OpGen Submits Updated 510(k) Summary to FDA and Successfully Completes Move to New Headquarters in Maryland

June 7, 2021

ROCKVILLE, Md., June 07, 2021 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN, “OpGen”), a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease, today announced that it has submitted an updated 510(k) summary document to the U.S. FDA for its Acuitas AMR Gene Panel for Isolates. This document incorporates all of the FDA's requested updates to various key documents such as the Package Insert, Electronic User Guide, and Operator Manual. Consistent with the FDA's previously communicated timeline, the FDA provided substantive feedback on all of these key documents by the end of May. The FDA previously informed OpGen that it intends to complete its review by the end of August 2021, but that it cannot commit to a timeline and that such timeline can be affected by various factors, including the FDA's other workload and public health priorities.

Oliver Schacht, CEO of OpGen commented: “We are excited to see the excellent progress that we have been able to make towards completion of our Acuitas AMR Gene Panel for Isolates filings with the FDA and the nice cadence of FDA responses and valuable inputs moving us much closer towards reaching a final FDA clearance decision point in the coming months.”

OpGen recently also completed the move of its U.S. headquarters, laboratories and operations as well as warehouse to its new Rockville, Maryland based facility. The Company plans to register this newly built-out facility with the FDA and other relevant authorities for the future business operations in the U.S. The new 10,000 square feet facility marks the completion of the business integration and will result in net savings of approximately $600 thousand annually in the coming years in terms of operating efficiencies and reduced rent.

Given recent new Unyvero installations in Q1 and 2021 year-to-date as well as anticipated strong demand for additional Unyvero system placements in the upcoming quarters, OpGen has also ordered an additional 30 Unyvero Analyzers from its Curetis subsidiary and will be moving these into its U.S. warehouse facilities in the coming weeks. Going forward, all Unyvero cartridges as well as Acuitas consumables will be stocked and shipped directly from the new Rockville based facility.

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 a potential FDA clearance decision for OpGen’s Acuitas AMR Gene Panel for Isolates in the U.S.. These statements and other statements regarding OpGen’s Unyvero products, their commercialization and launch, 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 fact that we may not effectively use proceeds from recent financings, including our November 2020 private placement, February 2021 Registered Direct and March 2021 warrant exercise and exchange, 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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