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): **August 26, 2022**

OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36751**	**04-3522315**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

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.

Attached as Exhibit 99.1 hereto and incorporated herein by reference is a presentation that Ocugen, Inc. will post on its website on August 26, 2022 and may use from time to time in presentations or discussions with investors, analysts, and other parties.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are being filed herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Ocugen, Inc. Presentation.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

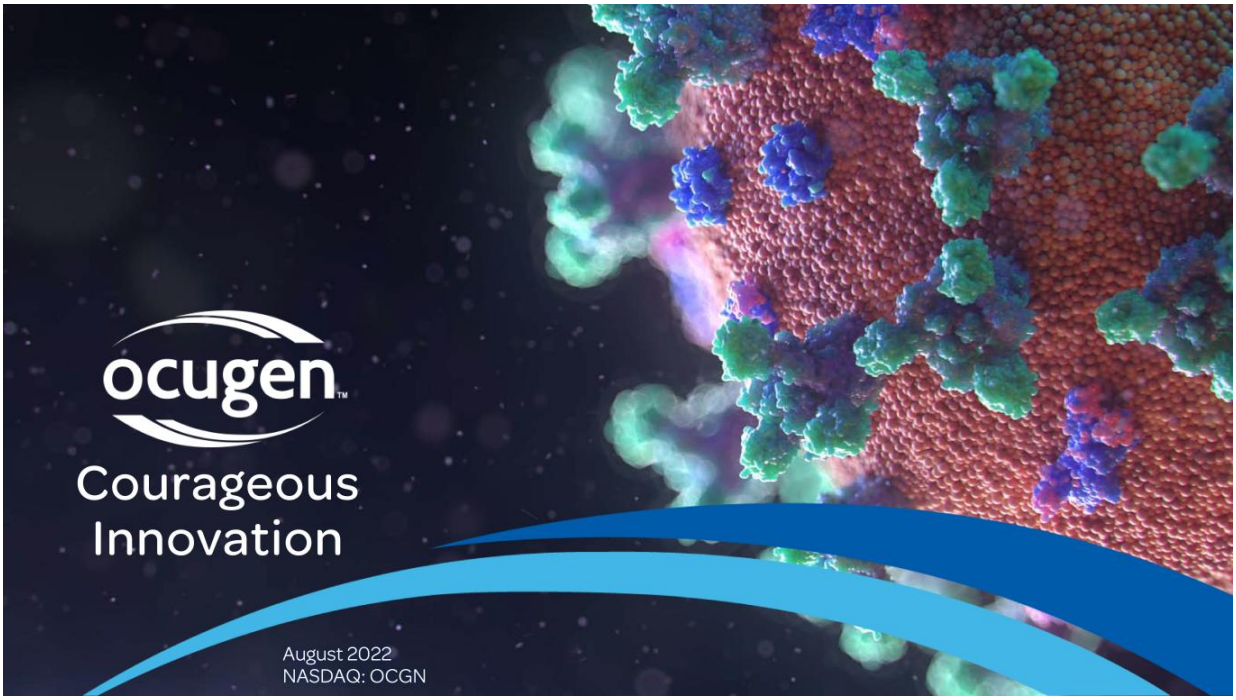
SIGNATURE

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: August 26, 2022

OCUGEN, INC.

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


ocugen™
Courageous
Innovation
August 2022
NASDAQ: OCGN

Forward Looking Statements

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, which are based on the beliefs and assumptions of Ocugen, Inc. and on information currently available to management. All statements contained in this presentation other than statements of historical fact are forward-looking statements. 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. 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. Forward-looking statements that we make in this presentation are based on a combination of facts and factors currently known to us and 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.

We're Here to Make an Impact Through *Courageous Innovation*

Mission: At Ocugen, we are developing novel solutions to medical challenges, approaching healthcare innovation with purpose and agility to deliver new options for people facing serious disease and conditions

Pioneering a breakthrough modifier gene therapy for several vision impairment diseases

Innovating a novel biologic to treat eye diseases that can lead to vision loss for millions of people

Co-developing a COVID-19 vaccine

Creating a restorative cell therapy (RCT) platform to treat serious conditions like articular cartilage lesions

Pipeline Overview

	Asset/Program	Indication	Status
Vaccine	COVAXIN™ (BBV152) SARS-CoV-2 virus	COVID-19	• EUA for adults in Mexico; EUA for 5 to 18-year-olds submitted • U.S. Phase 2/3 Immuno-bridging and broadening clinical trial in-progress • Health Canada NDS withdrawn, to be resubmitted with additional information, including U.S. clinical trial data*
Cell therapy	NeoCart® (Autologous chondrocyte-derived neocartilage)	Treatment of Articular Cartilage Defects in the Knee	U.S. Regenerative Medicine Advanced Therapy (RMAT) designation; Phase 3 clinical trial under development
Modifier Gene Therapy Platform	OCU400 *** AAV-hNR2E3	Gene mutation-associated retinal degeneration**	
		NR2E3 Mutation	Phase 1/2
		RHO Mutation	Phase 1/2
		CEP290 Mutation	To be submitted
	OCU410 AAV-hRORA	Dry Age-Related Macular Degeneration (Dry AMD)**	Preclinical
Novel Biologic	OCU200 Transferrin – Tumstatin	Diabetic Macular Edema	Preclinical
		Diabetic Retinopathy	Preclinical
		Wet Age-Related Macular Degeneration (Wet AMD)	Preclinical

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* Original submission based exclusively on Bharat Biotech-sponsored clinical trials in India has been withdrawn

** No approved therapies exist
https://www.aao.org/eye-health/diseases/retinitis-pigmentosa-treatment | https://www.aao.org/eye-health/diseases/amd-treatment

*** ORPHAN DRUG DESIGNATION in the US; Broad ORPHAN MEDICINAL PRODUCT DESIGNATION by the EC for the treatment of retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA)

COVAXIN™ (BBV152)

A Whole-Virion Inactivated COVID-19 Vaccine Candidate
Licensed from Bharat Biotech (BBIL) for North American Markets

Why COVAXIN™ (BBV152)?

Designed to augment our North American arsenal of vaccines against COVID-19

DESIGNED FOR BROAD SPECTRUM IMMUNE RESPONSE

- Adult and pediatric phase 2/3 data suggest both humoral & cellular responses generated against multiple viral proteins
- Data support that the vaccine induces a Th1 response (cell-mediated immunity) which can be vital for durable protection

RESULTS SHOW PREVENTION OF SEVERE COVID-19 DISEASE

- Phase 3 data suggest prevention of hospitalizations caused by COVID-19
- Booster dose provides robust neutralizing antibody responses against Omicron and Delta variants

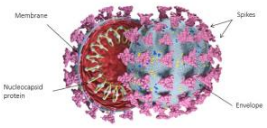
Image for illustrative purposes only

KNOWN SAFETY PROFILE USING VERO CELL PLATFORM

- Data demonstrate strong safety profile within adult and pediatric populations
- Similar technology platform used to produce Polio, Influenza and Rabies vaccines

TRANSPORTATION AND STORAGE EASE

- 10 dose vial that can be stored and shipped at 2°- 8° C with an expected 2-year shelf life and 6-month stability at room temperature



COVAXIN™ (BBV152) Adult and Pediatric Clinical Trial Data

Phase 3 Clinical Trial

93.4%	Efficacy vs Severe Disease	12.4%	Adverse Events COVAXIN™ and Placebo Arms	Less than 0.5%	Serious Adverse Events

n = 25,798 • Nov 2020 - Jan 2021 across 25 sites • Two doses, 28 days apart

Phase 2/3 Clinical Trial in Children (2-18 years) • Observed GMTR = 1.32 (0.92, 1.90 [CI 95%])

92%	Seroconversion to Wild-Type Neutralizing	92%*	Seroconversion to S1 IgG, RBD IgG, NP IgG *median	0%	SAEs defined as: hospitalizations, myocarditis, pericarditis, GBS, thrombosis, anaphylactic reactions

n = 526 • May 2021 - Jul 2021 across 6 sites • Two doses, 28 days apart

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Source: Ella, Reddy, Blackwelder, Potdar, Yadav, Sarangi et al. (2021) Efficacy, safety, and lot-to-lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): interim results of a randomised, double-blind, controlled, phase 3 trial: *The Lancet*. https://doi.org/10.1016/S0140-6736(21)02000-6

Source: Vadrevu K, Reddy S, Jogdand H, et al. (2022) Immunogenicity and reactogenicity of an inactivated SARS-CoV-2 vaccine (BBV152) in children aged 2 - 18 years: interim data from an open-label, non-randomised, age de-escalation phase 2/3 study; *The Lancet*. https://doi.org/10.1016/S1473-3099(22)00307-3

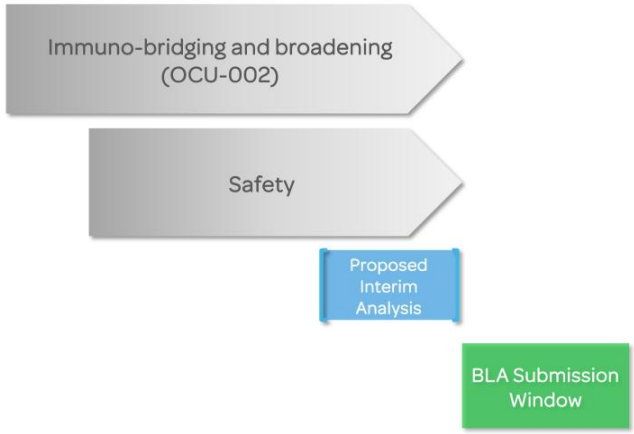
Pathway for COVAXIN™ (BBV152) development

NCT: 05258669

OCU-002

A Phase 2/3, Observer-Blind, Immuno-bridging, and Broadening Study of a Whole, Inactivated Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) Vaccine (BBV152) in Healthy Adults

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	400 participants
Allocation:	Randomized
Intervention Model:	Parallel assignment
Intervention Model Description:	1:1 randomization ratio
Primary Purpose:	Prevention



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MODIFIER GENE THERAPY PLATFORM

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

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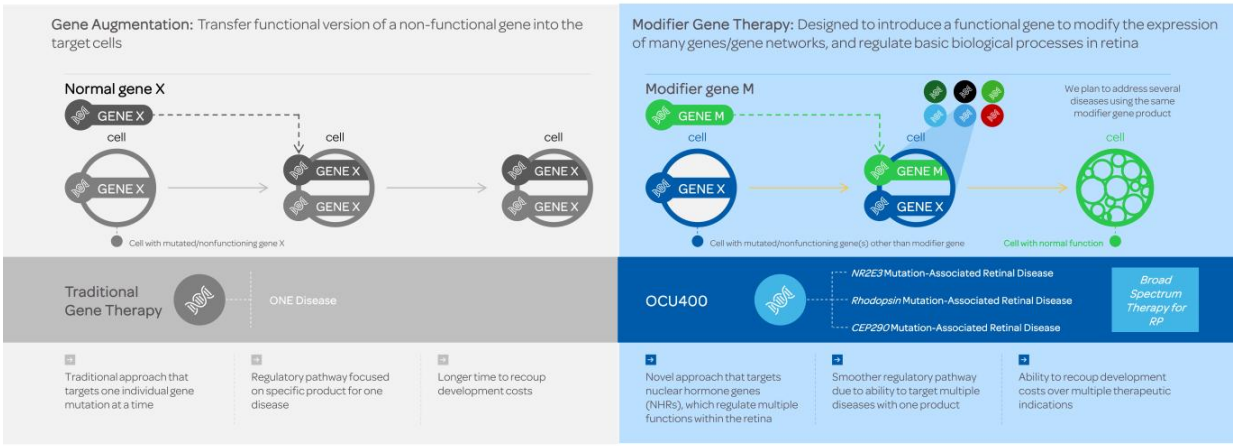
Our Vision: Inherited Retinal Diseases

Modifier Gene Therapy vs Traditional Gene Augmentation

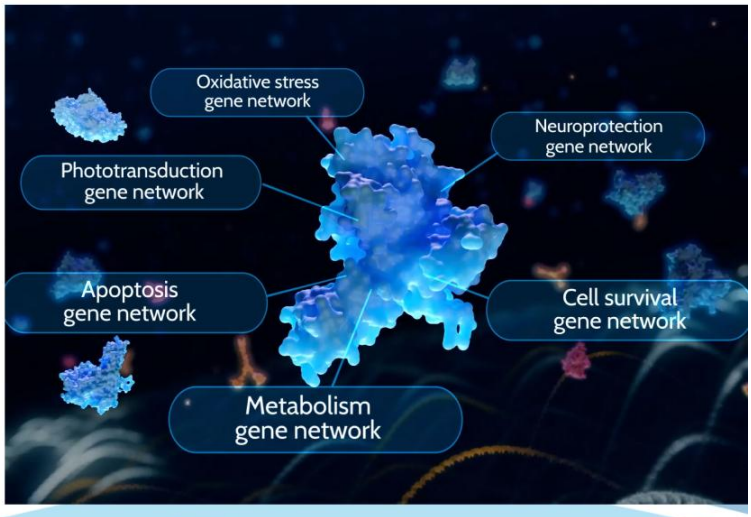


Our Focus: Nuclear Hormone Receptor Genes (NHRs)

NHRs in the retina are modulators of retinal development & function, acting as "master genes" in the retina

Molecular reset of key transcription factors and associated gene networks – retinal homeostasis

Gene modifier concept, including its impact on clinical phenotypes, is well known in other disease areas, such as cystic fibrosis and spinal muscular atrophy



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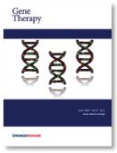
*References:
https://pubmed.ncbi.nlm.nih.gov/28556246/ | https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5409218/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4339951/ |
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0183526

Proof of Principle: Published in Nature Gene Therapy

- Efficacy results shown in five unique mouse models of RP
- Technology developed at Harvard Medical School, Dr. Neena Haider's Lab
- Study suggests potency of modifier gene therapy to elicit broad-spectrum therapeutic benefits in early and advanced stages of RP
- Results suggest evidence of vision rescue in early & advanced stages of disease



Important milestone for development of therapy; demonstrated proof of principle

Protection elicited in multiple animal models of degeneration caused by different mutations

Potential to represent first broad-spectrum gene agnostic therapy and provide rescue even after disease onset

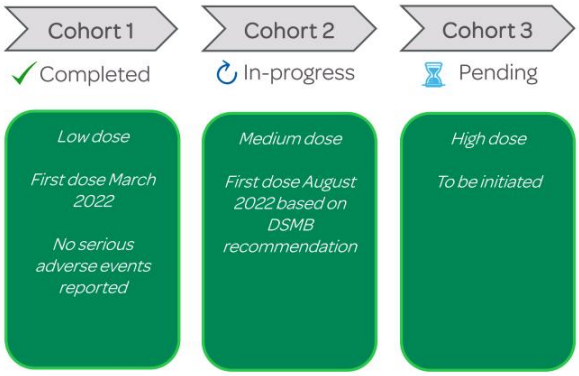
nature research
https://www.nature.com/articles/s41434-020-0134-z

OCU400 Phase 1/2 U.S. Clinical Trial Progress

OCU400

*A Phase 1/2 Study to Assess the Safety and Efficacy of **OCU400** for Retinitis Pigmentosa Associated with NR2E3 (Nuclear Receptor Subfamily 2 Group E Member 3) and RHO (Rhodopsin) Mutations*

NCT:	05203939
Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	18 participants
Clinical Trial Sites:	Seven
Allocation:	Non-randomized
Intervention Model:	Sequential assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Dosing:	Escalation study involving low, medium, high doses



Phase 1 enrollment expected to conclude by YE 2022

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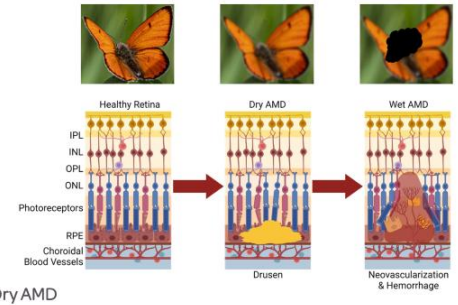
OCU400 Expected Pathway to Clinical Development & Potential Approval

OCU410 (AAV-RORA) Dry Age-Related Macular Degeneration

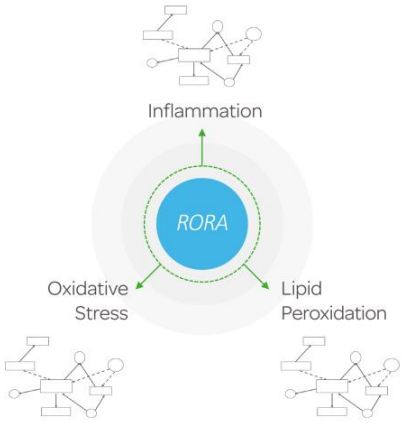
We believe OCU410 has the potential to address this disease through its multi-factor approach



Dry AMD

- Leads to irreversible blindness due to degeneration of the retina
- ~9-10M patients in the U.S.
- Currently no approved treatment for Dry AMD
- Contributing factors: aging, genetics, environmental factors

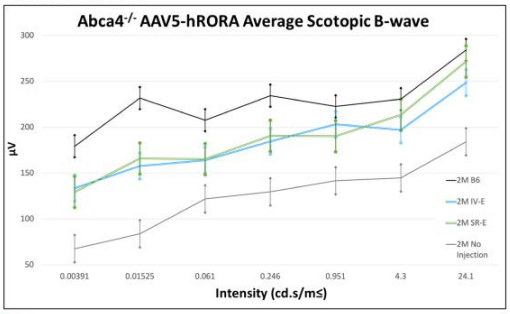
We are executing pre-IND studies to support a planned 2023 Phase 1/2 clinical trial



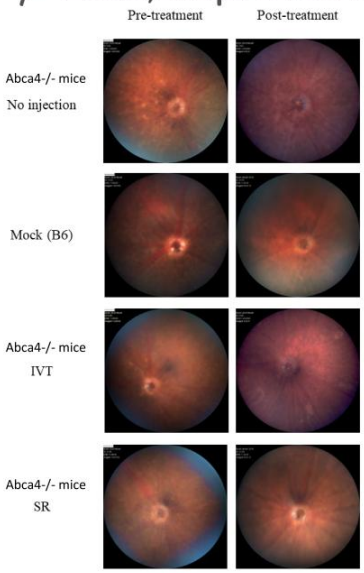
Sources
https://www.brightfocus.org/macular/article/age-related-macular-facts-figures
https://www.uniprot.org/uniprot/P35398#function
https://pubmed.ncbi.nlm.nih.gov/21998696/
https://pubmed.ncbi.nlm.nih.gov/19786043/

OCU410 Reduces Drusen in Abca4 -/- Mice, Improves Function

- ABCA4 is a retina-specific protein localized in outer segment disk edges of rod photoreceptors
- Mutations in ABCA4 have been linked to:
  a) Age-related macular degeneration (AMD)
  b) Stargardt macular dystrophy (STGD)
  c) Recessive RP
  d) Recessive cone-rod dystrophy
- OCU410 reduces drusen in Abca4 -/- mice and improves retinal function

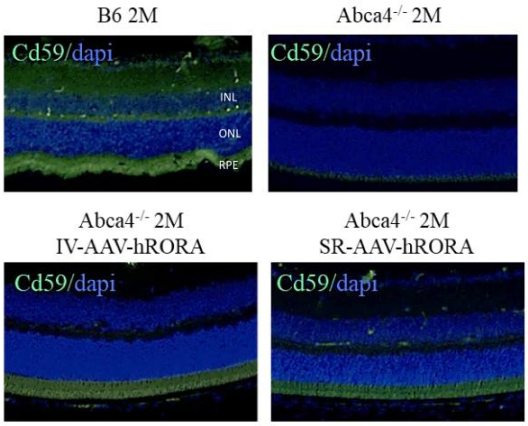


IV/IVT- Intravitreal dosing; SR-Subretinal dosing; 1M- 1 month; 2M- 2 month

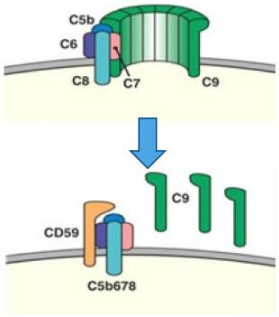


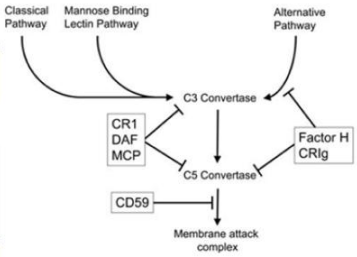
Abca4-/- mice show drusen deposits apparent as yellowish spots on the fundus by 1 month of age and persist at 2 months. Intravitreal (IVT) or subretinal (SR) injections of AAV5-hRora results in reduction of drusen spots

OCU410 Restores Cd59 Expression in Abca4-/- mice



IV - Intravitreal; SR-Subretinal; B6 - C57BL/6mice
INL - Inner nuclear layer, ONL - outer nuclear layer
RPE – Retinal Pigment Epithelium



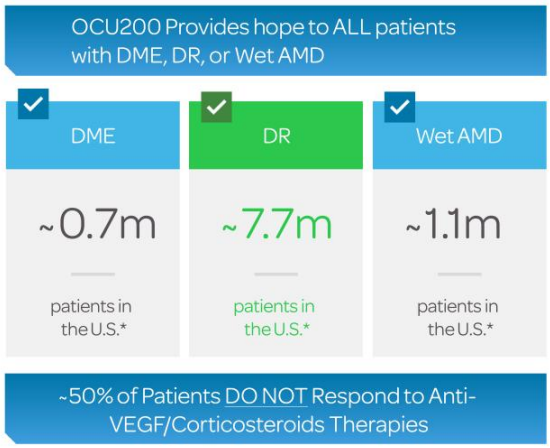


- Abca4 -/- mice show very low CD59 expression in their retinas
- CD59 prevents the formation of the complement membrane attack complex (MAC)
- OCU410 administered by intravitreal or subretinal routes restores CD59 expression in the RPE cells in the retina

OCU200

Novel biologic for treating Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) and Wet Age-Related Macular Degeneration (Wet AMD)

OCU200 Potential to Treat DME, DR & Wet AMD



- OCU200 is a Transferrin-Tumstatin Fusion Protein
  - Tumstatin: Multiple Mechanisms of Action (MOAs) for treatment and prevention of macular edema and neovascularization
  - Transferrin: Targets the site of action and improves uptake (better target engagement)
- Integrin Targeting provides hope to these patients who are non-responders to current therapies
- Distinct MOA through targeting Integrin pathways can potentially also help reduce number of injections for patients who do respond to Anti-VEGF & corticosteroids therapies
- We are executing pre-IND studies to support a planned 2023 Phase 1 clinical trial

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(*) https://www.gene.com/stories/retinal-diseases-fact-sheet
https://www.brightfocus.org/macular/article/age-related-macular-facts-figures

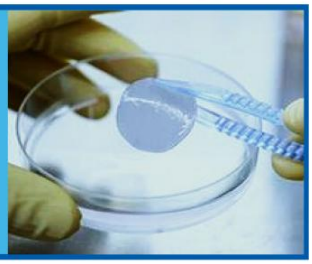
NeoCart®

(Autologous chondrocyte-derived neocartilage)

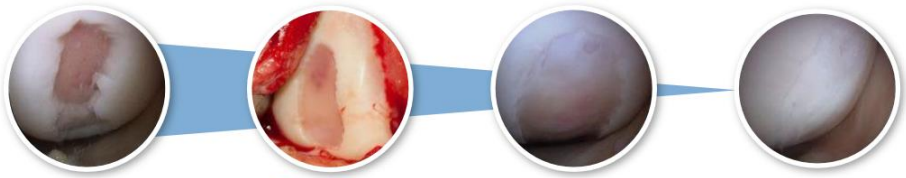
NeoCart®: Restorative Cell Therapy

Designated by FDA as "Regenerative Medicine Advanced Therapy"

- Combines breakthroughs in bio-engineering and cell processing to enhance the autologous cartilage repair process
- Merges a patient's own cells with a fortified 3-D scaffold designed to accelerate healing and reduce pain
- **Patients receive functional cartilage at the time of treatment**



Follow-up Arthroscopy Demonstrates NeoCart® Progression and Integration



Initial Lesion | Time Zero Implantation | 8 Weeks | 6 Months

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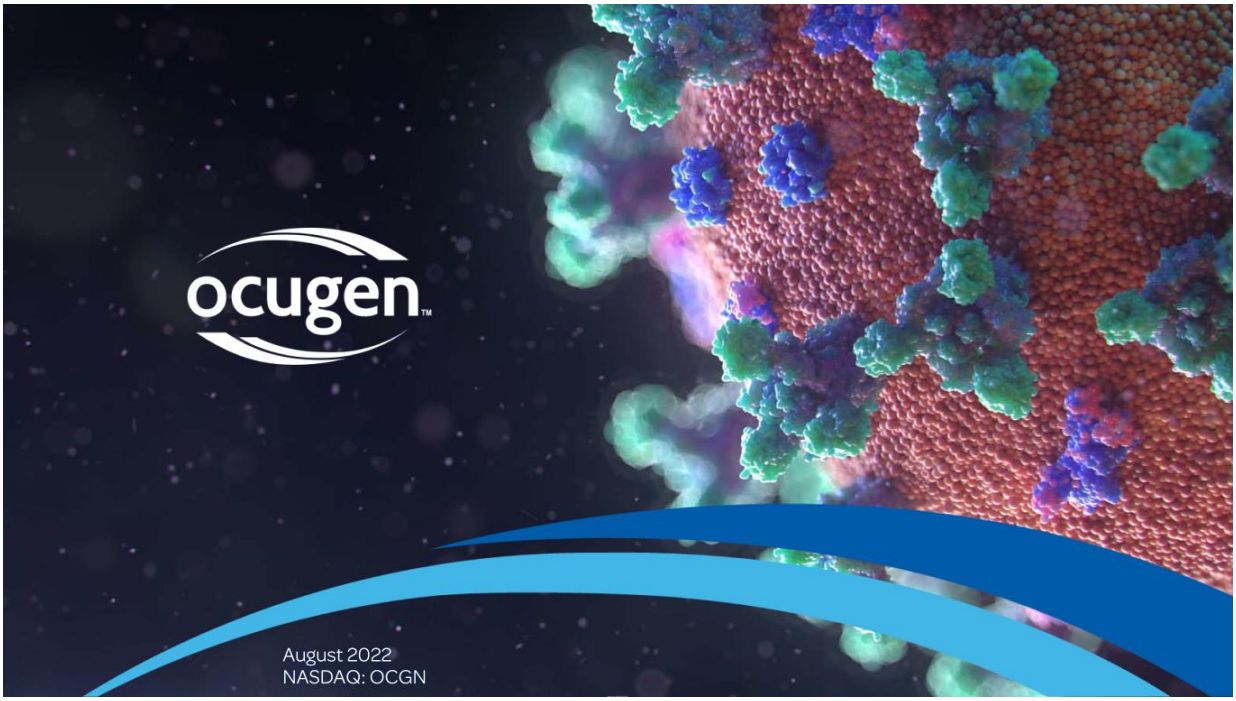
Phase 3 patient follow-up arthroscopies unrelated to NeoCart implant.

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**


ocugen™
August 2022
NASDAQ: OCGN