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 20, 2022
Date of Report (date of earliest event reported)

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

Delaware
(State or other jurisdiction of incorporation
or organization)

001-37367
(Commission
File Number)

06-1614015
(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:

<table>
<thead>
<tr>
<th>Title of each class</th>
<th>Trading Symbol(s)</th>
<th>Name of each exchange on which registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Stock</td>
<td>OPGN</td>
<td>The Nasdaq Capital Market</td>
</tr>
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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. ☐
On September 20, 2022, OpGen, Inc. (the “Company”) issued a press release announcing the entry by its subsidiary Curetis GmbH into a research and development collaboration agreement with FIND, the global foundation for innovative new diagnostics. The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

(d) Exhibits

99.1 Press Release, dated September 20, 2022

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)
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: September 20, 2022

OpGen, Inc.

By: /s/ Oliver Schacht

Name: Oliver Schacht

Title: Chief Executive Officer
OpGen Subsidiary Curetis and FIND Sign R&D Collaboration Agreement for Unyvero A30 RQ Platform

- FIND, the global alliance for diagnostics, together with German KfW bank, co-funds development of Unyvero A30 RQ platform for low and middle-income countries (LMICs)
- Initial project focuses on feasibility study for the rapid detection of antimicrobial resistance (AMR) markers from blood culture
- Feasibility phase of R&D project set to conclude by the end of Q1-2023 and co-funded by FIND with euro 700,000

ROCKVILLE, Md., Sept. 20, 2022 (GLOBE NEWSWIRE) – OpGen, Inc. (Nasdaq: OPGN, “OpGen” or “the Company”), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, today announced the signing of an R&D collaboration agreement with FIND, the global alliance for diagnostics, for the Unyvero A30 RQ platform for use in rapid pathogen ID and AMR testing from blood culture samples in low and middle-income countries (LMICs).

The Unyvero A30 RQ platform is a sample to answer instrument running a disposable one-time use cartridge that can test for up to 33 diagnostic targets from a single specimen. Time to result can be as fast as under 30 minutes for very simple tests and around 45 to 90 minutes for most applications. Given the favorable cost of goods profile of both the instrument as well as the disposable cartridge, this system also lends itself to being deployed in LMICs with constrained resources.

During the anticipated feasibility project, OpGen's R&D team at its German subsidiary Curetis GmbH will strive to develop a molecular test panel providing a comprehensive set of pathogen ID and AMR detection assays, develop an easy to perform workflow being compatible with available blood culture systems in target regions without any need for separate sample preparation steps and to adapt some key features of the A30 RQ platform important for use in environments often found in LMICs, such as those with continuous operation with unstable power grids.

Oliver Schacht, President & CEO of OpGen, commented, “We are excited to partner with FIND, in demonstrating that our Unyvero A30 RQ platform is ideally suited to being used in LMICs for rapid detection of AMR which is a truly global issue that must be addressed in a multilateral and indeed global fashion. The R&D contract and associated funding will support the required R&D efforts on our side and expedite such development.”

Cecilia Ferreyra, Director of AMR at FIND, said: “AMR is one of the most pressing health emergencies of our time, with the potential to undo decades of medical progress. Simplifying blood culture systems so that the pathogen responsible for an illness and its resistance profile can both be identified quickly is crucial for halting and preventing this silent pandemic, especially in LMICs that bear the greatest burden of AMR.”
If successful, after demonstrating feasibility and completing this initial R&D project phase, both parties have agreed to discuss the option of a potential future collaboration and commercialization agreement between OpGen and FIND. Such future collaboration agreement would aim to bring the Unyvero A30 RQ platform and initial application products through required clinical studies and regulatory approvals in LMICs to make them commercially available at an attractive cost profile to commercial distribution partners, which we believe can address this unmet medical need for rapid AMR detection in LMICs.

**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 current product portfolio includes Unyvero, Acuitas AMR Gene Panel, and the ARES Technology Platform including ARESdb, NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction including ARESiss, ARESid, and AREScloud, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit.

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

**Forward-Looking Statements**

This press release includes statements regarding the R&D collaboration agreement entered into by OpGen’s subsidiary Curetis GmbH and FIND, the global foundation for innovative new diagnostics. 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, the success of our commercialization efforts, 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, the continued realization of expected benefits of our business combination transaction with Curetis GmbH, the continued impact of COVID-19 on the Company’s operations, financial results, and commercialization efforts as well as on capital markets and general economic conditions, our ability to satisfy debt obligations under our loan with the European Investment Bank, the effect of the military action in Russia and Ukraine on our distributors, collaborators and service providers, our liquidity and working capital requirements, 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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