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): **November 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 November 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: November 9, 2023

OCUGEN, INC.

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

ocugen™

Courageous Innovation

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

November 2023
NASDAQ: OCGN

Forward Looking Statements

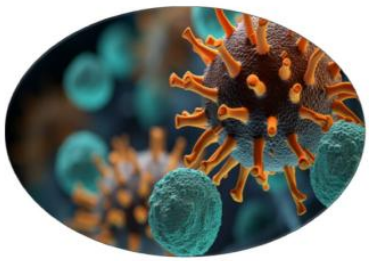
This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Refo Act of 1995, which are subject to risks and uncertainties. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "cou "might," "will," "should," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements include, but are not limited to, statements regarding our clinical development activities and related anticipated timelines. Such statements are subject to numerous important factors, risks, and uncertainties that may cause actual events or results to differ materially from our current expectations. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission (SEC), including the risk factors described in the section entitled "Risk Factor 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.

Through Courageous Innovation, We are Leveraging Our First-in-Class Platforms to Address Serious Unmet Medical Needs

Modifier Gene Therapy Platform

First-in-Class

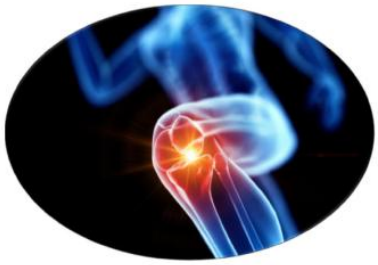
- **Therapeutic Focus:** inherited retinal diseases and larger blindness diseases with unmet need
- **Differentiator:** "master gene regulator"; gene-agnostic approach
- **Pipeline:**
  - OCU400 (Ph1/2): RP* & LCA**; Orphan drug designation from FDA/EMA
    - **Ph3 target: early 2024**
  - OCU410 (Ph1/2): dry AMD
  - OCU410ST (Ph1/2): Stargardt; Orphan drug designation from FDA



Inhalation Vaccines Platform

First-in-Class

- **Therapeutic Focus:** Flu and COVID-19
- **Differentiator:** inhalation for improved durability and transmission control
- **Pipeline:**
  - OCU500 (Preclin): COVID-19 vaccine (**NIH/NIAID Nextgen Collaboration - planned for early 2024**)
  - OCU510 (Preclin): flu quadrivalent
  - OCU520 (Preclin): COVID-19 + flu com



Regenerative Cell Therapy Platf

First-in-Class

- **Therapeutic Focus:** articular cartilage le
- **Differentiator:** 3-D scaffold
- **Pipeline:**
  - NeoCart (Ph3): articular cartilage defe the knee
  - **Ph3 target: 2H2024**
  - RMAT Designation by FDA

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*RP, retinitis pigmentosa
**LCA, Leber congenital amaurosis

Pipeline Overview

	Asset/Program	Indication	Current Status
Gene therapies	**OCU400** * AAV-hNR2E3 Gene mutation-associated retinal degeneration	*Retinitis pigmentosa (RP)--NR2E3 Mutation*	• Phase 1/2 • Completed dosing of RP and LCA patients • Phase 3 trial for the treatment of RP expected to be initiated in early 202
		RP--RHO Mutation	
		Leber congenital amaurosis (LCA)--CEP290 Mutation	
	OCU410 AAV-hRORA	Dry Age-Related Macular Degeneration (Dry AMD)	• Phase 1/2
	OCU410ST AAV-hRORA	Stargardt disease (orphan disease)	• Phase 1/2
Biologics	**OCU200** Transferrin – Tumstatin	Diabetic Macular Edema	• Continue to work on the Company's response to the FDA regarding the I application • Expect to initiate the Phase 1 clinical trial in the first half of 2024, contin on the lift of the FDA hold and adequate availability of funding
		Diabetic Retinopathy	• IND-ready
		Wet Age-Related Macular Degeneration (Wet AMD)	• IND-ready
Cell therapies (Regenerative Medicine)	**NeoCart®** (Autologous chondrocyte-derived neocartilage) RMAT**	Treatment of Articular Cartilage Defects in the Knee	• Phase 3 clinical trial is planned for 2H 2024
Vaccines	**OCU500 Series**		
	OCU500: COVID-19 (Bivalent)	For Prevention of Disease Caused by COVID-19	• OCU500 IND planned for early 2024 in collaboration with NIAID
	OCU510: Flu (Quadrivalent)	For Prevention of Disease Caused by Flu	
	OCU520: Flu + COVID-19	For Prevention of Diseases Caused by Flu and COVID-19	

*Broad, gene-agnostic, ORPHAN DRUG DESIGNATIONS FOR RP/LCA FROM FDA AND EMA
**Regenerative Medicine Advanced Therapy Designation

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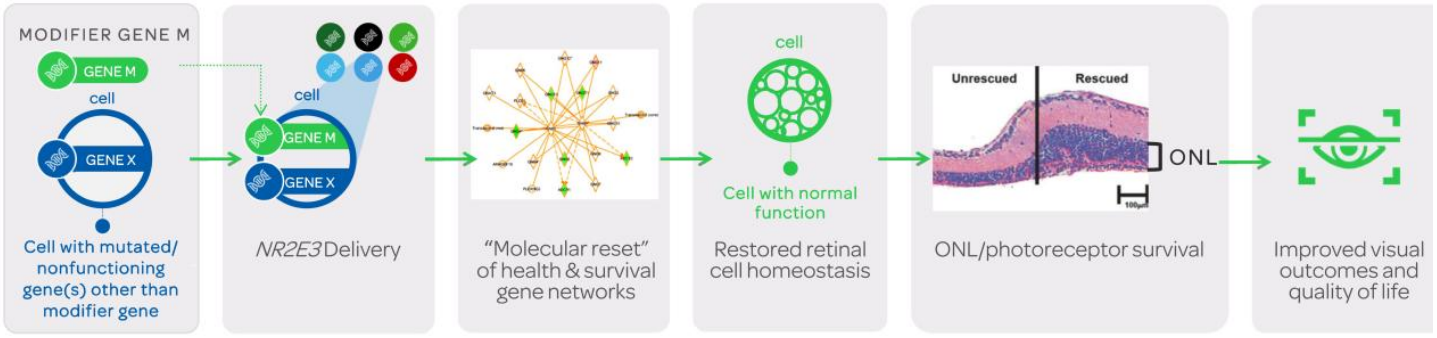
Modifier Gene Therapy Platform

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

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:



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nature research

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

OCU400: Phase 1/2 Clinical Trial Progressing as Planned, Developing a Novel Gene Therapy in Ophthalmic Areas of High Unmet Need

FDA granted expanded Orphan Drug Designations for all retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA) mutations

Despite its prevalence, RP and LCA patients have limited treatment options

- US: RP & LCA affect 110,000 and 15,000 people, respectively
- Worldwide: conditions affect approximately 1.6M people

Current approved and in-development gene therapies focus on individual gene

- More than 125 mutated genes associated with RP and LCA
- Developing a single therapy to treat each mutation is not feasible

OCU400 addresses shortcomings of current gene therapy approaches

- Broad-spectrum, gene-agnostic approach to genetically diverse inherited retinal diseases
- Potential one-time, curative therapy with a ***single*** sub-retinal injection, using NR2E3

Study summary:

- Completed dosing of RP patients and three LCA patients including a pediatric patient
- Phase 3 adult trial for the treatment of RP to be initiated in early 2024 following FDA concurrence on study design
- Expanding the OCU400 Phase 3 clinical trial for LCA patients in the second half of 2024 based on Phase 1/2 study results in LCA patients and alignment with the FDA

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OCU400 Clinical Program

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

Primary: Safety

- Safety of subretinal administration of OCU400
- Immune responses
- Systemic Distribution

Exploratory: Efficacy

- Best Corrected Visual Acuity (BCVA)
- Low Luminance Visual Acuity (LLVA)
- Multi-Luminance Mobility Test (MLMT)

Clinical Trials.gov Identifier: NCT05203939

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Safety Summary for OCU400—Clinical Study Update

- The Phase 1/2 clinical trial demonstrated that OCU400 continued to be generally safe and well-tolerated in subjects across different mutations and dose levels
- There were no serious adverse events (SAEs) related to the investigational product in the low and medium dose cohorts
- In the high dose and open-enrollment cohorts, SAEs were reported for two subjects. None of them were related to the study drug.
- Adverse events were mostly deemed related to the surgical procedure and resolved within a few days to weeks

RP and LCA—Unmet need and Treatment Benefit Target

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

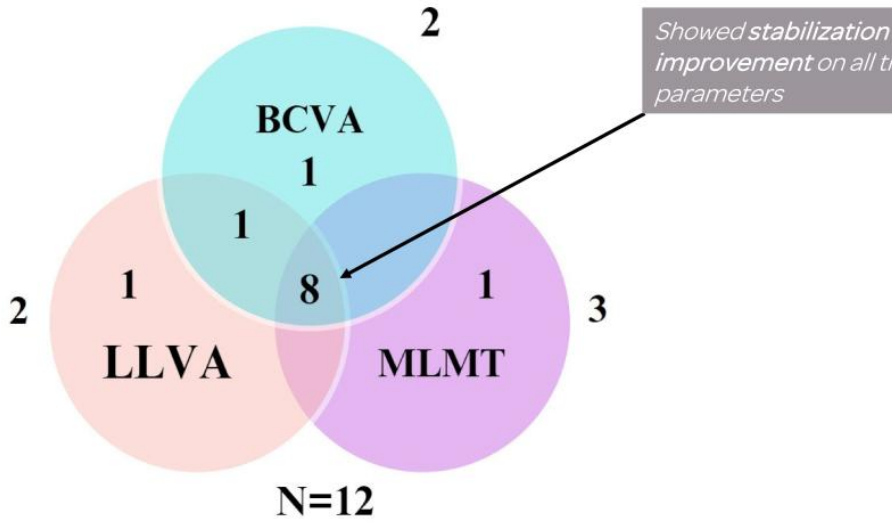
Responder Analysis

Stabilization/Improvement from Baseline [Treated Eyes]

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

Stabilization:
- BCVA: ± 4 letters change
- LLVA: ± 4 letters change
- MLMT: 0 change in Lux Level

Improvement:
- BCVA: ≥ 5 letters change
- LLVA: ≥ 5 letters change
- MLMT: ≥1 change in Lux Level



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Conclusions from Latest Clinical Study Results

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

OCU400: Expected Pathway to Clinical Development & Potential Approval

- Ocugen plans to meet with regulatory agencies in 4Q to potentially finalize Phase 3 clinical program and overall package
- Continue to dose adult LCA patients and pediatric RP and LCA patients

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

OCU410 (RORA): A Single-Injection Approach to Addressing Unme Needs in dAMD BEYOND the Complement System

- OCU410 Phase 1/2 study currently underway
- Limited options for dAMD, presenting significant unmet medical need
  - U.S.: 10M (GA: 1M)
  - Worldwide: 266M
- Distinct 4-Way MOA:
  Addresses multiple regulator pathways involved with the disease including:
  - Lipid Metabolism
  - Regulation of Inflammation
  - Oxidative Stress
  - Membrane Attack Complex (Complement)
- Optimal Delivery and Durability:
  - A single subretinal injection designed to eliminate patient compliance concerns and the treatment burden associated with multiple injections
- Improved Retinal function:
  - Improved photoreceptor function in OCU410 treated eyes with all doses*

- Advancement from recently approved therapies GA: Potential to address limitations of recently approved therapies for GA focused only on the complement system, including:
  - Patient Compliance
    - Frequent intravitreal injections (~6-12 doses per year)
  - Observed Structural Impact
    - Limited effect of GA lesion growth rate
  - Safety Considerations
    - 12% of patients experienced nAMD when therapy is administered every month for two years (Syfovre®)

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

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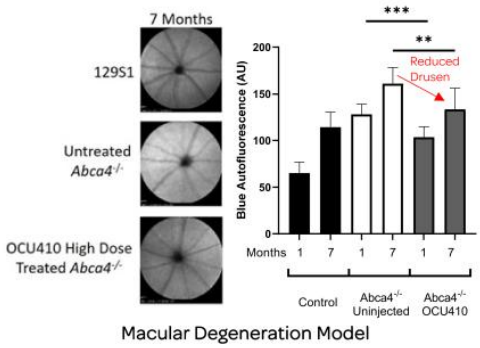
*As demonstrated in Peak scotopic B-wave amplitudes. N≥5 biological replicates

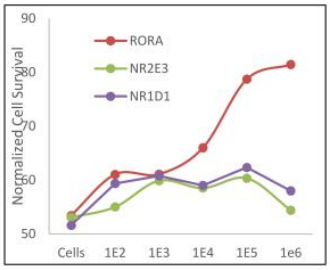
OCU410 (RORA): A Potential Modifier Therapeutic for Dry-AMD and S

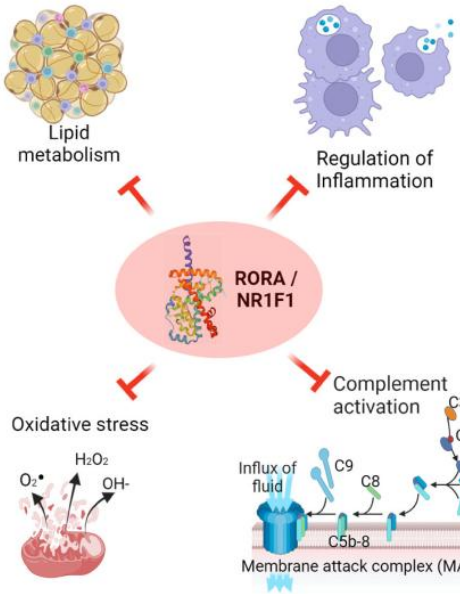
Anti-drusen activity and improves retinal function



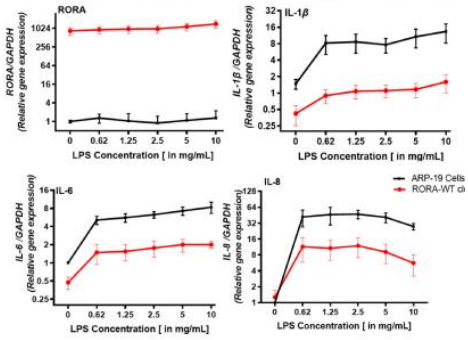
Macular Degeneration Model

Anti-oxidative: Improves ARPE19 cells survival

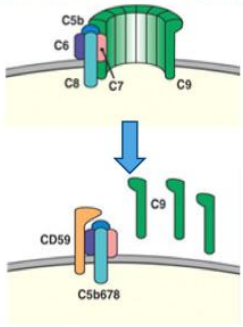


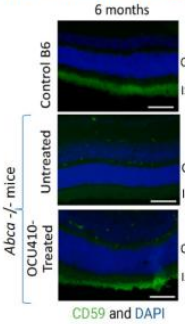


Anti-inflammatory: Suppresses inflammation in HMC



Anti-complement: Increased anti-compliment (Cd5





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

ABCA4-associated retinopathies—Genetic Rare Disease

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

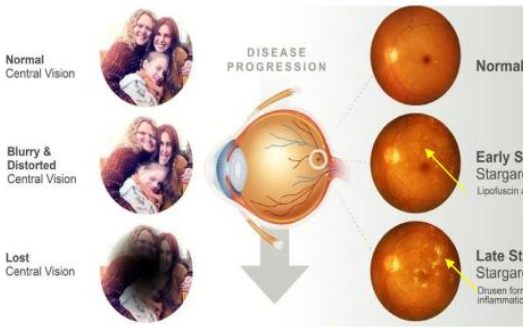
No treatment options exist

- U.S.: 44,000 patients

Modifier gene therapy platform addresses shortcomings of current approaches

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

Phase 1/2 underway



OCU200

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

OCU200: Submitted an IND with the U.S. FDA to Initiate a Phase 1 Clinical Trial Targeting Diabetic Macular Edema (DME)

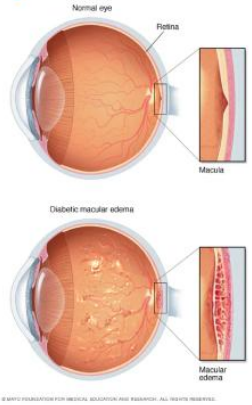
OCU200 is our novel biologics candidate for sight-threatening conditions
- A recombinant fusion protein of transferrin and tumstatin
- Potential to address diabetic macular edema (DME), diabetic retinopathy (DR), wet AMD

High prevalence of DME, DR and wet AMD patients
- DME: 21M worldwide
- DR: 162M worldwide
- Wet AMD: 30M worldwide

Limited treatment options available for the above patients
- Current therapies target only one pathway, either angiogenesis or inflammation
- Up to 50% of patient population are not responsive to current treatments

OCU200 potentially addresses shortcomings of current treatments
- Intended to target multiple causative pathways such as angiogenesis, oxidation, inflammation
- Potential to offer better treatment options for ***all*** patients

Company submitted an IND application*
- Initially targeting DME



Diabetic Macular Edema: bulges protrude from the blood vessels, leading to leakage of fluid and blood into the retina; leakage results in swelling (or "edema"), promoting vision loss.

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

NeoCart®

(Autologous chondrocyte-derived neocartilage)

NeoCart®: U.S. FDA Agreed to Proposed Control and Overall Design
Phase 3 Trial

NeoCart is a regenerative cell therapy
- Received RMAT designation
- Combines bioengineering and cell processing to enhance autologous cartilage repair
- Potential to accelerate healing and reduce pain through reconstructing damaged knee cartilage

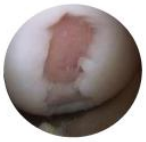
High prevalence of knee cartilage damage, with progression to osteoarthritis (OA)
- Arthroscopic knee procedures: over 1M annually*
- OA: 528M diagnosed worldwide
- Cell therapy global revenue forecast: $45B+, with North America expected to hold largest share**

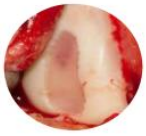
Current therapies to treat cartilage damage in the knee suboptimal
- Varying outcomes due to variable cellular responses
- Current standard of care suffers from one or more of the following pain, reduced knee function, failure to address cartilage damage, donor tissue availability, open surgery

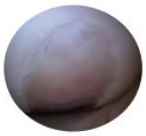
NeoCart potentially addresses shortcomings of current treatment
- Treat pain, improve function, and prevent progression to OA
- Potential for improved efficacy, long-term benefits

Program advancing on several fronts
- Received FDA concurrence on confirmatory trial design Phase 3 (initiate in 2H 2024)
- Construction of cGMP manufacturing facility to be completed by the end of 2023

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
**https://www.biospace.com/article/cell-therapy-market-size-cagr-trends-forecast-report-2022-2030/

OCU500 Series:

OCU500: COVID-19 Mucosal Vaccine

OCU510: Flu

OCU520: COVID-19/Flu

OCU500 Series: Next-Generation Vaccine Technology

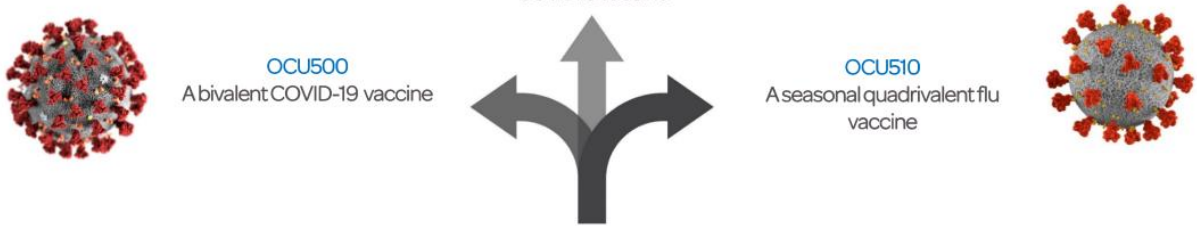
Inhaled mucosal vaccine platform based on ChAd vector

Inhalation technology as a differentiator

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

Alignment with American Pandemic Preparedness Plan to transform U.S. capabilities to rapidly and effectively respond to existing and emerging infectious diseases via:

- Legislative advocacy for next-generation mucosal vaccine development
- OCU500 was selected by the NIH/NIAID Project NextGen for inclusion in clinical trials. NIAID is planning to initiate the Phase 1 clinical trials in early 2024.



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Ocugen™ Vision

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