

**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**

Date of Report (Date of earliest event reported): March 23, 2017

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 No.)**

**708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878
(Address of principal executive offices, including 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))
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Item 2.02 Results of Operations and Financial Condition.

On March 23, 2017, OpGen, Inc. issued a press release announcing financial results for the quarter and year ended December 31, 2016. The full text of such press release is filed as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release, dated March 23, 2017, 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.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer

Date: March 23, 2017

EXHIBIT INDEX

Exhibit Document
No.

99.1 [Press Release, dated March 23, 2017, issued by OpGen, Inc.](#)



OPGEN ANNOUNCES 2016 FOURTH QUARTER AND YEAR END FINANCIAL RESULTS

Achieves Revenue of Approximately \$4.0 Million, a 27% Year Over Year Increase

GAITHERSBURG, Md., March 23, 2017 – OpGen, Inc. (NASDAQ:OPGN) today reported financial and operational results for the fourth quarter and year ended December 31, 2016 and summarized 2016 business highlights. Total revenue for the full year ended December 31, 2016 was \$4.0 million, a 27% increase from \$3.2 million recorded for the full year ended December 31, 2015. Net loss for the full year ended December 31, 2016 was \$19.2 million compared with \$17.4 million in 2015.

"In 2016 our investments in genomics and informatics for infectious disease management issues caused by multi-drug resistant organisms began to pay off. We successfully moved our Acuitas Rapid Test for drug resistant genes and pathogens and our Acuitas Lighthouse antibiotic resistance prediction technology to the development phase. Later this year we anticipate the first clinical evaluations of this breakthrough new technology along with the release of RUO test kits," said Evan Jones, Chairman & CEO of OpGen. "We also achieved key milestones including a strategic research collaboration with Merck and compelling data on health outcomes from our partnerships with distinguished U.S. health systems and collaborators."

2016 Year End and Fourth Quarter Financial Results

- **Revenue:** Total revenue for the full year ended December 31, 2016 was \$4.0 million, a 27% increase from the \$3.2 million in 2015. Total revenue for the fourth quarter of 2016 was \$1.0 million, a decrease of 24% from \$1.3 million in the fourth quarter of 2015 and an increase of 32% from the \$0.8 million in the third quarter of 2016.
- **Operating Expenses:** Operating expenses for the full year ended December 31, 2016 were \$23.0 million compared with \$18.2 million in 2015. Operating expenses for the fourth quarter of 2016 were \$5.7 million compared with \$6.2 million in the fourth quarter of 2015.
- **Net Loss:** Net loss for the full year ended December 31, 2016 was \$19.2 million compared with \$17.4 million in 2015. Net loss for the fourth quarter of 2016 was \$4.8 million compared to \$4.7 million in the fourth quarter of 2015.
- **Cash Position:** Cash and cash equivalents were \$4.1 million as of December 31, 2016 compared with \$4.3 million as of September 30, 2016.

2016 Enterprise Highlights and Recent Developments:

- Announced collaboration with Merck to develop novel rapid diagnostics and informatics tools to combat antibiotic resistance. The companies will collaborate to support OpGen's development of rapid DNA tests and a genomic knowledgebase of antibiotic-resistant pathogens for predicting antibiotic susceptibility based on test results. Under the terms of the agreement, Merck will provide access to its archive of over 200,000 bacterial pathogens gathered over the last 15 years through the Study for Monitoring Antimicrobial Resistance Trends (SMART), one of the world's largest surveillance studies of antimicrobial resistance.
 - Successfully moved the Acuitas Rapid Test and genome-based antibiotic resistance analysis technology from research into development phase, including transitioning our informatics infrastructure and genomic development engine into production and initial performance verification of top pathogens.
 - Participated with the District of Columbia Hospital Association as key technology provider to complete the first citywide quantification of multidrug-resistant organism (MDRO) prevalence in Washington, D.C. healthcare facilities. The results revealed the prevalence of carbapenem-resistant enterobacteriaceae (CRE) and other carbapenem-resistant organisms (CRO) was 5.1% and 6.4%, respectively.
 - Announced completion of the Intermountain Healthcare retrospective MDRO health outcomes study. The study is the largest of its kind conducted in an integrated health system and is anticipated to provide significant insights into how healthcare systems can reduce infections and improve health outcomes.
 - Completed a \$10.4 million Private Placement in the second quarter and raised \$4.7 million during the fourth quarter of 2016 under a previously announced "at the market" (ATM) offering.
 - Participated in nine posters and oral presentations at major medical meetings and published analytical validation results for the Acuitas MDRO Gene Test.
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2017 Outlook

"During 2017 we are focused on advancing the development of the Acuitas brand of rapid diagnostic products alongside the Acuitas Lighthouse Knowledgebase with a goal of implementing the technology for external research use in the second half of the year," continued Mr. Jones. "We are also working to further accelerate the growth of our business in the United States and international markets. We anticipate sharing additional commercial, technical and health outcomes data that support our position and capabilities as they become available."

In the fight to help address the global antibiotic resistance crisis, OpGen expects to advance the following business objectives in 2017:

- Genomic and antibiotic resistance testing of 10,000 multidrug resistant organisms to support initial development of the first Acuitas Rapid Test kits and deployment of the Acuitas Lighthouse Knowledgebase.
- Completion of initial Acuitas Rapid Test development and Acuitas Lighthouse genotype/phenotype predictive algorithms and clinical performance verification.
- Presentation of Acuitas Rapid Test and performance data at medical meetings and in peer reviewed journals.
- Announcement of in vitro diagnostic instrument supply and cooperation agreement to support global commercialization of the Acuitas Rapid Test.
- Establishment of distribution and partner relationships to support commercialization of Acuitas Rapid Test and the Acuitas Lighthouse Knowledgebase in international markets.
- Establishment of Acuitas Rapid Test early access and performance verification programs to support regulatory approval clinical trials and publications.
- Continued efforts to obtain third party development funding for Acuitas Rapid Test and Acuitas Lighthouse Knowledgebase development and deployment.

Conference Call Information

OpGen management will hold a conference call today beginning at 4:30 p.m. (EDT) to discuss fourth quarter and year end financial results and other business activities. The call can be accessed by dialing 844-420-8185 (domestic) or 216-562-0481 (international) and providing passcode 87850606. A live webcast of the conference call can be accessed by visiting the Investor Relations section of the company's website at <http://ir.opgen.com>. A replay of the webcast will be available shortly after the conclusion of the call on the company's website for 90 days.

A telephone replay also will be available at 7:30 p.m. ET through March 28, 2017 and may be accessed by dialing 855-859-2056 from within the U.S. or 404-537-3406 from outside the U.S. All listeners should provide passcode 87850606.

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. Learn more at www.opgen.com and follow OpGen on Twitter and LinkedIn.

OpGen, Acuitas MDRO, Acuitas Lighthouse and QuickFISH are registered trademarks of OpGen, Inc.

Forward-Looking Statements

This press release includes statements relating to the company's products and services, its commercialization plans for these products and services, and its product and services development efforts. These statements and other statements regarding our 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 approval 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 (SEC). 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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OpGen, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
Revenue				
Product sales	\$ 818,488	\$ 1,268,550	\$ 3,524,178	\$ 2,701,142
Laboratory services	46,774	33,275	228,904	120,476
Collaboration revenue	141,301	27,762	272,603	336,102
Total revenue	1,006,563	1,329,587	4,025,685	3,157,720
Operating expenses				
Cost of products sold	388,581	391,515	1,658,571	1,179,771
Cost of services	102,600	169,111	631,333	367,802
Research and development	2,334,407	2,105,892	8,613,236	6,002,941
General and administrative	1,647,512	2,140,499	6,602,608	5,834,642
Sales and marketing	1,246,646	1,342,889	5,529,274	4,305,444
Transaction expenses	—	687	—	526,283
Total operating expenses	5,719,746	6,150,593	23,035,022	18,216,883
Operating loss	(4,713,183)	(4,821,006)	(19,009,337)	(15,059,163)
Other expense				
Interest and other (expense)/income	(2,889)	1,411	(5,967)	26,657
Interest expense	(33,541)	(38,896)	(143,347)	(1,801,320)
Foreign currency transaction losses	(10,395)	—	(8,102)	—
Change in fair value of derivative financial instruments	—	—	—	(647,342)
Total other expense	(46,825)	(37,485)	(157,416)	(2,422,005)
Loss before income taxes	(4,760,008)	(4,858,491)	(19,166,753)	(17,481,168)
Provision for income taxes	—	(130,757)	—	(129,095)
Net loss	(4,760,008)	(4,727,734)	(19,166,753)	(17,352,073)
Preferred stock dividends and beneficial conversion	—	—	(332,550)	(243,762)
Net loss available to common stockholders	\$ (4,760,008)	\$ (4,727,734)	\$ (19,499,303)	\$ (17,595,835)
Net loss per common share - basic and diluted	\$ (0.21)	\$ (0.38)	\$ (1.10)	\$ (2.20)
Weighted average shares outstanding - basic and diluted	22,549,773	12,540,755	17,667,557	7,980,995
Net loss	\$ (4,760,008)	\$ (4,727,734)	\$ (19,166,753)	\$ (17,352,073)
Other comprehensive income/(loss) - foreign currency translation	6,176	(1,010)	7,235	(1,059)
Comprehensive loss	\$ (4,753,832)	\$ (4,728,744)	\$ (19,159,518)	\$ (17,353,132)

OpGen, Inc.
Consolidated Balance Sheets
(unaudited)

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 4,117,324	\$ 7,814,220
Accounts receivable, net	542,420	678,646
Inventory, net	692,368	826,012
Prepaid expenses and other current assets	329,646	566,239
Total current assets	5,681,758	9,885,117
Property and equipment, net	800,723	1,074,710
Goodwill	600,814	637,528
Intangible assets, net	1,620,998	1,888,814
Other noncurrent assets	279,752	270,327
Total assets	\$ 8,984,045	\$ 13,756,496
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 2,232,563	\$ 2,285,792
Accrued compensation and benefits	578,480	1,081,270
Accrued liabilities	1,215,283	920,286
Deferred revenue	37,397	50,925
Short-term notes payable	1,023,815	—
Current maturities of long-term capital lease obligation	184,399	251,800
Total current liabilities	5,271,937	4,590,073
Deferred rent	398,084	352,985
Note payable	—	993,750
Long-term capital lease obligation and other noncurrent liabilities	146,543	328,642
Total liabilities	5,816,564	6,265,450
Stockholders' equity		
Common stock, \$0.01 par value; 200,000,000 shares authorized; 25,304,270 and 12,547,684 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	253,042	125,477
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2016 and December 31, 2015, respectively	—	—
Additional paid-in capital	136,199,382	121,490,994
Accumulated other comprehensive income/(loss)	6,176	(1,059)
Accumulated deficit	(133,291,119)	(114,124,366)
Total stockholders' equity	3,167,481	7,491,046
Total liabilities and stockholders' equity	\$ 8,984,045	\$ 13,756,496