# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

| FORM 8-K | _ |
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CURRENT REPORT
Pursuant to Section 13 OR 15 (d)
of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): November 8, 2019

# OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

**Delaware** (State or Other Jurisdiction of Incorporation) **001-36751** 

(Commission File Number)

**04-3522315** (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)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o 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 classTrading Symbol(s)Name of each exchange on which registeredCommon Stock, \$0.01 par value per shareOCGNThe Nasdaq Stock Market LLC<br/>(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 x

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. o

# Item 2.02 Results of Operations and Financial Condition.

On November 8, 2019, Ocugen, Inc. (the "<u>Company</u>") issued a press release announcing its financial highlights for the third quarter ended September 30, 2019. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. The Company has scheduled a conference call and webcast for 8:30 a.m. Eastern time on November 8, 2019 to discuss these financial highlights and business updates.

The information disclosed under this Item 2.02, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any Company filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

# Item 9.01 Financial Statements and Exhibits

The following exhibits are being filed herewith:

# (d) Exhibits

| Exhibit<br>No. | Document   |
|----------------|--|
| 99.1           | Press Release of Ocugen, Inc. dated November 8, 2019 |
|                | 2  |

# 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: November 8, 2019

OCUGEN, INC.

By: /s/ Shankar Musunuri

Name: Shankar Musunuri

Title: Chief Executive Officer and Chairman



# Ocugen Provides Business Update and Third Quarter 2019 Financial Highlights

Conference Call and Webcast Today at 8:30 a.m. ET

MALVERN, PA, November 8, 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 reported financial highlights for the third quarter of 2019 and a business update.

"This is an exciting time for Ocugen as we've completed our merger and are now a publicly traded company," commented Shankar Musunuri, PhD, MBA, Chairman, CEO and Co-Founder of Ocugen. "We are focused on advancing our clinical and preclinical programs, which includes completing enrollment in our Phase 3 clinical trial of OCU300, our product candidate that has received orphan drug designation from the FDA and is being developed for the treatment of ocular graft versus host disease (oGVHD) and furthering our IND-enabling studies for OCU400, our first gene therapy product candidate with two distinct orphan drug designations. We believe our new strategic partnership with CanSinoBIO will be instrumental in accelerating the progress of our modifier gene therapy platform closer to the clinic. We are working to meet several milestones over the course of the next few years that we believe will continue to add value to Ocugen shareholders."

#### Third Quarter 2019 and Recent Highlights:

- · <u>OCU300 (oGVHD)</u> Enrollment continues in our Phase 3 program for patients suffering from oGVHD. Ocugen anticipates a statistical review in the first half of 2020 to determine any adjustments to sample size.
- OCU400 (NR2E3-AAV) In September 2019, Ocugen announced its second orphan drug designation for its OCU400 product candidate. To date,
  OCU400 has received orphan drug designation for two inherited retinal diseases: NR2E3 mutation-associated retinal diseases and CEP290 mutationassociated retinal diseases.
- · <u>Gene Therapy Manufacturing Partnership</u> In September 2019, Ocugen entered into a strategic partnership with CanSino Biologics ("CanSinoBIO", 6185.HK) on Ocugen's gene therapy pipeline product candidates for inherited retinal diseases. Under this strategic collaboration, CanSinoBIO will provide all CMC development and clinical supplies for the development of OCU400, Ocugen's first gene therapy product candidate using its modifier gene therapy platform.
- · <u>Merger with Histogenics</u> In September 2019, Ocugen announced the completion of its merger with Histogenics Corporation and the change of the combined company's name to "Ocugen, Inc." Ocugen began trading on The Nasdaq Capital Market under the ticker symbol "OCGN".
- <u>Private Placement Financing</u> Immediately prior to the merger, Ocugen completed a private placement financing of approximately \$25 million under the terms of the securities purchase agreement previously announced in June 2019, pursuant to

- which the Company received net cash proceeds of approximately \$17.2 million after factoring in fees, expenses and repayment of bridge loans.
- · <u>Asset Purchase Agreement</u> As part of the merger, Histogenics Corporation entered into an Asset Purchase Agreement with Medavate in May 2019 for the sale of Histogenics' NeoCart™ asset. The agreement was amended in October 2019 to increase the purchase price to \$7.0 million and now requires Medavate to pay Ocugen royalties in the low single digits for net sales of the NeoCart™ asset. The amendment requires the closing to occur when Medavate obtains its required financing, with the purchase price increasing by 10% on the first of each calendar month starting in November 2019 until the transaction closes. As of November 1, 2019, the purchase price has increased to \$7.7 million.
- Warrant Restructuring On November 6, 2019, Ocugen restructured warrants held by certain investors in connection with the private placement financing. Among other things, the warrant restructuring reduced the number of Series C warrants from 50 million to 20 million and amended the Series A warrants to exclude from the warrants' anti-dilution adjustment an equity financing which closes on or before May 31, 2020, with a research or non-profit foundation or organization in an amount of up to \$10 million. In addition to providing Ocugen with the flexibility to complete such an equity financing, the overall warrant restructuring reduces the potential dilution of Ocugen's common stock upon exercise of the warrants by 30 million shares.

# Third Quarter 2019 Financial Highlights

- Ocugen ended the quarter on September 30, 2019, with cash, cash equivalents and restricted cash totaling \$15.5 million compared to \$1.8 million at December 31, 2018.
- Research and development expenses for the third quarter of 2019 were \$1.3 million compared to \$1.6 million for the same period in 2018. General and administrative expenses for the third quarter of 2019 were \$1.4 million compared to \$0.8 million for the same period in 2018.
- · Ocugen ended the quarter with 10,013,605 shares outstanding.

#### Conference Call and Webcast Details

The Company has scheduled a conference call and webcast for 8:30 a.m. ET today to discuss the financial and recent business highlights. Ocugen's senior management team will host the call, which will be open to all listeners. There will also be a question and answer session following the prepared remarks.

The call can be accessed by dialing (844) 987-9316 (domestic) or (602) 563-8454 (international) and providing the conference ID 9979278. To access a live audio webcast of the call on the "Investors" section of the Ocugen website, please click here. A replay of the webcast will be archived on Ocugen's website for approximately 45 days following the call.

#### 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 diseases (IRDs) and dry AMD, based on nuclear hormone receptor genes NR2E3 (OCU400) and RORA (OCU410), respectively. OCU400 has received two orphan drug designations (ODD) 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 ocular graft versus host disease (oGVHD)(OCU300) leverages Ocugen's patented OcuNanoE — Ocugen's ONE Platform<sup>TM</sup> technology to enhance the efficacy of topical ophthalmic therapeutics. OCU300 is the first and only therapeutic with ODD for 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 our Registration Statement on Form S-3 (File No. 333-234127) and our Registration Statement on Form S-4 (Reg. No. 333-232147), as amended, filed with the SEC by Ocugen, Inc. (f/k/a Histogenics Corporation). 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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