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): **April 13, 2023**

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)

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 (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 April 14, 2023 Ocugen, Inc. (the "Company") issued a press release announcing positive preliminary data among retinitis pigmentosa (RP) participants treated in the first two cohorts of the Phase 1/2 trial to assess the safety and efficacy of OCU400 for RP associated with *NR2E3* and Rhodopsin (*RHO*) mutations and Leber Congenital Amaurosis (LCA) with mutation(s) in the *CEP290* gene. These preliminary results provide support that OCU400, Ocugen's first-in-class therapeutic approach utilizing a proprietary modifier gene therapy platform, has the potential to be a gene-agnostic therapeutic for RP and LCA patients with inherited retinal degeneration. A copy of the press release, and a presentation used by the Company with respect to the data, are filed as Exhibit 99.1 and Exhibit 99.2, respectively, herewith and incorporated herein by reference.

On April 13, 2023, the Company was notified by the United States Food and Drug Administration (the "FDA") that the Investigational New Drug application ("IND") submitted by the Company for the initiation of a Phase 1 clinical trial of OCU200, a fusion protein with a distinct mechanism of action ("MOA"), for the treatment of diabetic macular edema ("DME") was placed on clinical hold as part of its request for additional information related to chemistry and manufacturing controls ("CMC") prior to initiating the Phase 1 clinical trial. This program is part of the Company's biologics platform and unrelated to the Company's modifier gene therapy platform, including OCU400. Ocugen plans to work with the FDA and provide requested information as promptly as possible and does not currently expect the clinical hold to impact the anticipated overall timing of the OCU200 clinical development program.

This Current Report on Form 8-K contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, which are subject to risks and uncertainties, including, but not limited to, statements regarding the development of the Company's product candidates and associated timing, the interpretation of preliminary clinical trial results and the results of the Company's interactions with the FDA. The Company may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks, and uncertainties that may cause actual events or results to differ materially from the Company's current expectations, including, but not limited to, the risk that preliminary clinical data may not be indicative of final clinical data or data in later stage clinical trials and the risk that the FDA may not lift the clinical hold on OCU200 on the anticipated timeline or at all. These and other risks and uncertainties are more fully described in the Company's 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 the Company files with the SEC. Any forward-looking statements that we make in this Current Report on Form 8-K speak only as of the date hereof. Except as required by law, the Company assumes no obligation to update forward-looking statements contained in this Current Report on Form 8-K whether as a result of new information, future events, or otherwise, after the date hereof.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being filed herewith:

Exhibit No.	Document
99.1	Press Release of Ocugen, Inc. dated April 14, 2023
99.2	Presentation of Ocugen, Inc.
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 14, 2023

OCUGEN, INC.

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

Exhibit 99.1

Ocugen Announces Positive Preliminary Safety and Efficacy Results from the Phase 1/2 Trial of OCU400, a Modifier Gene Therapy Product Candidate, for the Treatment of Retinitis Pigmentosa and Leber Congenital Amaurosis

- *Favorable safety and tolerability profile related to OCU400 investigational product candidate*
- *Initial clinical data from low and medium dose cohorts indicates positive trend in Multi-luminance mobility testing and Best-Corrected Visual Acuity scores for OCU400 treated eyes*
- *71.4% (5/7) of OCU400 treated eyes in **low and medium dose** cohorts experienced at least ³ **1 Lux** luminance level improvement in mobility test from baseline*
- *66.7% (2/3) of OCU400 treated eyes in low dose cohorts at 9-month follow-up experienced at least ³ **2 Lux** luminance level improvement in mobility test from baseline*
- Ocugen believes these preliminary data supports potential of modifier gene therapy platform in gene-agnostic treatment of complex and heterogenous inherited genetic diseases

Malvern, Pa, April 14, 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 announced positive preliminary data among retinitis pigmentosa (RP) participants treated in the first two cohorts of the Phase 1/2 trial to assess the safety and efficacy of OCU400 for RP associated with *NR2E3* and Rhodopsin (*RHO*) mutations and Leber Congenital Amaurosis (LCA) with mutation(s) in the *CEP290* gene. These preliminary results provide support that OCU400, Ocugen's first-in-class therapeutic approach utilizing a proprietary modifier gene therapy platform, has the potential to be a gene-agnostic therapeutic for RP and LCA patients with inherited retinal degeneration.

"It is very gratifying to see these positive preliminary results from our novel modifier gene therapy approach," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "This is the first clinical validation of the platform where patient responses across various genetic mutations support that OCU400 has the potential to transform the lives of many patients who are struggling with debilitating blindness diseases."

This Phase 1/2 trial is a multicenter, open-label, dose ranging study. A total of 18 RP subjects have been enrolled in this study—10 subjects in the dose escalation and 8 subjects in the expansion phase, respectively. The age of subjects enrolled to date ranges from 18-77 years across *RHO* and *NR2E3* gene mutations. We further expanded this Phase1/2 trial to enroll LCA patients with *CEP290* gene mutation and pediatric patients with *NR2E3*, *RHO* and *CEP290* mutations.

In Cohort 1 and 2 of the clinical trial, 7 participants with severe vision impairment due to RP associated with *RHO* and *NR2E3* gene mutations received a unilateral subretinal injection of either a low dose (1.66×10^{10} vg/mL) or medium dose (3.33×10^{10} vg/mL) OCU400, respectively. In the preliminary data analysis, 9-month follow-up data for 3 subjects [Cohort 1], and 6-month follow-up data for 4 subjects [N=1 from Cohort 1 and N=3 from Cohort 2] were evaluated.

Results showed a favorable safety profile and visual improvements after treatment with OCU400 as measured by multi-luminance mobility testing (MLMT) and best corrected visual acuity assessment (BCVA).

Key efficacy outcomes from 7 subjects demonstrated:

- 100% of treated eyes showed a stable or improved MLMT score trend;
- 5 of 7 (71.4%) OCU400 treated eyes demonstrated a 1 or more Lux level improvement in MLMT score compared to 28.6 % of untreated eyes;
- 66.7% (2 of 3) of OCU400 treated eyes in Cohort 1 with 9-month follow-up demonstrated a 2 or more Lux level improvement in MLMT score compared to none of the untreated eyes; and
- 3 of 7 (42.9%) OCU400 treated eyes demonstrated 8-11 letters of improvement in BCVA score compared to none of the untreated eyes.

“I was not expecting such substantial improvements in visual function among the trial participants I have been working with because of the advanced stage of their retinal disease,” said David Birch, PhD, Scientific Director, Retina Foundation of the Southwest, principal investigator of the study. “I am very pleased by the outcomes I have seen in my own clinic and am hopeful that OCU400 could provide a therapeutic solution for RP patients who are not only facing loss of vision, but also challenged with the psychological burden of losing their independence.”

“The early results from patients treated in the Phase 1/2 clinical trial are encouraging and support the paradigm-changing potential of modifier gene therapy technology to address unmet medical needs for patients with RP and LCA,” said Arun Upadhyay, PhD, Chief Scientific Officer and Head of Research, Development and Medical at Ocugen. “With this favorable safety profile and positive trend in efficacy signals, we are very eager to see longer-term data, and to potentially initiate Phase 3 trials in the U.S. and EU.”

Ocugen will continue to monitor long-term safety and efficacy data from the treated patients, and advance development of OCU400 to bring a potential treatment option to RP and LCA patients.

CanSinoBIO, Ocugen’s strategic partner, provided all CMC development and clinical supplies for the Phase 1/2 trial of OCU400.

A webcast and conference call will take place today at 8 a.m.:
Dial-in Numbers: (800) 715-9871 for U.S. callers and (646) 307-1963 for international callers
Conference ID: 4898155
Webcast: Available on the events section of the Ocugen investor site

About Modifier Gene Therapy

Modifier gene therapy is designed to fulfill unmet medical needs related to retinal diseases, including IRDs, such as RP, LCA, and Stargardt disease, as well as dry AMD. Our modifier gene therapy platform is based on the use of NHRs, master gene regulators, which have the potential to restore homeostasis — the basic biological processes in the retina. Unlike single-gene replacement therapies, which only target one genetic mutation, we believe that our modifier gene therapy platform, through its use of NHRs, represents a novel approach that has the potential to address multiple retinal diseases caused by mutations in multiple genes with one product, and to address complex diseases that are potentially caused by imbalances in multiple gene networks. Currently Ocugen has three modifier gene therapy programs OCU400 (RP, LCA), OCU410 (dry AMD), OCU410ST (Stargardt disease).

About OCU400

OCU400 is the Company’s gene-agnostic modifier gene therapy product based on NHR gene, *NR2E3*. *NR2E3* regulates diverse physiological functions within the retina—such as photoreceptor development and maintenance, metabolism, phototransduction, inflammation and cell survival networks. Through its drive functionality, OCU400 resets altered/affected cellular gene-networks and establishes homeostasis—a state of balance, which has potential to improve retinal health and function in patients with inherited retinal diseases.

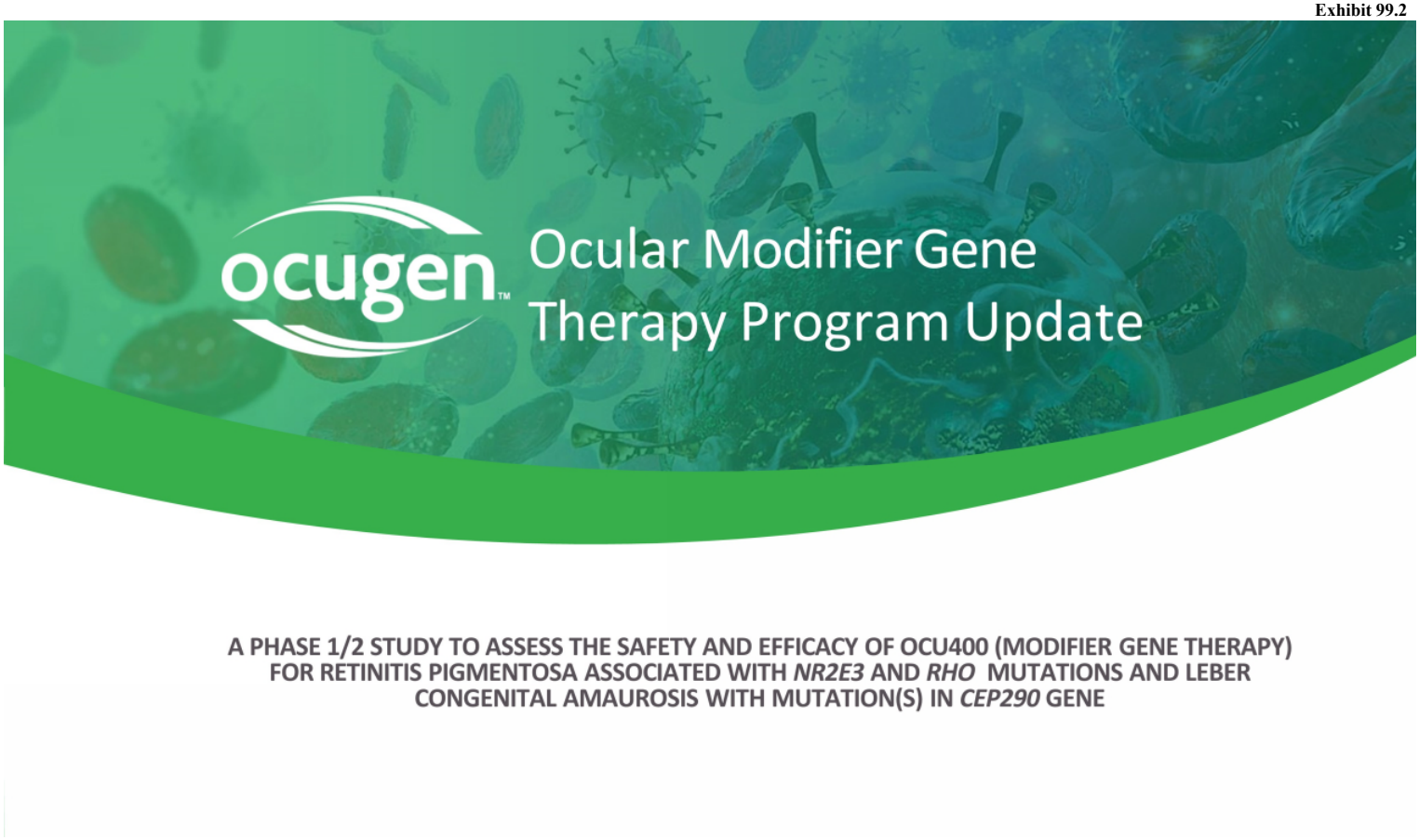
About Ocugen, Inc.

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 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, including, but not limited to, statements regarding the development of OCU400 and the interpretation of preliminary clinical trial results. 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 risk that preliminary clinical data may not be indicative of final clinical data or data in later stage clinical trials. 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 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.

Contact:
Tiffany Hamilton
Head of Communications
IR@ocugen.com



A PHASE 1/2 STUDY TO ASSESS THE SAFETY AND EFFICACY OF OCU400 (MODIFIER GENE THERAPY) FOR RETINITIS PIGMENTOSA ASSOCIATED WITH *NR2E3* AND *RHO* MUTATIONS AND LEBER CONGENITAL AMAUROSIS WITH MUTATION(S) IN *CEP290* GENE

Forward Looking Statements

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, which are subject to risks and uncertainties, including, but not limited to, statements regarding the development of OCU400 and the interpretation of preliminary clinical trial results. 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 risk that preliminary clinical data may not be indicative of final clinical data or data in later stage clinical trials. 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.

Today's Agenda

Opening	Shankar Musunuri, PhD, MBA Chairman, CEO and Co-founder, Ocugen
Overview of Preliminary Safety and Efficacy Results	Arun Upadhyay, PhD Chief Scientific Officer, Head of Research, Development and Medical, Ocugen
Closing	Shankar Musunuri, PhD, MBA

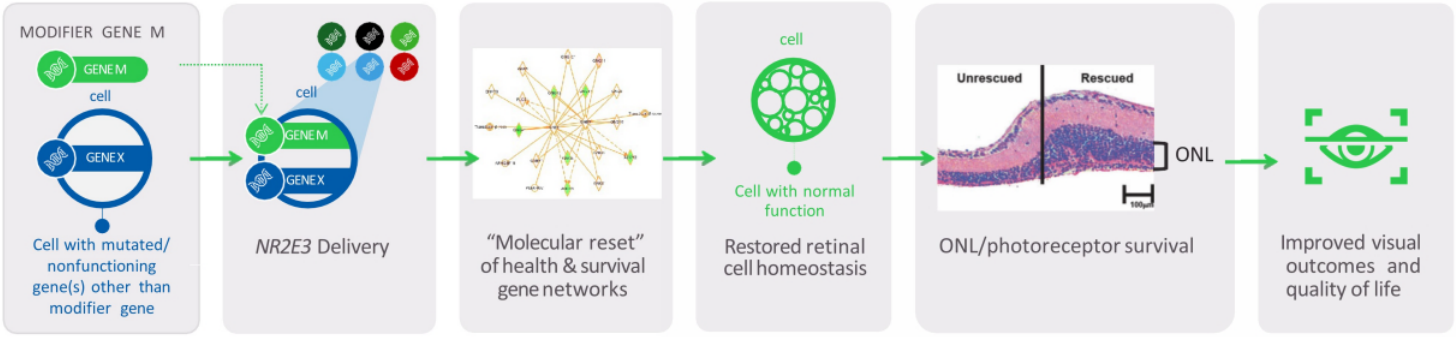
Q&A

- Huma Qamar, MD, MPH, Head of Clinical Development and Medical Affairs, Ocugen
- David Birch, PhD, Scientific Director, Retina Foundation of the Southwest, Primary Investigator of the Study
- Neena B. Haider, PhD, Fellow of ARVO and Inventor of Modifier Gene Therapy

Modifier Gene Therapy: A Broader Reach

Gene modifier therapy can potentially address multiple genetic defects with a single product utilizing a gene agnostic approach.

In patients with IRDs, this could mean:



Study Overview

Primary Endpoint: Safety

Safety of subretinal administration of OCU400

Exploratory Endpoint: Efficacy

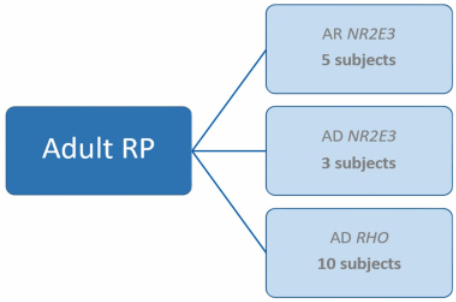
Multi-Luminance Mobility Test (MLMT)

Best Corrected Visual Acuity (BCVA)

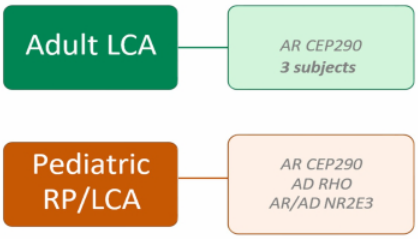
Clinical Trials.gov Identifier: **NCT05203939**

Enrollment Status

COMPLETED



ENROLLING



Multi-Luminance Mobility Test		
	Total Subjects for analyses (N=7) Subjects with 9-months follow-up : Cohort 1, N=3 Subjects with 6 months follow-up: N=1 from Cohor1 and N=3 from Cohort 2	
	Improvement ≥ 1 Lux	Improvement ≥ 2 Lux
Treated Eye	71.4%	28.6%
Untreated Eye	28.6%	0.0%

- 100% of treated eyes showed stability or improved MLMT scores
- 71.4% of treated eyes improved by at least 1 Lux Level vs ONLY 28.6% of untreated eyes
- 28.6 % of treated eyes improved by at least 2 Lux Level vs 0 % of untreated eyes

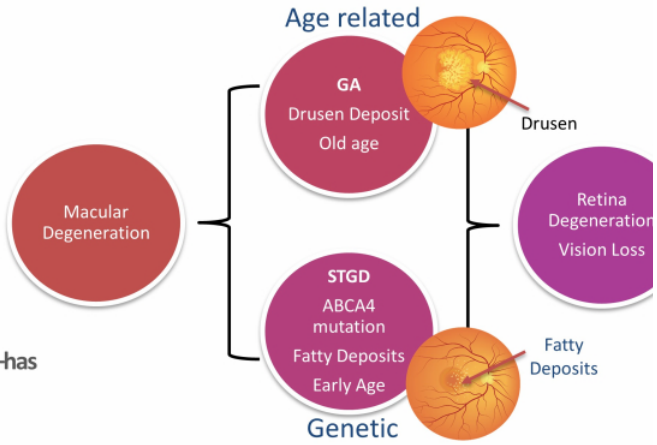
One subject had advanced RP at baseline with subsequent foveal detachment

MLMT is used as efficacy measure to assess visual function

ocugen

Best Corrected Visual Acuity (BCVA) Score		
	Total Subjects for analyses (N=7) Subjects with 9-months follow-up : Cohort 1, N=3 Subjects with 6 months follow-up: N=1 from Cohor1 and N=3 from Cohort 2	
	Improvement ≥ 8 Letters	
Treated Eye	42.9%	
Untreated Eye	0.0%	

OCU410: Dry Age-related Macular Degeneration (dAMD) and Stargardt Disease (STGD)



Dry AMD

Limited options, presenting significant unmet medical need

- US: 10M
- Worldwide: condition affects more than 266M people

Stargardt–an orphan disease

No treatment options exist

- US: 35,000
- Worldwide: condition affects approximately 800,000 people

Recently approved therapy for geographic atrophy (GA)—advanced form of dAMD–has limitations

- Frequent intravitreal injections (N ~6-12 doses per year); Patient compliance
- Limited effect of GA lesion growth rate
- Approximately 12% of patients experience neovascular AMD when the drug is administered every month for two years

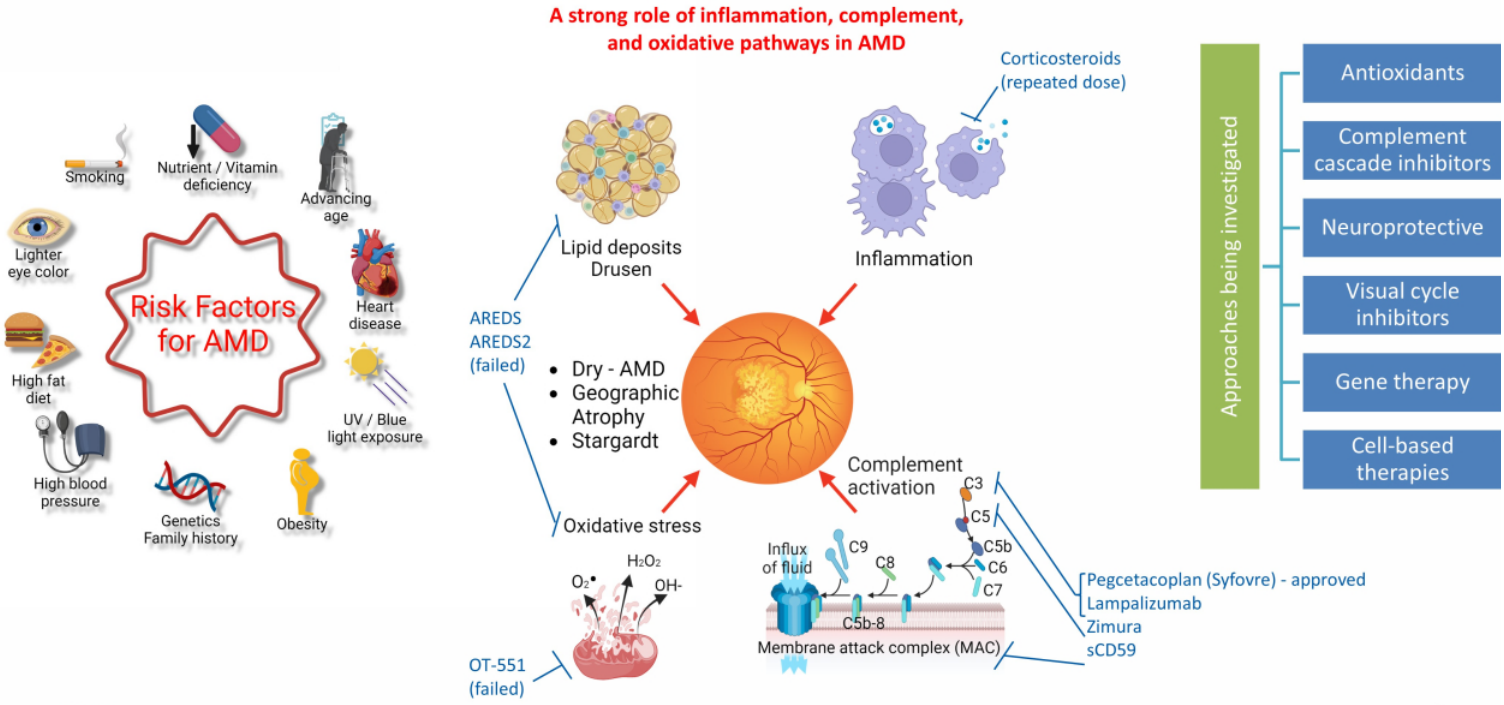
OCU410 addresses shortcomings of current approaches

- Broad-spectrum, gene-agnostic approach
- Potential one-time, curative therapy with a ***single*** sub-retinal injection, using RORA

Plan to Initiate Phase 1/2 clinical trial in 2Q 2023

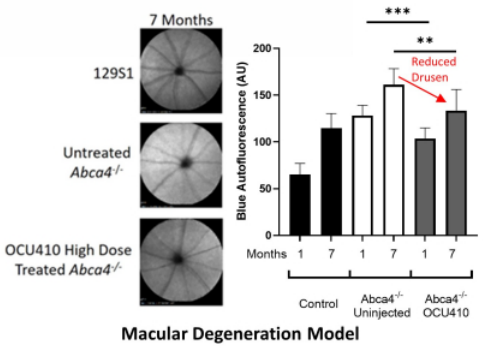
ocugen

AMD: Risk Factors, Treatment Options and Unmet Needs

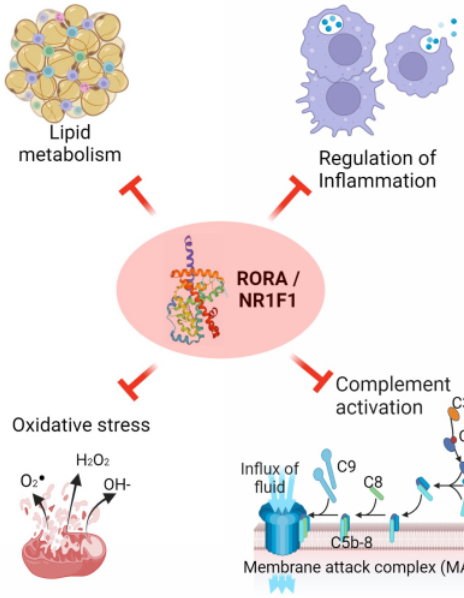


OCU410 (RORA): A Potential Modifier Therapeutic for Dry-AMD and STGD

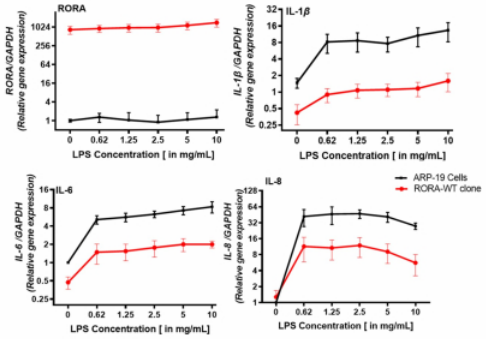
Anti-drusen activity and improves retinal function



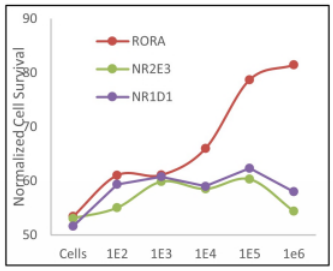
Macular Degeneration Model



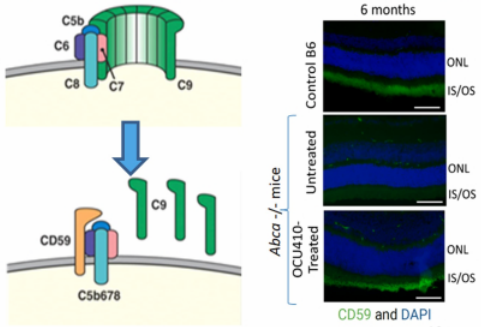
Anti-inflammatory: Suppresses inflammation in HMC3 cells



Anti-oxidative: Improves ARPE19 cells survival



Anti-complement: Increased anti-compliment (Cd59) prot



ocugen

Q&A

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**