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 15, 2022**

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 15, 2022, Ocugen, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") granted orphan drug designations to OCU400—human nuclear hormone receptor subfamily 2 group E member 3 (h*NR2E3*)—for the treatment of retinitis pigmentosa and Leber congenital amaurosis. A copy of this press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

On December 16, 2022, the Company issued a press release announcing that it has reached agreement with the FDA on the Phase 3 clinical trial protocol for its product candidate NeoCart®. A copy of this press release is filed herewith as Exhibit 99.2 to this Current Report on Form 8-K and 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 15, 2022.
99.2	Press Release of Ocugen, Inc. dated December 16, 2022.
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 16, 2022

OCUGEN, INC.

By: /s/ Shankar Musunuri
Name: Shankar Musunuri
Title: Chief Executive Officer and Chairman

Exhibit 99.1

Ocugen Announces OCU400 Receives Orphan Drug Designations for Retinitis Pigmentosa and Leber Congenital Amaurosis

U.S. Food & Drug Administration (FDA) acknowledges the potential of OCU400 to treat rare inherited retinal diseases

Malvern, Pa, December 15, 2022 (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 FDA granted orphan drug designations to OCU400—human nuclear hormone receptor subfamily 2 group E member 3 (h*NR2E3*)—for the treatment of retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA).

"Receiving orphan drug designation is incredibly encouraging at this stage in the development of OCU400," said Arun Upadhyay, PhD, Chief Scientific Officer, Ocugen. "We are excited by the potential of OCU400, a nuclear hormone-based modifier gene therapy product, to treat RP and LCA in a gene agnostic manner. We look forward to working collaboratively with the FDA and other agencies to progress OCU400 through clinical development to commercialization."

Orphan drug designation is a status given to certain drugs that show promise in the treatment, prevention, or diagnosis of orphan diseases. An orphan disease is a rare disease or condition that affects fewer than 200,000 people in the United States.

Currently, RP is associated with mutations in more than 100 genes, affecting approximately 110,000 people in the United States (U.S.). LCA is associated with mutations in more than 25 genes, affecting approximately 10,000 people in the U.S. There are currently no treatment options available for patients living with RP and LCA, and OCU400 has the potential to treat both with a single product.

OCU400 represents Ocugen's modifier gene therapy approach, which is based on Nuclear Hormone Receptors (NHRs) that regulate diverse physiological functions, such as homeostasis, reproduction, development, and metabolism to potentially improve retinal health and function.

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 Twitter 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, 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. 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

Exhibit 99.2

Ocugen Announces Phase 3 Confirmatory Clinical Trial Agreement for NeoCart®

Important next step for Ocugen's regenerative cell therapy in orthopedics since announcing pipeline expansion in May 2022

Malvern, Pa, December 16, 2022 (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 U.S. Food & Drug Administration (FDA) agreed to Ocugen's proposed control and overall design for the Phase 3 study of NeoCart®, a regenerative cell therapy for the repair of full-thickness lesions of the knee cartilage in adults.

"We are eager to get started on the final phase of NeoCart® development and pleased at the outcome of our discussions with the FDA," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "With this guidance, Ocugen has a clear path forward for the first candidate in our regenerative cell therapy program."

The Phase 3 study will be a randomized, controlled trial to demonstrate the superiority over standard of care, chondroplasty, in subjects with articular cartilage defects. Ocugen plans to enroll subjects with one or two articular cartilage lesions with a total surface area of 1-3 cm^2.

Ocugen is building a current Good Manufacturing Practice cell therapy manufacturing facility to support establishment of the clinical and commercial manufacturing process for NeoCart®. The Company plans to file an Investigational New Drug amendment to initiate a Phase 3 clinical trial in late 2023 / early 2024.

Earlier this year, the FDA granted a regenerative medicine advanced therapy (RMAT), designation to NeoCart®. NeoCart® combines breakthroughs in bioengineering and cell processing to enhance the autologous cartilage repair process by merging a patient's own cells with a fortified 3-D scaffold designed to accelerate healing and reduce pain.

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 Twitter and LinkedIn.

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