
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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 19, 2021**

OCUGEN, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-36751
(Commission
File Number)

04-3522315
(I.R.S. Employer
Identification Number)

263 Great Valley Parkway
Malvern, Pennsylvania 19355
(484) 328-4701

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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 and incorporated herein by reference is a presentation that Ocugen, Inc. will post on its website on May 19, 2021 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 exhibit is being filed herewith:

(d) Exhibits

<u>Exhibit No.</u>	<u>Document</u>
99.1	Ocugen, Inc. Presentation

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 19, 2021

OCUGEN, INC.

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



Our Mission is to
Develop **Gene Therapies** to Cure
Blindness Diseases

and

Develop a **Vaccine** to Save Lives
from COVID-19

NASDAQ: OCGN

Corporate Deck: May 2021



Forward Looking Statement

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our business strategy, future results of operations and financial position, prospective products, product approvals, research and development costs, timing and likelihood of success, estimated market size or growth, and plans and objectives of management for future operations, are forward-looking statements. When used in this presentation, the words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements involve known and unknown risks, uncertainties and other factors, including those risks set forth in the Company's filings with the Securities and Exchange Commission, which are available at www.sec.gov, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements are based on our management's beliefs and assumptions and on information available to management as of the date of this presentation. Our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

This presentation includes estimates by us of statistical data relating to market size and growth and other estimated data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. This presentation also includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.



Ocugen Overview

COVID-19 VACCINE

- COVAXIN™: Whole-virion inactivated COVID-19 vaccine candidate (with adjuvant). Licensed rights from Bharat Biotech for the US market (currently received EUA in India). Standard vaccine storage condition (2-8°C)
- 78% overall efficacy and 100% in severe COVID-19 disease (including hospitalization)
- Phase 3 clinical trial enrolled 25,800 participants between 18-98 years of age, including 2,433 over the age of 60 and 4,500 with comorbidities. Phase 1/2 enrolled 755 participants 12+ years of age
- Potential coverage against multiple protein antigens of the virus and potentially applicable to broader population
- Effectively neutralizes UK, BZ, and IN variant of SARS-Cov-2 reducing the possibility of mutant virus escape

OCUGEN'S BREAKTHROUGH MODIFIER GENE THERAPY PLATFORM

- Potential for one product to treat many diseases & multi-factor approach (POC study results published in Nature)
- OCU400 (AAV-NR2E3): Orphan medicinal product designation for the treatment of both retinitis pigmentosa (RP) and Leber Congenital amaurosis (LCA) covering diseases caused by mutations in over 175 genes. Initiation of Phase 1/2a this year
- OCU410 (AAV-*RORA*): Potential to treat dry age-related macular degeneration (Dry AMD) through multi-factor treatment approach – initiation of Phase 1/2 in 2022
- Strategic manufacturing partnership with CanSinoBio (~\$13B market cap) – sets clear path for critical manufacturing

NOVEL BIOLOGIC

- OCU200: Targeting major retinal diseases: Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Wet Age-Related Macular Degeneration (Wet AMD) (estimated global market size over \$10B) – initiation of Phase 1/2 in 2022
- Novel MoA: Potential to initially treat non-responders to anti-VEGF/ therapies (~50% of patients)

Leadership Team

Leadership Team



Shankar Musunuri, PhD, MBA
Chairman, CEO and Co-Founder



Bruce D. Forrest, MB, BS, MD, MBA
Acting CMO



Sanjay Subramanian, MBA
CFO and Head of Corporate Development



Vijay Tammara, PhD
SVP, Regulatory & Quality



Arun Upadhyay, PhD
VP, Head of Research & Development



Jessica Crespo, CPA
Corporate Controller



Zara Gaudioso, SHRM-CP
Head of Human Resources



J.P. Gabriel
SVP, Manufacturing & Supply Chain



Scientific Advisory Boards

Retina Scientific Advisory Board



David Boyer, MD



Carl D. Regillo, MD, FACS



Mark Pennesi, MD, PhD



Geeta Lalwani, MD



Vaccine Scientific Advisory Board



Satish Chandran, PhD



David Fajgenbaum, MD, MBA, MSc, FCPP



Bruce D. Forrest, MB, BS, MD, MBA



Catherine Pachuk, PhD



Harvey Rubin, MD, PhD



Susan Weiss, PhD



Pipeline Overview

Pre EUA

Vaccine	COVAXIN™	Active Immunization to Prevent COVID-19 caused by SARS-CoV-2	<ul style="list-style-type: none"> Phase 3 interim analysis - 78% efficacy; 100% against severe cases EUA in India for development partner US EUA pathway in development (Master File Submitted)
	Whole-Virion Inactivated Vaccine		

R&D Pipeline

	Program	Indication	Prevalence (US)	Discovery	Preclinical	IND-Enabling	Phase 1/2
Modifier Gene Therapy Platform	OCU400 AAV-hNR2E3	NR2E3 Mutation - Associated Retinal Degeneration **	500 - 600	[Progress bar]			
		RHO Mutation - Associated Retinal Degeneration **	10,400 - 12,700	[Progress bar]			
		CEP290 Mutation - Associated Retinal Degeneration **	2,500 - 3,000	[Progress bar]			
		PDE6B Mutation - Associated Retinal Degeneration **	1,800 - 2,800	[Progress bar]			
Novel Biologic	OCU410 AAV-hRORA	Dry Age Related Macular Degeneration ** (Dry AMD)	9M - 10M	[Progress bar]			
		Diabetic Macular Edema	0.75M	[Progress bar]			
		Diabetic Retinopathy	7.7M	[Progress bar]			
	OCU200 Transferrin-Tumstatin	Wet Age Related Macular Degeneration (Wet AMD)	1.1M	[Progress bar]			



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** No approved therapies exist

<https://www.aao.org/eye-health/diseases/retinitis-pigmentosa-treatment>
<https://www.aao.org/eye-health/diseases/amd-treatment>

*Orphan medicinal product designation for the treatment of both retinitis pigmentosa (RP) and Leber Congenital amaurosis (LCA)

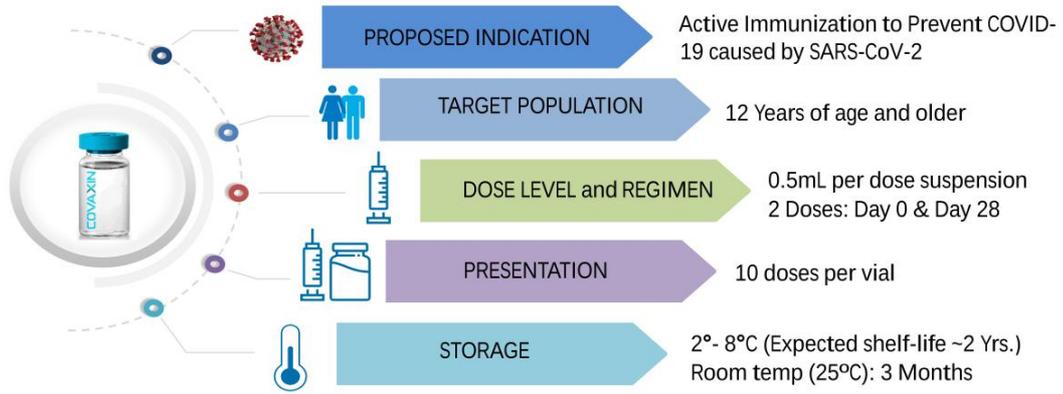


The logo for COVAXIN™ is centered in the upper half of the slide. It consists of the word "COVAXIN" in a white, sans-serif font, followed by a trademark symbol (™). The background behind the text is a dark blue gradient with a subtle grid pattern and a large, light blue curved shape that frames the text from the top and left.

Whole-Virion Inactivated COVID-19 Vaccine
Licensed from Bharat Biotech (BBIL) for the
US Market

COVAXIN™ - Product Profile

Whole virion inactivated SARS-CoV-2 (NIV-2020-770)
Antigen concentration & Adjuvant: 6µg + Algel-IMDG(TLR7/8)



Why COVAXIN™

Designed to fill a significant unmet need in our national arsenal of vaccines against COVID-19

B

Broad Spectrum Immune Response

Both humoral & cellular responses generated against multiple viral proteins
Induces a Th1 response (cell-mediated immunity)

E

Effective → 78% Efficacy in Ph3 interim data (100% against severe)

Highly effective in neutralizing UK, BZ P2, and India "double mutant" variants
Potentially serve as a universal booster to minimize/eliminate viral escape and control the Pandemic

S

Safe in 12+ (Pediatric population covered in Ph 2 clinical studies)

Proven technology platform and supply chain currently used for several licensed vaccines (Influenza, Polio, Rabies, JEV etc.).
Historically demonstrated acceptable safety, tolerability and efficacy in children and adults

T

Transportation and Storage Ease

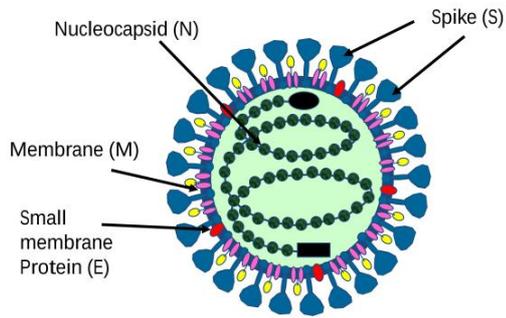
Stable for 3 months at room temperature
Can be stored in standard conditions (2° - 8°C) for several years. Can be stockpiled.

COVAXIN™ Presents Multiple Protein Targets to the Immune System Resulting in Broad Spectrum Response

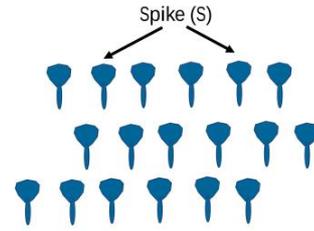


COVAXIN™, an adjuvanted inactivated virus vaccine candidate, elicited strong IgG responses against spike (S1) protein, receptor-binding domain (RBD), and the nucleocapsid (N) protein of SARS-CoV-2 along with strong cellular responses

COVAXIN™



mRNA and Adenovirus-Based Vaccines



COVAXIN™ Developed and Manufactured by Bharat Biotech

Established Robust Manufacturing Process for COVAXIN

Ocugen licensed COVAXIN™ on the back of Bharat's strong track record of developing & commercializing vaccines globally

Inactivated Vero cell derived vaccines are proven, time-tested and long-lasting. A few include:



COVAXIN™ is Distinct Amongst Leading COVID-19 Vaccines and Select Vaccine Candidates in the United States

Company	Technology	Antigen	Stage
COVAXIN™	Inactivated SARS CoV-2 Virus, Aluminum hydroxide, TLR agonist	Whole virus (Including S & N Proteins)	EUA in India; pre-EUA discussions with FDA
Pfizer/ BioNTech	Lipoplex of SARS CoV-2 S protein mRNA	S protein	EUA
Moderna	Lipoplex of SARS CoV-2 S protein mRNA	S protein	EUA
AstraZeneca	Non-replicating infectious Adenovirus	S protein	EUA in India & UK
Johnson & Johnson	Non-replicating infectious Adenovirus	S protein	EUA

Technology Comparisons: Target Product Profile

Characteristic	mRNA	Adeno- Based	COVAXIN™
Acceptable Safety	✓	✓	✓
Neutralizing antibody response	✓	✓	✓+
Cellular responses against multiple viral antigens	✓	✓	✓+
Efficacy	✓	✓	✓+
Stability at 2-8°C	X	✓	✓
Multiple Viral Antigens	X	X	✓

“+” : B and T cell immune responses to multiple proteins, Safety and Efficacy in Phase 1 and Phase 2 studies

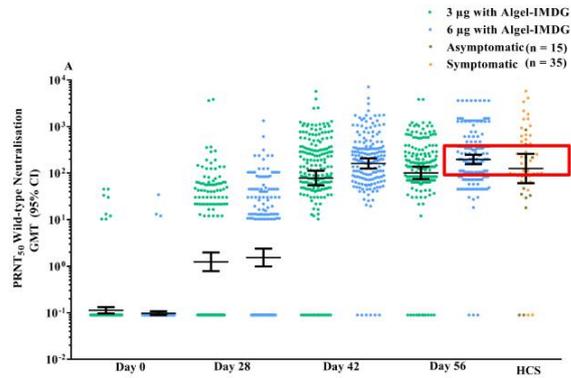
COVAXIN™ Progress and Planned Milestones for U.S. Dev.



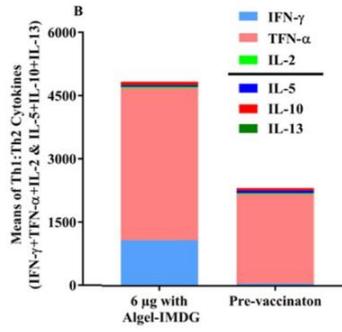
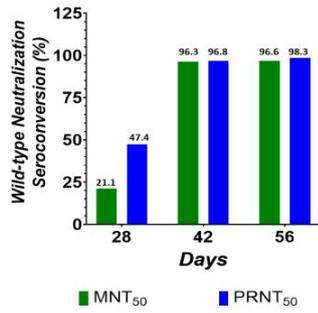
- 78% Overall Efficacy in Phase-3 Interim Analysis in India
- 100% in severe COVID-19 disease
- US EUA Pathway in Development (Master File Submitted)
- Initial US Supply from Partner, BBIL, upon receiving EUA
- Execute Tech Transfer to US Sites
- Target 100M Doses/Year Starting 2021

Phase 2: Study Results

- **6 μ g + Algel-IMDG** demonstrated high neutralizing Abs responses **compared to 3 μ g + Algel-IMDG group**
- Mean GMT (95% CI) **higher than human convalescent serum (HCS)**
- 6 μ g + Algel-IMDG (**Covaxin™**) selected for Phase 3 study



Phase 2: Study Results



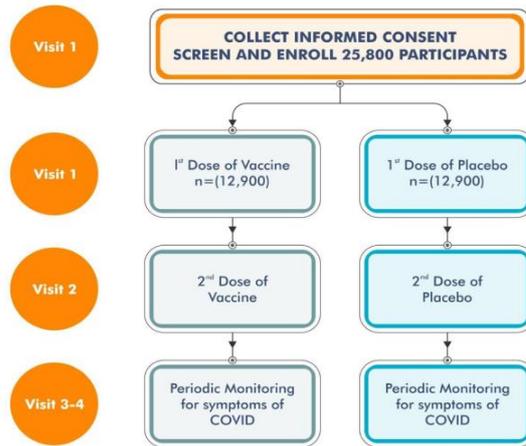
Safety

Events	Rate (%)	CI
Local	4.2% (1.8, 8.1)	95%
Systemic	7.4% (4.1, 12.1)	95%
Serious	0%	
Combined	10.3% (7.4, 13.8)	95%

- High Seroconversion rates (>96%) in both MNT50 and PRNT50 measured up to day 56
- Induction of Th1 cell mediated immunity as measured by IFN- γ , IL-2, TNF- α

- No vaccine-related severe or life-threatening adverse events reported to date

Phase 3: Study Outline



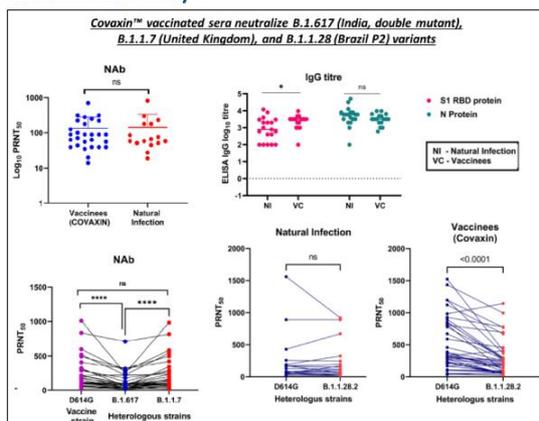
Phase 3: Efficacy - Second Interim Analysis

- Phase 3 clinical trial enrolled 25,800 participants including
 - 2,433 in the age group 60 to 98
 - 4,500 with comorbidities
 - First interim analysis at 43 cases
- Phase 1/2 enrolled 755 participants 12+ years of age



Effective Against at least 3 Key Variants

- COVAXIN-vaccinated sera effectively neutralized several SARS-CoV-2 variants in an in-vitro plaque reduction neutralization assay



✓ [B.1.617 \(India - double mutant\)](#)

✓ [B.1.1.7 \(United Kingdom\)](#)

✓ [B.1.1.28 \(Brazil P2\)](#)

- The study was conducted by Indian Council of Medical Research (ICMR)-National Institute of Virology
- These studies suggest that COVAXIN vaccination may be effective against multiple SARS-CoV-2 variants.

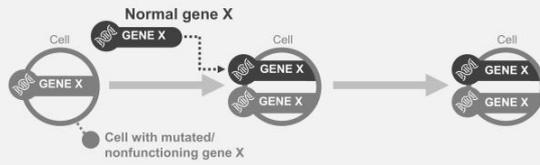
Ocugen's Modifier Gene Therapy Platform

Breakthrough Technology Designed to

**Address Multiple Diseases with One Product
Approach Complex Diseases Through Multiple Factors**

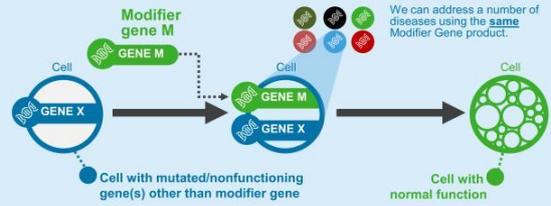
Traditional Approach vs. Ocugen's Novel Platform

Gene Augmentation: Transfer functional version of a non-functional gene into the target cells.



- ✓ Traditional approach that targets one individual gene mutation at a time
- ✓ Regulatory pathway focused on specific product for one disease
- ✓ Longer time to recoup development costs

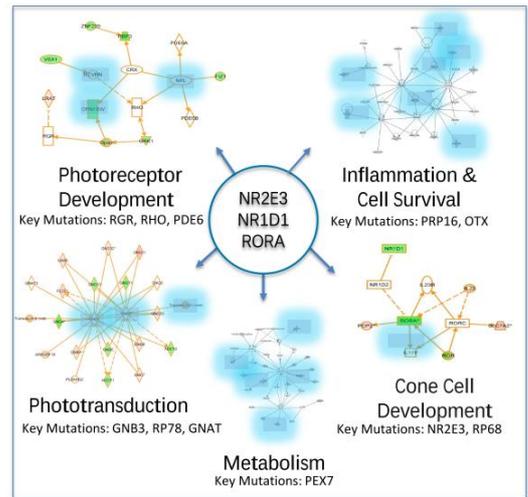
Modifier Gene Therapy: Introduce a functional gene to modify the expression of many genes, gene-networks and regulate basic biological processes in retina



- ✓ Novel approach that targets nuclear hormone genes (NHRs), which regulate multiple functions within the retina
- ✓ Smoother regulatory pathway due to ability to target multiple diseases with one product
- ✓ Ability to recoup development costs over multiple therapeutic indications

Why Target Nuclear Hormone Receptor Genes (NHRs)?

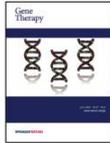
- Modulators of retinal development & function
- Act as “master genes” in the retina
- Molecular reset of key transcription factors and associated gene networks – retinal homeostasis
- Gene modifier concept including impact on clinical phenotypes is well known in other disease areas, CF and SMA *



Nature Gene Therapy Publication

Preclinical POC Data for *Nr2e3* Published in *Nature Gene Therapy*

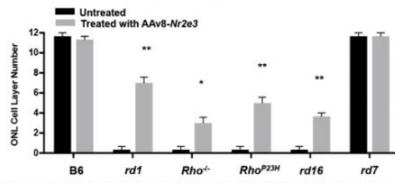
- Efficacy results shown in 5 unique mouse models of RP
- Technology developed at Harvard Medical School, Dr. Neena Haider's Lab
- Study demonstrates potency of modifier gene therapy to elicit broad-spectrum therapeutic benefits in early and advanced stages of RP
- Results show evidence of vision rescue 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 therapy and to provide rescue even after disease onset

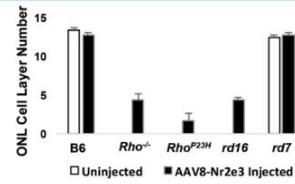
OCU400 – Rescue in Early & Advanced Stage of Disease

Early Stage Rescue



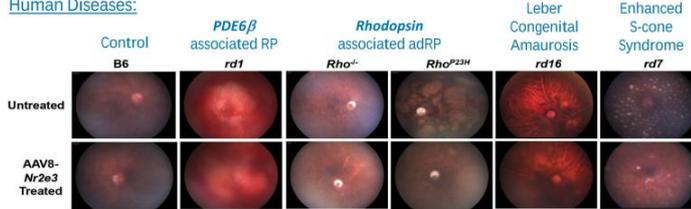
- P0 single subretinal injection, evaluation 3-4 months post injection
 - *rd1* evaluated one-month post injection
- ONL: Outer Nuclear Layer

Advanced Stage Rescue



- P21 subretinal injection, evaluation 2-3 months post injection
- Restored ONL photoreceptors morphology in *rd7*
- ONL cell layer change in *rd7* model doesn't progress until 4-5 mos. of age

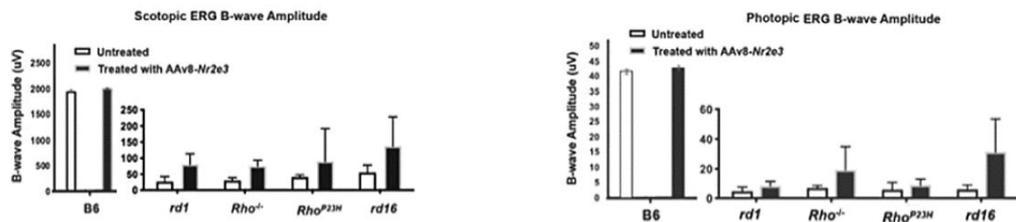
Human Diseases:



- Fundus images and ONL count show how single product rescues vision in multiple mutations

OCU400 – Demonstrates Improved Vision Signals in Retina

Electroretinogram (ERG) Response Reveals Rescue under Both Scotopic (dim-lit) as well as Photopic (well-lit) Conditions



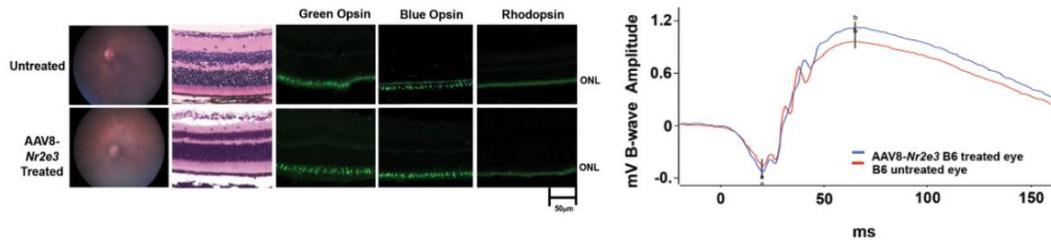
ERG response: P0 single subretinal injection, evaluation 3-4 months post injection

Human vision is enabled by three primary modes:

- Photopic vision: Vision under well-lit conditions, which provides for color perception and functions primarily due to cone cells in the eye
- Mesopic vision: A combination of photopic vision and scotopic vision in low lighting, which functions due to a combination of rod and cone cells in the eye
- Scotopic vision: Monochromatic vision in very low light, which functions primarily due to rod cells in the eye

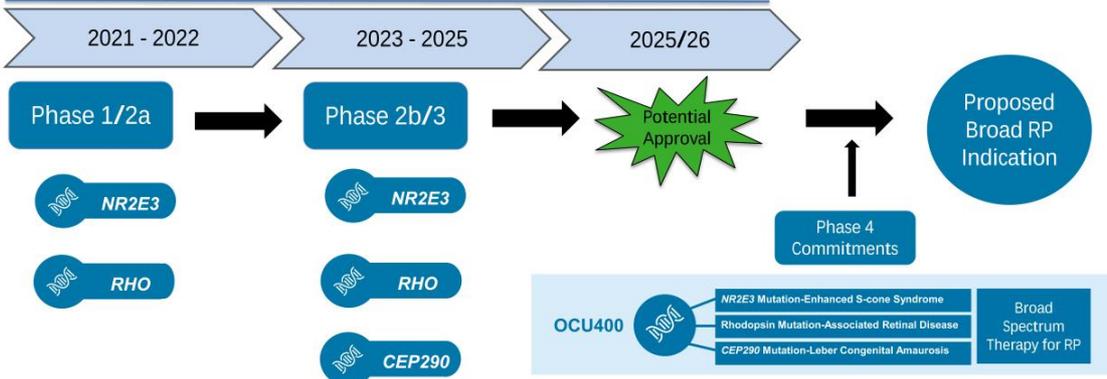
OCU400 – Demonstrated Safety in Mouse Model

Study Results Confirm Overexpression of *Nr2e3* by subretinal AAV8-*Nr2e3* Injection Is Not Detrimental to Retina – No Off-Target Effects



OCU400 – Clinical and Regulatory Strategy

Planned Timeline



- Successfully completed manufacturing at commercial scale (200L) at CanSinoBio to support clinical studies
- Preclinical tox studies in-progress
- On target to file IND in 2H21

OCU400 – Competitive Overview

Features	OCU400	Traditional Gene Therapy	Cell Therapy
			
One product for many IRDs (including broad RP indication)	✓	✗	Limited ✓
Technology established in the ocular disease space	✓	✓	✗
POC data in RP models with different genetic mutations	✓	✗	✗
Expected long-term outcome	Potentially longer benefit due to promotion of homeostasis	Potentially limited due to loss of retinal cells over time	Not established
Target Patient Population	Large	Small (specific to mutation)	Variable
Developmental cost	Low (economies of scale)	High (No economies of scale)	High



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Potential Competitors pursuing treatment of RP with Traditional Gene Therapy



Potential Competitors pursuing treatment of RP with Cell Therapy



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

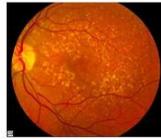
We Believe OCU410 Has the Potential to Address this Disease through its Multi-Factor Approach



Normal Retina

Dry AMD

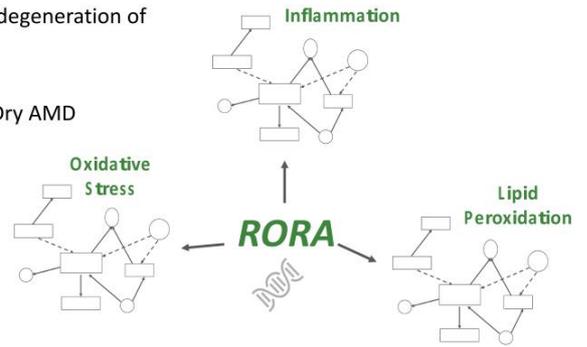
- Leads to irreversible blindness due to degeneration of the retina
- ~9-10M patients in the U.S.
- Currently no approved treatment for Dry AMD



Dry AMD

Contributing Factors

- Aging
- Genetics
- Environmental Factors



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References: <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/>



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OCU200:

Diabetic Macular Edema (DME)

Diabetic Retinopathy (DR)

Wet Age-Related Macular Degeneration (Wet AMD)

Novel Biologic Offering Benefits Beyond Anti-VEGF

OCU200 – Potential to Treat DME, DR & Wet AMD

OCU200 Provides Hope to All patients with DME, DR or Wet AMD

DME → ~0.7M patients in the US*
DR → ~7.7M patients in the US*
Wet AMD → ~1.1M patients in the US*

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

- OCU200 is a Transferrin-Tumstatin Fusion Protein
 - Tumstatin: Multiple MOAs for treatment and prevention of macular degeneration 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
- Significant global market potential



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



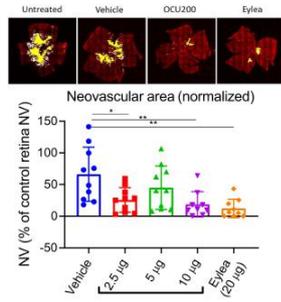
31

OCU200 –Transferrin-Tumstatin Fusion Protein

OCU200 Demonstrated Superior Efficacy Compared to Existing Anti-VEGF Therapies

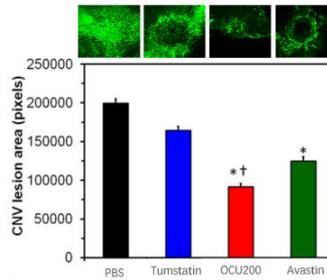
- Inhibits new blood vessel formation
- Anti-inflammatory
- Anti-oxidative

DME/DR
Oxygen-Induced Retinopathy (OIR) Mouse Model



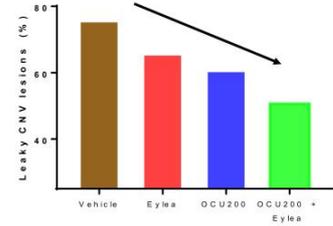
Effect of OCU200 intravitreal treatments on Neovascularization (NV). Data are presented as means SD. Filled circles represent data points from individual eyes
* P < 0.05, ** P < 0.01 (n = 9-10 eyes per group)

Wet AMD
In-Vivo Laser-Induced Rat CNV Model



* indicates p<0.05 when compared to PBS and/or tumstatin treatment
† indicates p<0.05 when compared to Avastin; CNV lesions measured on day 14 after treatment

Wet AMD
In-Vivo Laser-Induced Mouse CNV Model



Data expressed as percentage of CNV lesions on Day 10 after treatment. Laser induction & treatment start on Day 0

OCU200 – Distinct Mechanism of Action

We believe OCU200 has the potential to become a disease modifying therapeutic for broader patient population

Features	OCU200	Anti-VEGF	Anti-Integrin
		   KODIAK	 
Reduces VEGF level/Fluid	✓	✓	✓
Selectively works on active endothelial cells (Neovascular)	✓	✗	✓
Activates native anti-angiogenic response	✓	✗	✓
Enhanced effective delivery through Transferrin	✓	✗	✗
Pro-apoptotic and anti-oxidative	✓	✗	✓
Dosing Frequency	Expected once in 3 months	1-3 months	1-3 months



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Potential Competitors pursuing treatment using Anti-VEGF approach



Potential Competitors pursuing treatment using Anti-Integrin approach

(1) Approved

Key Inflection Points

- COVAXIN™ - Vaccine candidate for the US market with potential for significant revenues this year
- Ophthalmology
 - Modifier Gene Therapy Platform has the potential for one product to treat many diseases
 - Novel biologic has the potential to treat anti-VEGF /corticosteroids non-responders (~50% of the patients)
 - Multiple near and mid-term milestones with plan to initiate four Phase 1/2 trials over next 18 months

A Bold Vision to Cure
Blindness Diseases
and
Offer a Differentiated
Vaccine to Save Lives from
COVID-19

For more information, contact:

IR@ocugen.com



