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

May 13, 2021
Date of Report (date of earliest event reported)

OpGen, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	**001-37367**	**06-1614015**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(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)

708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878
(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 May 13, 2021, OpGen, Inc. (the "Company") issued a press release announcing its first quarter financial results for the quarter ended March 31, 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 May 13, 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.

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: May 13, 2021

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer

OpGen Reports First Quarter 2021 Financial Results and Provides Business Update

- *Total Revenue for Q1 2021 was approximately $0.8 million*
- *Balance sheet strengthened significantly with an additional $34.7 million cash raised in Q1 2021*

Conference call to be held at 8:30 a.m. Eastern Time today

GAITHERSBURG, Md., May 13, 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 months ended March 31, 2021 and provided a business update. Total OpGen revenue for the first quarter of 2021 was approximately $830,000, up 34.5% from $617,000 in the first quarter of 2020. Cash as of March 31, 2021 was approximately $39.4 million, up significantly from the $13.4 million at year-end 2020.

Oliver Schacht, President & CEO of OpGen, commented, "We are pleased with our first quarter results and are encouraged by the growth of our products and partnerships over the last several months. This excitement encompasses the recently announced extension and expansion of our strategic collaboration with the New York State and includes winning Chinese NMPA approval for the Curetis Unyvero instrument system as we await a clearance decision for the pneumonia cartridge in China, which is currently under review and pending approval. As the pandemic's effect on the global economy subsides, we believe our balanced product portfolio and long-term pipeline growth initiatives give us the ability to maintain momentum throughout 2021 and support our vision to be amongst the global leaders in infectious disease diagnostics."

First Quarter 2021 Financial Results of OpGen, Inc.

- Total revenue for the first quarter of 2021 was approximately $830,000 up 34.5% from $617,000 in the first quarter of 2020. This can be attributed to the business combination with Curetis which closed at the beginning of the second quarter of 2020.
- Operating expenses for the first quarter of 2021 were $7.1 compared with $4.6 million in the first quarter of 2020.
- The net loss for the first quarter of 2021 was $14.9 or $0.50 per share, compared with $3.9 million or $0.53 per share in the first quarter of 2020.
- Cash and cash equivalents were $39.4 million as of March 31, 2021 compared to $13.4 million as of December 31, 2020.

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

- Following the previously announced resumption of the FDA's review of the Acuitas AMR Gene Panel 510(k) submission, which had been delayed due to the FDA's prioritization of COVID-19 related emergency use authorizations, OpGen has worked closely with the FDA's review team to address any remaining edits and comments by the FDA to key documents such as the intended use statement, instructions for use, electronic user guide and others. The FDA recently informed OpGen that completion of its review would require additional time due to the current public health crisis. The FDA further informed OpGen that it intends to provide its written feedback to specific documents by the end of May 2021 and to complete its review by the end of August 2021. As of today, OpGen has already received feedback from the FDA on most of the aforementioned key documents under review. The FDA also clarified that these timelines can be affected by various factors including the FDA's other workload and public health priorities. Although the FDA has not committed to a clearance decision timeline, OpGen will continue to proactively engage with the FDA in order to facilitate a final clearance decision.
- OpGen announced signing an extension and expansion agreement for its strategic collaboration with the New York State Department of Health ("DOH") by another six months through September 30, 2021 with the focus of expanding the reach of the platform, increasing the volume of testing, and enhancing data collection.
- OpGen received Chinese NMPA approval for the IVD use of the Curetis Unyvero instrument system for the Chinese market with the application of the Unyvero cartridge for pneumonia currently under review and pending approval.
- OpGen subsidiary Curetis prepared and submitted a pre-submission request to the FDA to discuss and align on regulatory pathway and clinical trial design for the Unyvero UTI application. Due to the COVID pandemic, FDA has provided written feedback only in lieu of a meeting.
- OpGen subsidiary Curetis has continued to provide SARS-CoV-2 testing services, serving the community as a confirmatory PCR test lab for several local SARS-CoV-2 screening test centers.
- OpGen subsidiary Curetis entered into exclusive distribution partnership in Colombia with Annar Health Technologies for Curetis' Unyvero A50 platform.
- OpGen announced the results from its highly attended webinar titled "Pneumonia Diagnosis: Bacterial Superinfection in COVID-19 Patients," where two infectious disease professionals presented their independent study results from the Unyvero Hospitalized Pneumonia (HPN) and Unyvero Lower Respiratory (LRT BAL) panels, demonstrating the importance of distinguishing COVID-19 patients with bacterial superinfection early and accurately, and highlighted that Unyvero detected bacterial pathogens up to 7 days earlier and would have enabled prompt and appropriate targeted antibiotics in 41.3% of cases and reduced time to appropriate therapy by 25.7 hours.
- OpGen announced publication of final study results of the Unyvero HPN Panel for Diagnosis of Bacterial Co-Infections in ICU Patients with COVID-19 pneumonia showcasing that high negative predictive value of 99.8% may allow for reduction in unnecessary antibiotic use and support antibiotic stewardship efforts.
- Several scientific contributions illustrating the benefits of the Unyvero Lower Respiratory panels and the utility of the Acuitas AMR Gene Panel will be presented at the World Microbe Forum, June 20-24, 2021.
- OpGen subsidiary Ares Genetics announced publication of a study introducing best practice techniques for AI-powered prediction of antibiotic susceptibility testing which aimed at advancing good machine learning practices (GMLP) for WGS-based AST by describing best practice techniques for training and evaluation of predictive models, as well as introducing an optimized model architecture to reduce bias and promote robustness.
- OpGen subsidiary Ares Genetics signed several agreements with early access customers for the new Ares universal pathogen assay (ARESupa). The initial version of this target enrichment NGS panel is aimed at enabling testing for pathogens and AMR in native specimens and covers over 6,000 genetic markers for AMR selected from ARESdb.
- OpGen subsidiary Ares Genetics will be presenting at the upcoming Amazon Web Services (AWS) Healthcare & life Sciences Virtual Symposium on May 27, 2021 on "Bridging limitations in NGS-based infectious disease testing using machine learning."
- OpGen completed a $25 million registered direct offering priced at the market with one healthcare-focused U.S. institutional investor, as well as a warrant exercise and exchange deal for proceeds of $ 9.7 million.

Mr. Schacht commented, “We had a busy quarter that resulted in great progress towards the fight against AMR with multiple publications issued supporting OpGen’s products and mission, new and existing partnership growth that will help drive topline revenue and OpGen also announced regulatory progress particularly with the Chinese NMPA. We also significantly strengthened our balance sheet during the first quarter. As we push through the second quarter, we believe we can achieve an FDA clearance decision for our Acuitas AMR Gene Panel as soon as the FDA’s timelines will permit and work towards pipeline and growth objectives in the year ahead and I look forward to the company’s continued successes.”

Conference Call Information

OpGen’s management will host a conference call today, May 13 at 8:30 a.m. EDT to discuss the first 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=144749**
Conference ID: 13719409

Following the conclusion of the conference call, a replay will be available through May 27, 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. 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: 13719409

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.

Forward-Looking Statements

This press release includes statements regarding OpGen's first 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 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.

OpGen, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(unaudited)

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 39,397,437	$ 13,360,463
Accounts receivable, net	485,983	653,104
Inventory, net	1,417,440	1,485,986
Prepaid expenses and other current assets	1,472,666	1,388,090
Total current assets	**42,773,526**	**16,887,643**
Property and equipment, net	3,649,747	3,259,487
Finance lease right-of-use assets, net	338,673	449,628
Operating lease right-of-use assets	2,383,364	2,082,300
Goodwill	7,694,401	8,024,729
Intangible assets, net	15,656,651	16,580,963
Strategic inventory	2,057,016	1,686,342
Other noncurrent assets	602,220	779,953
Total assets	**$ 75,155,598**	**$ 49,751,045**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,249,461	$ 1,868,666
Accrued compensation and benefits	2,286,441	2,126,511
Accrued liabilities	1,712,008	1,437,141
Deferred revenue	9,808	9,808
Current maturities of long-term debt	282,055	699,000
Short-term finance lease liabilities	183,533	266,470
Short-term operating lease liabilities	849,895	964,434
Total current liabilities	**6,573,201**	**7,372,030**
Long-term debt, net	19,430,641	19,378,935
Long-term finance lease liabilities	29,265	46,794
Long-term operating lease liabilities	2,737,211	1,492,544
Derivative liabilities	206,973	112,852
Other long-term liabilities	147,026	156,635
Total liabilities	**29,124,317**	**28,559,790**
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, $0.01 par value; 50,000,000 shares authorized; 38,266,482 and 25,085,534 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	382,665	250,855
Additional paid-in capital	259,766,331	219,129,045
Accumulated deficit	(215,586,418)	(200,735,827)
Accumulated other comprehensive income	1,468,703	2,547,182
Total stockholders' equity	**46,031,281**	**21,191,255**
Total liabilities and stockholders' equity	**$ 75,155,598**	**$ 49,751,045**

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

	Three months ended March,	
	2021	**2020**
Revenue		
Product sales	$ 613,918	$ 366,933
Laboratory services	97,726	—
Collaboration revenue	118,072	250,000
Total revenue	**829,716**	**616,933**
Operating expenses		
Cost of products sold	554,054	276,554
Cost of services	104,984	137,666
Research and development	2,813,491	1,217,556
General and administrative	2,663,657	1,701,448
Sales and marketing	899,252	282,277
Transaction costs	—	245,322
Impairment of right-of-use asset	55,496	—
Impairment of intangibles assets	—	750,596
Total operating expenses	**7,090,934**	**4,611,419**
Operating loss	**(6,261,218)**	**(3,994,486)**
Other (expense) income		
Warrant inducement expense	(7,755,541)	—
Interest and other income	4,925	87,335
Interest expense	(1,164,982)	(38,267)
Foreign currency transaction losses	427,615	(3,876)
Change in fair value of derivative financial instruments	(101,390)	—
Total other (expense) income	**(8,589,373)**	**45,192**
Loss before income taxes	**(14,850,591)**	**(3,949,294)**
Provision for income taxes	—	—
Net loss	**$ (14,850,591)**	**$ (3,949,294)**
Net loss available to common stockholders	**$ (14,850,591)**	**$ (3,949,294)**
Net loss per common share - basic and diluted	**$ (0.50)**	**$ (0.53)**
Weighted average shares outstanding - basic and diluted	29,485,067	7,393,232
Net loss	$ (14,850,591)	$ (3,949,294)
Other comprehensive (loss) income - foreign currency translation	(1,078,479)	39,477
Comprehensive loss	**$ (15,929,070)**	**$ (3,909,817)**

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