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**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): **November 9, 2023**

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**OCUGEN, INC.**

(Exact Name of Registrant as Specified in its Charter)

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**Delaware**  
(State or Other Jurisdiction of  
Incorporation)

**001-36751**  
(Commission  
File Number)

**04-3522315**  
(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.

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**Item 2.02 Results of Operations and Financial Condition.**

On November 9, 2023, Ocugen, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2023. The Company has scheduled a conference call and webcast for 8:30 a.m. Eastern Time on November 9, 2023 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](http://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**

| <u>Exhibit No.</u> | <u>Document</u>  |
|--------------------|--|
| 99.1               | <a href="#">Press Release of Ocugen, Inc. dated November 9, 2023.</a>        |
| 99.2               | <a href="#">Earnings Release Presentation issued November 9, 2023.</a>       |
| 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: November 9, 2023

OCUGEN, INC.

By: /s/ Shankar Musunuri  
Name: Shankar Musunuri  
Title: Chairman, Chief Executive Officer, & Co-Founder

## Ocugen Provides Business Update with Third Quarter 2023 Financial Results

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

- OCU400 demonstrated favorable safety and tolerability profile in retinitis pigmentosa (RP) and Leber congenial amaurosis (LCA) subjects
  - Completed dosing of three LCA patients including a pediatric patient

- OCU400 Phase 1/2 study results suggest stabilization or improvement of Best-Corrected Visual Acuity (BCVA) or Multi-Luminance Mobility Testing (MLMT) or Low-Luminance Visual Acuity (LLVA) in treated eyes of 83% (10/12) subjects
  - Stabilization or improvement in MLMT scores from baseline in 86% (6/7) of RHO subjects demonstrated gene-agnostic property of OCU400 modifier gene therapy and its potential benefits in broader RP and LCA subjects
- Ocugen's inhaled mucosal vaccine candidate for COVID-19—OCU500—selected by National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases' (NIAID) Project NextGen for inclusion in clinical trials

MALVERN, Pa., November 9, 2023 (GLOBE NEWSWIRE) — Ocugen, Inc. (Ocugen or the Company) (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, biologics, and vaccines, today reported third quarter 2023 financial results along with a general business update.

“Ocugen has made significant pipeline progress in the third quarter,” said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. “In particular, based on the OCU400 data presented in September, I am as enthusiastic as ever regarding the potential for our modifier gene therapy approach to make an important difference in the lives of people living with blindness diseases. OCU400—our lead candidate—has the potential to address multiple genetic mutations with a single product compared to traditional gene therapies that target one gene at a time.”

This clinical efficacy update provided in September 2023 included data for 12 subjects who have completed a minimum of 6 months follow up. 83%, 83%, and 75% of subjects demonstrated stabilization or improvements in OCU400 treated eyes on BCVA, LLVA, and MLMT scores, respectively from baseline. 86% of subjects with the RHO gene mutation experienced either stabilization or increase in MLMT scores from baseline, including a subset of 29% that demonstrated a three Lux luminance level improvement. Preservation of remaining vision, slowing disease progression, or improving the vision can significantly impact patients' quality of life.

“The improvements in BCVA, LLVA and MLMT in RHO patients—a disease affecting more than 10,000 people in the U.S. alone—supports the gene-agnostic mechanism of action for OCU400,” said Dr. Musunuri.

In October 2023, OCU500, was selected by the NIAID Project NextGen for inclusion in clinical trials. OCU500 will be tested via two different mucosal routes, inhalation into the lungs and as a nasal spray. Currently used injected vaccines, including mRNA vaccines, are not effective in preventing infection and spread although effective against severe infection. Generating mucosal immunity in nasal and respiratory airways could help block the infection at its origin, thus limiting spread.

“NIAID support for our mucosal vaccine platform is the result of many months of hard work and dedicated effort by our Ocugen team and is a first step in potentially expanding the platform to flu and other respiratory viral diseases and infections,” said Dr. Musunuri. “Additionally, this funding makes it possible to focus the majority of Ocugen's R&D and clinical resources on our first-in-class gene and cell therapies.”

As Ocugen prepares to start Phase 3 for OCU400, begin dosing patients for OCU410 and OCU410ST, and initiate the Phase 1 trial for OCU500 in collaboration with NIAID, the company is making meaningful progress toward its long-term strategy and delivering on each of its scientific platforms in the near-term.

### Ophthalmic Gene Therapies—First-in-class

- **OCU400** — Completed dosing adult RP patients in the dose-escalation and dose-expansion portions of the trial; completed dosing three LCA patients including a pediatric patient. Phase 3 clinical trial for the treatment of RP to be initiated in early 2024 following FDA concurrence on study design. Subsequently, the Company is expecting to expand the OCU400 Phase 3 clinical trial for LCA patients in the second half of 2024 based on Phase 1/2 study results in LCA patients and alignment with the FDA.

- **OCU410 and OCU410ST** — IND applications to initiate Phase 1/2 trials for both OCU410 and OCU410ST were cleared by the FDA and the Company intends to dose patients in Phase 1/2 trials by the end of 2023.

#### Ophthalmic Biologic Product

- **OCU200** — Continuing to work on the Company's response to the FDA regarding the IND application and expect to initiate the Phase 1 clinical trial in the first half of 2024, contingent on the lift of the FDA hold and adequate availability of funding.

#### Regenerative Cell Therapies—First-in-class

- **NeoCart®** — Ocugen's autologous regenerative cell therapy (using patients' own cartilage cells) remains on track to begin its Phase 3 clinical trial in the second half of 2024. A cGMP facility for manufacturing NeoCart is expected to be completed at the end of 2023 and qualification is expected in the first half of 2024.

#### Vaccines Portfolio—First-in-class

- **Mucosal Vaccine Platform** — The Company is collaborating with NIAID to initiate clinical trials of OCU500 in early 2024.

#### Third Quarter 2023 Financial Results

- The Company's cash, cash equivalents, and investments totaled \$53.5 million as of September 30, 2023, compared to \$90.9 million as of December 31, 2022. The Company had 256.5 million shares of common stock outstanding as of September 30, 2023.
- Total operating expenses for the three months ended September 30, 2023 were \$15.4 million and included research and development expenses of \$6.3 million and general and administrative expenses of \$9.1 million. This compares to total operating expenses for the three months ended September 30, 2022 of \$23.1 million that included research and development expenses of \$15.6 million and general and administrative expenses of \$7.5 million.
- Ocugen reported a \$0.06 net loss per common share for the three months ended September 30, 2023 compared to a \$0.10 net loss per common share for the three months ended September 30, 2022.

#### 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: 1787631

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 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](http://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; and Ocugen’s financial condition. 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

(Tables to follow)

OCUGEN, INC.  
CONSOLIDATED BALANCE SHEETS  
(in thousands)  
(Unaudited)

|   | September 30, 2023 | December 31, 2022 |
|---|--------------------|-------------------|
| <b>Assets</b>                                     |                    |                   |
| Current assets                                    |                    |                   |
| Cash and cash equivalents                         | \$ 53,477          | \$ 77,563         |
| Marketable securities                             | —                  | 13,371            |
| Prepaid expenses and other current assets         | 3,081              | 7,558             |
| Total current assets                              | 56,558             | 98,492            |
| Property and equipment, net                       | 14,469             | 6,053             |
| Other assets                                      | 3,660              | 4,087             |
| <b>Total assets</b>                               | <b>\$ 74,687</b>   | <b>\$ 108,632</b> |
| <b>Liabilities and stockholders' equity</b>       |                    |                   |
| Current liabilities                               |                    |                   |
| Accounts payable                                  | \$ 2,921           | \$ 8,062          |
| Accrued expenses and other current liabilities    | 6,399              | 9,900             |
| Operating lease obligations                       | 540                | 498               |
| Current portion of long term debt                 | 1,276              | —                 |
| Total current liabilities                         | 11,136             | 18,460            |
| Non-current liabilities                           |                    |                   |
| Operating lease obligations, less current portion | 3,164              | 3,587             |
| Long term debt, net                               | 1,495              | 2,289             |
| Other non-current liabilities                     | 497                | 244               |
| Total liabilities                                 | 16,292             | 24,580            |
| Stockholders' equity                              |                    |                   |
| Convertible preferred stock                       | 1                  | 1                 |
| Common stock                                      | 2,566              | 2,217             |
| Treasury stock                                    | (48)               | (48)              |
| Additional paid-in capital                        | 322,452            | 294,874           |
| Accumulated other comprehensive income            | 27                 | 26                |
| Accumulated deficit                               | (266,603)          | (213,018)         |
| Total stockholders' equity                        | 58,395             | 84,052            |
| <b>Total liabilities and stockholders' equity</b> | <b>\$ 74,687</b>   | <b>\$ 108,632</b> |

**OCUGEN, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share amounts)  
(Unaudited)

|  | Three months ended September 30, |             | Nine months ended September 30, |             |
|--|----------------------------------|-------------|---------------------------------|-------------|
|  | 2023                             | 2022        | 2023                            | 2022        |
| Operating expenses   |                                  |             |                                 |             |
| Research and development   | \$ 6,342                         | \$ 15,622   | \$ 30,069                       | \$ 32,544   |
| General and administrative   | 9,082                            | 7,497       | 26,839                          | 28,174      |
| Total operating expenses   | 15,424                           | 23,119      | 56,908                          | 60,718      |
| Loss from operations   | (15,424)                         | (23,119)    | (56,908)                        | (60,718)    |
| Other income (expense), net  | 1,262                            | 1,197       | 3,323                           | 1,306       |
| Net loss   | \$ (14,162)                      | \$ (21,922) | \$ (53,585)                     | \$ (59,412) |
| Shares used in calculating net loss per common share — basic and diluted | 256,492,558                      | 216,591,011 | 240,222,667                     | 212,755,746 |
| Net loss per share of common stock — basic and diluted                   | \$ (0.06)                        | \$ (0.10)   | \$ (0.22)                       | \$ (0.28)   |



Courageous Innovation

3Q 2023  
Business Update

November 9, 2023  
NASDAQ: OCGN

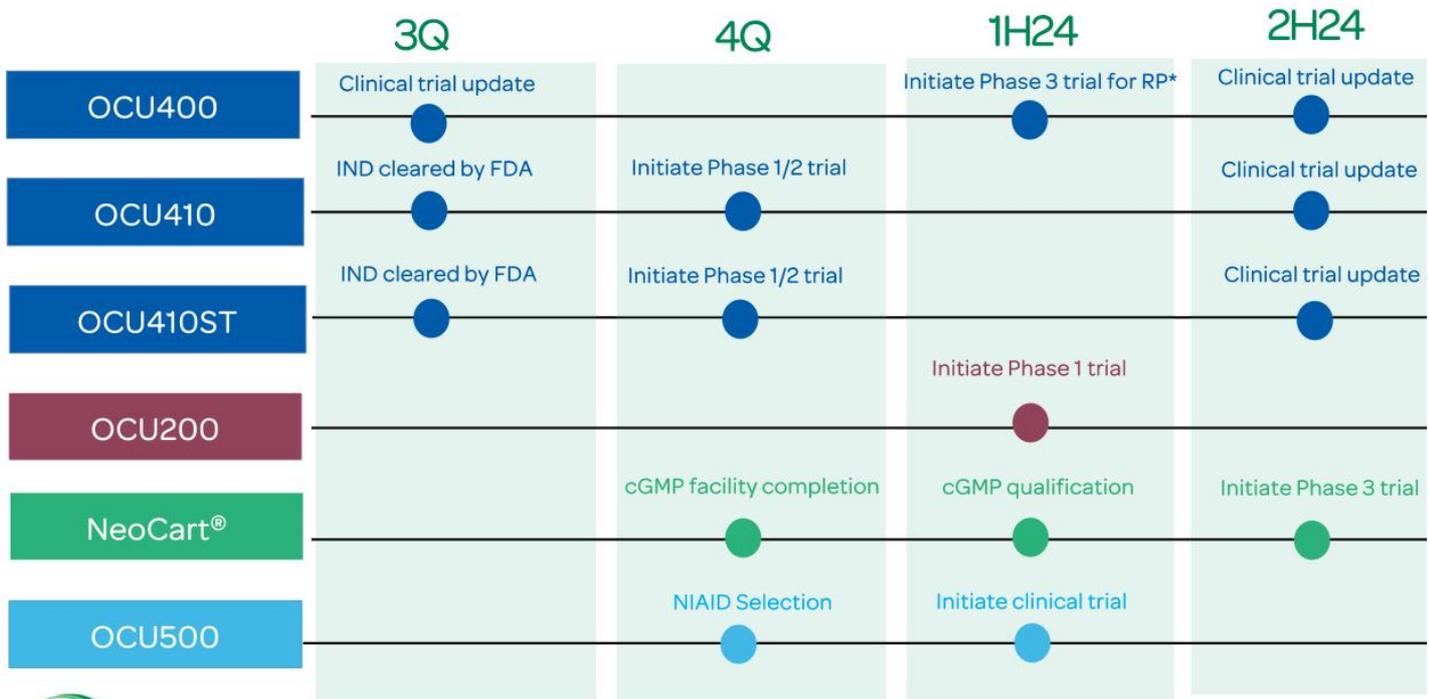


## Forward-Looking Statements

*This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Ref. 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 our clinical development activities and related anticipated timelines. 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 presentation speak only as of the date of this presentation. Except as required by law, we assume no obligation to update forward-looking statements contained in this presentation whether as a result of new information, future events, or otherwise, after the date of this presentation.*



## 2023/2024: Updated Anticipated Timing on Milestones



\* The Company will be expanding the OCU400 Phase 3 study for LCA patients in the latter part of 2024 based on Phase 1/2 study results in LCA patients and alignment with the FDA

## OCU400 Clinical Program

A Phase 1/2 Study to Assess the Safety and Efficacy of OCU400 for Retinitis Pigmentosa associated with *NR2E3* and *RHO* mutations and Leber Congenital Amaurosis with mutation(s) in *CEP290* gene

### Primary: Safety

Safety of subretinal administration of OCU400

Immune responses

Systemic Distribution

### Exploratory: Efficacy

Best Corrected Visual Acuity (BCVA)

Low Luminance Visual Acuity (LLVA)

Multi-Luminance Mobility Test (MLMT)

Clinical Trials.gov Identifier: NCT05203939



## Retinitis Pigmentosa (RP) and Leber Congenital Amaurosis (LCA)— Unmet need and Treatment Benefit Target

- Inherited retinal diseases (IRDs), such as RP and LCA, are a group of heterogeneous genetic disorders that affect the retina, the light-sensitive tissue at the back of the eye
- IRDs often lead to a gradual loss of vision over time and can ultimately result in blindness
- *Stabilization of vision is crucial* for patients with RP and LCA due to the progressive and degenerative nature of these diseases
- *Preservation of remaining vision, slowing disease progression, or improving the vision* can significantly impact the lives of patients. Such outcomes can not only enhance the quality of life for affected individuals but also provide hope that future treatments could ultimately lead to vision restoration.
- Comprehensive care, early diagnosis, and access to emerging therapies are essential components of a *strategy to stabilize vision in RP and LCA patients*



# Responder Analysis

## Stabilization/Improvement from Baseline [Treated Eyes]

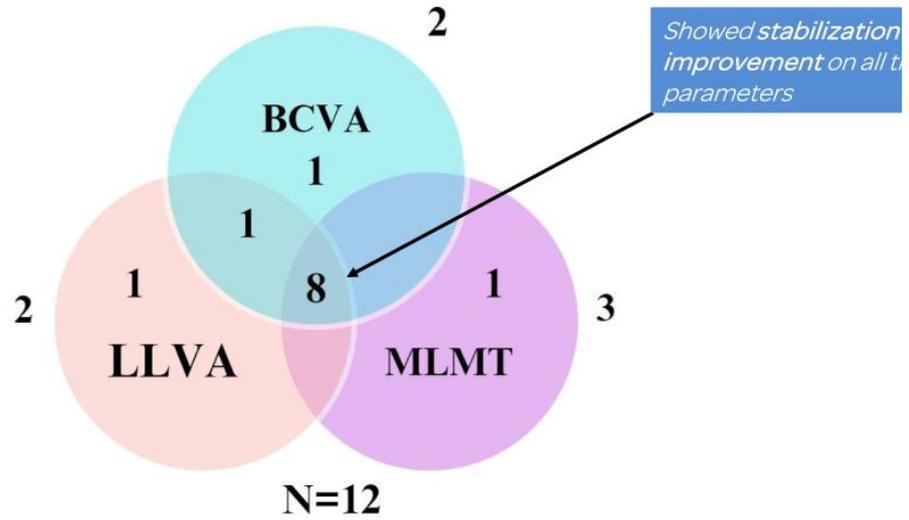
Assessed for subjects who have completed a minimum of 6 months follow-up post-OCU400 dosing

Stabilization:

- BCVA:  $\pm 4$  letters change
- LLVA:  $\pm 4$  letters change
- MLMT: 0 change in Lux Level

Improvement:

- BCVA:  $\geq 5$  letters change
- LLVA:  $\geq 5$  letters change
- MLMT:  $\geq 1$  change in Lux Level



## Encouraging Results from OCU400 Phase 1/2 Clinical Trial Update

*Results suggest gene modifier gene therapy has potential benefits in broader RP and LCA patient.*

- OCU400 continues to demonstrate a favorable safety and tolerability profile
- Clinical study update suggests continued positive trends in Best-Corrected Visual Acuity (BCVA) and Multi-Luminance Mobility Testing (MLMT), as well as positive trends in Low-Luminance Visual Acuity (LLVA) among treated eyes
- 83% (10/12) of subjects demonstrated stabilization or improvement in the treated eye either on BCVA or LLVA or MLMT scores from baseline
- 75% (9/12) of subjects demonstrated stabilization or improvement in treated eyes in MLMT scores from baseline
- 86% (6/7) of RHO mutation subjects experienced either stabilization or improvement in MLMT scores from baseline, among which 29% (2/7) demonstrated 3 Lux luminance level improvement
- Treatment effect in RHO patients—a disease affecting more than 10,000 people in the U.S. alone— supports the gene-agnostic mechanism of action of OCU400



## Continued Momentum in Progressing OCU400 Phase 1/2 Trial

- Completed dosing adult RP patients in the dose-escalation and dose-expansion portions of the trial
- Completed dosing three LCA patients including a pediatric patient
- Planning to initiate Phase 3 trial for the treatment of RP in early 2024 following FDA concurrence on study design
- Expecting to expand the OCU400 Phase 3 clinical trial for LCA patients in the second half of 2024 based on Phase 1/2 clinical trial results in LCA patients and alignment with FDA



# OCU410 (RORA): A Single-Injection Approach to Addressing Unmet Need in dAMD BEYOND the Complement System

## OCU410 Phase 1/2 Study Currently Underway

### Limited options for dAMD, presenting significant unmet medical need

- U.S.: 10M (GA: 1M)
- Worldwide: 266M

### Distinct 4-Way MOA:

Addresses multiple regulator pathways involved with the disease including:

- Lipid Metabolism
- Regulation of Inflammation
- Oxidative Stress
- Membrane Attack Complex (Complement)

### Optimal Delivery and Durability:

- A single subretinal injection designed to eliminate patient compliance concerns and the treatment burden associated with multiple injections

### Improved Retinal function:

- Improved photoreceptor function in OCU410 treated eyes with all doses\*

Advancement from recently approved therapies for GA: Potential to address limitations of recently approved therapies for GA focused only on the complement system, including:

- Patient Compliance
  - Frequent intravitreal injections (~6-12 doses per year)
- Observed Structural Impact
  - Limited effect of GA lesion growth rate
- Safety Considerations
  - 12% of patients experienced nAMD when therapy is administered every month for two years (Syfovre®)

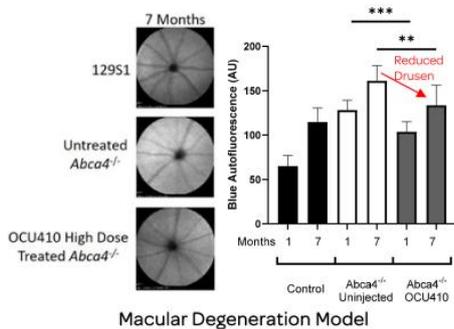
The potential for a one-time curative therapy with a single sub-retinal injection to address the unmet needs and treatment burden in patients with dAMD



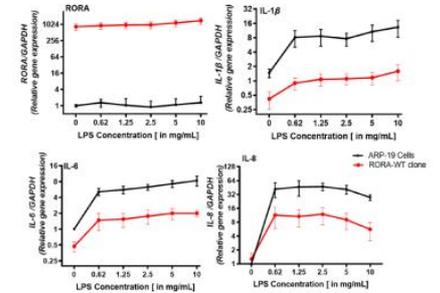
\*As demonstrated in Peak scotopic B-wave amplitudes, N≥5 biological replicates

# OCU410 (RORA): A Potential Modifier Therapeutic for Dry-AMD and STC

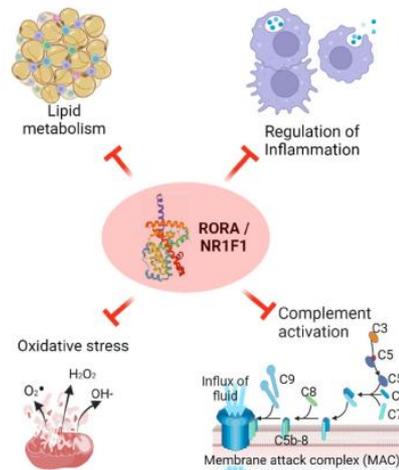
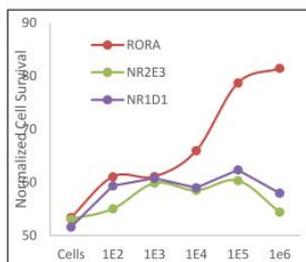
*Anti-drusen activity and improves retinal function*



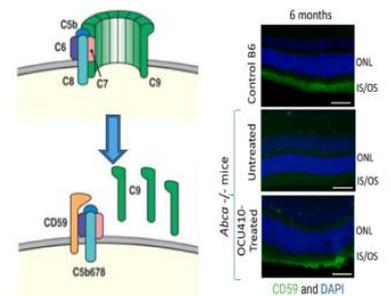
*Anti-inflammatory: Suppresses inflammation in HMC*



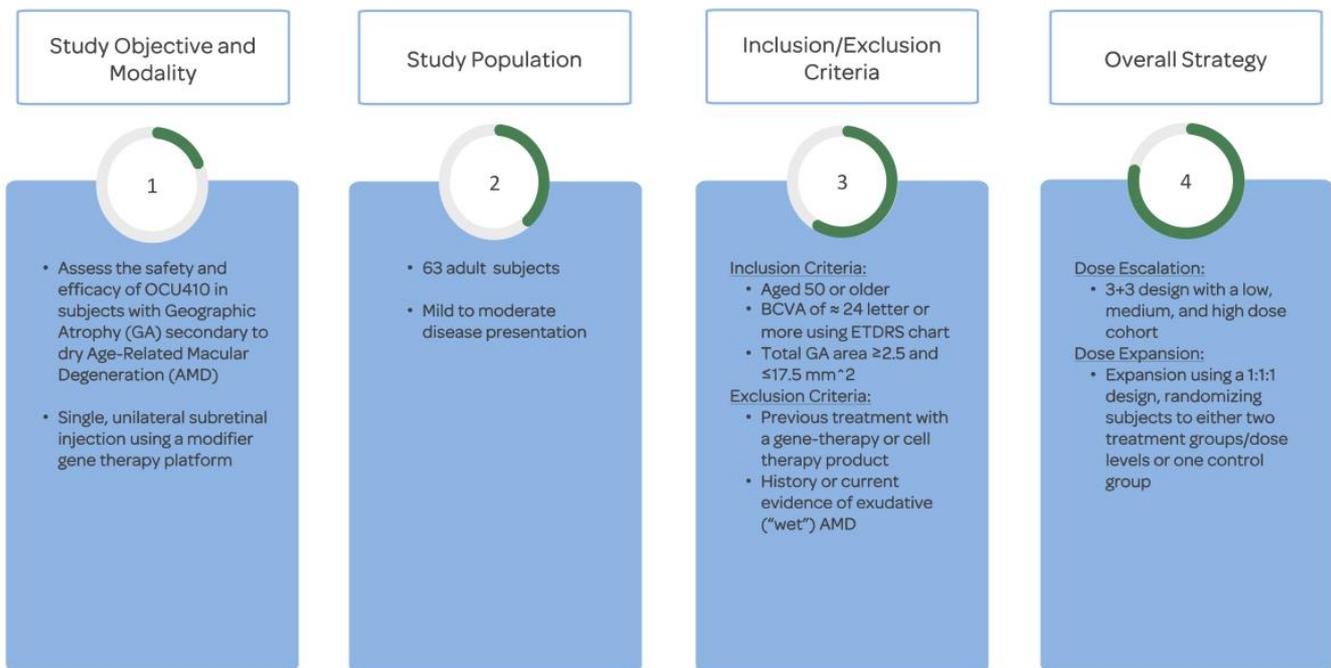
*Anti-oxidative: Improves ARPE19 cells survival*



*Anti-complement: Increased anti-complement (Cd59)*



# OCU410 Program Overview



<https://clinicaltrials.gov/study/NCT06018558?cond=Geographic%20atrophy&rank=2>

# OCU410ST: Received ODD for ABCA4-Associated Retinopathies: Stargardt, Retinitis Pigmentosa 19(RP19) & Cone-rod Dystrophy 3(CORD3)

## ABCA4-associated retinopathies—Genetic Rare Disease

- *ABCA4* gene produces an ATP-binding cassette (ABC) superfamily transmembrane protein involved in clearance of all-trans-retinal aldehyde, a byproduct of the retinoid cycle, from photoreceptor cells
- Mutation in *ABCA4* gene results in Stargardt disease. Different *ABCA4* alleles have been identified to cause other retinopathies such as cone-rod dystrophy type 3 (CORD 3), retinitis pigmentosa type 19 (RP 19)

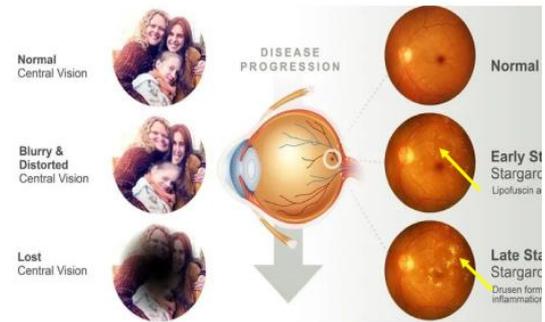
## No treatment options exist

- U.S.: 44,000 patients

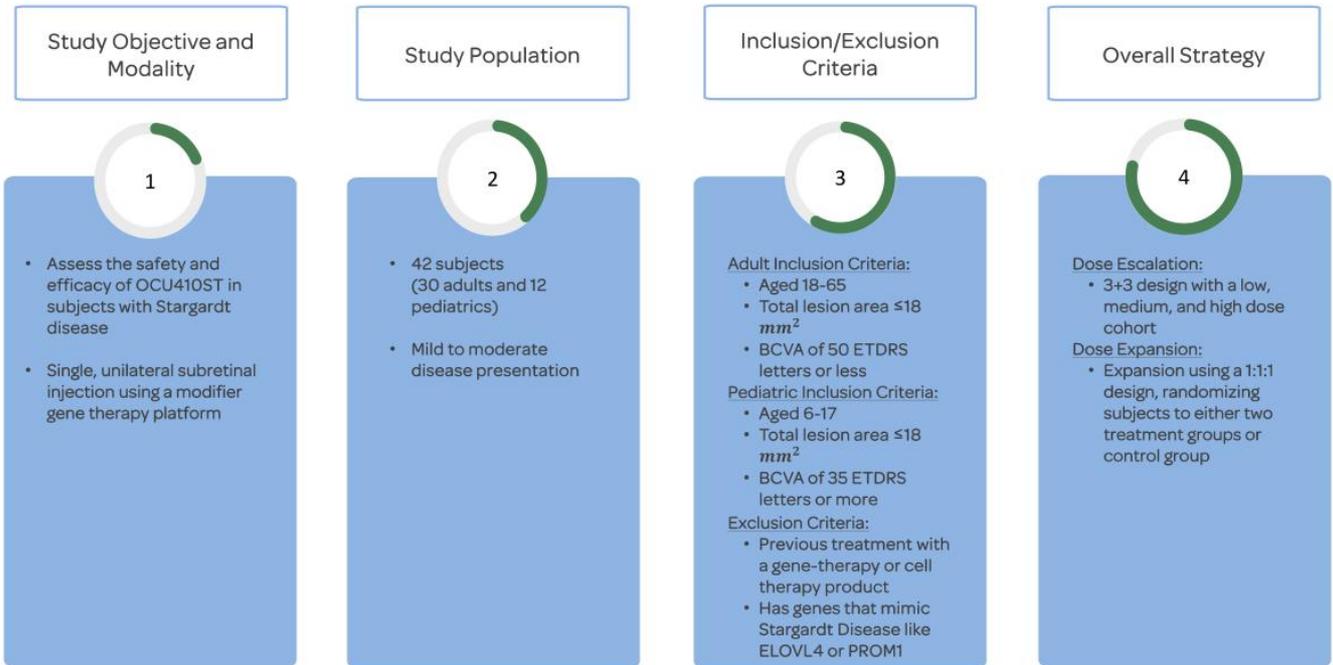
## Modifier gene therapy platform addresses shortcomings of current approaches

- AAV delivery platform delivers the *RORA* (RAR Related Orphan Receptor A)
- Broad-spectrum, gene-agnostic approach
- Potential one-time, curative therapy with a single sub-retinal injection

Phase 1/2 underway



# OCU410ST Program Overview



<https://clinicaltrials.gov/study/NCT05956626?cond=Stargardt%20Disease&rank=4>

# OCU500 Selected for NIAID's Project NextGen Covid-19 Clinical Trial

## OCU500 to expand vaccine options in fighting COVID-19

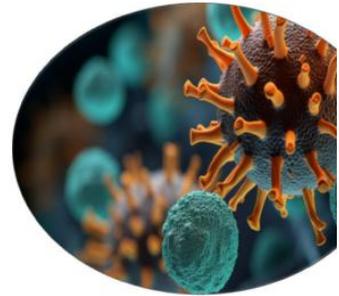
- NIAID Phase 1 clinical trials will evaluate the safety and immunogenicity of OCU500 using inhaled and intranasal routes of delivery
- Collaborating with NIAID to initiate the clinical trials in early 2024

## Inhalation technology as a differentiator

- Multiple preclinical studies using Ocugen's vector demonstrated vaccine-induced high neutralizing and effector responses
- Clinical studies using a similar vector administered via the inhalation platform showed mucosal antibodies, systemic antibodies, and durable immune response up to 1 year with 1/5 of the dose compared to the same vaccine given via intramuscular administration
- Inhaled method offers the potential for broad, durable protection from severe disease and reduction in transmission

## Strategic importance of government funding

- First step in potentially expanding the platform to flu and other respiratory viral diseases and infections
- Funding makes it possible to focus R&D and clinical resources on Ocugen's first-in-class gene and cell therapies



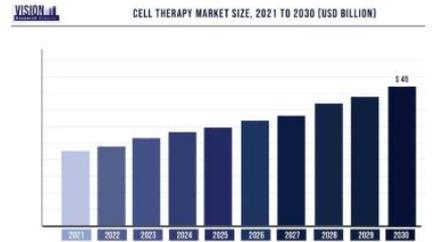
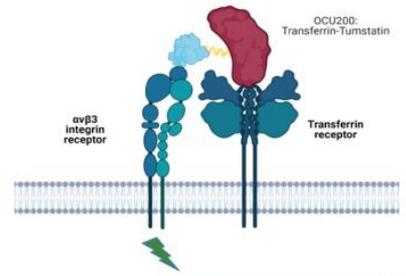
# Pipeline Updates

## NeoCart® Regenerative Cell Therapy

- Phase 3 clinical trial on track to be initiated in 2H2024
- Renovations to develop a cGMP facility for manufacturing NeoCart clinical trial material continues with expected completion at the end of 2023

## OCU200 Ophthalmic Biologic Product

- Continuing to work on the Company’s response to the FDA regarding the IND submission
- Expect to initiate the Phase 1 clinical trial in the first half of 2024, contingent on the lift of the FDA hold and adequate availability of funding



# Financial Update

## Financial Update

| Statement of Operations                                | Three months ended<br>September 30, |          | Nine months ended<br>September 30, |          |
|--|-------------------------------------|----------|------------------------------------|----------|
|  | 2023                                | 2022     | 2023                               | 2022     |
| Research and development expense                       | \$6.3                               | \$15.6   | \$30.1                             | \$32.1   |
| General and administrative expense                     | 9.1                                 | 7.5      | 26.8                               | 28.1     |
| Other income (expense), net                            | 1.3                                 | 1.2      | 3.3                                | 1.1      |
| Net loss   | \$(14.2)                            | \$(21.9) | \$(53.6)                           | \$(59.9) |
| Net loss per share of common stock – basic and diluted | \$(0.06)                            | \$(0.10) | \$(0.22)                           | \$(0.28) |

| Balance Sheet Data                      | September 30, 2023 | December 31, 2022 |
|---|--------------------|-------------------|
| Cash, cash equivalents, and investments | \$53.5             | \$90.1            |
| Debt                                    | \$2.8              | \$2.8             |
| Shares outstanding                      | 256.5              | 221.1             |



*Unaudited; in millions, except per share amounts  
Certain amounts may not add due to rounding*

# Questions & Answers



## Ocugen™ Vision

Fully integrated, patient-centric biotech company focused on vaccines in support of public health and gene and cell therapies targeting unmet medical needs through **Courageous Innovation**



