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): **January 9, 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.

Attached as Exhibit 99.1 hereto and incorporated herein by reference is a presentation that Ocugen, Inc. will post on its website on January 9, 2023 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).

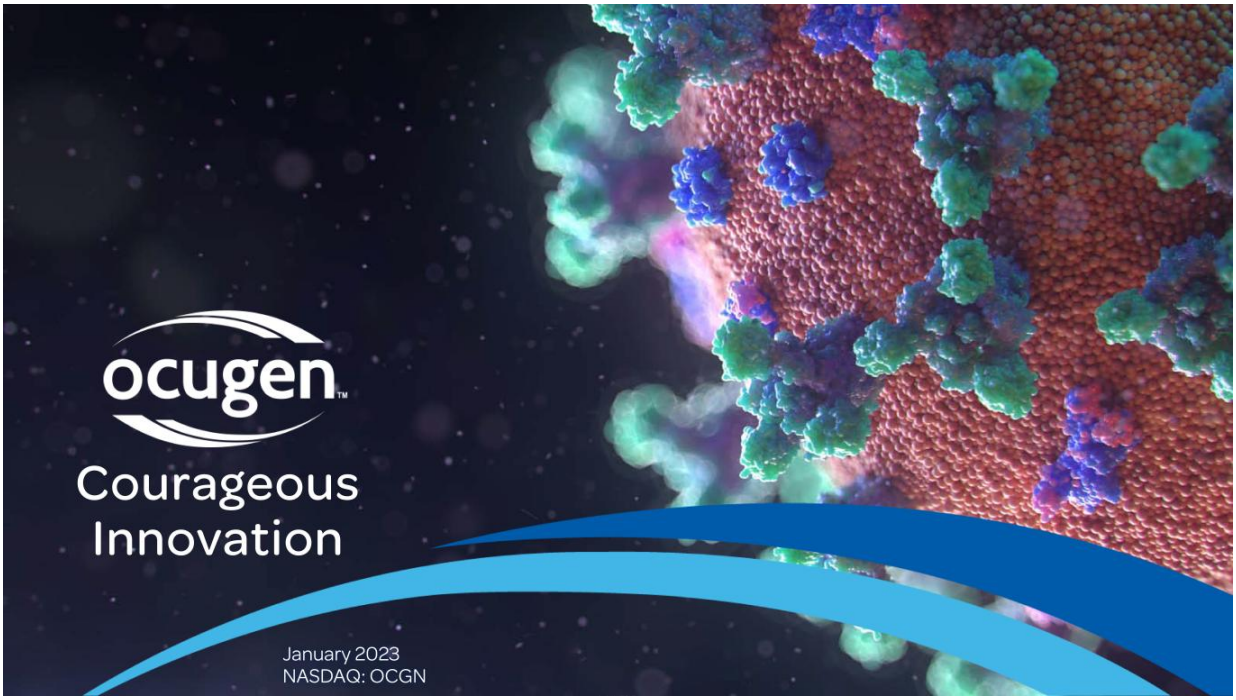
SIGNATURE

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: January 9, 2023

OCUGEN, INC.

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


ocugen
Courageous
Innovation
January 2023
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: Developing cutting-edge innovations for people facing serious disease and conditions with a commitment to ensuring global market access

Pioneering modifier gene therapy for inherited retinal diseases, as well as larger blindness diseases with unmet need

Developing vaccines to provide choice in the fight against COVID-19

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

Pursuing Regenerative Cell Therapy to treat serious conditions like articular cartilage lesions

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Pipeline Overview

	Asset/Program	Indication	Current Status
Vaccines	COVAXIN™ (BBV152) SARS-CoV-2 virus	COVID-19	• EUA for adults in Mexico; EUA for 5 to 18-year-olds submitted • Top line results show that the U.S. Phase 2/3 immuno-bridging and broadening clinical trial met both primary endpoints
	OCU500 Mucosal vaccine	COVID-19	• License secured from Washington University • Phase 1/2 pending FDA discussions
Cell therapies (Regenerative Medicine)	NeoCart® (Autologous chondrocyte-derived neocartilage)	Treatment of Articular Cartilage Defects in the Knee	• U.S. Regenerative Medicine Advanced Therapy (RMAT) designation • Received concurrence from the FDA on the control (chondroplasty) to be used in the Phase 3 clinical trial • Phase 3 clinical trial is planned to begin in late 2023/early 2024
Gene therapies	OCU400 ** AAV-hNR2E3	Gene mutation-associated retinal degeneration*	• Completed dose escalation and established maximum tolerable dose (MTD). • Encouraging safety profile to date
		NR2E3 Mutation (RP)	Phase 1/2
		RHO Mutation (RP)	Phase 1/2
		CEP290 Mutation (LCA)	Phase 1/2
	OCU410 AAV-hRORA	Dry Age-Related Macular Degeneration (Dry AMD)*	IND planned for Q2 2023
	OCU410ST AAV-hRORA	Stargardt disease (orphan disease)	IND planned for Q2 2023
Biologicals	OCU200 Transferrin – Tumstatin	Diabetic Macular Edema	IND planned for Q1 2023
		Diabetic Retinopathy	IND-enabling
		Wet Age-Related Macular Degeneration (Wet AMD)	IND-enabling

*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 DESIGNATIONS in the U.S.; Broad ORPHAN MEDICINAL PRODUCT DESIGNATION by the EC for the treatment of RP and 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

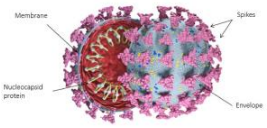
Image for illustrative purposes only

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



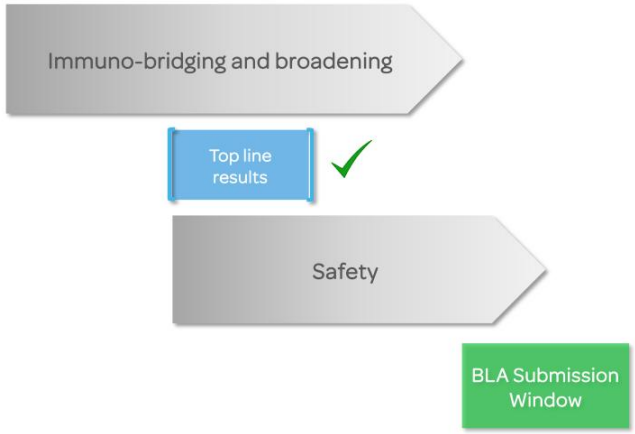
Pathway for COVAXIN™ (BBV152) Development

NCT: 05258669

Phase 2/3 Trial

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)
Enrollment:	419 participants
Allocation:	Randomized
Intervention Model:	Parallel assignment
Intervention Model Description:	1:1 randomization ratio
Primary Purpose:	Prevention



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Top-Line Data Meets Co-Primary Endpoints in Phase 2/3 Immuno-bridging Study through Day 56

Study Design

- This study enrolled 419 U.S. adult participants that were randomized 1:1 to receive two doses of COVAXIN or placebo, 28 days apart
- Approximately 24% of tested U.S. participants were vaccine-naïve while all participants in the Bharat Phase 3 study were vaccine -naïve
- Immune responses adjusted for differences between the U.S. and Indian cohorts in baseline neutralizing antibody, body mass index, gender and age
- Both co-primary immunogenicity endpoints were met:
  - 95% confidence interval (CI) for the propensity score-adjusted geometric mean titer ratio (U.S./India) well above the non-inferiority limit of 0.667
  - 95% CI for the propensity score-adjusted difference in seroconversion rates well above the non-inferiority limit of -10%

Blinded Safety Data (COVAXIN and Placebo Combined)

	Related	Unrelated
Potential immune mediated medical conditions (PIMMCs)	0	1
Adverse Events of Special Interest (AESIs)	0	1
Myocarditis, Pericarditis, Thrombotic events	0	0
Medically Attended Adverse Events (MAAEs)	0	30 events (18 subjects)
Serious AEs (SAEs)	0	2 events (1 subject)
Deaths or Life-Threatening SAEs	0	0

OCU500
Ocugen's COVID-19 Mucosal Vaccine

Exclusive license agreement with Washington University to develop, manufacture and commercialize its proprietary vaccine in the United States, Europe, and Japan

OCU500: Mucosal Vaccine

- **Potential to generate rapid local immunity** in the nose, mouth, upper airways, and lungs - where SARS-CoV-2 enters and infects the body
- Generates neutralizing IgG, mucosal IgA, and T cell responses to **help reduce transmission rate**
- Mucosal immunity has been demonstrated as a potential way to prevent infection and spread, thus **limiting the origin of new variants**
- This approach represents a **potential universal booster**, regardless of previous COVID-19 vaccination

Other features include:

- Non-invasive
- Needle-free administration
- Potential for increased compliance
- Scalable manufacturing
- Stored and shipped at standard refrigerated conditions
- Potential to develop multi-strain and variant specific versions

MODIFIER GENE THERAPY PLATFORM

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

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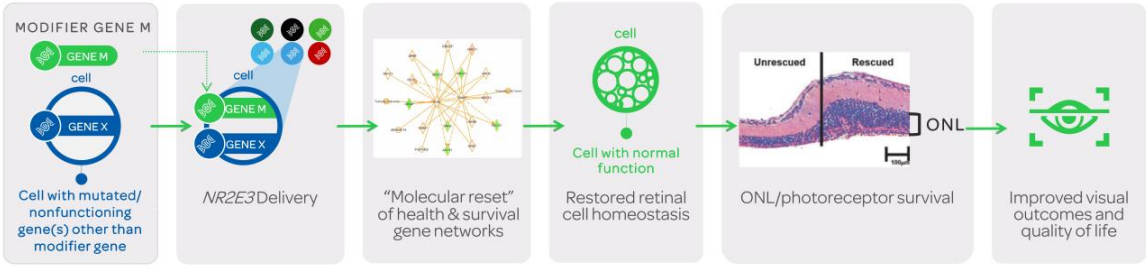
Modifier Gene Therapy: A Broader Reach

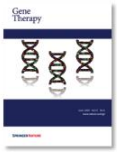
Gene modifier therapy can potentially **address multiple genetic defects with a single product utilizing a gene agnostic approach.**

In patients with IRDs, this could mean:



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

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 Mutations(s) in CEP290 Gene

NCT:	05203939
Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	21 participants
Clinical Trial Sites:	Seven
Allocation:	Non-randomized
Intervention Model:	Sequential assignment
Masking:	None (Open Label)
Primary Endpoint: **Observational endpoint**	Safety Efficacy (structural, functional, BCVA, mobility)
Dosing:	Escalation study involving low, medium, high doses

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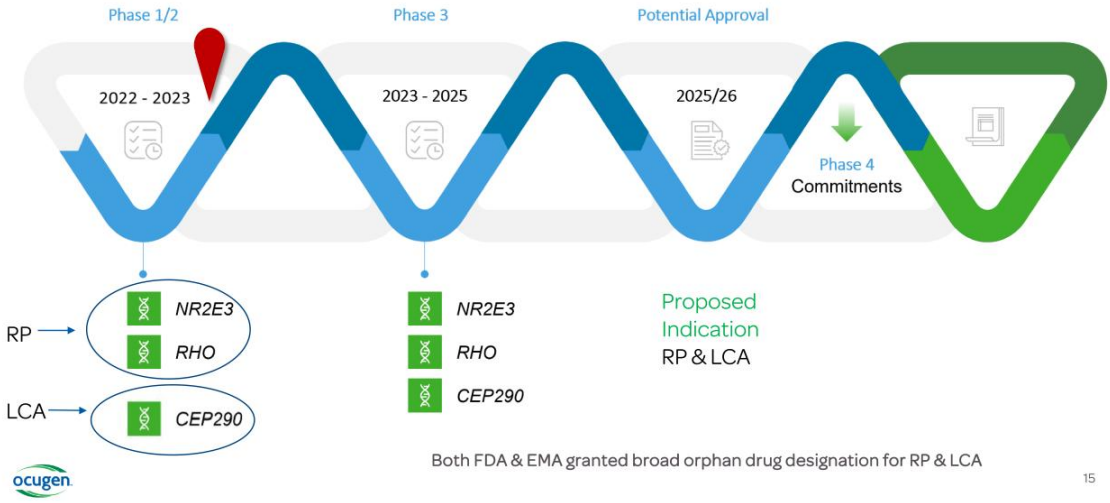
Cohort 1	Cohort 2	Cohort 3
✓ Completed	✓ Completed	✓ Completed
Low dose *First dose March 2022* *No serious adverse events reported*	*Medium dose* *First dose August 2022* *No serious adverse events reported*	*High dose* *First dose October 2022* *1 serious adverse event reported [causality assessment ongoing]*

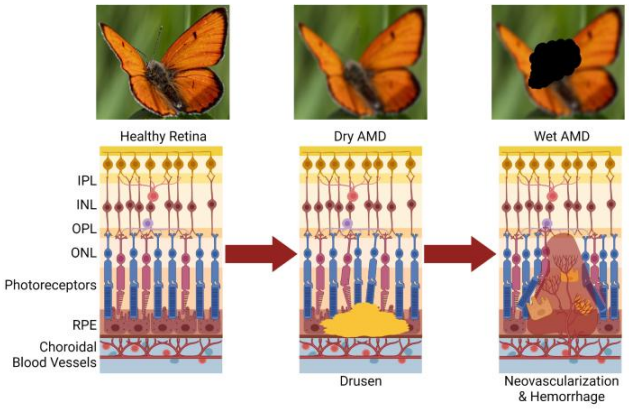
- Dose escalation completed & MTD established (high dose)
- Encouraging safety profile to date
- Expected efficacy signal mid-2023

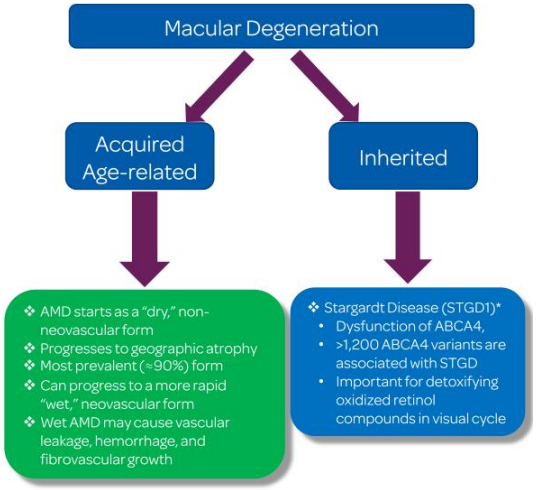
OCU400 Expected Pathway to Clinical Development & Potential Approval



Both FDA & EMA granted broad orphan drug designation for RP & LCA

Age-related Macular Degeneration(AMD) Stargardt Disease (STGD)





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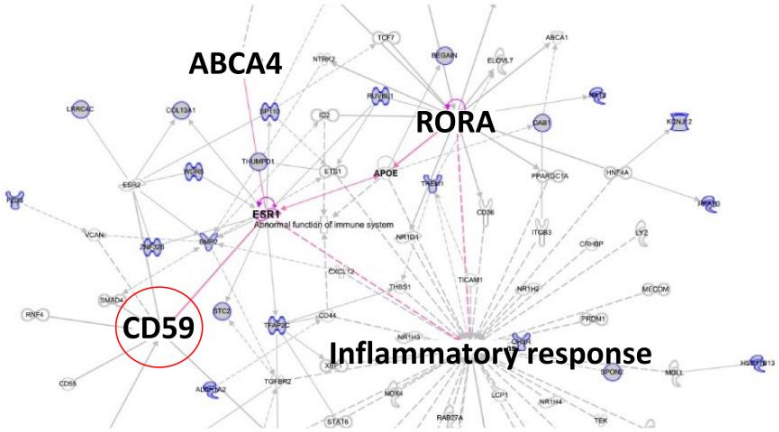
*Stargardt disease affects approximately 35,000 Americans and approximately 800,000 people globally.

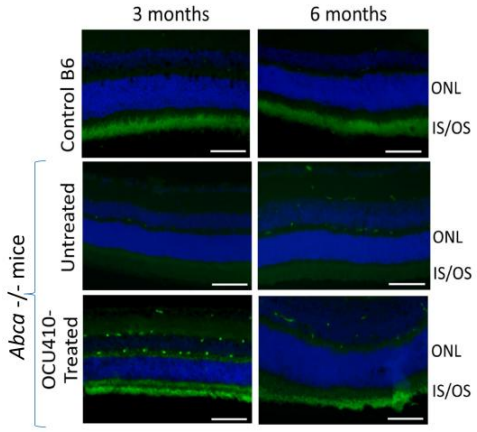
RORA Regulated Gene Networks are Relevant in AMD & Stargardt Disease

RORA regulated gene networks are relevant in AMD and Stargardt disease



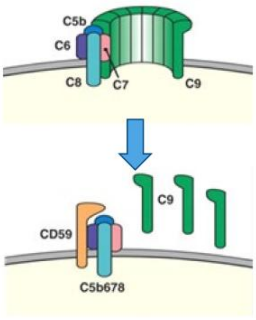
OCU410 Restores Cd59 Expression in Abca4-/- mice

- ABCA4 transports oxidized retinol compounds from photoreceptors to RPE cells for detoxification
- Gene variants of ABCA4 are associated with both Stargardt disease and AMD. *ABCA4*-/- mice show very low CD59 expression in their retinas
- OCU410 CD59 expression in the RPE cells
- CD59 prevents the formation of the complement membrane attack complex (MAC)

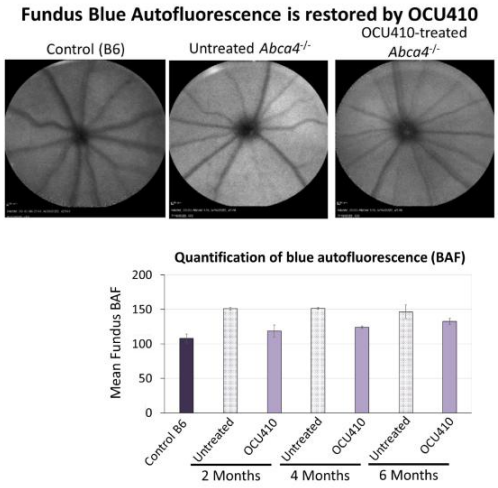


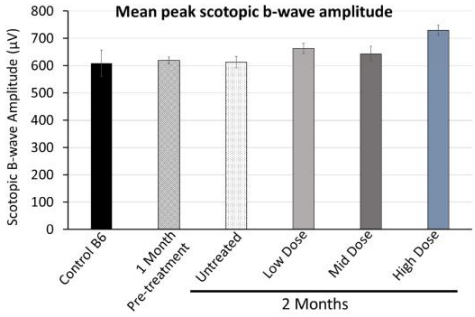
Immunohistochemistry of retina showing CD59 and DAPI

CD59 prevents the formation of the complement membrane attack complex



OCU410: Restoring Retinal Function in *ABCA4 -/-* Mice





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 Provides hope to ALL patients with DME, DR, or Wet AMD

DME	DR	Wet AMD
~0.7m	~7.7m	~1.1m
patients in the U.S.*	patients in the U.S.*	patients in the U.S.*

~50% of Patients DO NOT Respond to Anti-VEGF/Corticosteroids Therapies

- 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 IND-enabling studies and plan to submit an IND application in the first quarter of 2023

* 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® Regenerative Cell Therapy

Knee injury increases risk of developing OA by more than 5x
*1MM+ annual arthroscopic procedures of the knee**

Attributes:

- 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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*The Journal of Bone & Joint Surgery: June 1, 2011 - Volume 93 - Issue 11 - p 994-1000
**Phase 3 patient follow-up arthroscopies unrelated to NeoCart implant.

NeoCart® Regenerative Cell Therapy

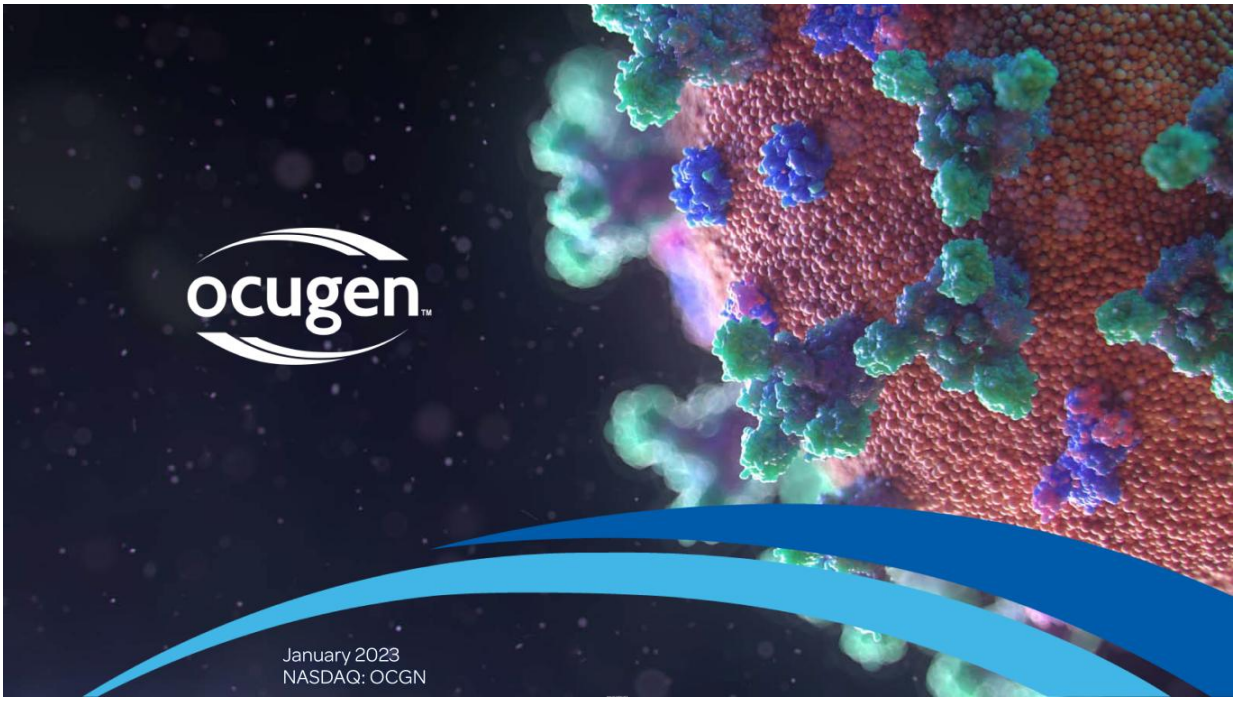
Received concurrence from the FDA on the control (chondroplasty) to be used in the Phase 3 clinical trial

Upgrading current facility to support clinical and commercial manufacturing processes

Phase 3 clinical trial is planned to begin in late 2023/ early 2024

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**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