# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# 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): **April 2, 2024**

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# OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

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| **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<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 ☐

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 2.02 Results of Operations and Financial Condition.**

On April 2, 2024, Ocugen, Inc. (the "Company") issued a press release announcing certain financial data for the fourth quarter and the fiscal year ended December 31, 2023. The Company has scheduled a conference call and webcast for 8:30 a.m. Eastern Time on April 2, 2024, to discuss these financial results and business updates. The Company will use presentation materials in connection with the conference call and webcast, which presentation materials will be posted on the Company's website at www.ocugen.com. Copies of the press release and presentation materials are furnished herewith as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K (this "Report") and incorporated herein by reference.

The information disclosed under Item 2.02 of this Report, including Exhibit 99.1 and Exhibit 99.2, 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 (the "Securities Act"), 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 furnished herewith:

**(d) Exhibits**

| Exhibit No. | Document |
|---|---|
| 99.1 | Press Release of Ocugen, Inc. dated April 2, 2024. |
| 99.2 | Earnings Release Presentation issued April 2, 2024. |
| 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: April 2, 2024

OCUGEN, INC.

By: /s/ Shankar Musunuri

Name: Shankar Musunuri

Title: Chairman, Chief Executive Officer, & Co-Founder

**Exhibit 99.1**

# Ocugen Provides Business Update with Certain Financials for the Year Ending 2023

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

- *Received alignment with FDA for broad retinitis pigmentosa (RP) indication in Phase 3 clinical trial of OCU400—first gene therapy program to receive a broad indication for RP. OCU400 Phase 3 clinical trial expected to commence in April 2024*
- *Regenerative Medicine Advanced Therapy (RMAT) designation granted by FDA to OCU400*
- *Completed Cohort 1 dosing for OCU410 and OCU410ST gene therapy clinical studies for geographic atrophy (GA) and Stargardt disease, respectively*

MALVERN, Pa., April 2, 2024 (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 provided a general business update with certain financials for the year ending 2023.

"In 2023, our diligent efforts laid the foundation for continued advancement towards our clinical and operational goals with a focus on our game-changing modifier gene therapy platform," said Dr. Shankar Musunuri, Chairman, CEO, and Co-Founder of Ocugen. "2024 is already proving to be a pivotal year with considerable developments in our modifier gene therapy programs for blindness diseases, and an increased understanding of the value of these assets among our stakeholders. Promising initial OCU400 Phase 1/2 study results for RP patients have been recognized by the FDA through the RMAT designation, potentially accelerating our path to deliver this critical therapy. With the FDA's support, we feel confident that this trial will continue to demonstrate the benefits of our gene-agnostic mechanism utilizing a potential one-time treatment for life via a single sub-retinal injection."

Additionally, the Company's OCU410 and OCU410ST modifier gene therapy programs are currently enrolling patients with GA secondary to dry AMD (dAMD) and Stargardt disease, respectively. In February 2024, Ocugen completed dosing patients in the first cohort of its Phase 1/2 OCU410ST trial for Stargardt disease, and in March, dosing was completed for the first cohort of the OCU410 trial for GA.

The current treatment landscape for both GA and Stargardt disease is extremely limited. The estimated 1 million patient GA market in the U.S. saw some momentum with recent drug approvals. However, these treatment options have significant limitations, as they require multiple injections per year (impacting compliance) and only target one pathway contributing to GA. OCU410 regulates multiple pathways involved with the disease including: lipid metabolism, regulation of inflammation, oxidative stress, and membrane attack complex (complement); and has the potential to provide a one-time treatment for life. Presently, there is no approved treatment for people living with Stargardt disease – an orphan blindness disease that affects approximately 40,000 people in the U.S. alone.

"As we pursue our pioneering efforts to change the paradigm for gene therapy, our dedication is unwavering to patients living with a constant fear of losing their sight," said Dr. Musunuri. "With millions of people affected by these conditions, our mission is clear: to deliver treatments that cannot only stop disease progression but potentially help to preserve or improve sight and allow patients to maintain independence."

Ocugen's team has strategically allocated resources to drive the ongoing progress of its gene therapy trials and continues to pursue government funding to support its vaccines programs. During the fourth quarter of 2023, the Company announced its mucosal vaccine candidate, OCU500, was chosen for the multi-billion-dollar NIAID Project NextGen initiative. As a result, OCU500 is slated to enter clinical trials mid-2024. In the planned Phase 1 clinical trial, OCU500 will be tested via two different mucosal routes: inhalation into the lungs and as a nasal spray. All administration of the clinical trial is being led by NIAID.

NeoCart®, the Company's 3-D regenerative cell therapy platform for cartilage repair, remains on track to begin a Phase 3 trial by the latter half of 2024 subject to availability of funding. Ocugen completed renovations on a world-class cGMP facility last year to produce NeoCart®, which has since received its full final clearance and occupancy certificate. Simultaneously, the Company is evaluating opportunities for NeoCart to maximize value for shareholders and patients.

Modifier Gene Therapies

- **OCU400 —** Received alignment with FDA for broad RP indication in the Phase 3 clinical trial of OCU400—the first gene therapy program to receive a broad indication for RP. The modified Phase 3 trial design will include 150 adult and pediatric RP patients with *RHO* and other gene mutations associated with RP. In December, the FDA granted RMAT designation to OCU400 for the treatment of RP. RP affects more than 100,000 people in the U.S. and 1.6 million globally.

- **OCU410** — Currently in Phase 1/2 stage of clinical development with active patient enrollment. The first patient was dosed in the Phase 1/2 trials to assess the safety and efficacy of OCU410 for GA secondary to dAMD in December 2023. Dosing is complete for Cohort 1 (low dose).

- **OCU410ST** — Currently in Phase 1/2 stage of clinical development with active patient enrollment. The first patient was dosed in the Phase 1/2 trials to assess the safety and efficacy of OCU410ST for Stargardt disease in November 2023. Dosing is complete for Cohort 1 (low dose). The Data and Safety Monitoring Board for the OCU410ST clinical trial determined that the safety and tolerability profile for OCU410ST is favorable and approved to proceed dosing with the medium dose of OCU410ST in the dose-escalation phase of the study.

Financial Results

- The Company intends to restate its consolidated financial statements as of and for the year ended December 31, 2022, in connection with the filing of its 2023 Form 10-K. Similarly, the Company will include restated unaudited financial information for each of the first three quarters of 2023 and 2022 in its 2023 Form 10-K (each such annual and quarterly period to be restated, a "Restated Period").

- The identified errors in each of the Restated Periods relate to the Company's non-cash accounting for the estimated costs in one of its collaboration arrangements. However, the Company does not expect the errors to result in any impact on its cash position, cash runway, or financial projections.

- Ocugen's cash, cash equivalents, and investments totaled $39.5 million as of December 31, 2023, compared to $90.9 million as of December 31, 2022. The Company estimates that its current cash, cash equivalents, and investments will enable it to fund its operations into the fourth quarter of 2024. The Company had 256.6 million shares of common stock outstanding as of December 31, 2023.

Conference Call and Webcast Details

Ocugen has scheduled a conference call and webcast for 8:30 a.m. ET today to discuss the financial results 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.

Attendees are invited to participate on the call or webcast using the following details:

Dial-in Numbers: (800) 715-9871 for U.S. callers and (646) 307-1963 for international callers
Conference ID: 4947142
Webcast: Available on the events section of the Ocugen investor site

A replay of the call and archived webcast will be available for approximately 45 days following the event on the Ocugen investor site.

**About Ocugen, Inc.**
Ocugen, Inc. is a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, biologics, and vaccines that improve health and offer hope for patients across the globe. We are making an impact on patients' 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, 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 include, but are not limited to, statements regarding the Company's clinical development activities and related anticipated timelines; strategy, business plans and objectives for its clinical stage programs; plans and timelines for the preclinical and clinical development of its product candidates, including the therapeutic potential, clinical benefits and safety thereof; expectations regarding timing, success and data announcements of current ongoing preclinical and clinical trials; the ability to initiate new clinical programs; Ocugen's financial condition and the expected impact of the restatement of certain financials. 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, as well as discussions of potential risks, uncertainties, and other important factors in Ocugen's subsequent filings with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. 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

# Business Update with Certain Financials for the Year Ending 2023

April 2, 2024

# Forward-Looking Statements

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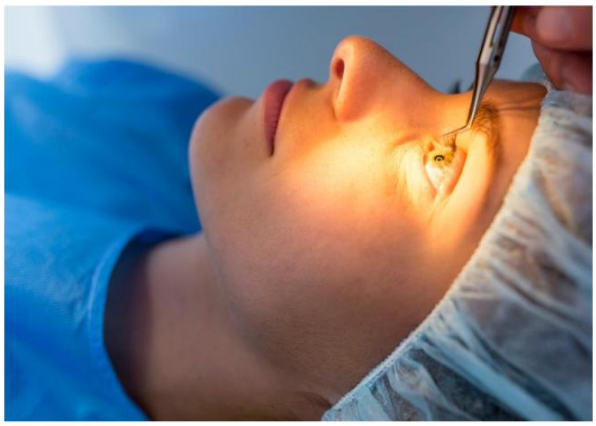
# The Journey of Hope: Battling  Retinitis Pigmentosa



*They told me about Ocugen, and I started the study. They did the surgery. I can see a little bit more in some areas that I didn't used to. You know, it was kind of dark, totally dark.*

*For a lot of people, it's not much. But for me, you know, it's a big step. I don't have to be guided."*

- Patient testimonial after 12 months of being treated in OCU400 trial

# 2023 & YTD Accomplishments – Continued Clinical Momentum

## Vaccines

**OCU500**

- ✓ Selected for inclusion in NIH/NIAID $5B Project Nextgen Initiative with other early-stage COVID-19 vaccine candidates
- ✓ Phase 1 trial planned for mid-2024

## Cell Therapy

**NeoCart®**

- ✓ Completed renovations on cGMP facility
- ✓ Received final clearance and occupancy certificate
- ✓ Evaluating strategic value-building opportunities to further develop Phase 3 asset through commercialization

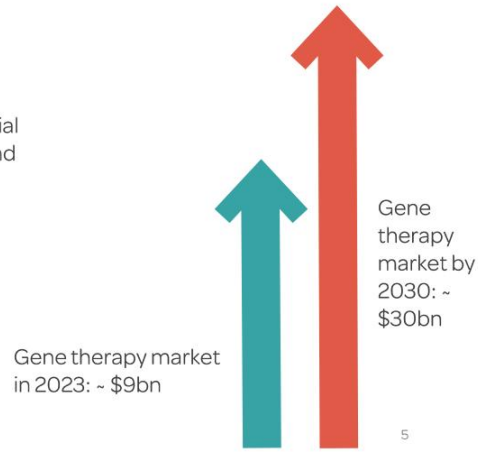
# Modifier Gene Therapy: OCU400 for RP & LCA

Potential to address multiple genetic defects with a single product utilizing a gene-agnostic approach

Ocugen is gradually growing its position within the gene therapy market as it progresses its programs

- ✓ Received concurrence from FDA on Phase 3 clinical trial design
- ✓ First gene therapy Ph3 trial to receive broad RP indication from FDA
- ✓ Primary endpoint: Luminance Dependent Navigation Assessment
- ✓ Randomized, multi-centered two arm 150 patient study
- ✓ Generated compelling preliminary results from OCU400 Phase 1/2 trial
- ✓ FDA & EMA granted expanded Orphan Drug Designations for all RP and LCA mutations
- ✓ FDA granted RMAT designation for RP

*Upcoming Catalyst: Initiate Phase 3 trial for RP in April 2024*



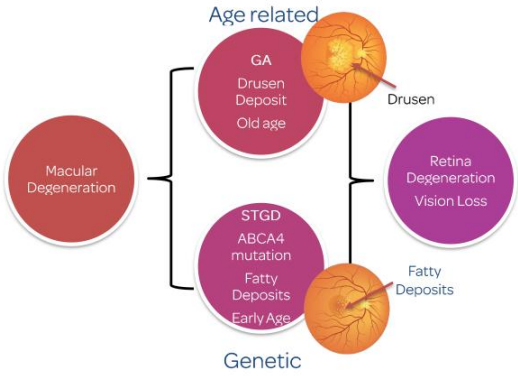
# OCU410 & OCU410ST : Tackling Geographic Atrophy Secondary to Dry AMD & Stargardt Disease

## OCU410 (ArMaDA Trial)

- ✓ Announced Cohort 1 dosing completion in Phase 1/2 trial in March 2024
- ✓ High addressable market for GA/DAMD with limited therapeutic options – affects ~10M people in the U.S. alone and ~ 266 million globally
- ✓ Current therapies have significant limitations: multiple injections/year, targets one pathway, patient compliance
- ✓ OCU410 targets all four pathways with a potential single injection therapy for life

## OCU410ST (GARDian trial)

- ✓ Announced Cohort 1 dosing completion in Phase 1/2 trial in February 2024
- ✓ Received Orphan Drug Designation from FDA
- ✓ Established Low Dose as Safe and Tolerable Dose in Current OCU410ST Clinical Trial
- ✓ DSMB Determination to Proceed with Medium Dose (Cohort 2)




**Safety/efficacy updates will be provided periodically in 2024**

# Financial Update

# Financial Update

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# Questions & Answers

ocugen

# Execution of High Value Gene Therapies— Increase Value for Patients & Shareholders

## Key Gene Therapy Milestones Achieved in 2023

- First gene therapy program to get alignment with FDA for broad RP indication in Ph3
- Initiated dosing in OCU410 Ph1/2 clinical trial (dry AMD/GA)
- Initiated dosing in OCU410ST Ph1/2 clinical trial (Stargardt)

## Key Gene Therapy Target Milestones for 2024

- Completed dosing in Cohort 1 for OCU410 (dry AMD/GA) and OCU410ST (Stargardt)
- Initiate OCU400 Ph3 clinical trial and recruit efficiently – in line with 2026 BLA approval target
- Continue to provide OCU400 Ph3 clinical updates
- Provide preliminary safety/efficacy updates from OCU410 Ph1/2 clinical trial in GA patients
- Provide preliminary safety/efficacy updates from OCU410ST Ph1/2 clinical trial in Stargardt patients
- Finalize a partner for OCU400

# Thank You

ocugen