OpGen Provides Business and Pipeline Update and Announces Preliminary Unaudited Revenue and Cash Position for the Third Quarter 2020

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- *OpGen takes strategic steps to expand the Unyvero platform and product pipeline, to focus on the pending Acuitas AMR Gene Panel (isolates) FDA clearance and expects to invest significantly in bioinformatics*
- *OpGen subsidiary Ares Genetics received notification of exercise of option to negotiate for a potential future license by its IVD Partner*
- *OpGen to discontinue Acuitas AMR Gene Panel (urine) clinical trial and discontinue FISH product line globally by mid-2021*
- *Total Revenue for Q3 2020 was approximately $1.0 million dollars*
- *Maintained strong balance sheet with $10.4 million cash as of September 30, 2020*

GAITHERSBURG, Md., Oct. 15, 2020 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN, “OpGen”), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, announced today that total preliminary unaudited revenue for the third quarter of 2020 was approximately $1.0 million, up from $648 thousand in the third quarter of 2019. The preliminary financial results for the three months ended September 30, 2020 reflect the consummation of our business combination with Curetis GmbH on April 1, 2020. The results for the nine months ended September 30, 2020 will be included in the Company’s Quarterly Report on Form 10-Q and earnings release for the third quarter of 2020. OpGen’s cash as of September 30, 2020 was approximately $10.4 million. The company also expanded its capacity under its ATM program by an additional $6.4 million, and continues to have access to an additional EUR5.0 million tranche of non-dilutive debt financing for COVID-19 related R&D programs from the European Investment Bank.

In addition, the company announced details regarding a strategic reprioritization of its product portfolio, platform pipeline and priorities going forward. This reprioritization was based on feedback from extensive market research, a customer survey of 150 stakeholders in the decision making on new diagnostic platforms, and key opinion leader interviews conducted by an independent market research firm over the past two quarters. Following a review of this research, OpGen and its Board decided to consolidate the company’s product portfolio on its proprietary Unyvero platform and unique bioinformatics capabilities. As a result of this change in priority, the company anticipates the following key impacts:

- Product portfolio going forward to be centered around rapid, molecular diagnostic platform offerings and increased focus on value added bioinformatics solutions, including Ares Genetics’ next generation sequencing-based and artificial intelligence powered AMR and AST prediction capabilities.
- Following the successful completion of the three phases of the partnered R&D program as announced in the H1-2020 earnings call, Ares Genetics has recently received formal notification from its undisclosed global leading IVD corporation partner that they have exercised their option to exclusively negotiate with Ares Genetics the scope and terms of a potential exclusive license or other arrangement with Ares to Ares Genetics’ technology in the field of human clinical diagnostics in the coming months.
- Platform consolidation to realize significant operational synergies and cost savings over time as fewer products and platforms would need to be maintained from a regulatory, quality management and logistics and service standpoint.
- Unyvero platform and product portfolio to be expanded beyond lower respiratory tract infections such as pneumonia (LRT / LRT BAL) to include complicated urinary tract infections (cUTI) and invasive joint infections (IJI) in the U.S. with clinical trials for future FDA submission and clearance anticipated to start in 2021. Products in both indications are fully developed and already CE-IVD marked and commercially available in Europe and other markets.
- Acuitas AMR Gene Panel for Isolates expected to see near term clearance decision by the U.S. FDA after OpGen’s October 2020 submission of a formal response to the FDA’s January 2020 Request for Additional Information (AI) request. If cleared by the FDA, OpGen anticipates swift commercial launch in the U.S. in the following months.
- Legacy FISH products business including Quick FISH® and PNA FISH® to be discontinued by mid-2021 in Europe, the U.S. and rest of world with last production lots to be manufactured in early 2021.
- Acuitas AMR Gene Panel (urine) clinical trial to be discontinued as focus shifts to Unyvero platform for complicated UTI indication as well as additional future applications.

The company also announced accomplishment of the following key milestones in the third quarter of 2020 and year to date:

- OpGen’s subsidiary Curetis GmbH obtained CE mark certification in the European Union for its own SARS-CoV-2 Kit with PULB for the detection of SARS-CoV-2, the virus that causes COVID-19.
- OpGen announced that subsidiary Ares Genetics GmbH won the Austrian national digitization award and was also nominated for the 40th Austrian Innovation Award for its artificial intelligence powered, next-generation sequencing based molecular antibiotic susceptibility test marketed under the brand name ARESupa – Universal Pathogenome Assay.
- OpGen’s subsidiary Curetis GmbH received EUR 350 thousand in grant funding in a collaboration project with InfectoGnostics campus at Jena University Hospital.

- OpGen's subsidiary Ares Genetics GmbH in collaboration with researchers from the Johns Hopkins University School of Medicine, announced the publishing of a peer-reviewed study on modifiable risk factors for the emergence of ceftolozane-tazobactam resistance in *P. aeruginosa* in the journal Clinical Infectious Diseases.
- OpGen announced the release of a new peer-reviewed publication that demonstrates the clinical utility of the Unyvero LRT panel and its potential impact on antibiotic use in hospitalized patients with suspected pneumonia compared to treatment directed based on microbiological culture results.
- OpGen successfully completed its study collaboration with Karolinska Institutet on bacterial co-infections in COVID-19 pneumonia patients and data on the Unyvero HPN Panel was presented by the Karolinska investigators at ECCVID 2020.
- OpGen significantly improved its working capital position in the third quarter of 2020 through the sale of approximately 1.8 million shares of common stock under the company's ATM program and the exercise of warrants from the October 2019 financing for gross proceeds of $4.4 million during the third quarter. During the nine months ended September 30, 2020, the Company sold approximately 11.4 million shares of common stock under the company's ATM program and upon exercise of warrants from the October 2019 offering for gross proceeds of $24.4 million.
- The German Federal Ministry for Economic Affairs and Energy (BMWi) concluded its investigation of the OpGen business combination with Curetis with regards to its impact on the public order and security of the Federal Republic of Germany as well as national healthcare interests in the light of the current COVID-19 pandemic. No further action is expected from the Federal government on this matter.

Oliver Schacht, President & CEO of OpGen commented, "OpGen reported a solid third quarter given the persistent challenging environment caused by the COVID-19 pandemic. In addition to announcing the CE mark certification for our SARS-CoV-2 Kit, we also highlighted the publication of several peer-reviewed studies. We believe that following the portfolio consolidation and strategic product pipeline decisions taken by the board, OpGen along with its subsidiary companies Curetis GmbH and Ares Genetics GmbH has a focused molecular diagnostics platform strategy and growing emphasis on bioinformatics offerings that will further generate shareholder value. I am truly excited about the future prospect of this company and I am convinced that our strategic initiatives will provide strong growth opportunities and secure our future as a global leader in infectious diseases and AMR diagnostics."

The preliminary financial results are estimates prior to the completion of OpGen's financial closing procedures and review procedures by its external auditors and therefore may be subject to adjustment when the actual results are available.

About OpGen, Inc.

OpGen, Inc. (Gaithersburg, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with subsidiaries, Curetis GmbH and Ares Genetics GmbH, we are developing and commercializing molecular microbiology solutions helping to guide clinicians with more rapid and actionable information about life threatening infections to improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. OpGen's product portfolio includes Unyvero, Acuitas AMR Gene Panel and Acuitas® Lighthouse, and the ARES Technology Platform including ARESdb, using NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction.

For more information, please visit www.opgen.com.

Forward-Looking Statements

This press release includes statements regarding OpGen's third quarter 2020 results, the company's strategic portfolio and product pipeline priorities, the ongoing integration of OpGen with its acquired subsidiaries, Curetis GmbH and Ares Genetics GmbH, and the impact of COVID-19 on the company and general market conditions. 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 realization of expected benefits of our business combination transaction with Curetis GmbH, the success of our commercialization efforts, the impact of COVID-19 on the Company's operations, financial results, and commercialization efforts as well as on capital markets and general economic conditions, 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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