full-year 2021 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: https://viaavid.webcasts.com/starthere.jsp?ei=1525984&tp_key=2d6460e1c0

Conference ID: 13726634

Following the conclusion of the conference call, a replay will be available through April 12, 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: 13726634

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.

Forward-Looking Statements

This press release includes statements regarding the fourth quarter 2021 and full year 2021 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, 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>December 31, 2021</u>	<u>December 31, 2020</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 36,080,392	\$ 13,360,463
Accounts receivable, net	1,172,396	653,104
Inventory, net	1,239,456	1,485,986
Prepaid expenses and other current assets	1,250,331	1,388,090
Total current assets	39,742,575	16,887,643
Property and equipment, net	4,011,748	3,259,487
Finance lease right-of-use assets, net	90,467	449,628
Operating lease right-of-use assets	1,814,396	2,082,300
Goodwill	7,453,007	8,024,729
Intangible assets, net	14,530,209	16,580,963
Strategic inventory	3,472,337	1,686,342
Other noncurrent assets	551,794	779,953
Total assets	\$ 71,666,533	\$ 49,751,045
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,307,081	\$ 1,868,666
Accrued compensation and benefits	1,621,788	2,126,511
Accrued liabilities	1,965,845	1,437,141
Deferred revenue	—	9,808
Short-term notes payable	14,519,113	699,000
Short-term finance lease liabilities	43,150	266,470
Short-term operating lease liabilities	459,792	964,434
Total current liabilities	19,916,769	7,372,030
Note payable	7,176,251	19,378,935
Derivative liabilities	228,589	112,852
Long-term finance lease liabilities	3,644	46,794
Long-term operating lease liabilities	2,977,402	1,492,544
Other long term liabilities	146,798	156,635
Total liabilities	30,449,453	28,559,790
Stockholders' equity		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2021 and 2020, respectively	—	—
Common stock, \$0.01 par value; 100,000,000 shares authorized; 46,450,250 and 25,085,534 shares issued and outstanding at December 31, 2021 and 2020, respectively	464,503	250,855
Additional paid-in capital	275,708,490	219,129,045
Accumulated deficit	(235,541,539)	(200,735,827)
Accumulated other comprehensive income	585,626	2,547,182
Total stockholders' equity	41,217,080	21,191,255
Total liabilities and stockholders' equity	\$ 71,666,533	\$ 49,751,045

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenue				
Product sales	\$ 1,177,399	\$ 1,134,565	\$ 2,656,669	\$ 2,704,364
Laboratory services	169,608	28,852	813,210	167,736
Collaboration revenue	78,561	188,941	836,152	1,342,341
Total revenue	1,425,568	1,352,358	4,306,031	4,214,441
Operating expenses				
Cost of products sold	750,896	1,019,514	2,295,828	3,360,280
Cost of services	106,388	(61,904)	552,620	488,211
Research and development, net	2,855,295	3,334,586	10,910,679	9,964,720
General and administrative	2,624,227	2,252,229	9,935,963	8,801,661
Sales and marketing	1,007,885	835,112	3,713,263	3,094,092
Transaction costs	—	1,200	—	471,522
Impairment of right-of-use asset	—	101,838	170,714	101,838
Impairment of intangibles assets	—	—	—	750,596
Gain on sale of equipment	—	(100,000)	—	(100,000)
Total operating expenses	7,344,691	7,382,575	27,579,067	26,932,920
Operating loss	(5,919,123)	(6,030,217)	(23,273,036)	(22,718,479)
Other expense				
Gain on extinguishment of debt	—	884,970	259,353	884,970
Warrant inducement expense	—	—	(7,755,541)	—
Interest and other income, net	3,708	3,983	45,179	105,627
Interest expense	(1,213,313)	(1,132,299)	(4,799,331)	(3,399,384)
Foreign currency transaction gains/(losses)	235,449	(674,023)	891,223	(1,468,855)
Change in fair value of derivative financial instruments	31,322	(30,328)	(129,731)	517,680
Total other expense	(942,834)	(947,697)	(11,488,848)	(3,359,962)
Loss before income taxes	(6,861,957)#	(6,977,914)	(34,761,884)	(26,078,441)
Provision for income taxes	43,828	132,403	43,828	132,403
Net loss	\$ (6,905,785)	\$ (7,110,317)	\$ (34,805,712)	\$ (26,210,844)
Deemed dividend on beneficial conversion feature	(7,166,752)	—	(7,166,752)	—
Net loss available to common stockholders	\$ (14,072,537)	\$ (7,110,317)	\$ (41,972,464)	\$ (26,210,844)
Basic and diluted net loss per share attributable to common stockholders	\$ (0.35)	\$ (0.34)	\$ (1.14)	\$ (1.66)
Weighted average shares outstanding - basic and diluted	40,444,815	21,056,199	36,674,083	15,800,781
Net loss	\$ (6,905,785)	\$ (7,110,317)	\$ (34,805,712)	\$ (26,210,844)
Other comprehensive (loss) income - foreign currency translation	(815,201)	933,180	(1,961,556)	2,564,497
Comprehensive loss	\$ (7,720,986)	\$ (6,177,137)	\$ (36,767,268)	\$ (23,646,347)