

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

August 12, 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)(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 [X]

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 August 12, 2020, OpGen, Inc. issued a press release announcing its second quarter financial results for the quarter ended June 30, 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 August 12, 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: August 12, 2020

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer



OpGen Reports Second Quarter 2020 Financial Results and Provides Business Update

- *Total Revenue for Q2 2020 was approximately \$1.2 million dollars*
- *Balance sheet strengthened significantly with \$6.1 million cash raised in Q2 2020*
- *Strategic co-promotion partnership with Menarini Silicon Biosystems to market and sell Menarini's COVID-19 related products*

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

GAITHERSBURG, Md., August 12, 2020 (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 six months ended June 30, 2020 and provided a business update. Total OpGen revenue for the second quarter of 2020 was approximately \$1.2 million up from \$1.0 million in the second quarter of 2019. The financial results for the three months ended June 30, 2020 reflect the consummation of our business combination with Curetis GmbH on April 1, 2020. OpGen’s cash as of June 30, 2020 was approximately \$12.9 million, an increase from the \$11.5 million as of March 31, 2020.

Oliver Schacht, President and CEO of OpGen commented, “I am pleased with OpGen’s second quarter performance in context of the unprecedented uncertainty caused by the COVID-19 pandemic and resulting pipeline delays. Operating as a combined company, our business has grown year-over-year and we could not be more pleased with the quick and successful integration of our companies. Our team has worked around the clock to re-prioritize R&D efforts to not only meet the most critical healthcare needs relating to COVID-19, but also to ensure we are delivering best-in-class diagnostics to our healthcare providers and customers. Our recent agreement with the European Investment Bank (EIB) providing us with access to an additional EUR 5 million tranche in non-dilutive debt financing bolsters our ability to expand efforts relating to COVID-19, as we believe crucial to be able to rapidly and comprehensively perform infectious disease diagnostics.”

Mr. Schacht continued, “Additionally, we are excited and encouraged by the recently announced co-promotion partnership with Menarini Silicon Biosystems to market and promote Menarini’s portfolio of COVID-19 related products such as the Healgen antibody test cassette and the Menarini CELLSEARCH CEC kit. This partnership we believe highlights our marketing expertise and sales capabilities to a network of infectious disease healthcare providers and researchers across North America.”

Second Quarter and First Half 2020 Financial Results

- Total revenue for the second quarter of 2020 was approximately \$1.2 million up from \$1.0 million in the second quarter of 2019. Total revenue for the first half of 2020 was \$1.8 million, compared with \$2.0 million for the first half of 2019;
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- Operating expenses for the second quarter of 2020 were \$7.7 million, compared with \$3.6 million in the second quarter of 2019. Operating expenses for the first half of 2020 were \$12.3 million, compared with \$8.4 million for the first half of 2019;
- The net loss for the second quarter of 2020 was \$7.5 million or \$0.49 per share, compared with \$2.6 million or \$2.94 per share in the second quarter of 2019. The net loss for the first half of 2020 was \$11.4 million or \$1.00 per share, compared with a net loss of \$6.4 million or \$9.54 per share for the first half of 2019; and
- Cash and cash equivalents were \$12.9 million as of June 30, 2020.

The company also announced accomplishment of the following key milestones during the second quarter of 2020 and year to date:

- OpGen's subsidiary Ares Genetics GmbH continued executing in its strategic partnering programs with globally leading IVD and pharma companies as well as its collaborations with top-tier medical and public health institutions. Ares Genetics completed all three phases of the R&D program and successfully improved performance of molecular antibiotic susceptibility prediction based on ARESdb in its R&D collaboration with its undisclosed IVD partner as well as signed a second technology evaluation agreement with another undisclosed global IVD corporation. Ares Genetics significantly advanced its own R&D programs for AI-powered antibiotic susceptibility testing based on next-generation sequencing and published strong results from its collaborations with Sandoz, Johns Hopkins and Mayo Clinic as well as initiated further commercial projects with new customers including Siemens Technology Accelerator GmbH and AGES (Austrian Agency for Health and Food Safety).
 - Curetis has successfully completed the verification and clinical validation testing of its proprietary, rapid SARS CoV-2 PCR test kit which it expects to CE-IVD mark in due course. The test allows to detect SARS CoV-2 directly from patient swabs in less than 1 hour and does not require prior RNA isolation.
 - OpGen announced a strategic co-promotion partnership with Menarini Silicon Biosystems to market and sell Menarini's portfolio of COVID-19 related products to infectious disease healthcare providers and researchers in North America.
 - OpGen's subsidiary Curetis GmbH secured access to an additional EUR 5 million tranche in non-dilutive debt financing for COVID-19 related R&D from the European Investment Bank (EIB). Curetis can draw down the tranche at its sole discretion during a nine-month period and the tranche will have a five-year maturity and is interest-only until then.
 - Preliminary data was released from an investigator-initiated collaboration with Karolinska Institutet, Stockholm, Sweden, to identify bacterial co-infections in hospitalized patients with COVID-19 pneumonia. OpGen's Unyvero HPN Panel for Pneumonia identifies life-threatening bacterial co-infections in COVID-19 patients in just five hours, and Unyvero LRT and LRT BAL panels are FDA-cleared in the U.S. for rapid detection of lower respiratory tract infections such as pneumonia. Furthermore, performance of the Unyvero system was highlighted in several posters and abstracts in ASM Microbe 2020 online.
 - 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 anticipates approaching a clearance decision for the marketing submissions and applications on hold as of June 2020, which resulted in OpGen's original submission deadline of July 15, 2020 being extended to October 13, 2020.
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- The German Federal Ministry for Economic Affairs and Energy (BMWi) has initiated an investigation of the OpGen business combination with Curetis under Sections 55 et seq. of the Foreign Trade and Payments Ordinance (AWV) with regards to its impact on the public order and security of the Federal Republic of Germany as well as national healthcare interests in the light of the current COVID-19 pandemic. OpGen has already responded to all questions currently raised by the BMWi and will remain in constructive dialogue with the BMWi with a view to completing the process as swiftly as possible.

Mr. Schacht commented, “We continue to anticipate an FDA clearance decision for our Acuitas AMR Gene Panel product for isolates in the second half of 2020. Our pipeline continues to grow with the recent strategic partnership agreement with Menarini for the co-marketing of a portfolio of COVID-19 related products and platforms in North America. Although our current work environment continues to be highly uncertain, with continued investments in such strategic initiatives, we strongly believe OpGen is well positioned to meet our long-term product and profitability targets.”

Conference Call Information

OpGen’s management will host a conference call today, August 12 at 4:30 p.m. ET to discuss the second 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=141125>
Conference ID: 13707986

Following the conclusion of the conference call, a replay will be available through August 26, 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 (844) 512 2921
International Dial-in Number: +1 (412) 317 6671
Replay PIN: 13707986

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 second 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)

	June 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 12,886,547	\$ 2,708,223
Accounts receivable, net	231,427	567,811
Inventory, net	2,898,185	473,030
Note receivable	—	2,521,479
Prepaid expenses and other current assets	810,391	396,760
Total current assets	16,826,550	6,667,303
Property and equipment, net	3,587,341	130,759
Finance lease right-of-use assets, net	696,333	958,590
Operating lease right-of-use assets	1,653,603	1,043,537
Goodwill	7,650,642	600,814
Intangible assets, net	15,566,528	817,550
Other noncurrent assets	309,347	203,271
Total assets	\$ 46,290,344	\$ 10,421,824
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,745,499	\$ 1,056,035
Accrued compensation and benefits	1,730,129	855,994
Accrued liabilities	2,514,992	1,046,661
Deferred revenue	393,739	9,808
Short-term notes payable	1,378,380	373,599
Short-term finance lease liabilities	432,494	579,030
Short-term operating lease liabilities	1,271,700	1,017,414
Total current liabilities	9,466,933	4,938,541
Note payable	16,794,652	329,456
Derivative liabilities	234,224	—
Long-term finance lease liabilities	135,521	313,263
Long-term operating lease liabilities	782,494	547,225
Other long term liabilities	147,977	—
Total liabilities	27,561,801	6,128,485
Commitments		
Stockholders' equity		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Common stock, \$0.01 par value; 50,000,000 shares authorized; 17,693,932 and 5,582,280 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	176,939	55,823
Additional paid-in capital	204,154,419	178,779,814
Accumulated deficit	(185,949,916)	(174,524,983)
Accumulated other comprehensive income/(loss)	347,101	(17,315)
Total stockholders' equity	18,728,543	4,293,339
Total liabilities and stockholders' equity	\$ 46,290,344	\$ 10,421,824

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue				
Product sales	\$ 601,304	\$ 504,293	\$ 968,237	\$ 1,024,470
Laboratory services	25,992	5,250	25,992	5,250
Collaboration revenue	561,089	500,000	811,089	1,000,000
Total revenue	1,188,385	1,009,543	1,805,318	2,029,720
Operating expenses				
Cost of products sold	713,916	198,493	990,470	419,195
Cost of services	252,655	251,981	390,321	396,463
Research and development	2,979,025	1,153,584	4,196,581	2,929,966
General and administrative	2,491,571	1,592,845	4,193,019	3,340,430
Sales and marketing	1,044,032	393,567	1,326,309	765,800
Transaction costs	225,000	—	470,322	—
Impairment of intangible assets	—	—	750,596	—
Impairment of right-of-use asset	—	—	—	520,759
Total operating expenses	7,706,199	3,590,470	12,317,618	8,372,613
Operating loss	(6,517,814)	(2,580,927)	(10,512,300)	(6,342,893)
Other (expense) income				
Interest and other income/(expense)	(5,656)	15,166	81,679	(9,256)
Interest expense	(1,044,891)	(37,129)	(1,083,158)	(93,573)
Foreign currency transaction losses	(289,788)	9,879	(293,664)	(472)
Change in fair value of derivative financial instruments	382,511	—	382,511	67
Total other expense	(957,824)	(12,084)	(912,632)	(103,234)
Loss before income taxes	(7,475,638)	(2,593,011)	(11,424,932)	(6,446,127)
Provision for income taxes	—	—	—	—
Net loss	\$ (7,475,638)	\$ (2,593,011)	\$ (11,424,932)	\$ (6,446,127)
Net loss per common share - basic and diluted	<u><u>\$ (0.49)</u></u>	<u><u>\$ (2.94)</u></u>	<u><u>\$ (1.00)</u></u>	<u><u>\$ (9.54)</u></u>
Weighted average shares outstanding - basic and diluted	<u><u>15,403,986</u></u>	<u><u>882,286</u></u>	<u><u>11,427,322</u></u>	<u><u>675,932</u></u>
Net loss	\$ (7,475,638)	\$ (2,593,011)	\$ (11,424,932)	\$ (6,446,127)
Other comprehensive income/(loss) - foreign currency translation	324,939	(4,950)	364,416	(2,124)
Comprehensive loss	\$ (7,150,699)	\$ (2,597,961)	\$ (11,060,516)	\$ (6,448,251)