OpGen Reports Preliminary Fourth Quarter and Full Year 2016 Financial Results

January 26, 2017

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

GAITHERSBURG, Md., Jan. 26, 2017 (GLOBE NEWSWIRE) -- OpGen, Inc. (NASDAQ:OPGN) today announced preliminary unaudited results for the fourth quarter and full year ended December 31, 2016, and summarized 2016 business highlights. Total revenue for the full year ended December 31, 2016 was approximately $4.0 million, a 27% increase from the $3.2 million recorded for the full year ended December 31, 2015. Total revenue for the fourth quarter of 2016 is expected to be approximately $1.0 million, a decrease of approximately 24% from $1.3 million in the fourth quarter of 2015 and an increase of 32% from the $0.8 million recorded in the third quarter of 2016.

The Company disclosed the following estimated, unaudited operating expenses for the fourth quarter of 2016 and the full year ended December 31, 2016. Operating expenses for the full year ended December 31, 2016 are expected to be in the range of approximately $22.8 million and $23.3 million. Full year 2016 operating expenses at the midpoint of the range represents an increase of approximately 27% from $18.2 million in the full year 2015. Operating expenses for the fourth quarter of 2016 are expected to be in the range of approximately $5.5 million and $6.0 million. Fourth quarter 2016 operating expenses at the midpoint of the range represents an increase of approximately 3% from $5.6 million in the third quarter of 2016 and a decrease of approximately 7% from $6.2 million in the fourth quarter of 2015.

Net loss for the full year ended December 31, 2016 is expected to be in the range of approximately $19.0 million and $19.5 million. Full year 2016 net loss at the midpoint of the range represents an increase in the net loss of approximately 11% from $17.4 million in the full year 2015. Net loss for the fourth quarter of 2016 is expected to be in the range of approximately $4.6 million and $5.1 million. Fourth quarter 2016 net loss at the midpoint of the range represents no change from $4.8 million in the third quarter of 2016 and an increase in the net loss of approximately 3% from $4.7 million in the fourth quarter of 2015. Net loss for the fourth quarter of 2016 and the full year ended December 31, 2016 are subject to change as the Company completes its impairment testing of the intangible assets acquired as part of the purchase of AdvanDx in July 2015. The Company's intangible assets, net, balance as of September 30, 2016 was $1.7 million. Any impairment in intangible assets would represent a non-cash operating expense.

Cash and cash equivalents were approximately $4.1 million as of December 31, 2016 compared with $4.3 million as of September 30, 2016.

"During 2016, we continued to build our unique position helping to address the rising global antibiotic resistance crisis," stated Evan Jones, Chairman & CEO. "We invested heavily to solidify our leadership in leveraging genomics and informatics to help combat urgent infectious disease management issues caused by multi-drug resistant organisms. From an operations perspective, we finished the fourth quarter with steady results for our core QuickFISH® business, and building interest for our Acuitas® Lighthouse service offerings. We achieved key technical milestones for our lead genome-based antibiotic decision making products and participated in the development of compelling data from distinguished US health systems and collaborators that position us well going into 2017."

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 Acuitas mAST™ 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.
- Progressed automated QuickFISH Pathogen ID product development for positive blood culture specimens in anticipation of FDA 510(k) clinical trials. In early 2017, determined to delay production scale-up and clinical trial investment to allow work on new pathogen ID and quantitation opportunities, to conserve cash, and to provide incremental resources to the Acuitas mAST project.
- Participated with the District of Columbia 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 $10.4 million Private Placement in the second quarter and raised $4.7 million during the fourth quarter of 2016 under previously announced ATM "at the market" program.
- Participated in nine posters and oral presentations at major medical meetings and published analytical validation results for the Acuitas MDRO Gene Test.

2017 Outlook

“During 2017, our focus will continue to be on the development of our Acuitas mAST rapid DNA tests and the Acuitas Lighthouse Knowledgebase with a goal of transitioning to external clinical trials and subsequent full commercialization, in conjunction with receipt of appropriate regulatory clearances,” continued Mr. Jones. “We anticipate growth from our Acuitas Lighthouse Knowledgebase enabled CLIA lab services for MDRO surveillance and a continuation of historical revenue trends from our QuickFISH products.”

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 approximately 10,000 multidrug resistant organisms to support initial development of the first Acuitas mAST test kits and deployment of the Acuitas Lighthouse Knowledgebase.
- Completion of initial Acuitas mAST test development including genotype/phenotype predictive algorithms and performance verification.
- Presentation of Acuitas mAST 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 Acuitas mAST test.
- Establishment of distribution and partner relationships to support commercialization of Acuitas mAST and the Acuitas Lighthouse knowledgebase in international markets.
- Establishment of Acuitas mAST early access and performance verification programs to support regulatory approval clinical trials and publications.
- Continued efforts to obtain third party development funding for Acuitas test and Lighthouse Knowledgebase development and deployment.

Complete 2016 full year and fourth quarter financial results will be announced in March in conjunction with the company’s fourth quarter and fiscal year 2016 financial results conference call.

This press release contains certain preliminary financial results for the company. These results could change as a result of further review by the company’s management and the independent auditors. The decision to delay production scale-up and clinical trial investment for the automated QuickFISH pathogen ID product will likely lead to an impairment charge on the intangible assets that were acquired as a part of the purchase of AdvanDx in July 2015. The amount and timing of such a potential charge has not been determined.

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.

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.

OpGen Contact:
Michael Farmer
Director, Marketing
240-813-1284
mfarmer@opgen.com
InvestorRelations@opgen.com

OpGen Investor and Media Contact:
MacDougall Biomedical Communications
Cammy Duong
781-591-3443
cduong@macbiocom.com

OpGen, Inc.