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

September 30, 2021
Date of Report (date of earliest event reported)

OpGen, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	**001-37367**	**06-1614015**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

9717 Key West Ave, Suite 100
Rockville, MD 20850
(Address of principal executive offices)(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OPGN	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 — Other Events.

On October 4, 2021, OpGen, Inc. (the "Company") announced that on September 30, 2021, the Company received clearance from the U.S. Food and Drug Administration ("FDA") of its 510(k) application for its Acuitas AMR Gene Panel test for use with bacterial isolates. The Company's press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Also, on October 4, 2021, the Company issued a press release announcing preliminary financial results for the quarter ended September 30, 2021. The Company's press release is filed as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01 — Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, dated October 4, 2021.
99.2	Press Release dated October 4, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: October 4, 2021

OpGen, Inc.

By: /s/ Oliver Schacht PhD

Name: Oliver Schacht PhD

Title: Chief Executive Officer

OpGen Receives FDA Clearance for Acuitas® AMR Gene Panel

- *OpGen's Acuitas® AMR Gene Panel allows testing for a comprehensive panel of 28 genetic AMR markers in isolated bacterial colonies from 26 different pathogens*
- *An aid to clinicians in the management of patients with known or suspected antibiotic non-susceptible or resistant bacterial infections*
- *OpGen targets commercial launch of the Acuitas® AMR Gene Panel in the U.S. in Q4-2021*

ROCKVILLE, Md., October 4, 2021 -- 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 it has received 510(k) clearance by the U.S. Food and Drug Administration (FDA) to market the Acuitas® AMR Gene Panel, and is finalizing preparations for its swift commercial launch in the U.S.

The Acuitas® AMR Gene Panel detects 28 genetic antimicrobial resistance (AMR) markers in isolated bacterial colonies from 26 different pathogens. We believe the panel provides clinicians with a valuable diagnostic tool that informs about potential antimicrobial resistance patterns early and supports appropriate antibiotic treatment decisions in this indication. The Acuitas® AMR Gene Panel expands the diagnostic capability of clinicians to rapidly and simultaneously test for select drugs in 9 classes of antibiotics, including aminoglycosides, carbapenems, cephalosporins, fluoroquinolones, penicillins, polymyxins, sulfonamides, trimethoprim, and vancomycin, to aid in the identification of potentially antimicrobial-resistant organisms that might otherwise escape detection and hence can prevent prolonged inappropriate treatment of patients. Furthermore, we believe the Acuitas® AMR Gene Panel is the first FDA cleared molecular diagnostic panel that detects such a broad panel of AMR markers from isolates.

"Overcoming the challenges associated with antibacterial resistance begins with an understanding and knowledge of the pathogen's genetic profile, especially a profile of relevant resistant genes they harbor," commented Dr. James W. Snyder, Professor of Pathology and Laboratory Medicine, and Director of Microbiology and Molecular Diagnostics, University of Louisville Hospital, KY. "The benefits of this AMR panel for predicting antibiotic resistance include the provision of genomic profile data much sooner in about 2.5 hours versus conventional phenotypic information which can take 1-4 days, supports the goal of antimicrobial stewardship, institution of infection control and prevention measures, and alerts the provider to resistant genes representing nine classes of antibiotics. In this era of "rapid diagnostics", availability of critical information impacts all phases of the healthcare system and potentially reduces cost. AMR panel is regarded as "state of the art", genomic-based technology."

Indiscriminate overuse and misuse of antibiotics are key drivers of dramatically spreading antibiotic resistance, a substantial global health threat. A report recently issued[1] by the Centers for Disease Control and Prevention (CDC) revealed that drug-resistant bacteria cause almost 3 million infections and 35,000 deaths a year in the United States alone, meaning that antibiotic-resistant pathogens cause a serious infection every 11 seconds and a death every 15 minutes.

[1] https://www.cdc.gov/DrugResistance/Biggest-Threats.html

By providing a fast and reliable solution for the rapid detection of antimicrobial resistance markers associated with relevant pathogens, we believe the Acuitas® AMR Gene Panel is an essential, indispensable tool for targeted antimicrobial therapy improving patient outcomes, facilitating stringent antibiotic stewardship.

“The Acuitas® AMR Gene Panel is the third molecular diagnostic panel that OpGen, as a group, has successfully received clearance for from the FDA,” commented Johannes Bacher, Chief Operating Officer of OpGen. “Along with the Unyvero® LRT and LRT BAL Application Cartridges, OpGen’s rapid testing solutions offer what we believe are the most comprehensive multiplex molecular panels for the rapid diagnosis of antimicrobial resistance in bacteria and fungi associated with life threatening infectious disease.”

“We expect that the clearance of our Acuitas® AMR Gene Panel will expand the total addressable market for this product in the U.S.,” said Oliver Schacht, PhD, President and CEO of OpGen. “It will provide us with substantial opportunities to grow our business in detecting AMR in life-threatening infections since rapid detection of antimicrobial resistance in both surveillance and diagnostic settings is still a major challenge for the clinical lab. Moreover, by providing laboratorians and clinicians with a powerful diagnostic tool to identify resistance earlier, faster and more reliably, the Acuitas® AMR Gene Panel is expected to support antibiotic stewardship efforts to avoid the unnecessary use of antibiotics.”

With commercial launch preparations well advanced, the Company expects to swiftly make the Acuitas® AMR Gene Panel for isolates broadly available to U.S. customers.

About OpGen, Inc.

OpGen, Inc. (Rockville, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with our 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 Acuitas® AMR Gene Panel for Isolates and clearance with the U.S. FDA. 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 fact that we may not effectively use proceeds from financings, 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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OpGen Provides Business Update and Announces Preliminary Unaudited Revenue and Cash Position for Third Quarter 2021

- *Preliminary Total Revenue for Q3 2021 was approximately $1.2 million*
- *Cash as of September 30, 2021 was approximately $25.4 million, up significantly from the $13.4 million at year-end 2020*
- *OpGen concluded search and expects to announce new CFO once appointment has been formalized*

ROCKVILLE, Md., October 4, 2021 (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 2021 was approximately $1.2 million, up from $1.1 million in the third quarter of 2020. Cash as of September 30, 2021 was approximately $25.4 million, an increase from the $13.4 million as of December 31, 2020.

The company announced accomplishment of the following key milestones and recent developments in the third quarter as well as 2021 to date:

- OpGen received 510(k) FDA clearance for its Acuitas AMR Gene Panel
- OpGen initiated prospective multicenter clinical trial in the U.S. for the Unyvero UTI application
- OpGen concluded search and expects to announce new CFO once appointment has been formalized
- OpGen announced data from prospective randomized controlled multicenter clinical study using the Unyvero HPN panel for hospitalized patients with suspicion of pneumonia
- OpGen filed a universal shelf registration statement on Form S-3 for up to $ 150 million
- OpGen achieved key milestone in Unyvero A30 *RQ* development program with 10 systems now available for verification and validation testing which is ongoing
- OpGen subsidiary Ares Genetics completed another project with Sandoz and continued commercial roll-out and growth of the ARESiss isolate sequencing service business

Mr. Schacht commented, "As we continue into the fourth quarter, we are extremely excited by the recent FDA 510(k) clearance of our Acuitas AMR Gene Panel which we believe to have the potential to aid clinicians in the diagnosis of and treatment decision making for patients with severe, life-threatening infections who are suffering from multi drug resistant organisms. We are getting ready for a swift commercial launch of the Acuitas AMR Gene Panel this quarter here in the U.S. We are also in regular dialog with the Chinese NMPA via our strategic partner Beijing Clear Bio. The Chinese NMPA has requested supplemental clinical data to be generated and submitted in China. We are working with our partners to finalize study design and prepare for subsequent study execution in due course, and we anticipate receiving feedback on the submission of the pneumonia application cartridge documents filed with the NMPA thus far. We are also thrilled to have successfully completed the search for our new Chief Financial Officer to join the OpGen team and we anticipate making the announcement upon formalizing the appointment. Together with our board, we are continuing to evaluate alternatives for financing the future growth of OpGen and believe these are steps that will help drive the company forward and on its desired path."

The preliminary Q3-2021 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.

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

Forward-Looking Statements

This press release includes statements regarding OpGen's third quarter 2021 results and the current business of OpGen. 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 fact that we may not effectively use proceeds from our financings, 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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