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

April 18, 2023
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)

(301) 869-9683
(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 April 18, 2023, OpGen, Inc. issued a press release announcing its entry into a distribution agreement with Fisher Healthcare, a part of Thermo Fisher Scientific Inc. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, dated April 18, 2023.
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: April 19, 2023

OpGen, Inc.

By: /s/ Albert Weber

Name: Albert Weber

Title: Chief Financial Officer

OpGen Enters Into Distribution Agreement for Unyvero in the U.S. with Fisher Healthcare

- *Fisher Healthcare, a part of Thermo Fisher Scientific, will become the non-exclusive national laboratory distribution partner alongside OpGen, Inc.'s direct sales in the U.S. for the Unyvero A50 platform*
- *Initial focus on FDA cleared Unyvero LRT (BAL) cartridges for hospitalized pneumonia patients and research use only Unyvero UTI for urinary tract infections*

ROCKVILLE, MD., April 18, 2023 (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 that the Company has entered into a non-exclusive distribution agreement with Fisher Healthcare, a part of Thermo Fisher Scientific. The agreement is for the distribution of OpGen's Unyvero A50 platform and in vitro diagnostic (IVD) tests for bacterial pneumonia (Unyvero LRT and LRT BAL) as well as its research use only (RUO) test for urinary tract infection (Unyvero UTI).

The Unyvero LRT cartridge for hospitalized patients with suspected pneumonia is the first ever FDA cleared IVD product specifically targeting bacterial pneumonia and antimicrobial resistance markers. The Unyvero UTI cartridge has recently completed its pivotal clinical trial and OpGen has recently submitted a *De Novo* classification request for Unyvero UTI to the FDA. The Unyvero UTI product is available as a RUO test to laboratories that do their own validation.

Under the distribution agreement, Fisher Healthcare will have access to the Unyvero A50 platform and products to distribute and sell to hospitals and laboratories across the United States.

Oliver Schacht, Chief Executive Officer of OpGen, commented, "We are very excited about the strategic distribution partnership with Fisher Healthcare as we believe the partnership will increase our Unyvero platform's commercial presence and footprint across the U.S. We view this expansion in our commercial channel strategy as the next step towards driving commercial adoption of Unyvero in the U.S. and achieving our revenue growth objectives in the coming years."

About OpGen, Inc.

OpGen, Inc. (Rockville, Md., U.S.A.) 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, ARESasp, 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 Company's entry into a distribution agreement with Fisher Healthcare. 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 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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