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

Date of Report (Date of Earliest Event Reported): **December 9, 2019**

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)

5 Great Valley Parkway, Suite 160
Malvern, Pennsylvania 19355
(484) 328-4701
(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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

Press Release

On December 9, 2019, Ocugen, Inc. (the "Company") issued a press release announcing that its Phase 3 BRAVO study for its product candidate OCU300 for patients with ocular Graft Versus Host Disease (oGVHD) had reached 50% enrollment. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Ocugen Warrant Update

As of December 9, 2019, there were 1000 Series B warrants and 1000 Series C warrants outstanding, which represented less than 0.005% of the total Series B and Series C warrants issued by the Company. As of December 9, 2019, the Company had 52,625,228 shares of common stock issued and outstanding.

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.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 10, 2019

OCUGEN, INC.

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

Exhibit 99.1

Ocugen Announces Completion of 50% of Enrollment of its Phase 3 Clinical Trial for ocular GVHD

Topline data anticipated in second half of 2020

MALVERN, PA, December 9, 2019 (GLOBE NEWSWIRE) - Ocugen, Inc., (NASDAQ: OCGN),), a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies that address rare and underserved eye diseases, today announced that it has completed 50% of enrollment of its Phase 3 clinical trial for OCU300 for patients with ocular Graft Versus Host Disease (oGVHD). Ocugen is the first and only company to receive Orphan Drug Designation for a product candidate designed to treat oGVHD and is the first company to conduct a Phase 3 clinical trial in patients with this disease.

The ongoing Phase 3 trial is a double-masked, placebo-controlled 84-day trial, in which 60 patients will be randomized in a 2:1 ratio to receive either OCU300 (brimonidine 0.18% nanoemulsion) or a placebo. The purpose of the trial is to evaluate the safety and efficacy of brimonidine tartrate nanoemulsion eye drop solution in the treatment of ocular redness and ocular discomfort in patients with oGVHD. The trial has co-primary endpoints of ocular discomfort based on a 10-point visual analog scale and ocular redness based on a 100-point validated bulbar redness score.

Daniel Jorgensen, M.D., M.P.H., M.B.A., Chief Medical Officer of Ocugen, stated, “The achievement of 50% enrollment is a key milestone towards the completion of this important Phase 3 trial. oGVHD is a severe ocular autoimmune disease that occurs in up to 60% of allogeneic bone marrow transplant patients. There is no approved therapy for this debilitating condition, and it is our belief that OCU300 will provide needed relief for patients suffering from this disease.” Dr. Jorgensen continued, “We remain on track to report topline results from this trial in the second half of 2020.”

About OCU300
OCU300 is in pivotal stage clinical development for treating ocular discomfort and ocular redness in patients with the debilitating autoimmune condition called ocular Graft Versus Host Disease (oGVHD), which develops in many patients following an allogeneic bone marrow transplant. It is the only product candidate to be granted Orphan Drug Designation for this indication from the U.S. Food and Drug Administration (FDA), and it consists of an improved 0.18% ophthalmic nanoemulsion of brimonidine tartrate, an FDA-approved drug with established safety for ocular use, enabling Ocugen to develop OCU300 under the accelerated 505(b)(2) regulatory pathway. Ocugen's patented OcuNanoE™ technology is designed to enhance efficacy by prolonging retention of this potent anti-inflammatory drug on the eye surface. In addition, it allows OCU300 to be sterile filtered into single-use vials as preservative-free nanoemulsion, thereby eliminating potentially irritating effects of preservatives.

About Ocugen, Inc.
Ocugen, Inc. is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies that address rare and underserved eye diseases. The Company offers a robust and diversified ophthalmology portfolio that includes novel gene therapies, biologics, and small molecules and targets a broad range of high-need retinal and ocular surface diseases. Ocugen is leveraging its groundbreaking modifier gene therapy platform to address genetically diverse inherited retinal disorders (IRDs) and dry age-related macular degeneration (AMD), based on nuclear hormone receptor genes *NR2E3* (OCU400) and *RORA* (OCU410), respectively. OCU400 has received two Orphan Drug Designations targeting two distinct IRDs. Ocugen is also developing novel biologic therapies for wet-AMD, diabetic macular edema and diabetic retinopathy (OCU200), as well as for retinitis pigmentosa (OCU100). The Company's late-stage Phase 3 trial for patients with oGVHD(OCU300) leverages Ocugen's patented OcuNanoE – Ocugen's ONE Platform™ technology to enhance the efficacy of topical ophthalmic therapeutics. OCU300 is the first and only product candidate to receive Orphan Drug Designation for the treatment of oGVHD, providing certain regulatory and economic benefits. For more information, please visit www.ocugen.com.

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 the Company's current expectations. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission (the "SEC"), including the risk factors described in the section entitled "Risk Factors" in the Company's Quarterly Report on Form 10-Q filed with the SEC on November 12, 2019. Any forward-looking statements that the Company makes in this press release speak only as of the date of this press release. The Company assumes 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.

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