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): **May 5, 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 May 5, 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).

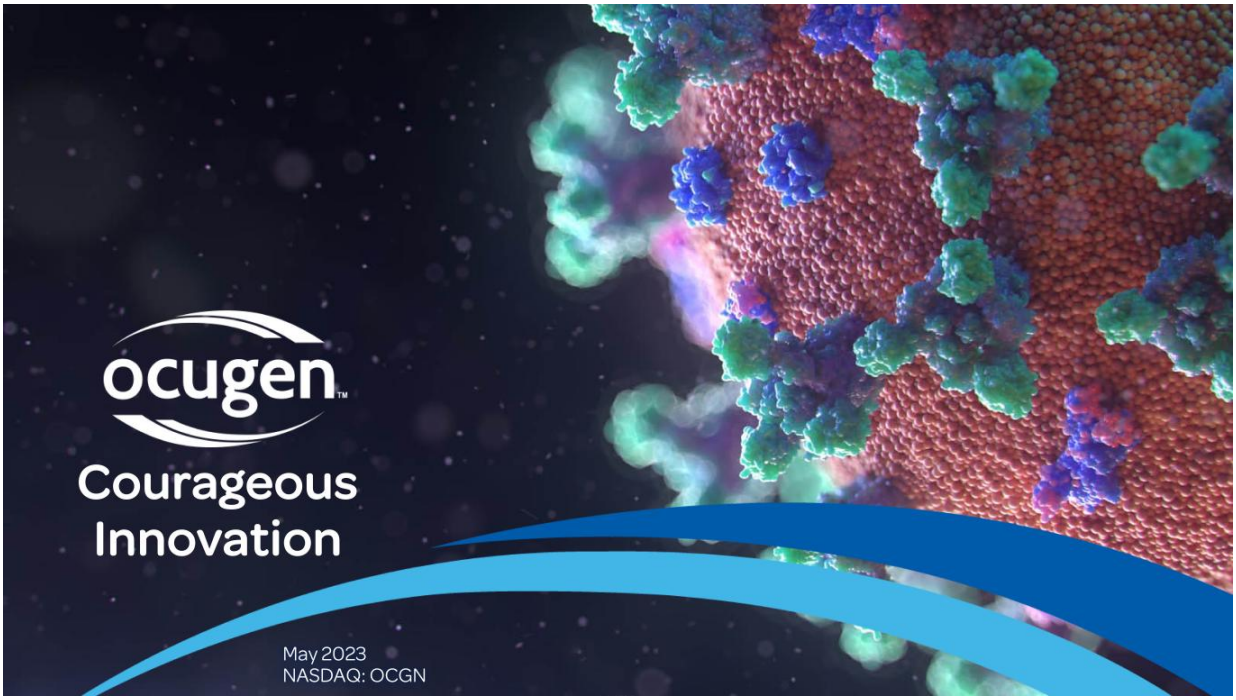
SIGNATURE

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: May 5, 2023

OCUGEN, INC.

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


ocugen™
Courageous Innovation
May 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 for flu & 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

ocugen

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 • Favorable safety and tolerability profile • 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
		RP--RHO Mutation	
		Leber congenital amaurosis (LCA)--CEP290 Mutation	
	OCU410 AAV-hRORA	Dry Age-Related Macular Degeneration (Dry AMD)	• IND planned for 2Q 2023
	OCU410ST AAV-hRORA	Stargardt disease (orphan disease)	
Biologics	**OCU200** Transferrin – Tumstatin	Diabetic Macular Edema	• IND submitted. Waiting for FDA clearance before initiating Phase 1 trial.
		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 2024
Vaccines	**OCU500 Series**		
	OCU500: COVID-19 (Bivalent)	For Prevention of Disease Caused by COVID-19	• IND planned for 4Q 2023 (pending government funding)
	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

Modifier Gene Therapy Platform

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

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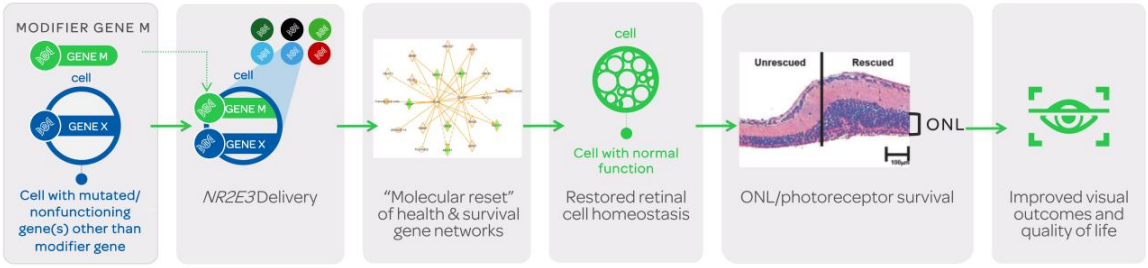
Modifier Gene Therapy: A Broader Reach

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:



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

Dose escalation and recruitment of RP patients completed

- High dose established as Maximum Tolerable Dose (MTD)
- Continue to enroll patients with LCA
- Intend to initiate a Phase 3 trial near the end of 2023

Study Overview

Primary Endpoint: Safety

Safety of subretinal administration of OCU400

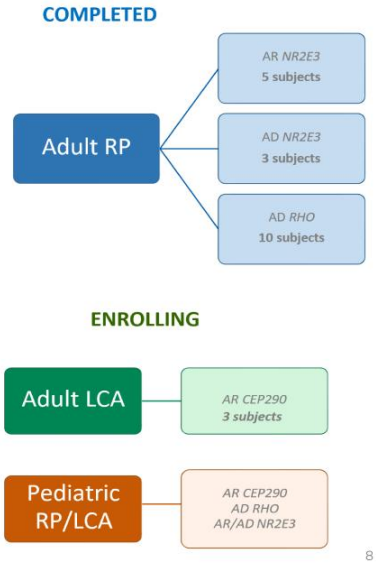
Exploratory Endpoint: Efficacy

Multi-Luminance Mobility Test (MLMT)

Best Corrected Visual Acuity (BCVA)

Clinical Trials.gov Identifier: NCT05203939

Enrollment Status



Multi-Luminescence Mobility Test			
	Total Subjects for analyses (N=7); pooled analyses Subjects with 9-months follow-up : Cohort 1, N=3 Subjects with 6 months follow-up: N=1 from Cohort 1 and N=3 from Cohort 2		Total Subject for analyses (N=3) Cohort 1 with 9 month follow-up
	Improvement ≥ 1 Lux	Improvement ≥ 2 Lux	Improvement ≥ 2 Lux
Treated Eye	71.4%	28.6%	66.7%
Untreated Eye	28.6%	0.0%	**0.0%**

- *100% of treated eyes showed stability or improved MLMT scores*
- *71% of treated eyes improved by at least 1 Lux Level in pooled analyses vs ONLY 29% of untreated eyes*
- *29 % of treated eyes improved by at least 2 Lux Level in pooled analyses vs 0 % of untreated eyes*
- *67 % treated eyes improved by at least 2 Lux Level in cohort 1 subjects with 9 months follow up vs 0 % of untreated eyes*

MLMT is used as efficacy measure to assess visual function

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 Cohort 1 and N=3 from Cohort 2	
	Improvement ≥ 8 Letters	
Treated Eye	42.9%	
Untreated Eye	0.0%	

OCU400: Expected Pathway to Clinical Development & Potential Approval

- Ocugen plans to meet with regulatory agencies in 3Q to potentially finalize Phase 3 clinical program and overall package
- Continuing to enroll LCA and pediatric patients in Phase 1/2 trial

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

OCU410ST: Received ODD for the Treatment of ABCA4-Associated Retinopathies Including Stargardt, Retinitis Pigmentosa 19 (RP19) and Cone-rod Dystrophy 3 (CORD3)

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)

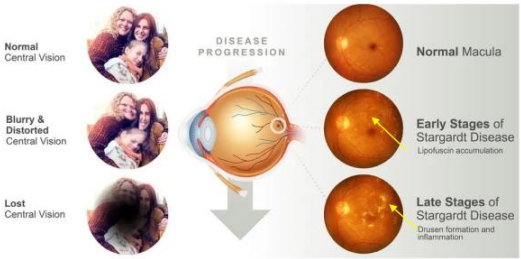
No treatment options exist

- US: 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

Plan to submit IND for initiation of Phase 1/2 clinical trial in 2Q 2023



OCU410 for the Treatment of Dry Age-related Macular Degeneration (dAMD)

dAMD

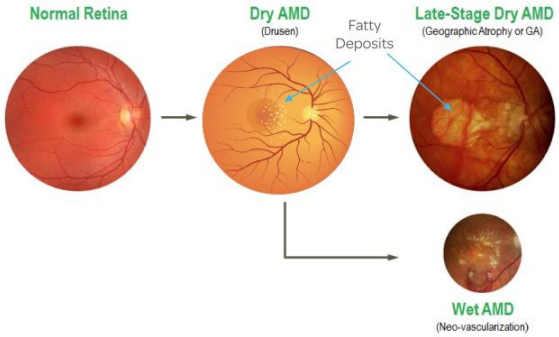
Limited options, presenting significant unmet medical need

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

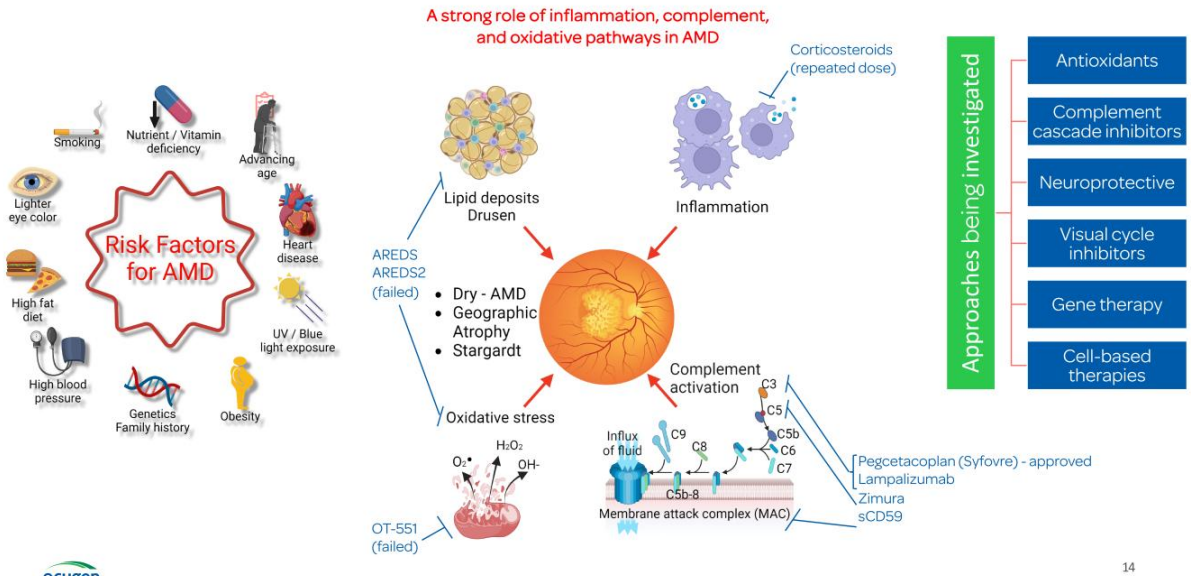
Recently approved therapy for geographic atrophy (GA)—advanced form of dAMD–has limitations

- 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

Plan to submit IND for initiation of Phase 1/2 clinical trial in 2Q 2023

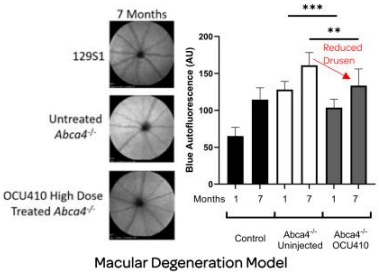


AMD: Risk Factors, Treatment Options and Unmet Needs



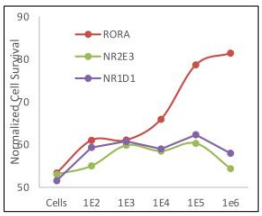
OCU410 (RORA): A Potential Modifier Therapeutic for Dry-AMD and STGD

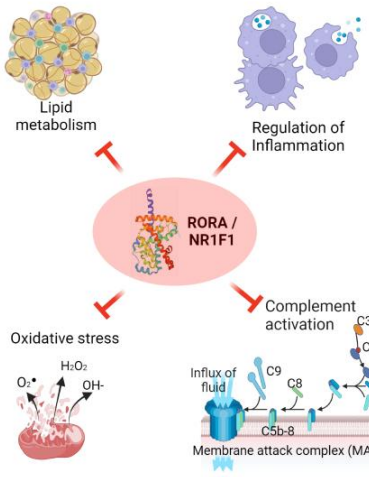
Anti-drusen activity and improves retinal function



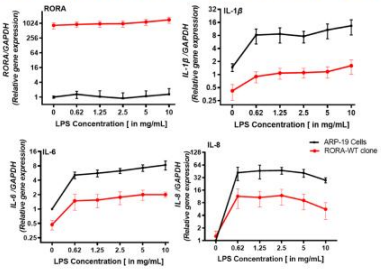
Macular Degeneration Model

Anti-oxidative: Improves ARPE19 cells survival

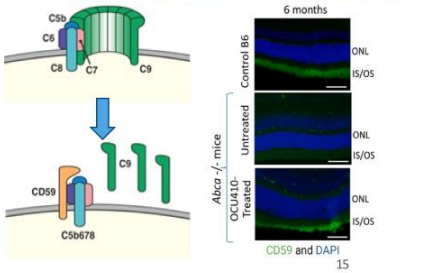




Anti-inflammatory: Suppresses inflammation in HMC3 cells



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



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)

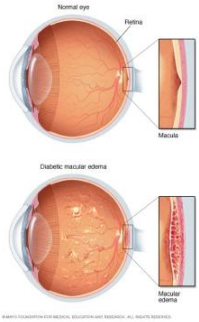
OCU200 is our novel biologics candidate for sight-threatening conditions
- A recombinant fusion protein of transferrin and tumstatin
- Potential to address diabetic macular edema (DME), diabetic retinopathy (DR), wet AMD

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 on February 27, 2023*
- 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.

* The IND was placed on clinical hold by the FDA as part of its request for additional information related to chemistry, manufacturing, and controls prior to initiating the Phase 1 trial. The company plans to respond to the FDA promptly to get FDA clearance to initiate the Phase 1 clinical trial.

NeoCart®

(Autologous chondrocyte-derived neocartilage)

NeoCart®: U.S. FDA Agreed to Proposed Control and Overall Design for Phase 3 Trial to Evaluate Safety and Efficacy Compared to Chondroplasty Standard of Care

NeoCart is a regenerative cell therapy technology

- 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 treatments

- 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 of Phase 3 (initiate in 2024)
- Renovating facility to accommodate cGMP manufacturing

Follow-up Arthroscopy Demonstrates NeoCart® Progression and Integration**

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

*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 Candidates Using Inhalation Technology

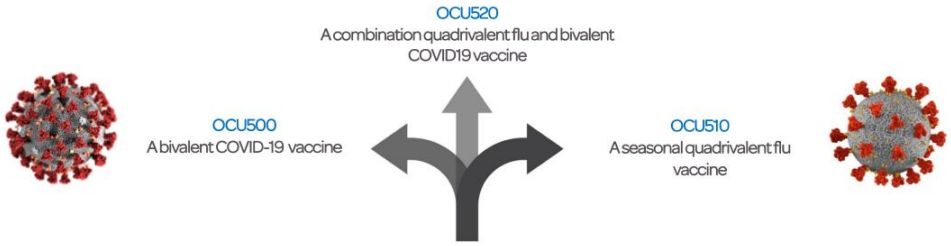
Current focus solely on the development of our inhaled mucosal vaccine platform based on chAd vector

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

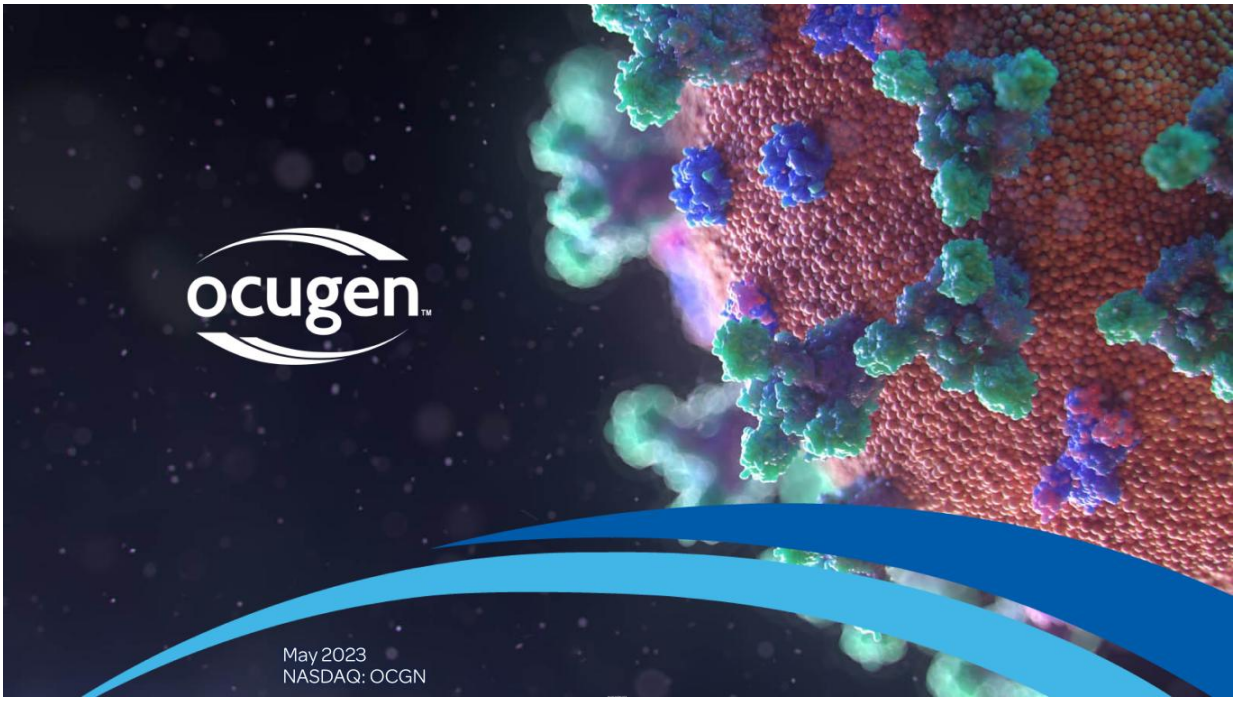
Alignment with American Pandemic Preparedness Plan to transform U.S. capabilities to rapidly and effectively respond to existing and emerging infectious diseases via:

- Legislative advocacy for next-generation mucosal vaccine development
- Multiple proposal submissions for federal funding of Ocugen's inhaled vaccines platform for COVID-19 and flu
- Ongoing dialogue with several government agencies regarding the development of the inhaled vaccines platform



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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