

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): September 1, 2026

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
(IRS Employer
Identification No.)

11 Great Valley Parkway
Malvern, Pennsylvania
(Address of principal executive offices)

19355
(Zip Code)

Registrant's telephone number, including area code: (484) 328-4701

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, par value \$0.01 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 7.01 Regulation FD Disclosure.

Attached as Exhibit 99.1 and incorporated herein by reference is a presentation that Ocugen, Inc. (the “Company” or “Ocugen”) will post on its website on September 8, 2026 and may use from time to time in presentations or discussions with investors, analysts, and other parties.

The information disclosed under Item 7.01 of this Current Report on Form 8-K (the “Report”), 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 8.01 Other Events.

On September 1, 2026, the Company announced that the first patient was dosed in the global Phase 3 registrational trial of OCU410 (AAV5-hRORA), its first-in-class modifier gene therapy candidate for Geographic Atrophy (“GA”) secondary to dry age-related macular degeneration (“dAMD”). The initiation of dosing follows the successful completion of a Type B End-of-Phase 2 (EOP2) meeting with the Center for Biologics Evaluation and Research (CBER) of the U.S. Food and Drug Administration (the “FDA”) in July 2026, resulting in alignment on all critical Phase 3 design elements, including primary and secondary endpoints, dose, adaptive design, and a single pivotal trial pathway to support a Biologics License Application (BLA). In July 2026, the Company also announced that the FDA granted OCU410 Regenerative Medicine Advanced Therapy (“RMAT”) designation for the treatment of GA, secondary to dAMD.

On September 3, 2026, the independent Data Monitoring Committee (the “DMC”) for the Phase 2/3 clinical trial of OCU410ST completed a pre-specified interim analysis and provided its recommendation to modify and continue the clinical study as described below. This interim analysis examined atrophic lesion size in 26 subjects (16 treated and 10 control subjects) after they had completed their 8-month clinical assessments. The DMC recommended that the study be continued per the existing protocol in order to obtain 8 months follow-up of the entire study population. The DMC noted that one could consider futility based on the negative direction of treatment effect on the interim sample and other interim results, but the DMC recommended the modification to obtain the entire dataset at 8 months in order to observe the results without the baseline lesion size imbalance that existed between the treatment and control arms in the small interim analysis population and that does not exist in the entire dataset at 8 months. The Company intends to follow the DMC’s recommendation to obtain 8 months follow-up of the entire study population.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Ocugen, Inc. Presentation, September 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Cautionary Note on Forward-Looking Statements

This Report contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding strategy, business plans and objectives for Ocugen’s clinical programs, plans and timelines for the preclinical and clinical development of Ocugen’s 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, including the timing of enrollment and data readouts, the ability to initiate new clinical programs, statements regarding qualitative assessments of available data, potential benefits, expectations for ongoing clinical trials, anticipated regulatory filings and anticipated development timelines, statements regarding potential market size and commercial possibilities of Ocugen’s product candidates, 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 our current expectations, including, but not limited to, the risks that receipt of RMAT designation may not lead to faster development or accelerated regulatory review or approval; that preliminary, interim and top-line clinical trial results may not be indicative of, and may differ from, final clinical data; that unfavorable new clinical trial data may emerge in ongoing clinical trials or through further analyses of existing clinical trial data; that earlier non-clinical and clinical data and testing may not be predictive of the results or success of later clinical trials; and that clinical trial data are subject to differing interpretations and assessments, including by regulatory authorities. These and other risks and uncertainties are more fully described in our annual and quarterly 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 Report speak only as of the date of this Report. Except as required by law, we assume no obligation to update forward-looking statements contained in this Report whether as a result of new information, future events, or otherwise, after the date of this Report.

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.

OCUGEN, INC.

Date: September 8, 2026

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



Courageous Innovation

Dedicated to Bringing Game-Changing Gene
Therapies to Market and Working Even Harder to
Provide Access to Patients Globally

September 2026

Forward Looking Statement

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including, but not limited to, strategy, business plans and objectives for Ocugen's clinical programs, plans and timelines for the preclinical and clinical development of Ocugen's product candidates, including the therapeutic potential, clinical benefits and potential safety thereof, expectations regarding timing, success and data announcements of current ongoing preclinical and clinical trials, the ability to initiate new clinical programs, statements regarding qualitative assessments of available data, potential benefits, expectations for ongoing clinical trials, anticipated regulatory filings and anticipated development timelines, which are subject to risks and uncertainties.

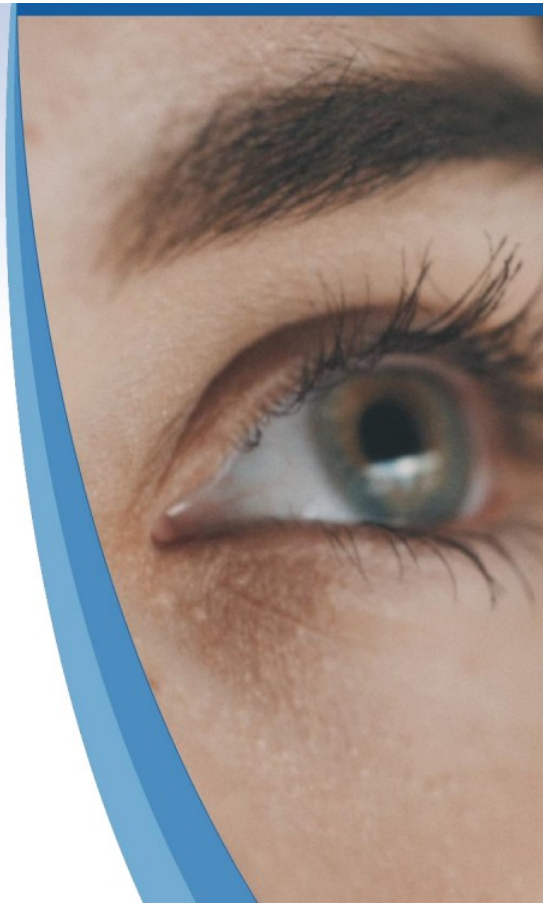
We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks, and uncertainties that may cause actual events or results to differ materially from our current expectations, including, but not limited to, risks that preliminary, interim and top-line clinical trial results may not be indicative of, and may differ from, final clinical data; that unfavorable new clinical trial data may emerge in ongoing clinical trials or through further analyses of existing clinical trial data; that earlier non-clinical and clinical data and testing of may not be predictive of the results or success of later clinical trials; and that that clinical trial data are subject to differing interpretations and assessments, including by regulatory authorities.

These and other risks and uncertainties are more fully described in our annual and 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 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 result of new information, future events, or otherwise, after the date of this presentation.

Leader in Ophthalmology Gene Therapy

Pioneering biotechnology company
leading the way to address major
blindness diseases with novel modifier
gene therapy



Targeting Three Biologics License Applications (BLAs) by 2028



¹Regenerative Medicine Advanced Therapy (RMAT); ²Orphan Drug Designation (ODD); ³Orphan Medicinal Product Designation (OMPD); ⁴Advance Therapy Medicinal Products (ATMP); ⁵Rare Paediatric Disease Designation (RPDD)

* Market Authorization Application will follow BLA submission

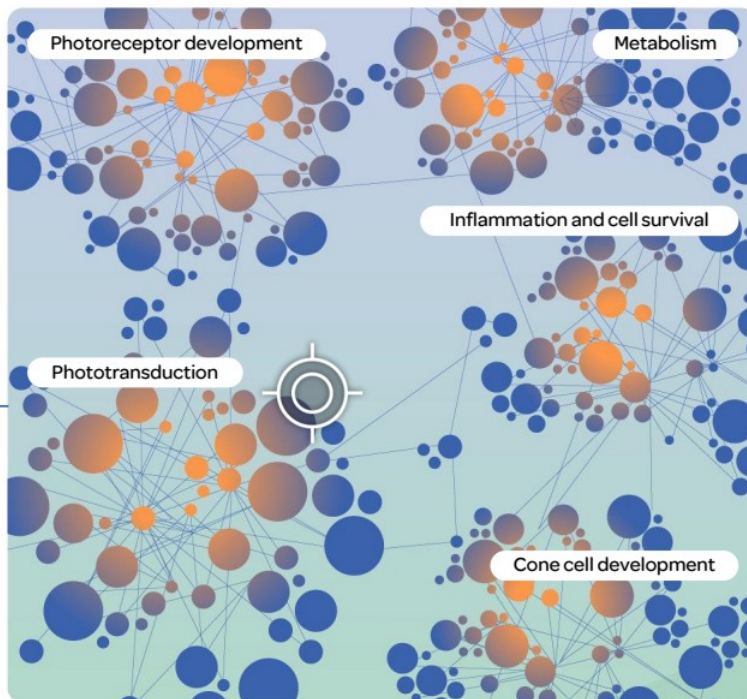
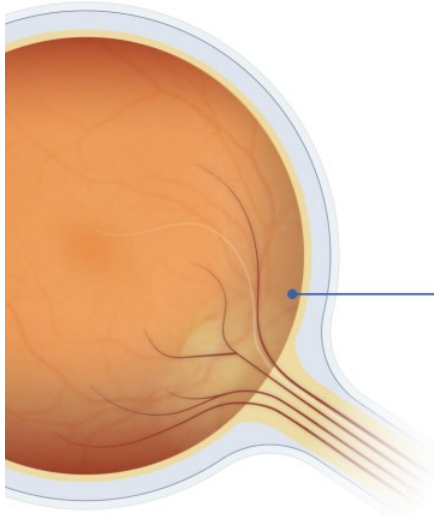


Modifier Gene Therapy Platform

Breakthrough technology designed to address many rare diseases as well as complex diseases that affect millions

Traditional therapy has limited therapeutic potential

Traditional therapy can only target one single gene at a time, limiting therapeutic potential.



65%

of all human proteins are expressed in the retina

785

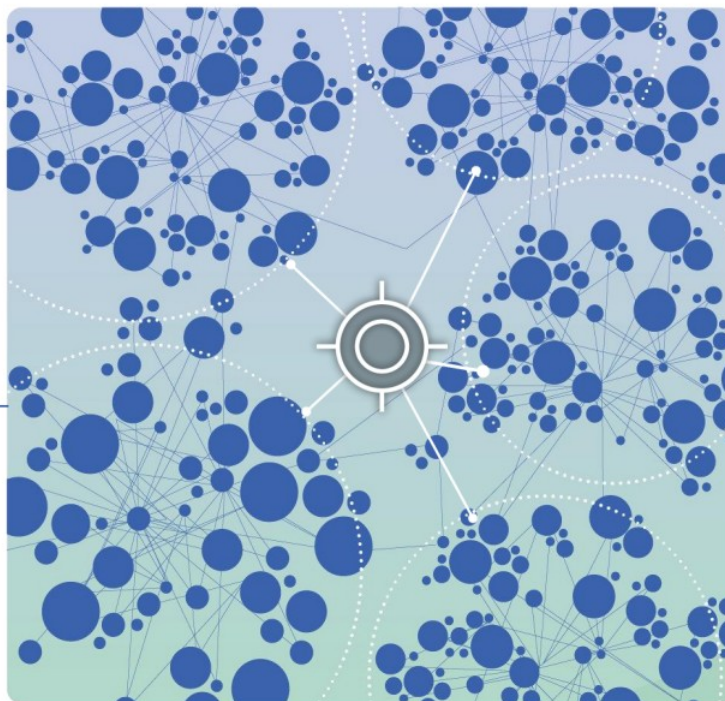
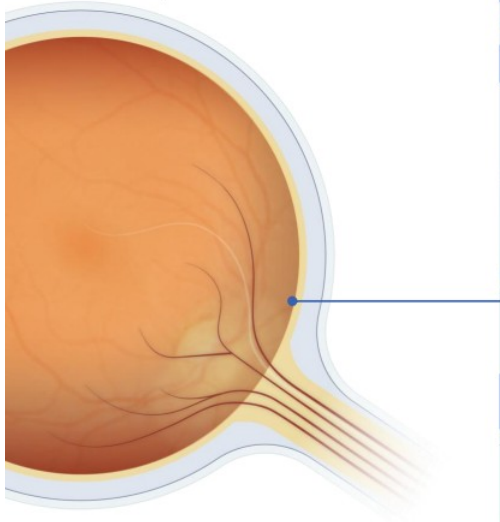
genes are highly specialized to it, interacting through complex pathways

250+

mutations affecting the retina have already been identified

The Solution is a Gene-Agnostic Approach

Our breakthrough technology is designed to address rare diseases and complex diseases



Targeting master regulators

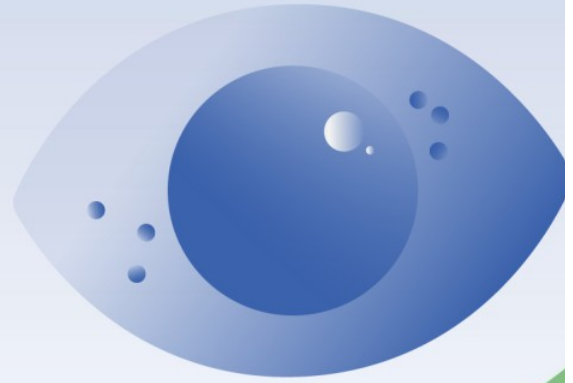
Master regulators control gene expression networks. By targeting these master regulators, Ocugen's gene therapy platform addresses the root cause of many multifactorial diseases (e.g., cancer, neurodegeneration).

- ✓✓ Gene-Agnostic
- ✓✓ Multifactorial
- ✓✓ Durable Effect
- ✓✓ Broad Impact

OCU400

Retinitis Pigmentosa (RP)

Broad indication, gene-agnostic, targets 100+ genes



First-in-Class Gene Therapy for Retinitis Pigmentosa

Retinitis Pigmentosa

Retinitis Pigmentosa (RP) is a group of rare, inherited retinal diseases caused by mutations in over 100 genes, leading to progressive vision loss and, in many cases, blindness.

1.6 million

globally suffer from RP

1

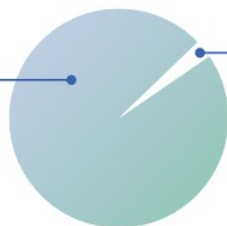
approved treatment available

Market Potential

U.S. + EU

298,000

Patients going untreated



2,000

Luxturna® only addresses one gene (RPE65)

\$52M peak annual sales

OCU400

One product for all 100 genes delivered via a single, subretinal injection

Regulatory Milestones (Anticipated)

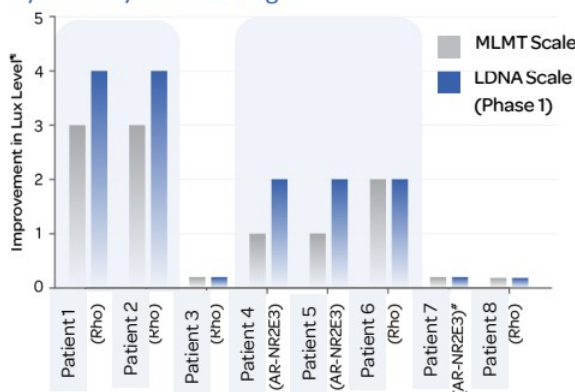
- **2026**
Phase 3 trial underway – largest orphan gene therapy trial for RP
- Enrollment completed; Manufacturing process validation completed; Launch supplies ready
- **2027**
Topline Clinical Readout followed by U.S. (BLA) and EU (MAA)

Designations

- ✓ FDA (RMAT + ODD)
- ✓ EMA (ATMP + OMPD)

Improved Patient Visual Function and Field in Phase 1/2 Clinical Trials

Eye Mobility Under Low Light

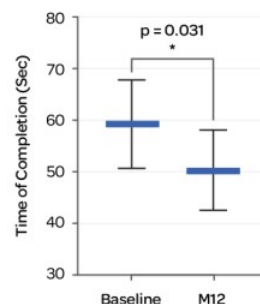


63%

of Treated Eyes Showed Improvement

from baseline after 12 months

Mobility Test Improvement



10s

Improvement

statistically significant improvement in MT completion in Treated Eyes (p=0.031)

Subject ID (with Mutation)

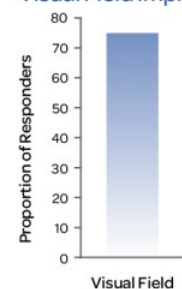
MLMT Scale (Phase 1/2)



LDNA Scale (Phase 3)



Visual Field Improvement



75%

Improvement

of VF in Treated Eyes in IT subgroup demonstrated compared to untreated eyes (6/8)

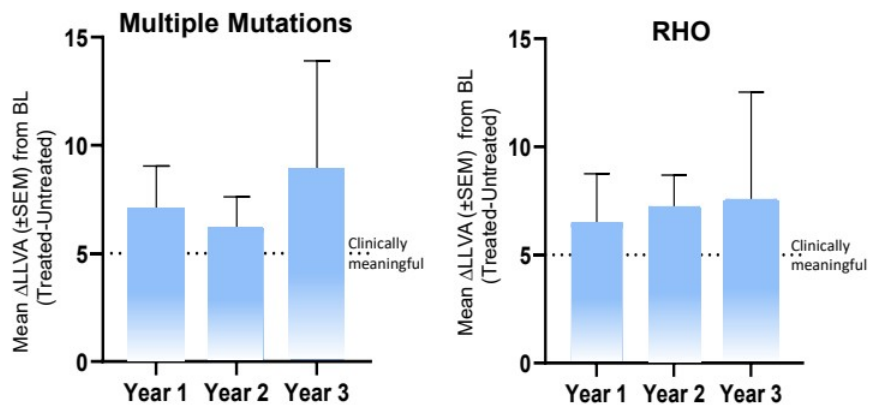
*RHO + AR-NR2E3 Subjects (- Adverse Events, Sentinel); and Ceiling Effect (RHO) Subjects; ^ ceiling effect (AR-NR2E3)

AR-NR2E3 Subjects: Baseline MLMT at 5 Lux level; 1 Lux level improvement resulted in ceiling effect on old scale on 0-6 Lux levels

† Subjects 001-003, 003-001, 001-005, 002-002 and 003-006 were responders based on the adapted LDNA Scale rounded to the nearest Lux level. Visual field is represented as improvements in VTOT or V30 compared to untreated eyes

Long-Term Durability, Safety and Tolerability Data at 3 Years

Mean Change in LLVA (ETDRS Letters) from Baseline



Results from Phase 1/2 Study

Improvement in visual function in treated eyes when compared to untreated eyes demonstrates gene-agnostic Mechanism of Action

0
Severe Adverse Events Reported related to OCU400

88 %
treated evaluable subjects demonstrated improvement or preservation in visual function compared to untreated eyes at 3 Y

OCU400 demonstrated a durable improvement in visual function (LLVA) in all evaluable treated subjects at 3 Yr when compared to untreated eyes

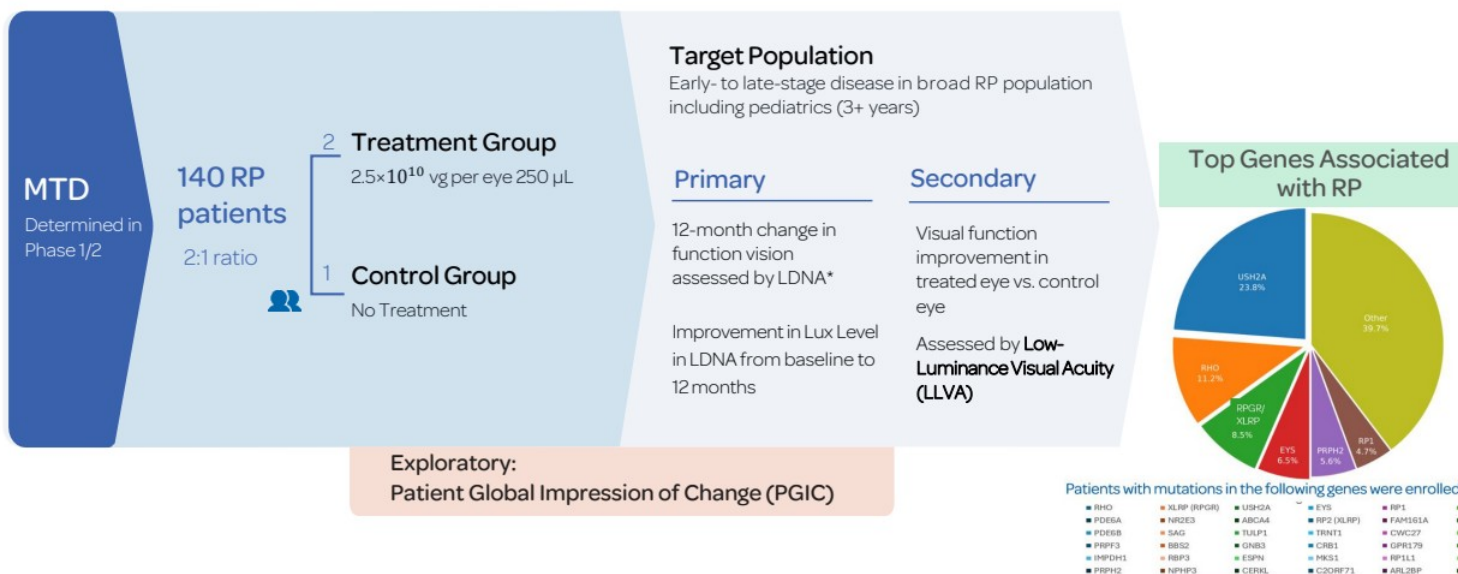
Evaluable, consented subjects for multiple mutations at Year 1 (N=11), Year 2 (N=11), Year 3 (N=8)
Evaluable, consented subjects for RHO mutations at Year 1 (N=10), Year 2 (N=8), Year 3 (N=5)
LogMar equivalent of ETDRS letters are represented for Year 3
Ocugen – September 2026

Improvement or Preservation in evaluable Treated Eyes
Preservation = -/+4 letters from Baseline, Improvement: $\geq$ 5 Letters from Baseline

Phase 3 liMeliGhT Trial—Largest RP Data Set

Phase 3 Study Design

Endpoints

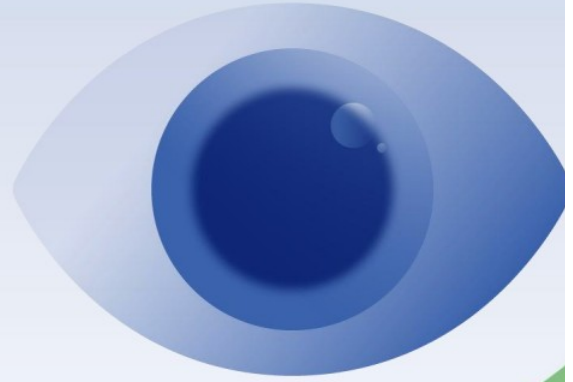


*LDNA= Luminance Dependent Navigation Assessment is a mobility test administered on a maze under different lux levels

OCU410ST

Stargardt Disease

ABCA4 -associated retinopathies >1,200 mutations



First-in-Class Gene Therapy for Stargardt Disease

Stargardt Disease

A rare IRD associated with 1,200+ mutations of the *ABCA4* gene

1 million

globally suffer from *ABCA4*-associated retinopathies

0

approved treatments available

Market Potential

U.S. + EU

100,000

Potential Patients

100%

of Patients going untreated

OCU410ST

for upregulation of networks of key genes improving the cell environment and survival with a single, subretinal injection

Regulatory Milestones

(Completed/anticipated)

● **2025**
Initiated pivotal Phase 2/3

● **2026**
Enrollment completed

†

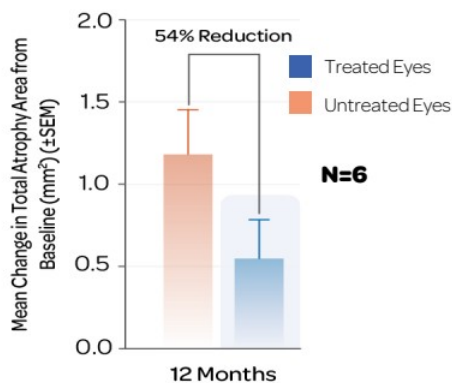
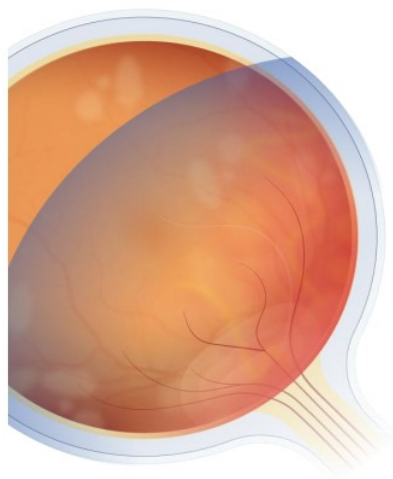
● **2027**
Topline Data;
BLA submission

Designations

✓ FDA
(RPDD + ODD)

✓ EMA
(ATMP + OMPD)

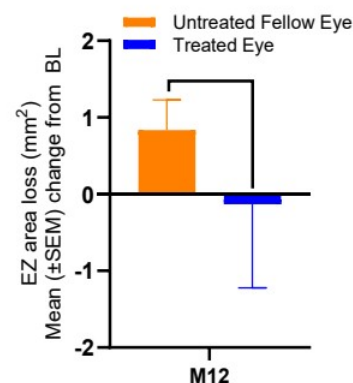
Phase 1 GARDian1 Trial Demonstrated Clinically Meaningful Benefit



Lesion Size Reduction

54%

treated vs. Control



EZ Preservation

116%

Treated vs. Control

Improvement or Preservation in evaluable Treated Eyes

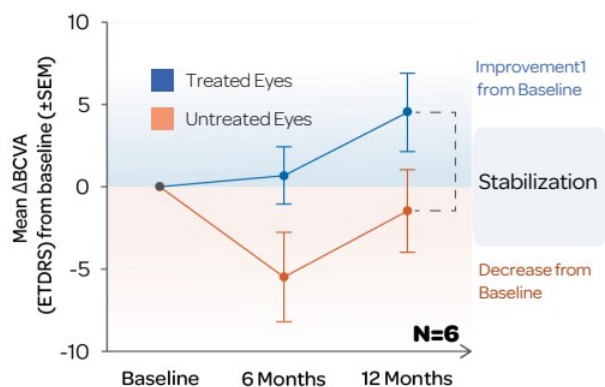
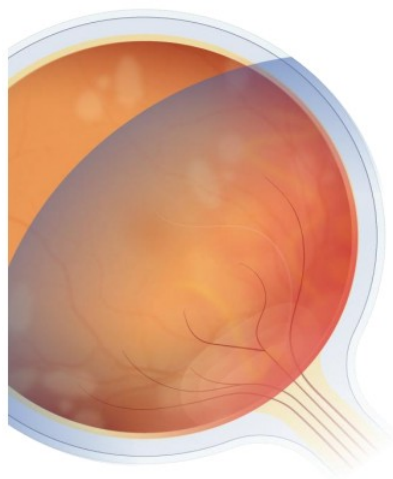
Preservation = ± 4 letters from Baseline, Improvement: ≥ 5 Letters from Baseline

*Khanani et al., Nature Eye, January 10, 2026 (<https://doi.org/10.1038/s41433-025-04202-5>)

Ocugen – September 2026

No Serious Adverse Events Reported

Phase 1 GARDian1 Trial Demonstrated Clinically Meaningful Benefit



Nearly
1-line gain

In visual acuity compared to untreated eyes

Visual Function*

100%

Stabilized or Improved compared to untreated eyes

*Khanani *et al.*, Nature Eye, January 10, 2026 (<https://doi.org/10.1038/s41433-025-04202-5>)

Improvement: ≥ 5 ETDRS letters; Stabilization: ± 4 ETDRS letters

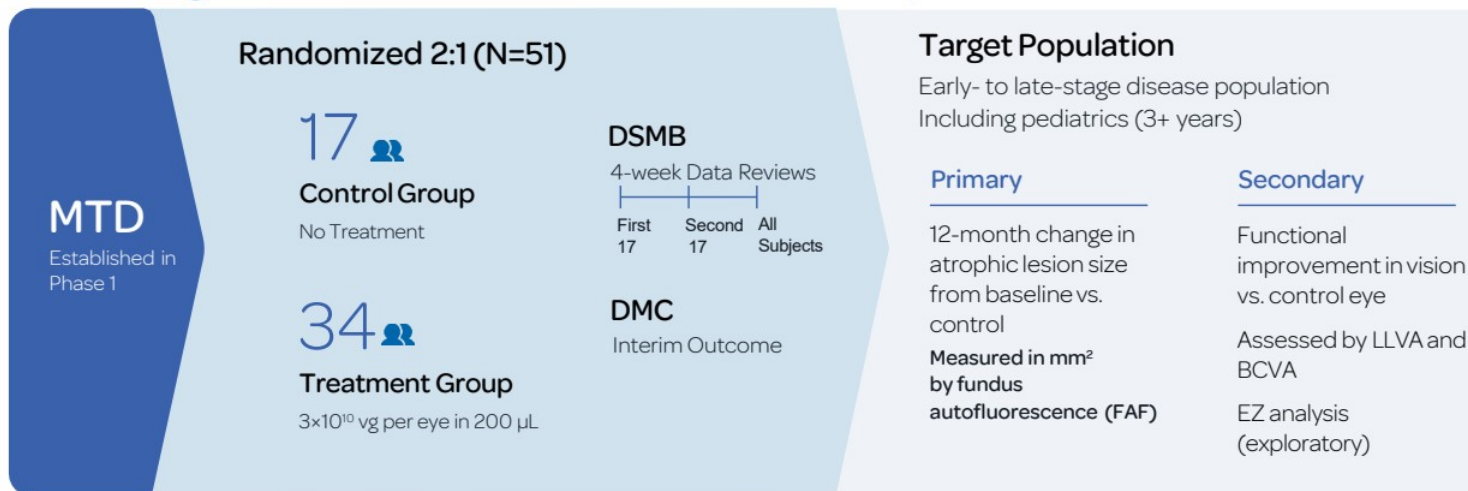
Data points for M6 (N=6); M12 (N=6); *Nearly 6 Letters (Early Treatment Diabetic Retinopathy scale)

Two patients with worsening cataract (1 Low, 1 Med), 1 High dose patient with loss-to-follow up were not included in the analysis

GARDian3- Phase 2/3 Pivotal Confirmatory Trial

Trial Design

Endpoints



OCU410

Geographic Atrophy

Advanced dry age-related macular degeneration (dAMD)



First-in-Class Gene Therapy for GA Patients

Geographic Atrophy

Geographic Atrophy (GA) is an advanced form of dry AMD. GA causes irreversible degeneration of retina cells in the macula, leading to loss of central vision.

~8 million

globally suffer from advanced dAMD

2

approved treatments available that address only 1 of the 4 pathways involved in disease progression

Market Size

U.S. + EU

2-3M

Patients

Approved Products in US

SYFOVRE® and IZERVAY®

>\$1B combined annual sales

OCU410

Designed to address all four pathways associated with GA without 6-12 injections per year and related side effects

Regulatory Milestones (Anticipated)

- **2026**
Phase 2 topline data released
- **3Q 2026**
Initiated Phase 3
- **2027**
Complete enrollment
- **2028**
Phase 3 topline data; BLA submission

Designations

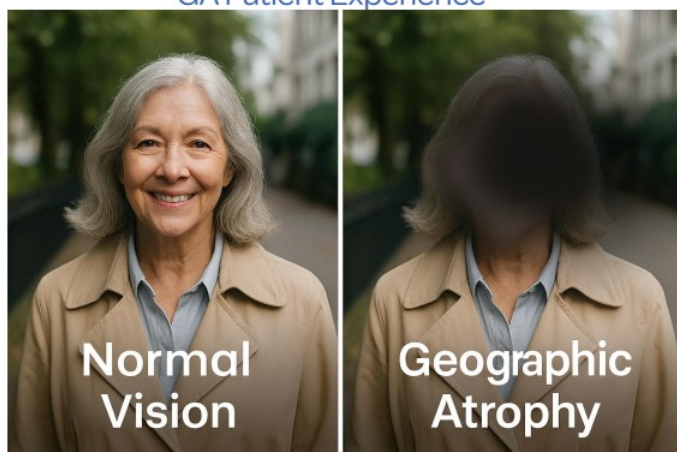
- ✓ EMA (ATMP)
- ✓ FDA (RMAT)

Recent Milestone

Positive 12-month Phase 2 data; first patient dosed in Phase 3

OCU410 Aims to Disrupt GA Treatment Driven by a Novel MOA

GA Patient Experience

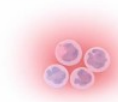


Driving global change at the patient level
(2-3M patients in U.S. and EU)

RORA 4-way MOA¹



Lipid deposits/
Drusen

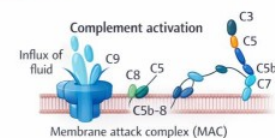
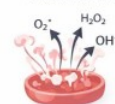


Inflammation



RORA /
NR1F1

Oxidative stress



Membrane attack complex (MAC)

Addresses all disease pathways – marketed therapies only
address the complement system

¹Akula et al. *Gene Ther* 2024; MOA= Mechanism of Action: anti-drusen activity (improves retinal function), anti-inflammatory (suppresses inflammation in HMC3 cells), anti-oxidative (improves ARPE19 cell survival), and complement (increases Cd59 protein)

Phase 2 ArMaDa Trial: To Assess Safety and Efficacy of OCU410 in (

Target Population: Geographic atrophy secondary to dry AMD

Key Protocol Inclusion Criteria:

Randomization

1:1:1

17 

Medium Dose

1x 10¹⁰ vg per eye, 200 µL

17 

High Dose

3x 10¹⁰ vg per eye, 200 µL

17 

Control Group

No Treatment

Endpoints

Primary: Change in GA lesion size measured in mm² by FAF at Month 12

Exploratory: EZ preservation (correlates to visual function)

- Subjects 50 years and older
- BCVA of ≥21 ETDRS Letters
- Total GA area ≥2.0 and ≤ 20.5 mm² (1 to 8 disk areas)
- GA within foveal and nonfoveal region
- CNV in fellow eye is not exclusionary
- Subjects who had a history of pegcetacoplan or avacincaptad pegol use were enrolled with 3M washout period

Phase 2 (ArMaDa Trial): NCT06018558

OCU410 Demonstrates Favorable Safety and Tolerability Profile

Adverse Events (AE), Serious AEs, Adverse Events of Special Interest (AESI)	Control (N=13)	OCU410 Med Dose (N=16)	OCU410 High Dose (N=16)
Endophthalmitis and Retinal Detachments	0	0	0
Retinal Vasculitis and/or Retinal Vascular Occlusion	0	0	0
Choroidal Neovascularization (CNV)	1*	2*	1*
Intraocular Inflammation	0	0	1#
Ischemic Optic Neuropathy	0	0	0
Treatment Emergent Serious Adverse Events	0	0	0
Treatment Emergent Adverse Events Considered Severe	0	0	0

No OCU410-related SAEs and AESIs reported to date

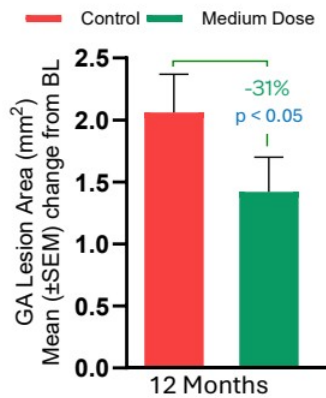
Intraocular Inflammation deemed related to study procedure – resolved

*CNV reported as AEs were not related to OCU410 based on DSMB review

Phase 2 Data Driving Optimal Dose for Phase 3

Change in GA Lesion Area (FAF; N=28)

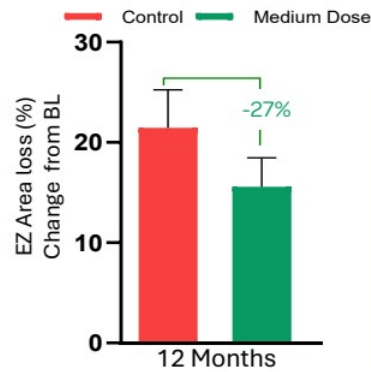
Ellipsoid Zone Loss (SD-OCT; N=25)
(Correlates to Visual Function)



Lesion Size Reduction

31%

treated vs control



EZ Preservation

27%

treated vs control

No disease progression in ~2 of treated subjects

75% of treated subjects showed >30% reduction in lesion growth

References for Natural History: Mones and Biarnes, 2018, TVST, N=117;
For Primary Endpoint analysis evaluable subjects include controls (N=12) and medium dose (N=16); for EZ loss analysis, Controls (N=12) and medium dose (N=13)
GA Lesion $\geq 2.5 \text{ mm}^2$ and $\leq 17.5 \text{ mm}^2$ (Lesion criteria in prior pivotal trials supporting approval); FAF= Fundus Autofluorescence; SD-OCT= Spectral Domain Optical Coherence Tomography;
Primary analysis conducted by MMRM and p-value <0.05
Phase 3 considerations: Dose - 1×10^{10} vg per eye; Primary Endpoint - Lesion Size Reduction; Secondary Endpoint - EZ Preservation

OCU410 Demonstrates Statistically Significant Reduction in Lesion Size at 12 Months

OCU410 shows ~2X effect size compared to approved therapies

Potentially addresses current unmet need in treating GA:

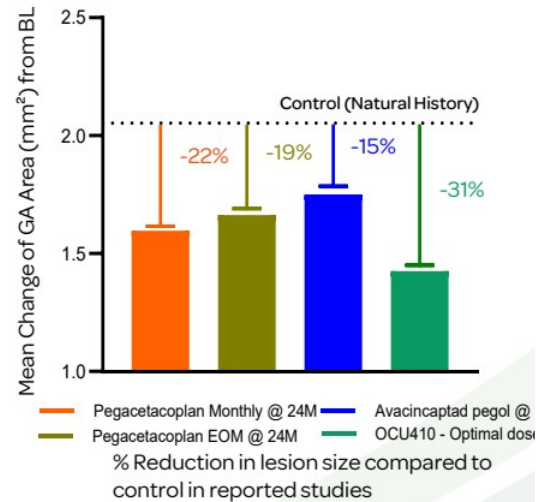
- Potential one-time treatment for life versus 6-12 injections per year
- May overcome up to 40% drop-out reported in the current standard of care

Topline, 12-month efficacy results in Phase 1 and Phase 2:

- Promising efficacy in Phase 1 and Phase 2
- Apparent structural preservation on GA lesion
- EZ preservation may support visual function

Topline data suggests favorable safety and tolerability profile:

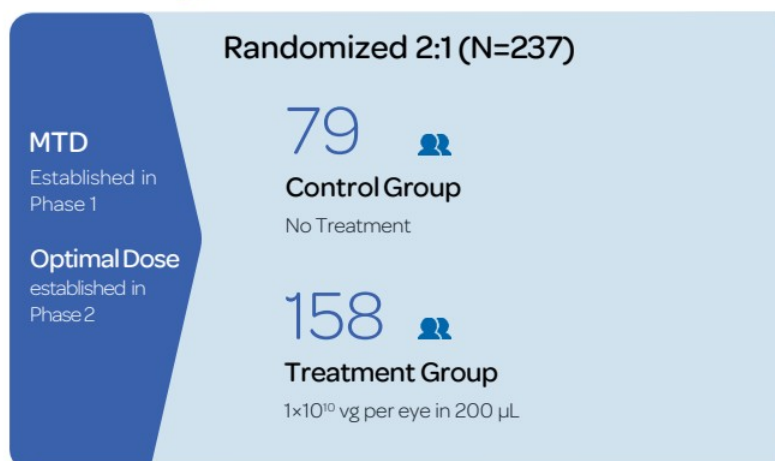
- No SAEs and AESIs deemed related to OCU410



References: Apellis OAKS/DERBY (Heier et al, Lancet, Product Insert), Iveric GATHER 2 (Liao 2023, Khanani 2024, Lancet/Ophthalmology, Product Insert), Natural History Meta-analysis (Fleckenstein 2018, Ophthalmology), from Baseline for OCU410 was against ArMaDa control subjects; Dropout rates for approved therapies reported after 10 injections (PIPER[SANDLER Industry Note, June 2025]; OCU410 Optimal Dose = Medium Dose

Phase 3 – Assess Efficacy, Safety and Tolerability of OCU410 in GA

Trial Design



Endpoints

Target Population

Adults (55+years) with geographic atrophy secondary to dry AMD (55+ years), early to late-stage disease

Primary

12-month change in GA lesion size from baseline vs. control
Measured in square root mm by fundus autofluorescence (FAF)

Secondary

Proportion of subjects with LLVA ≥15 Letter Loss from Baseline to M12 as assessed by ETDRS visual charts at two consecutive visits
12-month change in EZ Loss Area in study eyes vs. control (SD-OCT)

Phase 3 ArMaDa Trial: NCT07770828

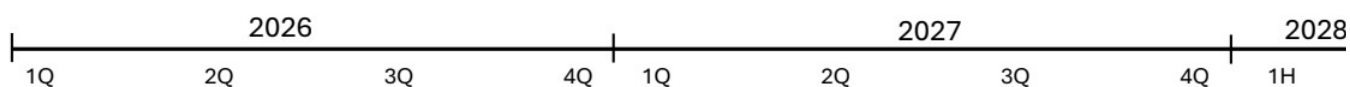
Ocugen Hopes to Deliver on Its Promise to Transform the Treatment Landscape for Patients with GA

OCU410 potentially creates a new standard of care



- **First-in-class** RORA MOA designed to support central retina and photoreceptor integ
- **Promising Phase 2 results** indicate 31% reduction in lesion size and 27% slower EZ lo
- **Potential to eliminate treatment burden** and patient fatigue to reduce treatment i
- **Optimized Phase 3 trial design** and targeted GA lesion size for vision preservation
- **Current Global Phase 3**, n=~237, >95% power, Initiated in 3Q 2026

Anticipated Milestones – Three BLAs by 2028



OCU400

Retinitis
Pigmentosa

Phase 3
Topline Data

BLA
Submission

Approval/
Launch

OCU410ST

Stargardt
Disease

100% Enrollment
Completion

Phase 3
Topline Data

BLA
Submission

Approval/
Launch

OCU410

Geographic
Atrophy

Phase 2 Study Results

Initiate Phase 3

Phase 3
Enrollment Completion

S

Ocugen – September 2026

¹Re-estimation to minimize clinical risk (Outcome - Impact / no-impact to BLA timeline)



Advancing cures for blindness



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