# 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): **May 24, 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) |

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

**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 May 24, 2022, Ocugen, Inc. (the "Company") issued a press release announcing that it is diversifying its innovative pipeline by introducing a cell therapy program called NeoCart® (autologous chondrocyte-derived neocartilage), a Phase 3 technology, which has been granted a Regenerative Medicine Advanced Therapy designation by the U.S. Food and Drug Administration for the repair of full-thickness lesions of the knee cartilage in adults. 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 May 24, 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 24, 2022

OCUGEN, INC.

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

**Exhibit 99.1**

# Ocugen Announces New Cell Therapy Program Following FDA Regenerative Medicine Advanced Therapy (RMAT) Recognition

NeoCart® (autologous chondrocyte-derived neocartilage) receives regulatory designation intended to help expedite development of new regenerative medicines

MALVERN, Pa. — May 24, 2022 (GLOBE NEWSWIRE) — Ocugen, Inc. (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene therapies, biologicals, and vaccines, today announced that it is diversifying its innovative pipeline by introducing a Phase 3, cell therapy platform technology called NeoCart® (autologous chondrocyte-derived neocartilage). Recently, the U.S. Food and Drug Administration (FDA) granted a Regenerative Medicine Advanced Therapy (RMAT) designation to NeoCart® for the repair of full-thickness lesions of the knee cartilage in adults.

NeoCart® is a three-dimensional tissue-engineered disc of new cartilage that is manufactured by growing chondrocytes – the cells responsible for maintaining cartilage health – derived from the patient on a unique scaffold. NeoCart® has the potential to accelerate healing and reduce pain by rebuilding a patient's damaged knee cartilage. It treats pain at the source, creating a similar, functional joint surface as it was before the injury. Ultimately, the goal is to prevent a patient's progression to osteoarthritis. NeoCart® was acquired as a part of Ocugen's reverse merger with the original developer of the therapy, Histogenics, in 2019.

"We're excited that NeoCart® has received this RMAT designation, an important regulatory milestone, especially as we view this product as an enabling technology in cell and regenerative therapy for orthopedic indications. Our next step will be working with the FDA to construct the Phase 3 program to bring this innovation to this emerging treatment area," said Dr. Shankar Musunuri, Chairman, CEO, and Co-Founder, Ocugen, Inc. "People living with articular cartilage lesions literally have holes in their knees that are extremely difficult to heal, and without proper treatment, they're at high risk of getting osteoarthritis. We believe that NeoCart® offers the potential for an innovative new option where treatments in this area are still limited and results are not optimal."

The Regenerative Medicine Advanced Therapy (RMAT) designation is part of the 21st Century Cures Act. The program was created to expedite the development and review of regenerative medicine therapies intended to treat, modify, reverse or cure a serious condition. Receiving an RMAT designation offers sponsor companies all the benefits of the fast track and breakthrough therapy designation programs, including early interactions with the FDA. Ocugen is working with the FDA to finalize the Phase 3 protocols necessary to advance the clinical development program of NeoCart® required for eventual market authorization.

Articular cartilage lesions are a serious and often mobility-limiting condition. When the cartilage is healthy, it makes movement easy, allowing the bones to glide over each other with very little friction, but it can be damaged by injury or normal wear and tear. Cartilage that is damaged can, over time, cause pain and reduce one's ability to function. Small articular lesions have a limited capacity to self-repair, and full thickness injuries have no ability to naturally heal. There are no blood vessels or nerves to support healing, and as cartilage matures, chondrocytes have limited ability to replicate. Untreated damage eventually can lead to osteoarthritis.

Details of the NeoCart® development program will be shared at a future date.

**About Ocugen, Inc.**

Ocugen, Inc. is a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, biologicals and vaccines that improve health and offer hope for people and global communities. We are making an impact through courageous innovation, taking science in new directions in service of patients. Our breakthrough modifier gene therapy platform has the potential to treat multiple diseases with one drug and we are advancing research in other therapeutic areas to offer new options for people with 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. Ocugen 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 forward-looking statements include, but are not limited to, statements about Ocugen's intention to work with the U.S. Food and Drug Administration ("FDA") to finalize the Phase 3 protocols necessary to advance the clinical development program of NeoCart® (autologous chondrocyte-derived neocartilage) required for eventual market authorization. Such statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements, including, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, ability to timely enroll clinical trial participants, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, Ocugen's ability to utilize accelerated FDA review designations, such as the Regenerative Medicine Advanced Therapy designation, which does not guarantee an accelerated pathway or timeline for regulatory approval of any such product candidates, including NeoCart® (autologous chondrocyte-derived neocartilage), or increase the likelihood of any such approvals, and the other risks and uncertainties 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 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.*

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