

OpGen Reports 2017 Third Quarter Financial Results and Provides Business Update

November 7, 2017

Affirms plans to release Acuitas® AMR Gene Panel in the first quarter of 2018

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

GAITHERSBURG, Md., Nov. 07, 2017 (GLOBE NEWSWIRE) -- OpGen, Inc. (NASDAQ:OPGN) reports financial and operational results for the three and nine months ended September 30, 2017, and provides a summary of recent business highlights.

"During the third quarter and recent weeks, we continued to achieve important corporate milestones in the development of our new Acuitas gene tests and informatics for multi-drug resistant organisms" said Evan Jones, Chairman and CEO of OpGen. "We continued to advance development of our first Acuitas® AMR Gene Panel u5.47 test and the Acuitas Lighthouse® Knowledgebase and are planning to begin clinical validation studies during the fourth quarter of 2017. Consistent with our corporate initiative to obtain third party funding for priority development programs, we were awarded a one-year, \$860,000 contract from the Centers for Disease Control and Prevention (CDC) to develop smartphone-based clinical decision support solutions for antimicrobial stewardship (AMS) and infection control in low- and middle-income countries."

Additional developments during the third quarter and recent weeks include:

- Advanced development of the Acuitas AMR Gene Panel u5.47 for complicated urinary tract infections (cUTI) for release in the first half of 2018 for research and investigational use
- Produced the first AMR Gene Panel test kits for cUTI and clinical isolate testing
- Began analytical validation studies for the cUTI panel
- Advanced plans to begin clinical validation studies for the cUTI panel in the fourth quarter of 2017
- Continued development of genotype/phenotype predictive algorithms based on the testing of 7,400 clinical isolates from the Merck SMART surveillance network and clinical collaborators, contributing to the 15,800 isolates contained in the Acuitas Lighthouse Knowledgebase
- Achieved stated operating expense reduction during the quarter, with a 29% reduction compared with the third quarter of 2016
- Completed a \$10.0 million public offering with net proceeds to OpGen of \$8.8 million

2017 Third Quarter and Year-to-Date Financial Results

- Revenue: Total revenue for the three months ended September 30, 2017 was \$745,000, compared with \$760,000 for the three months ended September 30, 2016. Total revenue for the nine months ended September 30, 2017 was \$2.2 million, compared with \$3.0 million for the nine months ended September 30, 2016.
- Operating Expenses: Operating expenses for the three months ended September 30, 2017 were \$3.9 million, compared with \$5.6 million for the three months ended September 30, 2016. Operating expenses for the nine months ended September 30, 2017 were \$14.6 million, compared with \$17.3 million for the nine months ended September 30, 2016.
- Net Loss Available to Common Stockholders: Net loss for the three months ended September 30, 2017 was \$3.3 million or \$0.07 per share, compared with \$4.8 million or \$0.23 per share for the three months ended September 30, 2016. Net loss for the nine months ended September 30, 2017 was \$12.5 million or \$0.37 per share, compared with \$14.7 million or \$0.92 per share for the nine months ended September 30, 2016.
- Cash Position: Cash and cash equivalents were \$4.9 million as of September 30, 2017, compared with \$4.1 million as of December 31, 2016.

2017 Third Quarter Enterprise Highlights and Recent Developments

- Awarded \$860,000 CDC Contract funding development and evaluation of cloud- and mobile-based software integrating electronic patient data and local empiric treatment guidelines to support antimicrobial stewardship and infection control for low- and middle-income countries. OpGen will work with partners TEQQA, LLC and Universidad El Bosque of Bogota, Colombia led by Maria Virginia Villegas, M.D., M.Sc. and will work to establish connectivity to WHONET, an information system developed to support the World Health Organization's goal of global surveillance of bacterial resistance to antimicrobial agents. WHONET analyzes the data of over 4,000 laboratories worldwide and is used in more than 120 countries.
- Presented study results on the company's new rapid test in development, the Acuitas AMR Gene Panel u5.47, and the Acuitas Lighthouse Knowledgebase for the prediction of antibiotic susceptibility at the 2017 ASM/ESCMID Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance. The semi-quantitative PCR test detects 5 bacterial pathogens in clinical isolates and urine specimens and detects 47 antimicrobial resistance genes.

"We were pleased with our financial performance during the third quarter with the significant narrowing of our net loss," continued Mr. Jones. "We maintained product sales and collaboration revenue at \$736,000, which was comparable to levels from Q3 2016. We set out to reduce operating expenses by 25% to 30% in the second half of 2017 compared with the first half, or a reduction of \$4.0 million to \$5.0 million of annualized operating expenses and a marked improvement in our cash burn. The 29% reduction in operating expenses compared with the third quarter of 2016, or a reduction of \$1.6 million during the third quarter, was consistent with these objectives."

"Our Acuitas Rapid Test for cUTI is on track to be evaluated at third-party clinical sites in the fourth quarter and released for research use only in the first quarter of 2018," added Mr. Jones. "This antimicrobial resistance test is expected to be the first of a series of OpGen tests that will help address the global antibiotic resistance crisis by identifying antibiotic resistant pathogens in less than three hours. Along with the Acuitas Lighthouse Knowledgebase, a dynamic cloud-based information store that is continuously updated for new resistance genes, results will help inform proper patient treatments."

2017 Outlook

OpGen expects to advance the following business objectives through the remainder of 2017:

- Finalize initial Acuitas Lighthouse Knowledgebase antibiotic resistance prediction algorithms and begin clinical validation studies for Acuitas AMR Gene Panel u5.47 at major academic medical centers and health systems.
- Complete analytical validation studies for the AMR Gene Panel u5.47 to allow commercial release in Q1 2018 and FDA clinical trials during 2018.
- Enter into additional supply and cooperation agreements in support of the new Acuitas product family under development.
- Complete first program milestones in CDC contract, with our collaboration partners, for development of smartphone-based clinical decision support solutions for antimicrobial stewardship (AMS) and infection control in low- and middle-income countries.
- Continue to reduce costs and overall cash burn rate to help provide extended operating cash runway.

Conference Call Information

OpGen management will hold a conference call today beginning at 4:30 p.m. Eastern time to discuss third quarter 2017 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 the conference ID: 2498769. 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 of the conference call will be available from 7:30 p.m. Eastern time today through November 13, 2017 and can be accessed by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international). All listeners should provide the conference ID: 2498769.

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.

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

Forward-Looking Statements

This press release includes statements relating to the proceeds from the Company's public offering and its products and services. 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 (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.

Condensed Consolidated Balance Sheets

(unaudited)

	Se	eptember 30, 2017	De	ecember 31, 2016
Assets				
Current assets				
Cash and cash equivalents	\$	4,854,031	\$	4,117,324
Accounts receivable, net		469,954		542,420
Inventory, net		461,129		692,368
Prepaid expenses and other current assets		340,923		329,646
Total current assets		6,126,037		5,681,758
Property and equipment, net		750,090		800,723
Goodwill		600,814		600,814
Intangible assets, net		1,420,136		1,620,998
Other noncurrent assets		321,592		279,752
Total assets	\$	9,218,669	\$	8,984,045
Liabilities and Stockholders' Equity				
Current liabilities				
Accounts payable	\$	1,939,175	\$	2,232,563
Accrued compensation and benefits		902,892		578,480
Accrued liabilities		857,024		1,215,283
Deferred revenue		31,239		37,397
Short-term notes payable		1,100,012		1,023,815
Current maturities of long-term capital lease obligation		160,485		184,399
Total current liabilities		4,990,827		5,271,937
Deferred rent		319,273		398,084
Warrant liability		28,378		_
Long-term capital lease obligation and other noncurrent liabilities		119,764		146,543
Total liabilities		5,458,242		5,816,564
Commitments				
Stockholders' equity				
Common stock, \$0.01 par value; 200,000,000 shares authorized; 51,964,878 and 25,304,270 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively		519,648		253,042
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at September 30, 2017 and December 31, 2016, respectively		_		_
Additional paid-in capital		148,994,194		136,199,382
Accumulated other comprehensive (loss)/income		(7,649)	6,176
Accumulated deficit		(145,745,766)	(133,291,119)
Total stockholders' equity		3,760,427		3,167,481
Total liabilities and stockholders' equity	\$	9,218,669	\$	8,984,045

OpGen, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)

Three Months I	Ended September 30,	Nine Months	Ended September 30,
2017	2016	2017	2016

Product sales	\$ 729,742		\$ 730,325		\$ 2,145,371		\$ 2,705,690	
Laboratory services	9,070		23,036		41,025		182,130	
Collaboration revenue	6,302		6,302		33,699		131,302	
Total revenue	745,114		759,663		2,220,095		3,019,122	
Operating expenses								
Cost of products sold	448,407		400,001		1,266,148		1,269,990	
Cost of services	49,119		51,802		228,115		528,733	
Research and development	1,513,157		2,178,818		5,397,906		6,278,829	
General and administrative	1,600,577		1,639,996		5,319,811		4,955,096	
Sales and marketing	330,305		1,294,640		2,345,293		4,282,628	
Total operating expenses	3,941,565		5,565,257		14,557,273		17,315,276	
Operating loss	(3,196,451)	(4,805,594)	(12,337,178)	(14,296,154)
Other expense								
Other (expense)/income	(87,292)	623		(87,270)	(3,078)
Interest expense	(90,317)	(41,423)	(173,974)	(109,806)
Foreign currency transaction gains/(losses)	8,018		(1,269)	19,636		2,293	
Changes in fair value of warrant liabilities	97,395		-		124,139		-	
Total other expense	(72,196)	(42,069)	(117,469)	(110,591)
Loss before income taxes	(3,268,647)	(4,847,663)	(12,454,647)	(14,406,745)
Provision for income taxes	_		_		_		_	
Net loss	(3,268,647)	(4,847,663)	(12,454,647)	(14,406,745)
Preferred stock dividends and beneficial conversion	_		_		_		(332,550)
Net loss available to common stockholders	\$ (3,268,647)	\$ (4,847,663)	\$ (12,454,647)	\$ (14,739,295)
Net loss per common share - basic and diluted	\$ (0.07)	\$ (0.23)	\$ (0.37)	\$ (0.92)
Weighted average shares outstanding - basic and diluted	47,078,415		20,938,700		33,956,494		16,028,047	
Net loss	\$ (3,268,647)	\$ (4,847,663)	\$ (12,454,647)	\$ (14,406,745)
Other comprehensive (loss)/income - foreign currency translation	(6,234)	672		(13,825)	1,059	
Comprehensive loss	\$ (3,274,881)	\$ (4,846,991)	\$ (12,468,472)	\$ (14,405,686)

OpGen, Inc.