# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# FORM 8-K

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**CURRENT REPORT**
**Pursuant to Section 13 OR 15 (d)**
**of The Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): **March 13, 2023**

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# OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

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| **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<br>(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 March 13, 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). |

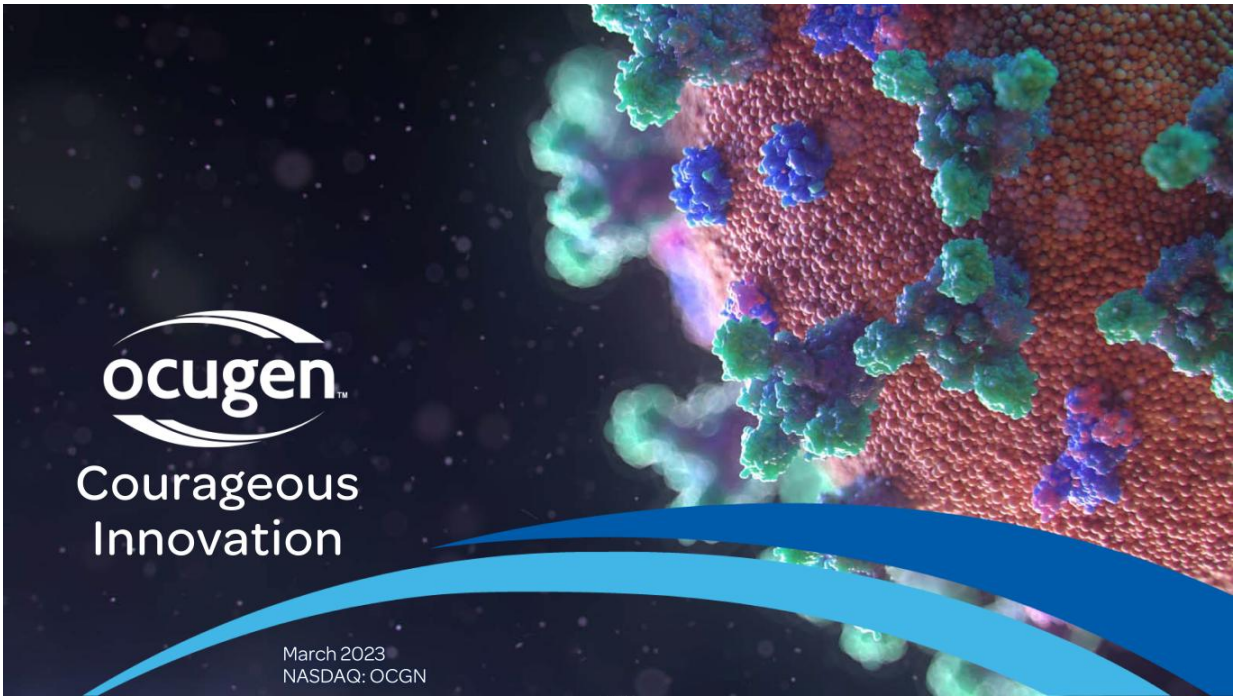
**SIGNATURE**

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: March 13, 2023

OCUGEN, INC.

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


ocugen™
Courageous
Innovation
March 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

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# Pipeline Overview

| | Asset/Program | Indication | Current Status |
|---|---|---|---|
| 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 1H 2024 |
| Gene therapies | OCU400 ** AAV-hNR2E3 Gene mutation-associated retinal degeneration* | *Retinitis pigmentosa (RP)--NR2E3 Mutation* | • Phase 1/2<br>• Completed dose escalation and established maximum tolerable dose (MTD)<br>• Completed recruitment of RP Patients<br>• Encouraging safety profile to date |
| | | *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 in February 2023; preliminary results anticipated 4Q 2023 |
| | | Diabetic Retinopathy | • IND-ready |
| | | Wet Age-Related Macular Degeneration (Wet AMD) | • IND-ready |
| Vaccines | OCU500 Series | | |
| | **OCU500**: COVID-19 (Bivalent) | For Prevention of Disease Caused by COVID-19 | • IND planned for 4Q 2023 |
| | **OCU510**: Flu (Quadrivalent) | For Prevention of Disease Caused by Flu | |
| | **OCU520**: Flu + COVID-19 | For Prevention of Diseases Caused by Flu and COVID-19 | |
| | **COVAXIN™** (BBV152) SARS-CoV-2 virus | For Prevention of Disease Caused by COVID-19 | • EUA for adults in Mexico<br>• Phase 2/3 enrollment complete and top line results released<br>o Final data and analysis anticipated mid-year 2023 |

*Regenerative Medicine Advanced Therapy Designation

**Broad, gene-agnostic, ORPHAN DRUG DESIGNATIONS FOR RP/LCA FROM FDA AND EMA

# 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 1H 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/

# Modifier Gene Therapy Platform

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

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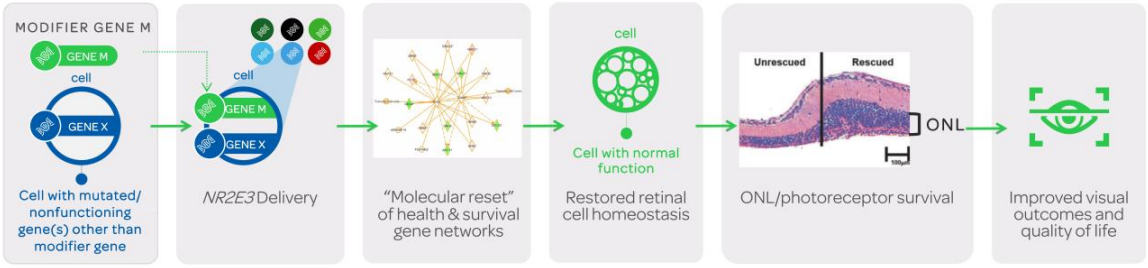
# Modifier Gene Therapy: A Broader Reach

**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

# OCU400-101 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 Endpoint: Safety

Safety of subretinal administration of OCU400

Key Exploratory Efficacy Measures

- Best Corrected Visual Acuity (BCVA)
- Multi-Luminance Mobility Test (MLMT)
- Full-Field Stimulus Test (FST)
- NEI-VFQ-25

Clinical Trials.gov Identifier: NCT05203939

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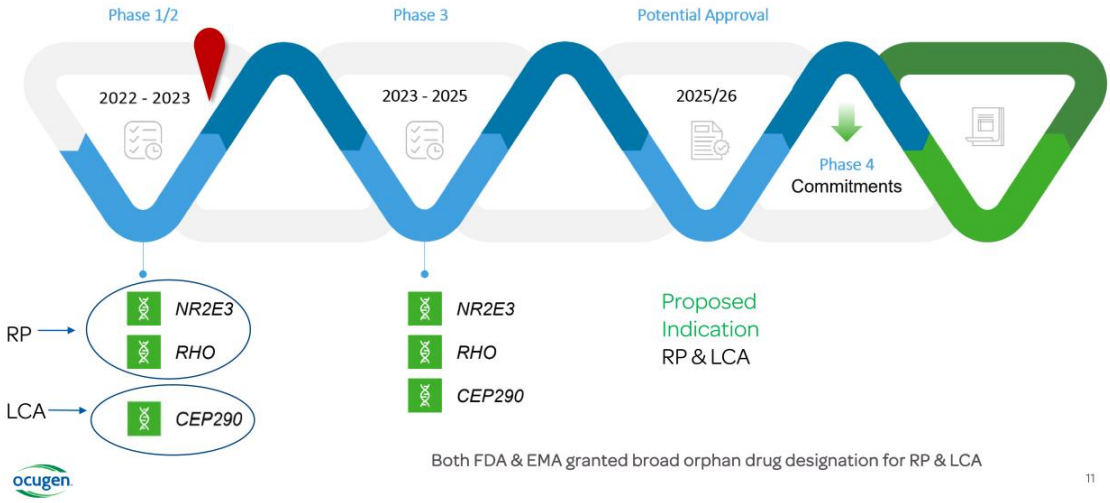
# OCU400:Expected Pathway to Clinical Development & Potential Approval




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

# 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

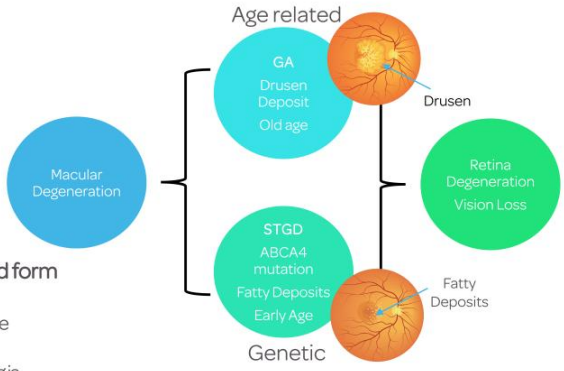
**Recently approved therapy for geographic atrophy (GA)—advanced form of dAMD–has limitations**

- 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

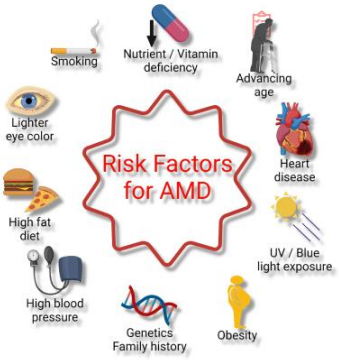
**OCU410 addresses shortcomings of current approaches**

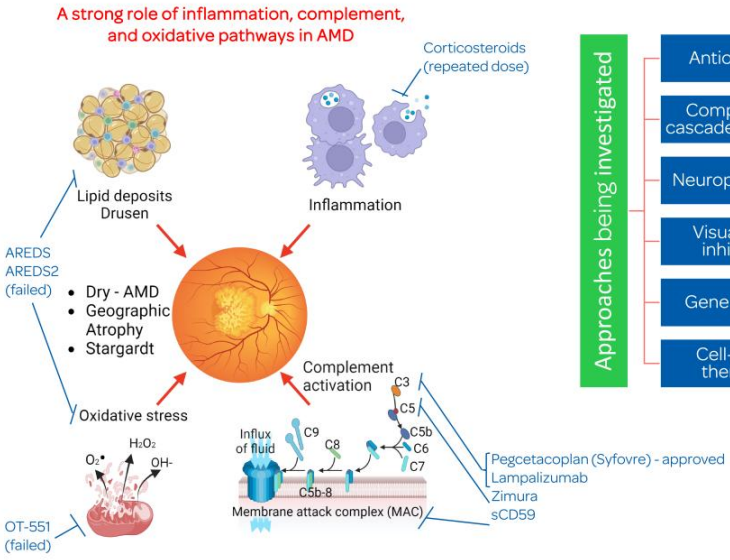
- Broad-spectrum, gene-agnostic approach
- Potential one-time, curative therapy with a ***single*** sub-retinal injection, using RORA

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



# AMD: Risk Factors, Treatment Options and Unmet Needs







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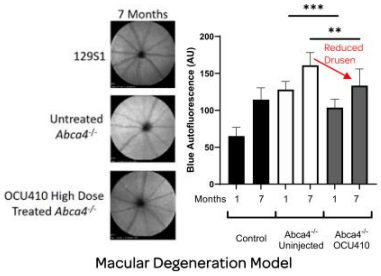
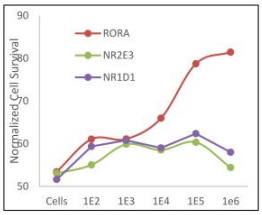
# OCU410 (RORA): A Potential Modifier Therapeutic for Dry-AMD and STGD

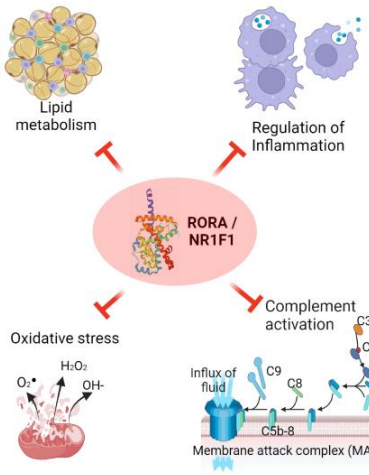
*Anti-drusen activity and improves retinal function*



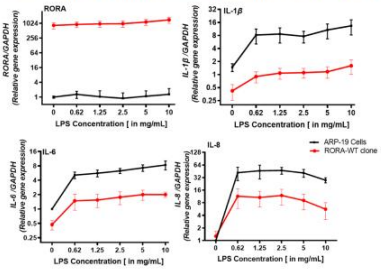

Macular Degeneration Model

*Anti-oxidative: Improves ARPE19 cells survival*

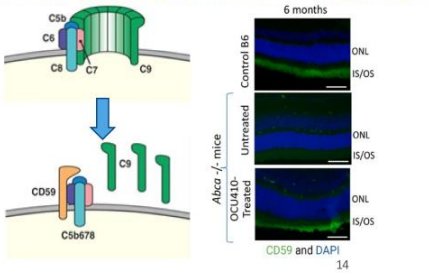



*Anti-inflammatory: Suppresses inflammation in HMC3 cells*




*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)

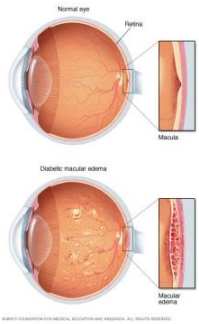
**OCU200 is our novel biologics candidate for sight-threatening conditions**
- A recombinant fusion protein of transferrin and tumstatin
- Potential to address diabetic macular edema (DME), diabetic retinopathy (DR), wet AMD

**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

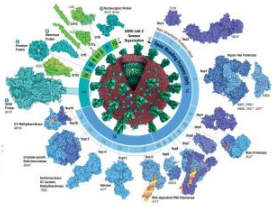



*Diabetic Macular Edema: bulges protrude from the blood vessels, leading to leakage of fluid and blood into the retina; leakage results in swelling (or "edema"), promoting vision loss.*

# OCU500 Series:

## OCU500: COVID-19 Mucosal Vaccine
## OCU510: Flu
## OCU520: COVID-19/Flu

# Challenges and Opportunities: Flu and Covid-19 Vaccines



Antigenic Landscape

COVID-19 and flu infections continue to be a public health concern

- COVID-19: 1M+ U.S. cases in the last 30 days; 5M+ WW cases with 47K deaths in the last 28 days
- Flu: 50%+ of U.S. population 6-months and older received a shot for the 2022 to 2023 flu season, totaling 170M doses

Limitations of current Flu vaccines

- Sub-optimal vaccine efficacy (~20-40%); rapid decline in immune responses; poor local immunity at infection
- Manufacturing challenges for egg-based vaccines; antigenic drift during production- reducing vaccine efficacy

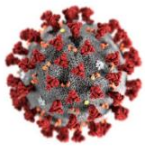
Limitations of current COVID-19 vaccines

- Lack of durability: immunity wanes significantly over time, requiring repeated boosters
- Inability to stop transmission: breakthrough infections prevalent, increasing potential for mutations

Inhalation vaccine advantages

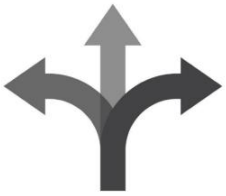
- Potential to generate rapid mucosal immunity in respiratory pathways, limiting infection and transmission
- COVID-19 preclinical studies demonstrated vaccine induced high neutralizing and effector responses

Next-Generation Vaccine Candidates Using Inhalation Technology to Potentially Overcome Durability and Transmission Challenges

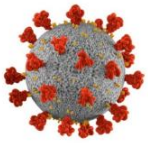


OCU500
A bivalent COVID-19 vaccine

OCU520
A combination quadrivalent flu and bivalent COVID19 vaccine



OCU510
A seasonal quadrivalent flu vaccine



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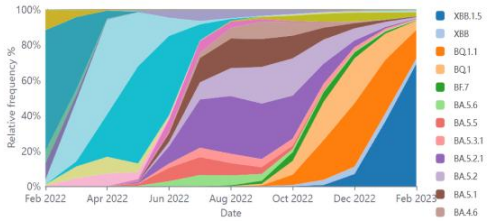
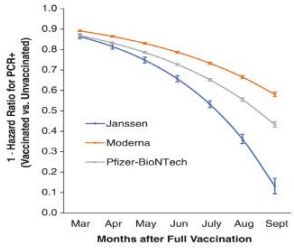
# Factors Responsible for the Rapid Decline in Vaccine Efficacy

New SARS-CoV-2 variant frequencies in U.S.




Decline in Vaccine Efficacy




https://www.science.org/doi/10.1126/science.abm0620

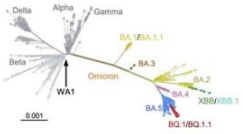
### The rapid emergence of variants

- Multiple RBD mutations > less cross-protection
- Change in infection and pathogenesis pattern > reduced latency period
- Reduce cellular memory > limited tissue-resident memory T-cells

### Limited local immunity at site of infection

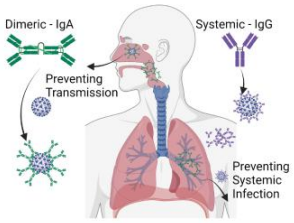
- Decrease in neutralizing IgG antibody levels
- Lack of a robust secretory IgA response

# Strategies to Improve COVID-19 and Flu Vaccines




## Updated vaccine antigens

- Introduction of bivalent / multivalent vaccines
- Variant-modified COVID-19 vaccine boosters
- QuadFlu constructs ( type A and B)




## Prevent both transmission and systemic spread with mucosal vaccines

- Induction of polymeric IgA in the respiratory tract prevents viral transmission
- Prevent systemic spread by inducing high levels of circulating IgG titers
- Mucosal vaccines proved in multiple animal models of infection and clinical trials


## Enhancing mucosal vaccines

- Maximizing the area of vaccine delivery to the respiratory tract (Intranasal vs. Inhalation)
- Formulations to facilitate the adsorption and prolong the retention time on respiratory epithelial cells
- Delivery and uptake of antigens to target APC cells such as M-cells, DCs, and macrophages

# Approved (Ex-U.S.) Mucosal COVID-19 Vaccines: Demonstrated Safety & Efficacy as a Heterologous Booster

*Studies demonstrating the benefit of AAV*

## Bharat Biotech: ChAd-Nasal Dropper

Ph 3 (N=2160): Superior Immune Response
- iNCOVACC® (N=3000) vs.
- COVAXIN™ (N=160)

Improved Immunogenicity in Ph3: iNCOVACC vs. COVAXIN
- Superior GMT ratio of nAb for Wuhan (1.45)
- Superior GMT ratio of nAb for Omicron BA.5 (2.1)
- GMT ratio for secretory IgA in saliva (1.3)

Improved Safety in Ph3: iNCOVACC vs. COVAXIN
- Systemic AEs 2.7% (iNCOVACC) vs. 6.2% (COVAXIN)
- Nasal reactions 4.9% (iNCOVACC)
- Injection reactions 23% (COVAXIN)

## CanSino Bio: Ad5-Nebulizer/Inhaled

Five booster studies
Ph 3 (SeiHOPE trial): N=13000
Dose : 1/5 of IM dose

Improved Immunogenicity:
- Cross protection against Omicron with heterologous booster
- Produced T-cell responses higher than IM route
- Significantly higher neutralizing antibody responses to WT and Omicron BA.1 compared with inactivated vaccine
- Improved serum IgA antibody titers vs. inactivated and subunit vaccines for BA.4/5

Improved Safety: iNCOVACC vs. Inactivated Vaccine
- Significantly lower number of injection site reactions vs. inactivated vaccine

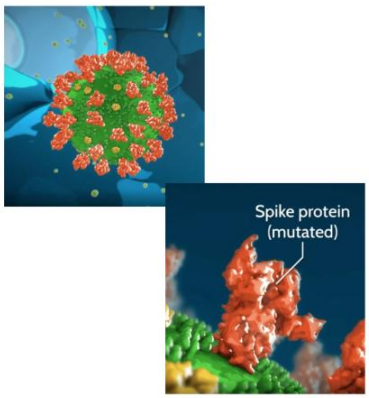
*Ocugen using ChAd vector with inhalation technology for the mucosal vaccine platform (Flu, COVID-19 & Combo )*


References:
https://doi.org/10.1101/2022.03.08.22271816;
https://doi.org/10.1101/2022.06.03.22275983;
https://doi.org/10.1080/22221751.2022.2132881
https://doi.org/10.1080/22221751.2022.2155251
https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(22)00087-X/fulltext
https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(23)00049-8/fulltext
https://doi.org/10.1101/2022.07.26.22278072
https://ssrn.com/abstract=4000565
https://ssrn.com/abstract=4304747

# COVAXIN™ (BBV152)

A whole-virion inactivated COVID-19 vaccine candidate licensed from Bharat Biotech (BBIL) for North American Markets

# COVAXIN™(BBV152): Final Data and Analysis Expected Mid-Year 2023 for Our Injectable COVID-19 Vaccine



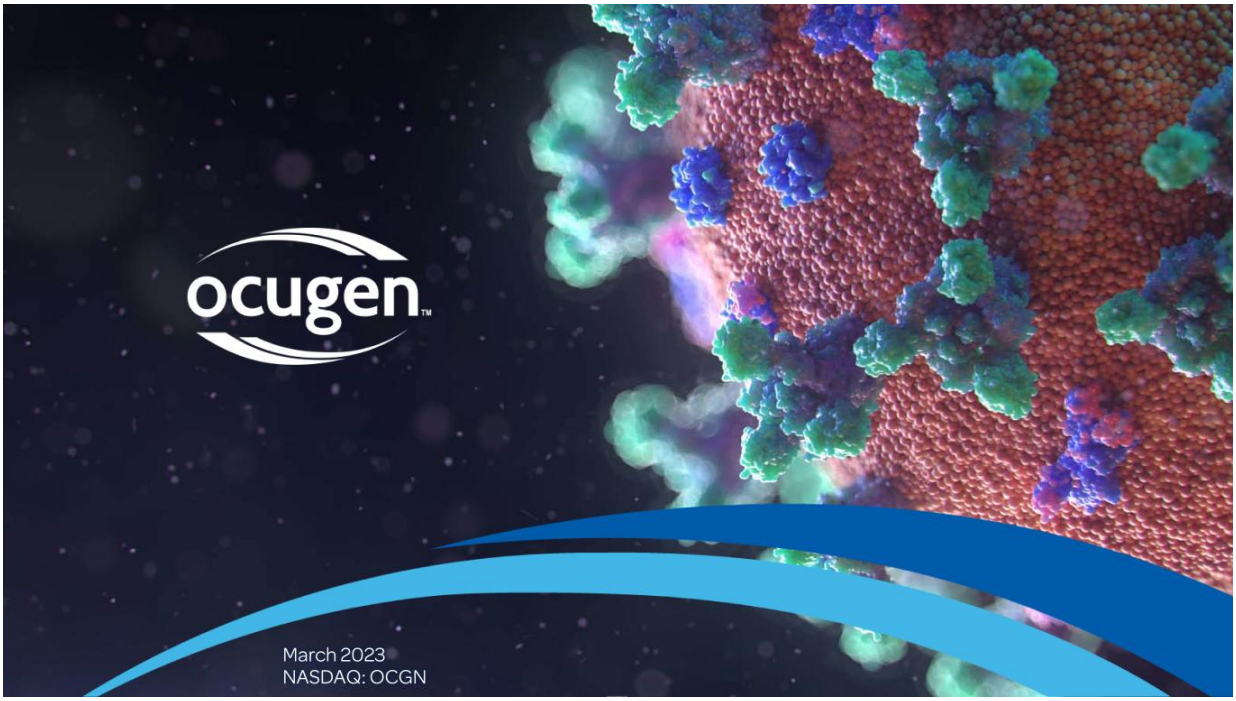

Enrollment completed for Phase 2/3 immuno-bridging and broadening clinical trial in December 2022

Topline data highlights, reported in January 2023, include the following:

- Safety: well-tolerated with no related serious adverse events (no thrombotic, myocarditis, pericarditis cases)
- Efficacy: immunogenicity demonstrated
- Final data and analysis: anticipated mid-year 2023

# 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
March 2023
NASDAQ: OCGN