

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 6, 2020
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 205
Gaithersburg, MD 20878
(Address of principal executive offices)

(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 May 7, 2020, OpGen, Inc. (the “Company”) issued a press release announcing its first quarter financial results for the quarter ended March 31, 2020. The full text of such press release is furnished as Exhibit 99.1 to this report.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On May 6, 2020, the Board of Directors of the Company (the “Board”) adopted revisions to the cash portion of its non-employee director compensation plan (as amended, the “Plan”) for providing cash compensation to its non-employee directors for their service on the Board and its committees. The principal changes are to provide an annual retainer for the Chair of the Board in an amount of \$75,000 and to provide certain adjustments to the retainers for committee chairs and committee members. The equity compensation portion of the Plan remains unchanged. The following table presents the revised annual cash retainers payable to non-employee directors under the Plan:

Non-employee director (other than chair):	\$	25,000
Board Chair:	\$	75,000
Audit Committee member:	\$	7,000
Audit Committee Chair:	\$	15,000
Compensation Committee member:	\$	6,000
Compensation Committee Chair:	\$	12,000
All other committee membership:	\$	3,500
All other committee Chair:	\$	7,500

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

[99.1 Press Release, dated May 7, 2020](#)

The information included 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 7, 2020

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer



OpGen Reports First Quarter 2020 Financial Results and Provides Business Update

- *Total Revenue for Q1 2020 was approximately \$617,000 (excluding Curetis Revenue)*
- *Curetis and Ares revenue was approximately \$900,000 for the first quarter generating a pro forma combined unaudited revenue of over \$1.5 million*
- *Balance sheet strengthened significantly with \$13.9 million cash raised in Q1 2020*
- *OpGen and Curetis successfully completed business combination effective April 1, 2020*
- *Multiple shipments of BGI SARS-CoV-2 rapid PCR kits completed by Curetis in Europe. Additional actions planned to address the global COVID-19 pandemic*

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

GAITHERSBURG, Md., May 7, 2020 (GLOBE NEWSWIRE) – OpGen, Inc. (Nasdaq: OPGN, “OpGen”), a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease, reported today its stand-alone financial and operating results for the three months ended March 31, 2020 and provided a business update. Total OpGen revenue for the first quarter of 2020 was approximately \$617,000 down from \$1.0 million in the first quarter of 2019. Revenue from Curetis and Ares, OpGen’s wholly owned subsidiaries, was approximately \$900,000 for the first quarter generating a pro-forma combined unaudited revenue of over \$1.5 million. OpGen’s cash as of March 31, 2020 was approximately \$11.5 million, up significantly from the \$2.7 million as of December 31, 2019. This amount did not include the approximately \$900,000 in cash held by Curetis and Ares at March 31, 2020.

Oliver Schacht, President and CEO of OpGen commented, “Despite the unprecedented global crisis situation with COVID-19, we are pleased with our first quarter results and remain confident in the strength of our 2020 pipeline. We acknowledge that this is an ever-changing situation and are prepared to mitigate any further potential impact that COVID-19 might have on our global operations. We would like to reassure you that as a company we are resilient and OpGen with its subsidiaries Curetis and Ares Genetics boasts a strong proprietary product portfolio that is extremely agile, flexible and has elements in place to rapidly identify, develop and create potential offerings needed to address future infectious disease outbreaks.”

Mr. Schacht continued, “We expect the CoV-2 rapid PCR test kit sales in Europe to continue contributing positively to our top-line revenue in Q2 of 2020. Since mid-March 2020, we sold approximately 15,000 CoV-2 tests into our distribution network. Additionally, we recently announced our collaboration with Sweden’s Karolinska Institutet to test COVID-19 pneumonia patients with Unyvero HPN panel for bacterial co-infections. Due to the nature of the CoV-2 virus, we believe it is crucial to be able to rapidly detect a comprehensive spectrum of bacterial and fungal pathogens and antibiotic resistance markers in lower respiratory tract specimens that could be a critical factor in saving patients lives during the ongoing pandemic. The study has already started and we expect to see initial results in the coming weeks.”

First Quarter 2020 Financial Results of OpGen, Inc. Stand-alone

- Total revenue for the first quarter of 2020 was approximately \$617,000 down from \$1.0 million in the first quarter of 2019. This decrease can be attributed to Acuitas AMR Gene Panel and Acuitas® Lighthouse revenue, which was approximately \$254,000, while revenues from the company's rapid FISH products decreased to \$363,000. Curetis and Ares revenue was approximately \$900,000 for the first quarter generating a pro forma combined unaudited revenue of over \$1.5 million.
- Operating expenses for the first quarter of 2020 were \$4.6 million, compared with \$4.8 million in the first quarter of 2019.
- The net loss for the first quarter of 2020 was \$3.9 million or \$0.53 per share, compared with \$3.9 million or \$8.25 per share in the first quarter of 2019.

The Company also provided the following business updates that were achieved during the first quarter of 2020:

- Successful closure of the business combination between OpGen and Curetis on April 1, 2020. At the closing, William E. Rhodes III, the former chairman of the Supervisory Board of Curetis N.V., was appointed chairman of the board of OpGen, and Oliver Schacht, Ph.D., the former Chief Executive Officer of Curetis N.V., was appointed the President and Chief Executive Officer of OpGen and to the board of directors;
 - The newly formed board of directors of OpGen now also includes Evan Jones, former Chairman and CEO of OpGen, Don Elsey, Mario Crovetto, and Prabhavathi Fernandes, PhD;
 - Announced the start of an investigator initiated collaboration with Karolinska Institutet, Sweden, to identify bacterial co-infections in patients admitted to the ICU for COVID-19 pneumonia using the Unyvero HPN panel;
 - OpGen significantly improved its working capital position in the first quarter of 2020 through \$5.8 million of sales under the company's ATM program and \$8.1 million in proceeds from the exercise of warrants issued in the company's public offering in October 2019;
 - Clinical trials were initiated during the first quarter of 2020 at nine participating sites for the Acuitas AMR Gene Panel (Urine) test. Testing and the trial have been suspended due to hospital actions to focus resources on the COVID-19 pandemic;
 - Acuitas Lighthouse® was utilized in a research study conducted by the Mayo Clinic to predict phenotypic resistance and antimicrobial susceptibility among clinical isolates, with findings published in *Diagnostic Microbiology & Infectious Disease*; and
 - Curetis, Ares Genetics, and BGI announced a partnership around BGI's CoV-2 test kit commercialization in Europe; Curetis has begun selling the BGI CoV-2 product via its distribution network in EMEA during Q1 2020 and to date has sold over 15,000 tests into its distribution network.
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Additional key business updates and strategic milestones include:

- OpGen' expects that its submission to the U.S. Food and Drug Administration ("FDA") for clearance of the Acuitas® AMR Gene Panel (Isolates) for the detection of antimicrobial resistance genes in bacterial isolates is nearing completion. OpGen has responded, and is continuing to respond, to the FDA's additional information requests and now anticipates approaching a clearance decision for the Acuitas® AMR Gene Panel for isolates. Exact timing is unknown as a result of the COVID-19 pandemic;
- OpGen successfully achieved the last of the first year milestones in the groundbreaking collaboration with the New York State Department of Health and ILUM Health Solutions, LLC, to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions statewide. In response to the COVID-19 emergency in New York State, testing under the program has been put on hold by the Wadsworth Center and participating hospitals; however, the parties are currently engaged in active negotiations and discussions for a second year of the collaboration and expect to resume the project and expand it into its second year once the COVID-19 situation permits;
- OpGen's subsidiary Ares Genetics in April announced that a study on the feasibility and potential of antibiotic susceptibility testing and bacterial pathogen identification using next-generation sequencing (NGS) has been pre-published in the Journal of Clinical Microbiology. The study was performed by Ares Genetics GmbH and Curetis GmbH, and scientists at the Max Perutz Labs (Austria), a joint venture of the University of Vienna and the Medical University of Vienna, and the Mayo Clinic (Rochester, MN, U.S.A.); and
- Curetis and Quaphaco entered into an exclusive three-year distribution partnership for the Unyvero product line in Vietnam; the contract includes minimum commitments by Quaphaco totaling approximately \$ 2.1 million over the initial three-year term.

Mr. Schacht continued, "We have a strong pipeline heading into the second quarter of 2020 despite the unique market challenges presented at this time. With the anticipated near term FDA clearance decision and subsequent launch of our Acuitas AMR Gene Panel product for isolate and the exciting combination of the Acuitas Lighthouse® database with the ARESdb, our strong, proprietary product pipeline attests to our ability to deliver premier AI-powered bioinformatics solutions and diagnostic products. We are especially excited about an upcoming major milestone in the Ares collaboration with its strategic R&D collaboration partner, a leading global IVD corporation, where completion of the R&D phase is expected for the third quarter this year. The IVD corporate partner has pre-funded an option which upon exercise would then grant it 90 days of exclusive negotiations with Ares regarding a potential future partnering and licensing deal."

Conference Call Information

OpGen's management will host a conference call today, May 7 at 4:30 p.m. ET to discuss 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 (844) 420-8185

International Dial-in Number: +1 (216) 562-0481

Webcast: <https://edge.media-server.com/mmc/p/iggnmjim>

Conference ID: 8595009

Following the conclusion of the conference call, a replay will be available through May 14, 2020. 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 (855) 859-2056

International Dial-in Number: +1 (404) 537-3406

Conference ID: 8595009

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 2020 results, the integration of OpGen with its acquired subsidiaries, Curetis GmbH and Ares Genetics GmbH, the current business and strategic initiatives of OpGen, and the impact of COVID-19 on the company and general market conditions. 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 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:

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OpGen, Inc.
Consolidated Balance Sheets
(unaudited)

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 11,469,455	\$ 2,708,223
Accounts receivable, net	165,931	567,811
Inventory, net	436,683	473,030
Note receivable	4,808,712	2,521,479
Prepaid expenses and other current assets	264,013	396,760
Total current assets	17,144,794	6,667,303
Property and equipment, net	102,579	130,759
Finance lease right-of-use assets, net	826,243	958,590
Operating lease right-of-use assets	885,882	1,043,537
Goodwill	600,814	600,814
Intangible assets, net	—	817,550
Other noncurrent assets	203,212	203,271
Total assets	\$ 19,763,524	\$ 10,421,824
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,054,261	\$ 1,056,035
Accrued compensation and benefits	988,291	855,994
Accrued liabilities	1,047,019	1,046,661
Deferred revenue	9,808	9,808
Short-term notes payable	348,494	373,599
Short-term finance lease liabilities	517,042	579,030
Short-term operating lease liabilities	947,610	1,017,414
Total current liabilities	4,912,525	4,938,541
Note payable	163,401	329,456
Long-term finance lease liabilities	212,798	313,263
Long-term operating lease liabilities	392,106	547,225
Total liabilities	5,680,830	6,128,485
Stockholders' equity		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at March 31, 2020 and December 31, 2019, respectively	—	—
Common stock, \$0.01 par value; 50,000,000 shares authorized; 12,468,214 and 5,582,280 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	124,682	55,823
Additional paid-in capital	192,410,127	178,779,814
Accumulated deficit	(178,474,277)	(174,524,983)
Accumulated other comprehensive income/(loss)	22,162	(17,315)
Total stockholders' equity	14,082,694	4,293,339
Total liabilities and stockholders' equity	\$ 19,763,524	\$ 10,421,824

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

	Three Months Ended March 31,	
	2020	2019
Revenue		
Product sales	\$ 366,933	\$ 520,177
Collaboration revenue	250,000	500,000
Total revenue	616,933	1,020,177
Operating expenses		
Cost of products sold	276,554	220,702
Cost of services	137,666	144,482
Research and development	1,217,556	1,776,382
General and administrative	1,701,448	1,747,585
Sales and marketing	282,277	372,233
Transaction costs	245,322	—
Impairment of intangible assets	750,596	—
Impairment of right-of-use asset	—	520,759
Total operating expenses	4,611,419	4,782,143
Operating loss	(3,994,486)	(3,761,966)
Other income (expense)		
Interest and other income (expense)	87,335	(24,422)
Interest expense	(38,267)	(56,444)
Foreign currency transaction losses	(3,876)	(10,351)
Change in fair value of derivative financial instruments	—	67
Total other income (expense)	45,192	(91,150)
Loss before income taxes	(3,949,294)	(3,853,116)
Provision for income taxes	—	—
Net loss	\$ (3,949,294)	\$ (3,853,116)
Net loss per common share - basic and diluted	\$ (0.53)	\$ (8.25)
Weighted average shares outstanding - basic and diluted	7,393,232	467,286
Net loss	\$ (3,949,294)	\$ (3,853,116)
Other comprehensive income - foreign currency translation	39,477	2,826
Comprehensive loss	\$ (3,909,817)	\$ (3,850,290)