

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): November 12, 2015

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 November 12, 2015, OpGen, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2015. The full text of such press release is furnished as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release, dated November 12, 2015, 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: November 12, 2015

EXHIBIT INDEX

Exhibit No.

Document

99.1 Press Release, dated November 12, 2015, issued by OpGen, Inc.



OpGen Reports Third Quarter Financial Results and Provides Business Update

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

GAITHERSBURG, Md. (November 12, 2015) – OpGen, Inc. (NASDAQ: OPGN), an early commercial-stage company using molecular testing and bioinformatics to help guide antibiotic therapy and to assist healthcare providers combat multi-drug resistant infections, today reported financial results for the three and nine months ended September 30, 2015. Highlights of the third quarter of 2015 and recent weeks include:

- OpGen chosen to track the threat of potentially lethal multi-drug resistant infectious in a major metro region; government funded program to commence in November
- Acquired AdvanDx, Inc., a market leader in rapid molecular testing for microorganism identification
- Completed a \$6 million financing with Merck Global Health Innovation Fund, LLC (Merck GHI)

Financial Results

Total revenue for the third quarter of 2015 was \$1.0 million, compared with \$0.8 million for the third quarter of 2014. The 17.5% increase in revenue includes \$0.8 million in sales of QuickFISH™ rapid molecular diagnostics products as a result of the Company's acquisition of AdvanDx in July, 2015. Total operating expenses for the third quarter of 2015 were \$5.0 million, compared with \$2.2 million for the third quarter of 2014. The increase reflects inclusion of \$1.3 million of AdvanDx operating expenses and \$0.5 million of transaction-related costs associated with the AdvanDx acquisition.

The net loss for the third quarter of 2015 was \$4.7 million, compared with a net loss for the third quarter of 2014 of \$1.6 million. Net loss attributable to common stockholders for the third quarter of 2015 was \$4.7 million, or \$0.38 per share, compared with a net loss attributable to common stockholders for the third quarter of 2014 of \$1.8 million, or \$4.92 per share.

Total revenue for the nine months ended September 30, 2015 was \$1.8 million, compared with \$3.0 million for the same period of 2014. Revenue from product sales and laboratory services increased 24.5% to \$1.5 million from \$1.2 million in 2014 primarily as a result of sales of QuickFISH rapid molecular diagnostic testing products. Collaboration revenues decreased to \$0.3 million from \$1.8 million as a result of nearing completion of a technology development agreement. Total operating expenses for the nine months ended September 30, 2015 were \$11.2 million, compared with \$6.6 million for the nine months ended September 30, 2014. The increase reflects the inclusion of \$1.3 million of AdvanDx costs, \$0.8 million of public company costs, \$1.0 million of stock-based compensation costs and \$0.5 million in transaction costs associated with the AdvanDx acquisition.

Net loss was \$12.6 million for the first nine months of 2015, compared with a net loss of \$4.3 million for the first nine months of 2014. Net loss attributable to common stockholders was \$12.9 million for the nine months ended September 30, 2015, or \$2.00 per share, compared with a net loss attributable to common stockholders of \$4.7 million for the nine months ended September 30, 2014, or \$13.03 per share.

The Company had cash and cash equivalents of \$11.2 million as of September 30, 2015, compared with \$0.7 million as of December 31, 2014. During the quarter the Company completed a \$6.0 million financing with Merck GHI, pursuant to which Merck GHI purchased 1,136,364 shares of OpGen common stock at a price of \$4.40 per share, and OpGen issued Merck GHI a senior secured promissory note in the principal amount of \$1.0 million with a two-year maturity from the date of issuance. The Company also has \$0.5 million in capital lease obligations of which \$0.2 million are current maturities.

Management Commentary

“The third quarter and recent weeks were a productive time for OpGen as we continued to execute on our plans to build a leading company helping to improve antibiotic therapy and combat drug-resistant infections,” said Evan Jones, the Company’s chairman and chief executive officer.

Mr. Jones continued, “We are well positioned with FDA-cleared molecular diagnostic tests for rapid pathogen identification, CLIA lab-based tests for MDRO drug resistance testing and our Acuitas Lighthouse bioinformatics for reporting and helping interpret patient and lab data. Our sales and marketing organization, which now numbers 13, is trained on both the Acuitas MDRO test offerings and the QuickFISH tests. With our commercial organization in place and a number of planned new products in development, we are well positioned to grow revenue in the coming years,” Mr. Jones concluded.

Commenting on the third quarter financial results, Tim Dec, the Company’s chief financial officer, said, “Our third quarter financial results reflect the operations of AdvanDx beginning July 14, the date the transaction closed. The revenue growth in the quarter highlights the transition of the company’s business to proprietary, high-margin diagnostic products from our legacy genome mapping products and collaborative research activities. Our expenses reflect the increased investments in both infrastructure and human capital to support our planned growth.”

Conference Call and Webcast

OpGen management will host a conference call to discuss third quarter financial results and answer questions today at 4:30 p.m. Eastern time.

To access the conference call, U.S.-based participants should dial (888) 883-4599 and international participants should dial (484) 653-6821. All participants should provide the following passcode: 63158584. Following the conclusion of the conference call, a replay will be available through November 18, 2015 and can 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 63158584. Individuals interested in listening to the live conference call via the Internet may do so by logging on to the Investor Relations portion of the Company’s website at www.opgen.com.

About MDROs

Multi-drug resistant organisms (MDROs) are common bacteria that have developed resistance to multiple classes of antibiotics. They are a leading cause of hospital-acquired infections and are associated with an increase in morbidity and mortality. Each year, more than 2 million Americans acquire infections that are resistant to antibiotics and every year in the U.S., about 23,000 people die from them. The cost of treating these infections is estimated to be between \$20 billion to \$35 billion. Asymptomatic carriers are at a higher risk of an MDRO infection and become reservoirs for transmission to other patients in health care systems if not accurately identified early. Since there are many types of antibiotic-resistant organisms, and the way they cause disease is dictated by their genetics, knowing the exact genetic profile of these organisms is a key step to preventing their ability to infect.

About OpGen

OpGen is an early-stage company using rapid molecular testing and bioinformatics to help guide antibiotic therapy and to assist healthcare providers to combat multi-drug resistant infections, or MDROs. OpGen's lead products are its QuickFISH® and PNAFISH products, which are advanced *in vitro* diagnostic kits for the diagnosis and prevention of infectious diseases, the Acuitas® MDRO Gene Test, a CLIA lab-based test that provides a profile of MDRO resistant genes from patients screened for colonization or infection and the Acuitas Lighthouse to aid in the interpretation of MDRO diagnostic test results. The company develops, markets and sells its products principally for use in hospitals and clinical laboratories in the United States and internationally. Learn more at www.opgen.com

Forward-Looking Statements

This press release includes statements relating to the company's Acuitas MDRO Gene Test and Acuitas Lighthouse MDRO Management System and QuickFISH products commercialization plans for these products and services. 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, the rate of adoption of our products and services by hospitals, 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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(Tables to follow)

OpGen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	\$ 11,187,129	\$ 749,517
Accounts receivable, net	553,938	503,983
Inventory, net	1,155,488	369,742
Prepaid expenses and other current assets	538,312	90,233
Total current assets	13,434,867	1,713,475
Property and equipment, net	1,021,971	587,956
Deferred IPO issuance costs	-	296,041
Intangible assets, net	1,955,769	-
Goodwill	291,747	-
Other noncurrent assets	293,135	57,459
Total assets	\$ 16,997,489	\$ 2,654,931
Liabilities, Redeemable Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	\$ 1,274,657	\$ 1,160,081
Accrued compensation and benefits	840,637	423,099
Accrued liabilities	1,232,328	993,657
Deferred revenue	158,860	339,171
Short-term notes payable	1,250	1,505,000
Current maturities of long-term capital lease obligation	227,049	100,499
Short-term convertible notes, net of discounts	-	1,500,000
Total current liabilities	3,734,781	6,021,507
Note payable	1,000,000	-
Long-term capital lease obligations and other noncurrent liabilities	317,854	134,149
Total liabilities	5,052,635	6,155,656
Commitments and contingencies (Note 10)		
Redeemable convertible preferred stock		
Series A redeemable convertible preferred stock, \$.01 par value; 6,000,000 shares authorized; 3,999,864 shares issued and outstanding at December 31, 2014 (none at September 30, 2015); aggregate liquidation preference of \$7,999,728 at December 31, 2014 (none at September 30, 2015)	-	4,564,899
Total redeemable convertible preferred stock	-	4,564,899
Stockholders' equity (deficit)		
Common stock, \$.01 par value; 200,000,000 shares authorized; 12,539,704 and 493,178 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	125,397	4,932
Additional paid-in capital	121,216,140	88,701,737
Accumulated other comprehensive loss	(49)	-
Accumulated deficit	(109,396,634)	(96,772,293)
Total stockholders' equity (deficit)	11,944,854	(8,065,624)
Total liabilities, redeemable preferred stock and stockholders' equity (deficit)	\$ 16,997,489	\$ 2,654,931

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue				
Product sales	\$ 929,241	\$ 268,854	\$ 1,432,592	\$ 841,567
Laboratory services	23,765	88,190	87,201	379,339
Collaboration revenue	27,780	477,780	308,340	1,783,340
Total revenue	980,786	834,824	1,828,133	3,004,246
Cost of products sold (excluding depreciation and amortization)	562,694	101,425	712,016	276,831
Cost of services (excluding depreciation and amortization)	46,634	129,120	191,738	336,616
Total costs of sales (excluding depreciation and amortization)	609,328	230,545	903,754	613,447
Gross profit	371,458	604,279	924,379	2,390,799
Operating expenses				
Research and development	1,724,127	1,029,650	3,741,247	3,075,420
General and administrative	1,610,828	555,444	3,687,313	1,590,085
Sales and marketing	979,681	459,064	2,815,976	1,486,801
Depreciation and amortization	185,177	141,060	392,404	461,432
Transaction expenses	525,596	-	525,596	-
Total operating expenses	5,025,409	2,185,218	11,162,536	6,613,738
Operating loss	(4,653,951)	(1,580,939)	(10,238,157)	(4,222,939)
Other income (expense)				
Interest income	2,513	37	9,675	120
Interest expense	(17,482)	(32,331)	(1,746,853)	(47,468)
Change in fair value of derivative financial instruments and other	-	4,400	(647,342)	4,400
Total other income (expense)	(14,969)	(27,894)	(2,384,520)	(42,948)
Loss before income taxes	(4,668,920)	(1,608,833)	(12,622,677)	(4,265,887)
Provision for income taxes	1,662	-	1,662	-
Net loss	(4,670,582)	(1,608,833)	(12,624,339)	(4,265,887)
Preferred stock dividends	-	(175,246)	(244,508)	(458,799)
Net loss available to common stockholders	\$ (4,670,582)	\$ (1,784,079)	\$ (12,868,847)	\$ (4,724,686)
Net loss per common share - basic and diluted	\$ (0.38)	\$ (4.92)	\$ (2.00)	\$ (13.03)
Weighted average shares outstanding - basic and diluted	12,261,238	362,537	6,444,373	362,537
Net loss	(4,670,582)	(1,608,833)	(12,624,339)	(4,265,887)
Other comprehensive loss - foreign currency translation	(49)	-	(49)	-
Comprehensive loss	\$ (4,670,631)	\$ (1,608,833)	\$ (12,624,388)	\$ (4,265,887)

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