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, 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)

(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 August 12, 2021, OpGen, Inc. (the "Company") issued a press release announcing its second quarter financial results for the quarter ended June 30, 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 August 12, 2021.

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: August 12, 2021

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer

OpGen Reports Second Quarter 2021 Financial Results and Provides Business Update

- *Total Revenue for Q2 2021 was approximately $0.8 million*
- *Cash as of June 30, 2021 was approximately $31.2 million, up significantly from the $13.4 million at year-end 2020*

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

ROCKVILLE, Md., August 12, 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 and six months ended June 30, 2021 and provided a business update. Total OpGen revenue for the second quarter of 2021 was approximately $0.8 million, down 32% from $1.2 million in the second quarter of 2020. Cash as of June 30, 2021 was approximately $31.2 million, up significantly from the $13.4 million at year-end 2020.

Oliver Schacht, President & CEO of OpGen, commented, "We are continuing to execute on our key development milestones as recently seen with our assembly of 10 final pre-series release analyzers of the Unyvero A30 *RQ* platform. In this growth-oriented quarter we presented key clinical data at several conferences, provided an update to our robust R&D pipeline, and successfully completed a move to our new corporate headquarters. I am pleased with our accomplishments and continue to believe we are putting our company in a position to succeed."

Second Quarter 2021 Financial Results of OpGen, Inc.

- Total revenue for the second quarter of 2021 was approximately $0.8 million, down 32% from $1.2 million in the second quarter of 2020. This decrease is primarily attributable to exiting the FISH business at the end of the first quarter of 2021 as well as the conclusion of non-recurring partnering revenues from a completed R&D collaboration at Ares Genetics in 2020. Total revenue for the first half of 2021 was approximately $1.6 million, as compared to $1.8 million for the first half of 2020. This decrease is primarily attributable to a decline of $0.4 million in revenue due to our exit from the FISH business and a decline of $0.5 million in revenue due to the conclusion of non-recurring partnering revenues from a completed R&D collaboration at Ares Genetics in 2020 offset by an increase in lab service revenue of $0.4 million and a $0.3 million increase in Unyvero product revenue.
- Operating expenses for the second quarter of 2021 were approximately $7.0 million compared with $7.7 million in the second quarter of 2020. Operating expenses for the first half of 2021 were approximately $14.0 million, as compared to $12.3 million for the first half of 2020.
- The net loss for the second quarter of 2021 was $7.1 million, or $0.19 per share, compared with $7.5 million, or $0.49 per share, in the second quarter of 2020. The net loss for the first half of 2021 was $21.9 million, or $0.65 per share, as compared with a net loss of $11.4 million, or $1.00 per share, for the first half of 2020;
- Cash and cash equivalents were $31.2 million as of June 30, 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 second quarter as well as 2021 to date:

- Curetis, an OpGen subsidiary, successfully achieved a key development milestone by completing the assembly of 10 final pre-series release Unyvero A30 *RQ* analyzers. The systems have now commenced final verification and validation testing. The Unyvero A30 *RQ* platform can be made available to third party development and commercialization partners and licensees for their own assay menu and product portfolio. Discussions are currently ongoing with several potential platform partners for various content-and-licensing or partnering scopes.
- OpGen submitted an updated 510(k) summary to the FDA for our Acuitas AMR Gene Panel for Isolates in June 2021. We believe the FDA has provided substantive feedback on all key documents, including the Package Insert, Electronic User Guide, and Operator Manual in May. The FDA previously stated that they expect to complete its review by the end of August 2021. Since such communications, there have been no changes to the timeline, and the FDA has not provided any additional requests or questions. The FDA previously clarified that their 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 timeline, we currently expect to see a completed review based on this timeline.
- OpGen completed the move of its U.S. headquarters, labs, and operations to a new facility in Rockville, Maryland. The 10,000 square foot facility results in net savings of approximately $0.6 million annually in operating efficiencies and reduced rent. Going forward, all Unyvero cartridges, as well as Acuitas consumables, will be stocked and shipped directly from the new Rockville-based facility.
- OpGen announced prospective clinical data on the Unyvero LRT BAL at the June 29, 2021 webinar titled "One Academic Medical Center's Experience with the Unyvero Multiplex Platform for Testing Bronchoalveolar Lavage Fluids: Analytical and Clinical Assessment", which studied patients in the intensive care unit for whom bronchoalveolar lavage (BAL) specimen was ordered for diagnostic purpose and prospectively evaluated with the Unyvero LRT BAL panel in conjunction with quantitative bacterial culture and antimicrobial susceptibility testing. The clinical impact of the Unyvero results on antibiotic stewardship and patient management were discussed and acted upon in real-time, enabling earlier adjustment of antimicrobial therapy in 53% of cases.
- Dr. Cory Hale, Infectious Disease Clinical Pharmacist at the Penn State Health Milton S. Hershey Medical Center, presented on Unyvero LRT at the virtual World Microbe Forum 2021. In their talk titled "Antimicrobial Stewardship Opportunities Using Results from a Multiplex Molecular Lower Respiratory Tract Panel as Compared to Conventional Culture", their data characterized the potential impact of Unyvero LRT on antibiotic therapy in patients being treated for pneumonia. Retrospective chart reviews were performed in 92 of these patients, including 51 critically ill ICU patients and 39 pediatric patients. They reported complete agreement between Unyvero LRT and culture results in 50% of cases, and in 45.7% of cases, Unyvero yielded more information than culture. This demonstrates the potential value that Unyvero LRT could bring in clinical patient management.

- An ‘i-poster’ presented at the virtual World Microbe Forum 2021 by Dr. Drew Bell of Indiana University School of Medicine, titled “Clinical Evaluation of a Multiplex Molecular Diagnostic Lower Respiratory Tract Panel for Bronchoalveolar Lavage Specimens,” demonstrated that the Unyvero LRT BAL provided a basis for appropriate escalation and de-escalation of antibiotic therapies in 42% of cases, reducing time to appropriate therapy by 31 hours.
- Ares Genetics, an OpGen subsidiary, recently entered into several additional collaborations that are expected to help expand the ARESdb as a curated AMR marker database. These additional collaborations include on the one hand, a scientific and clinical project with UPMC, Pittsburgh, PA and on the other hand a strategic collaboration with a leading U.S. CRO and reference lab. Under the latter collaboration agreement Ares Genetics will be able to select a large number of clinical isolates to augment and grow its unique ARESdb with curated data sets. In return Ares has committed to providing certain next generation sequencing (NGS) services to the collaboration partner. Several additional collaboration and licensing agreements are currently in various stages of negotiation and pricing discussions.
- Dr. Johannes Weinberger, NGS Lab Director at Ares Genetics provided an update on their culture-free genomic assay for AMR surveillance via virtual presentation at a conference sponsored by Twist Bioscience. Dr. Weinberger commented that “The sensitivity for AMR marker detection in native urine samples from septic patients with confirmed mono-infections in our study was determined to be between 94% and 100% when compared to comparator data obtained from whole genome sequencing of the corresponding bacterial isolate.”
- Dr. Arne Materna, CEO of Ares Genetics, presented virtually at the Genomics-Track discussion at the Amazon Web Services healthcare & life sciences symposium. Dr. Materna discussed that the Ares universal pathogenome assay (ARESupa), is currently being evaluated in a paid-for early access program for which Ares has already signed up five public health organizations from different European countries.
- Dr. Materna presented preliminary data of an ongoing, multicenter validation of long-read nanopore sequencing of clinical isolates through two virtual seminars, furthering OpGen’s R&D updates. Ares Genetics is conducting the multicenter validation by Oxford Nanopore Technology (ONT) in combination with AREScloud for data analysis. AREScloud assisted conversion of ONT data into clinically and epidemiologically relevant information proved highly accurate for participating labs, with consistent average accuracies of 100% for pathogen identification, up to 97% for AMR marker detection, and up to 100% for predictive antimicrobial susceptibility testing (AST).

Mr. Schacht commented, “As we continue into the third quarter, we are waiting for the FDA to complete their review of our AMR Gene Panel for Isolates. We are also in regular dialog with the Chinese NMPA via our strategic partner Beijing Clear Bio. The Chinese NMPA recently requested supplemental clinical data to be generated and submitted in China, and we are working with our partners to finalize study design and swift study execution in due course. We are also working diligently on finding a new Chief Financial Officer to join the OpGen team following the resignation of our current CFO Tim Dec. Together with our board, we are continuing to evaluate alternatives for financing the future growth of OpGen and believe these are steps that will help drive the company forward and on its desired path.”

Conference Call Information

OpGen's management will host a conference call today, August 12 at 4:30 p.m. EDT 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: +1-800-458-4121
International Dial-in Number: +1-323-794-2093
Webcast: **http://public.viavid.com/index.php?id=146054**
Conference ID: 7301173

Following the conclusion of the conference call, a replay will be available through August 26, 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: 7301173

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 OpGen’s second quarter and first half of 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 our financings, 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)

	June 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 31,182,385	$ 13,360,463
Accounts receivable, net	472,567	653,104
Inventory, net	1,333,880	1,485,986
Prepaid expenses and other current assets	2,081,549	1,388,090
Total current assets	**35,070,381**	**16,887,643**
Property and equipment, net	4,223,155	3,259,487
Finance lease right-of-use assets, net	227,209	449,628
Operating lease right-of-use assets	2,038,073	2,082,300
Goodwill	7,790,595	8,024,729
Intangible assets, net	15,662,324	16,580,963
Strategic inventory	2,995,436	1,686,342
Other noncurrent assets	555,190	779,953
Total assets	**$ 68,562,363**	**$ 49,751,045**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,207,113	$ 1,868,666
Accrued compensation and benefits	1,541,898	2,126,511
Accrued liabilities	1,137,196	1,437,141
Deferred revenue	—	9,808
Current maturities of long-term debt	—	699,000
Short-term finance lease liabilities	116,829	266,470
Short-term operating lease liabilities	854,233	964,434
Total current liabilities	**4,857,269**	**7,372,030**
Long-term debt, net	20,670,941	19,378,935
Long-term finance lease liabilities	18,693	46,794
Long-term operating lease liabilities	2,910,810	1,492,544
Derivative liabilities	222,387	112,852
Other long-term liabilities	146,344	156,635
Total liabilities	**28,826,444**	**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 June 30, 2021 and December 31, 2020	—	—
Common stock, $0.01 par value; 50,000,000 shares authorized; 38,270,250 and 25,085,534 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	382,703	250,855
Additional paid-in capital	260,027,841	219,129,045
Accumulated deficit	(222,672,979)	(200,735,827)
Accumulated other comprehensive income	1,998,354	2,547,182
Total stockholders' equity	**39,735,919**	**21,191,255**
Total liabilities and stockholders' equity	**$ 68,562,363**	**$ 49,751,045**

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Revenue				
Product sales	$ 307,804	$ 601,304	$ 835,383	$ 968,237
Laboratory services	266,784	25,992	450,849	25,992
Collaboration revenue	237,027	561,089	355,099	811,089
Total revenue	**811,615**	**1,188,385**	**1,641,331**	**1,805,318**
Operating expenses				
Cost of products sold	342,580	713,916	896,634	990,470
Cost of services	137,934	252,655	242,918	390,321
Research and development	2,859,590	2,979,025	5,673,081	4,196,581
General and administrative	2,692,255	2,491,571	5,355,912	4,193,019
Sales and marketing	802,549	1,044,032	1,701,801	1,326,309
Transaction costs	—	225,000	—	470,322
Impairment of right-of-use asset	115,218	—	170,714	—
Impairment of intangibles assets	—	—	—	750,596
Total operating expenses	**6,950,126**	**7,706,199**	**14,041,060**	**12,317,618**
Operating loss	**(6,138,511)**	**(6,517,814)**	**(12,399,729)**	**(10,512,300)**
Other (expense) income				
Gain on extinguishment of debt	259,353	—	259,353	—
Warrant inducement expense	—	—	(7,755,541)	—
Interest and other income (expense)	4,702	(5,656)	9,627	81,679
Interest expense	(1,198,169)	(1,044,891)	(2,363,151)	(1,083,158)
Foreign currency transaction (losses) gains	(915)	(289,788)	426,700	(293,664)
Change in fair value of derivative financial instruments	(13,021)	382,511	(114,411)	382,511
Total other (expense) income	**(948,050)**	**(957,824)**	**(9,537,423)**	**(912,632)**
Loss before income taxes	**(7,086,561)**	**(7,475,638)**	**(21,937,152)**	**(11,424,932)**
Provision for income taxes	—	—	—	—
Net loss	**$ (7,086,561)**	**$ (7,475,638)**	**$ (21,937,152)**	**$ (11,424,932)**
Net loss available to common stockholders	**$ (7,086,561)**	**$ (7,475,638)**	**$ (21,937,152)**	**$ (11,424,932)**
Net loss per common share - basic and diluted	**$ (0.19)**	**$ (0.49)**	**$ (0.65)**	**$ (1.00)**
Weighted average shares outstanding - basic and diluted	38,268,293	15,403,986	33,900,964	11,427,322
Net loss	$ (7,086,561)	$ (7,475,638)	$ (21,937,152)	$ (11,424,932)
Other comprehensive income (loss) - foreign currency translation	529,651	324,939	(548,828)	364,416
Comprehensive loss	**$ (6,556,910)**	**$ (7,150,699)**	**$ (22,485,980)**	**$ (11,060,516)**

OpGen:
Oliver Schacht
President and CEO
InvestorRelations@opgen.com

OpGen Press Contact:
Matthew Bretzius
FischTank Marketing and PR
matt@fischtankpr.com

OpGen Investor Contact:
Max Colbert
Edison Group
mcolbert@edisongroup.com