UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15 (d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **December 22, 2023**

OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36751**	**04-3522315**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

11 Great Valley Parkway
Malvern, Pennsylvania 19355
(484) 328-4701
(Address, including zip code, and telephone number, including area code, of principal executive office)

N/A
(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, $0.01 par value per share	OCGN	The Nasdaq Stock Market LLC (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 December 21, 2023, Ocugen, Inc. ("Ocugen") issued a press release announcing that Ocugen received alignment from the FDA on key aspects of the Phase 3 clinical trial design to assess the safety and efficacy of OCU400 in patients with RHO and other gene mutations associated with Retinitis Pigmentosa (RP). A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are being filed herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Press Release of Ocugen, Inc. dated December 21, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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 hereunto duly authorized.

Date: December 22, 2023

OCUGEN, INC.

By: /s/ Shankar Musunuri
Name: Shankar Musunuri
Title: Chairman, Chief Executive Officer, & Co-Founder

Exhibit 99.1

Ocugen Gains FDA Alignment on Key Aspects of OCU400 - Modifier Gene Therapy - Pivotal Phase 3 Study Design

MALVERN, Pa., December 21, 2023 (GLOBE NEWSWIRE) — Ocugen, Inc. (Ocugen or the Company) (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies and vaccines, today announced that the Company received alignment from FDA on key aspects of the Phase 3 clinical trial design to assess the safety and efficacy of OCU400 in patients with *RHO* and other gene mutations associated with Retinitis Pigmentosa (RP).

"This news brings us even closer to fulfilling our mission to bring our first-in-class, gene-agnostic therapies to market and provide access to patients globally," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "We look forward to beginning the Phase 3 clinical trial, which we plan to initiate in early 2024."

During a multidisciplinary meeting with FDA, based on preliminary results from an ongoing Phase 1/2 study, Ocugen received alignment on key aspects of the Phase 3 study design—including the study endpoint, patient enrollment strategy, and study duration of one year. The Phase 3 clinical trial will enroll a broader group of RP patients, including patients with the most common *RHO* gene mutation, based on OCU400's potentially gene-agnostic mechanism of action.

With orphan drug and RMAT designations in place for OCU400, FDA's alignment on key aspects of the Phase 3 study design positions Ocugen to confidently move forward in pursuing product development and licensure for OCU400.

Currently there are approximately 110,000 patients in the United States with RP and 1.6 million patients globally. Of these patients, more than 10% have the *RHO* genetic mutation. Advancing OCU400 to Phase 3 clinical development will be an important step toward addressing unmet needs in the RP patient community.

About Ocugen, Inc.
Ocugen, Inc. is a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies and vaccines that improve health and offer hope for patients across the globe. We are making an impact on patient's lives through courageous innovation—forging new scientific paths that harness our unique intellectual and human capital. Our breakthrough modifier gene therapy platform has the potential to treat multiple retinal diseases with a single product, and we are advancing research in infectious diseases to support public health and orthopedic diseases to address unmet medical needs. Discover more at www.ocugen.com and follow us on X and LinkedIn.

Cautionary Note on Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding qualitative assessments of available data, potential therapeutic and clinical benefits of our product candidates, expectations for clinical trial timing and results, anticipated timing of clinical trial updates and expectations for timing and outcome of regulatory interactions, which are subject to risks and uncertainties. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks, and uncertainties that may cause actual events or results to differ materially from our current expectations, including, but not limited to, the risks that preliminary, interim and top-line clinical trial results may not be indicative of, and may differ from, final clinical data; that unfavorable new clinical trial data may emerge in ongoing clinical trials or through further analyses of existing clinical trial data; that earlier non-clinical and clinical data and testing of may not be predictive of the results or success of later clinical trials; that that clinical trial data are subject to differing interpretations and assessments, including by regulatory authorities; that receipt of orphan drug and RMAT designations may not lead to faster development or regulatory review; and that regulatory authorities may disagree with additional aspects of our clinical trial designs or may not approve our future IND applications on the anticipated timeline or at all. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission (SEC), including the risk factors described in the section entitled "Risk Factors" in the quarterly and annual reports that we file with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. Except as required by law, we assume no obligation to update forward-looking statements contained in this press release whether as a result of new information, future events, or otherwise, after the date of this press release.

Contact:
Tiffany Hamilton
Head of Communications
IR@ocugen.com