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 2, 2018
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)**

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))

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 2, 2018, OpGen, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2018. The full text of such press release is furnished as Exhibit 99.1 to this report.

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.

Item 9.01 — Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release, dated August 2, 2018 issued by OpGen, Inc.

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.

OpGen, Inc.

Date: August 6, 2018

By: /s/ Timothy C. Dec
Timothy C. Dec
Chief Financial Officer

OPGEN REPORTS SECOND QUARTER 2018 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

Revenue increases 12% to $0.8 million, net loss narrows 21% to $3.3 million

Conference call begins at 4:30 p.m. Eastern time today

GAITHERSBURG, Md. (August 2, 2018) – OpGen, Inc. (NASDAQ: OPGN) today reported financial and operating results for the three and six months ended June 30, 2018 and provided a business update. Total revenue for the second quarter of 2018 was $0.8 million, up 12% from $0.7 million for the second quarter of 2017. The net loss for the second quarter of 2018 was $3.3 million, a 21% improvement compared with the net loss of $4.2 million for the second quarter of 2017.

"During the second quarter we continued to advance development of our lead rapid test, the Acuitas® AMR Gene Panel u5.47," said Evan Jones, Chairman and CEO. "We reached agreement with the U.S. Food and Drug Administration (FDA) regarding the regulatory pathways and clinical trial protocols for clearance of the new AMR Gene Panel Tests and the Acuitas Lighthouse® Software. Our goal is to complete our first clinical trial for bacterial isolates and file an *in vitro* diagnostic (IVD) 510(k) submission for the Acuitas AMR Gene Panel u5.47 during the fourth quarter of 2018. Subsequent 510(k) submissions are expected to follow during the first quarter of 2019. We are encouraged by the introduction of the Acuitas AMR Gene Panel u5.47 Research Use Only (RUO) earlier this year and have been in discussions with leading CROs and hospital systems for its use and as participants in our clinical trials.

"At the ASM Microbe conference in June we presented positive data from our ongoing clinical verification studies for the Acuitas AMR Gene Panel u5.47 (RUO). In the study, 229 remnant urine specimens were provided by Intermountain Healthcare and Beth Israel Deaconess Medical Center and tested with the AMR Gene Panel test (link to poster: OPGN-ASM18). The test data were analyzed by the Acuitas Lighthouse (RUO) to predict antibiotic resistance and these predictions were then compared with conventional antibiotic susceptibility testing. For the four Gram-negative pathogens featured in the presentation, the accuracy for predicting resistance across 12 antibiotics ranged from 91% to 100%. This followed our presentation at April's European Congress of Clinical Microbiology and Infectious Diseases, where we presented results with the Acuitas Lighthouse Software to predict phenotypic resistance for 35 isolates from the CDC and FDA Antibiotic Resistance Isolate Bank. The Acuitas AMR Gene Panel u5.47 was used for isolate testing along with conventional microbiology to determine antibiotic susceptibility. The Acuitas Lighthouse antibiotic resistance predictions had agreement to conventional microbiology ranging from 88% to 100%. Importantly, we were able to reduce the time to results to two hours, compared with three hours previously with our test and current microbiology standards that require up to two days."

Mr. Jones continued, "At ASM Microbe we also presented results of a prospective clinical trial evaluating the impact of using rapid diagnostic testing for the identification and treatment of bacteremia and fungemia in hospital intensive care units in Colombia. The study showed the survival rate for patients tested with the OpGen QuickFISH® was 74%, compared with 47% for patients receiving current standard-of-care protocols."

2018 Second Quarter and First Half Financial Results

- Revenue: Total revenue for the second quarter of 2018 was $0.8 million, compared with $0.7 million for the second quarter of 2017. Total revenue for the first half of 2018 was $1.6 million, compared with $1.5 million for the first half of 2017.
- Operating Expenses: Operating expenses for the second quarter of 2018 were $4.0 million, compared with $4.9 million for the second quarter of 2017. Operating expenses for the first half of 2018 were $7.9 million, compared with $10.6 million for the first half of 2017.
- Net Loss: The net loss for the second quarter of 2018 was $3.3 million or $0.57 per share, compared with a net loss of $4.2 million or $3.73 per share for the second quarter of 2017. The net loss for the first half of 2018 was $6.4 million or $1.29 per share, compared with a net loss of $9.2 million or $8.45 per share for the first half of 2017.
- Cash Position: Cash and cash equivalents were $7.4 million as of June 30, 2018, compared with $1.8 million as of December 31, 2017.

Second Quarter 2018 Enterprise Highlights and Recent Developments:

Summary highlights from the second quarter and recent weeks included:

- Completed preliminary reviews with the FDA resulting in plans to file two 510(k) submissions for the Acuitas AMR Gene Panel u5.47, one for bacterial isolates and a second de novo submission for urine specimens and a separate de novo 510(k) submission for the Acuitas Lighthouse Software.
- Completed planning for the Acuitas AMR Gene Panel (Isolates) 510(k) FDA submission with testing of approximately 900 stock bacterial isolates and analytical validation testing of IUO product to begin during August.
- Expanded the OpGen Clinical Advisory Board and Medical Affairs team with the addition of Patricia Simner, Ph.D. D(ABMM), Associate Professor of Pathology, Director of Bacteriology and Parasitology, the Johns Hopkins Medical Institutions, as an advisor to the company.
- Achieved development milestone in CDC funded program for development of smartphone-based clinical decision support software with hospital testing underway in Colombia.
- Presented data at ASM Microbe 2018 demonstrating 91% to 100% accuracy for predicting antibiotic resistance using the Acuitas® AMR Gene Panel u5.47 (RUO).
- Presented data at ASM Microbe 2018 from a prospective clinical trial in Colombia demonstrating a 57% improvement in survival and reductions in antibiotic usage with the Company's QuickFISH rapid diagnostic test.
- Reported successful analytical validation and clinical verification results for the Acuitas AMR Gene Panel u5.47 (RUO).
- Modified the terms of the debt held by Merck Global Health Innovation Fund to extend the note's maturity and satisfy interest payments with issuance of Company's common stock.
- Continued to achieve stated operating expense reduction, down 17% compared with the second quarter of 2017 and down 26% for the six (6) months ended June 30, 2018 as compared to the six (6) months ended June 30, 2017.

"We made solid progress with research and development, operations and expense reduction during the quarter. We are encouraged by the progress to date with our Acuitas AMR Gene Panel for bacterial isolates and urine specimens and anticipate further progress towards our strategic objectives during 2018," concluded Mr. Jones.

2018 Outlook

OpGen expects to achieve the following business objectives during the remainder of 2018 as it transitions to the commercial phase of its molecular informatics business:

- Derive revenue from the sale of the RUO Acuitas AMR Gene Panel u5.47 to large hospitals, pharmaceutical companies and clinical research organizations.
- Complete third-party clinical verification studies and clinical trials to support FDA clearance for IVD use of the Acuitas AMR Gene Panel u5.47 test and the Acuitas Lighthouse Software.
- File a first 510(k) submission with the FDA in the fourth quarter of 2018 for the Acuitas AMR Gene Panel u5.47 (IVD) to support full commercial launch for clinical use.
- Add QuantStudio 5® and EZ1 Advanced XL® revenue-generating system placements.
- Enter into additional supply and cooperation agreements in support of the new Acuitas product family under development.
- Decommission the company's CLIA laboratory operations in the third quarter of 2018 to provide incremental resources in support of efforts to gain FDA clearance for the company's new Acuitas products.
- Complete CDC contract demonstration in Colombia for development of smartphone-based clinical decision support solutions for anti-microbial stewardship and infection control in low- and middle-income countries.
- Continue to seek third-party funding for development programs.
- Maintain cost reductions and overall cash burn rate to extend operating cash runway.

Conference Call Information

OpGen management will hold a conference call today beginning at 4:30 p.m. Eastern time to discuss second quarter financial results and other business activities, and answer questions. The call can be accessed by dialing (888) 883-4599 (domestic) or (484) 653-6821 (international) and providing conference ID: 9795495. A live webcast of the conference call can be accessed by visiting the Investor Relations section of the company's website at www.ir.opgen.com. A replay of the webcast will be available shortly after the conclusion of the call for 90 days.

A telephone replay of the conference call will be available from 7:30 p.m. Eastern time today through August 8, 2018 and can be accessed by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international). All listeners should provide the conference ID: 9795495.

About OpGen

OpGen, Inc. is harnessing the power of informatics and genomic analysis to provide complete solutions for patient, hospital and network-wide infection prevention and treatment. For more information, please visit www.opgen.com.

The Acuitas AMR Gene Panel u5.47 (RUO) is intended for Research Use Only and is not for use in diagnostic procedures. The Acuitas Lighthouse Software is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

Forward-Looking Statements

This press release includes statements relating to OpGen's second quarter 2018 and six months 2018 results. 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 success of our commercialization efforts, 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.

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(Tables to follow)

OpGen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	June 30, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 7,428,993	$ 1,847,171
Accounts receivable, net	516,472	809,540
Inventory, net	614,423	533,425
Prepaid expenses and other current assets	525,484	311,644
Total current assets	**9,085,372**	**3,501,780**
Property and equipment, net	932,215	835,537
Goodwill	600,814	600,814
Intangible assets, net	1,219,274	1,353,182
Other noncurrent assets	289,032	328,601
Total assets	**$ 12,126,707**	**$ 6,619,914**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,283,469	$ 1,691,712
Accrued compensation and benefits	868,802	746,924
Accrued liabilities	1,377,055	1,160,714
Deferred revenue	14,122	24,442
Short-term notes payable	476,567	1,010,961
Current maturities of long-term capital lease obligations	248,305	154,839
Total current liabilities	**4,268,320**	**4,789,592**
Deferred rent	230,122	290,719
Note payable	825,911	—
Warrant liability	298	8,453
Long-term capital lease obligations and other noncurrent liabilities	403,291	130,153
Total liabilities	**5,727,942**	**5,218,917**
Commitments		
Stockholders' equity		
Common stock, $0.01 par value; 50,000,000 shares authorized; 6,067,039 and 2,265,320 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	60,670	22,653
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at June 30, 2018 and December 31, 2017, respectively	—	—
Additional paid-in capital	161,449,185	150,114,671
Accumulated other comprehensive loss	(20,366)	(25,900)
Accumulated deficit	(155,090,724)	(148,710,427)
Total stockholders' equity	**6,398,765**	**1,400,997**
Total liabilities and stockholders' equity	**$ 12,126,707**	**$ 6,619,914**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenue				
Product sales	$ 632,525	$ 681,127	$ 1,266,021	$ 1,415,629
Laboratory services	1,100	15,850	9,790	31,955
Collaboration revenue	155,276	6,233	359,316	27,397
Total revenue	**788,901**	**703,210**	**1,635,127**	**1,474,981**
Operating expenses				
Cost of products sold	303,663	392,791	646,495	817,741
Cost of services	179,402	78,763	347,955	178,996
Research and development	1,308,388	1,762,234	2,538,817	3,884,749
General and administrative	1,827,063	1,750,018	3,617,585	3,719,234
Sales and marketing	426,297	909,402	756,070	2,014,988
Total operating expenses	**4,044,813**	**4,893,208**	**7,906,922**	**10,615,708**
Operating loss	**(3,255,912)**	**(4,189,998)**	**(6,271,795)**	**(9,140,727)**
Other (expense)/income				
Interest and other income	5	22	5,303	43
Interest expense	(54,533)	(53,813)	(112,379)	(83,657)
Foreign currency transaction (losses)/gains	(21,762)	8,998	(9,581)	11,618
Change in fair value of derivative financial instruments	(11)	26,744	8,155	26,744
Total other expense	**(76,301)**	**(18,049)**	**(108,502)**	**(45,252)**
Loss before income taxes	**(3,332,213)**	**(4,208,047)**	**(6,380,297)**	**(9,185,979)**
Provision for income taxes	—	—	—	—
Net loss	**(3,332,213)**	**(4,208,047)**	**(6,380,297)**	**(9,185,979)**
Net loss available to common stockholders	**$ (3,332,213)**	**$ (4,208,047)**	**$ (6,380,297)**	**$ (9,185,979)**
Net loss per common share - basic and diluted	**$ (0.57)**	**$ (3.73)**	**$ (1.29)**	**$ (8.45)**
Weighted average shares outstanding - basic and diluted	5,826,947	1,128,426	4,950,517	1,086,477
Net loss	$ (3,332,213)	$ (4,208,047)	$ (6,380,297)	$ (9,185,979)
Other comprehensive loss - foreign currency translation	18,113	(3,834)	5,534	(7,591)
Comprehensive loss	**$ (3,314,100)**	**$ (4,211,881)**	**$ (6,374,763)**	**$ (9,193,570)**

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