
**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): **September 8, 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 September 8, 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 exhibits are being filed herewith:

(d) Exhibits

<u>Exhibit No.</u>	<u>Document</u>
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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 8, 2021

OCUGEN, INC.

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



Taking Science to New Heights for Patients

September 2021
NASDAQ: OCGN

Forward Looking Statement



This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform 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," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such forward-looking statements include information about qualitative assessments of available data, potential benefits, expectations for clinical trials, and anticipated timing of clinical trial readouts and regulatory submissions. This information involves risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, including the risk that such dates are not met due to impacts from the ongoing COVID-19 pandemic, as well as risks associated with preliminary and interim data, including the possibility of unfavorable new clinical trial data and further analyses of existing clinical trial data; the risk that the results of in-vitro studies will not be duplicated in human clinical trials; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when data from Bharat Biotech's clinical trials will be published in scientific journal publications and, if so, when and with what modifications; whether we will be able to provide the U.S. Food and Drug Administration ("FDA") with sufficient additional information regarding the design of and results from preclinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India in order for those trials to support a Biologics License Application ("BLA"); the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to support a BLA; any additional chemistry, manufacturing, and controls information that we may be required to submit; the timing of our BLA filing; whether and when a BLA for COVAXIN™ will be submitted to the FDA; whether and when a BLA may be approved by the FDA, an application for authorization under the Interim Order for emergency use may be approved by Health Canada, or a New Drug Submission application may be approved by Health Canada, which authorizations or approvals will depend on myriad factors, including making a determination as to whether the vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate's efficacy and, if authorized or approved, whether it will be commercially successful; whether developments with respect to the COVID-19 pandemic will affect the regulatory pathway available for vaccines in the United States, Canada, or other jurisdictions; manufacturing capabilities, manufacturing capacity, and supply restrictions, including whether sufficient doses of COVAXIN™ can be manufactured or supplied within our projected time periods; market demand for COVAXIN™ in the United States or Canada; decisions by the FDA or Health Canada impacting labeling, manufacturing processes, safety, and/or other matters that could affect the availability or commercial potential of COVAXIN™ in the United States or Canada, including development of products or therapies by other companies. 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. 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 presentation whether as a result of new information, future events, or otherwise, after the date of this presentation.

Ocugen: A Diversified Portfolio Designed to Serve Unmet Needs



Vaccine development with an investigational COVID-19 vaccine candidate currently being reviewed by Health Canada. Discussions with US FDA ongoing

Modifier gene therapies designed to cure multiple rare and broad diseases with one product. Clinical trials anticipated to commence phased launches starting in Q4 2021 and into 2022

Novel biologic treatment targeting diabetic macular edema, diabetic retinopathy, and wet age-related macular degeneration

An integrated capability to bring innovations to the market

Research | Clinical development
| Supply Chain | Medical |
Regulatory | Commercial

Strong balance sheet to support all programs



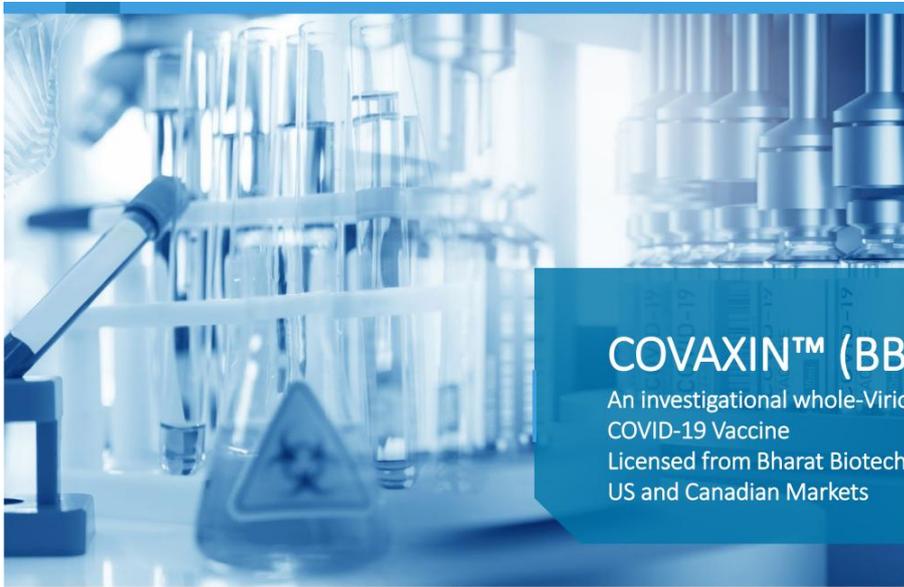
Pipeline and Regulatory Overview

	Asset/Program	Indication	Phase	Notes
Vaccine	COVAXIN™ (BBV152) Whole-Virion Inactivated Vaccine	COVID-19	Phase 3*	Rolling submission with Health Canada completed (July 2021) Discussions with FDA ongoing
Modifier Gene Therapy Platform	OCU400 AAV-hNR2E3	Gene mutation-associated retinal degeneration**		
		<i>NR2E3 Mutation</i>	IND Enabling	Orphan designation in the US
		<i>RHO Mutation</i>	IND Enabling	Broad orphan medicinal product designation in the EU for the treatment of both retinitis pigmentosa (RP) and Leber Congenital amaurosis (LCA)
		<i>CEP290 Mutation</i>	IND Enabling	
	<i>PDE6B Mutation</i>	IND Enabling		
OCU410 AAV-hRORA	Dry Age-Related Macular Degeneration (Dry AMD)	Preclinical		
Novel Biologic	OCU200 Transferrin – Tumstatin	Diabetic Macular Edema	Preclinical	
		Diabetic Retinopathy	Preclinical	
		Wet Age-Related Macular Degeneration (Wet AMD)	Preclinical	

*Bharat Biotech-sponsored clinical trial

** No approved therapies exist
<https://www.aao.org/eye-health/diseases/retinitis-pigmentosa-treatment> | <https://www.aao.org/eye-health/diseases/damd-treatment>





COVAXIN™ (BBV152)

An investigational whole-Virion Inactivated
COVID-19 Vaccine
Licensed from Bharat Biotech (BBIL) for the
US and Canadian Markets

Forward Momentum for COVAXIN™ (BBV152)



01

Published phase 3 clinical trial suggests demonstration of efficacy against COVID-19 and variants of concern and interest



02

Rolling submission to Health Canada completed; Bharat Biotech submission to the World Health Organization (WHO) under review; Discussions with FDA ongoing



03

Manufacturing partner selected; Tech transfer from Bharat Biotech in progress; Targeting 100M doses/year

Product Profile

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



Proposed indication

Prevention of COVID-19 caused by SARS-CoV-2



Target population

18 years of age and older



Dose Level and Regimen

0.5mL per dose suspension 2 Doses: Day 0 & Day 28



Presentation

Ten doses per vial



Expected Shelf Life

Approximately two years at 2°- 8°C and three months at room temp (25°C)



Why COVAXIN™ (BBV152)?

Designed to augment our North American arsenal of vaccines against COVID-19

DESIGNED FOR BROAD SPECTRUM IMMUNE RESPONSE 01

- Data suggest both humoral & cellular responses generated against multiple viral proteins
- Data support that the vaccine induces a Th1 response (cell-mediated immunity) which can be vital for durable protection

RESULTS AGAINST OVERALL, SEVERE AND DELTA VARIANT 02

- Only vaccine with Phase 3 clinical trial data suggesting broad protection against variants of concern

KNOWN SAFETY PROFILE 03

- Phase 3 adverse event profile similar to placebo
- Technology platform used to produce Polio, Influenza and Rabies vaccines

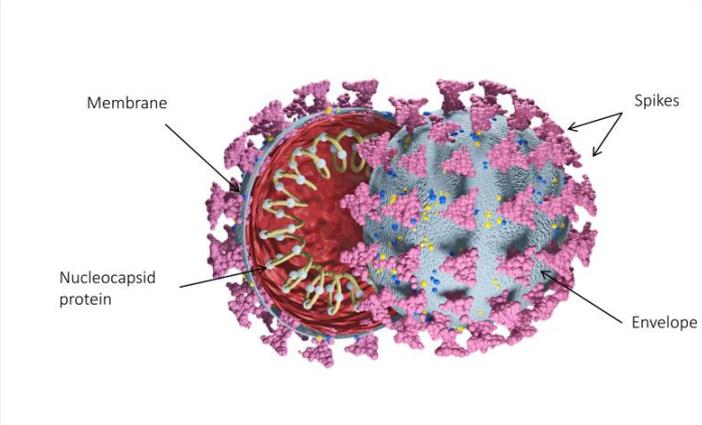
TRANSPORTATION AND STORAGE EASE 04

- 10 dose vial that can be stored and shipped at 2°-8° C, with a 2-year shelf life and 3-month stability at room temperature



Image for illustrative purposes only

Why COVAXIN™ (BBV152)? Broad Spectrum Response



Membrane

Spikes

Nucleocapsid protein

Envelope

Research suggests COVAXIN™ elicits a strong IgG responses against spike protein, receptor-binding domain, and the nucleocapsid protein of SARS-CoV-2 along with strong cellular responses

Current mRNA and adenovirus-based vaccines only elicit responses against the spike protein

Why COVAXIN™ (BBV152)? The Only Investigational COVID-19 Vaccine with Clinical Results Against Delta Variant



Source: Efficacy, safety, and lot to lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): a double-blind, randomised, controlled phase 3 trial; Elio, Reddy, Blackwelder, Patidar, et al.; [medRxiv 2021.06.30.21259439](https://doi.org/10.1016/S0140-6736(21)00443-9); accessed July 7, 2021



Summary of Efficacy and Safety Results from Phase 3 Clinical Trial

Parameter	Cases			Vaccine efficacy (95% CI)
	BBV152	Placebo	Total	
Symptomatic	24	106	130	77.8% (65.2 – 86.4)
Severe	1	15	16	93.4% (57.1 – 99.8)
Asymptomatic	13	33	46	63.6% (29.0 – 82.4)

Adverse Events	BBV152 (n=12879)		Placebo (n=12874)		Total (n=25753)	
	m	n (%)	m	n (%)	m	n (%)
All adverse events	2930	1597 (12.40)	3029	1597 (12.41)	5959	3194 (12.40)
Unsolicited adverse events	981	489 (3.80)	1309	609 (4.73)	2290	1098 (4.26)
All serious adverse events	40	39 (0.30)	66	60 (0.47)	106	99 (0.38)

1

Primary endpoint:
Preventing symptomatic COVID-19 occurring at least 14 days after second dose

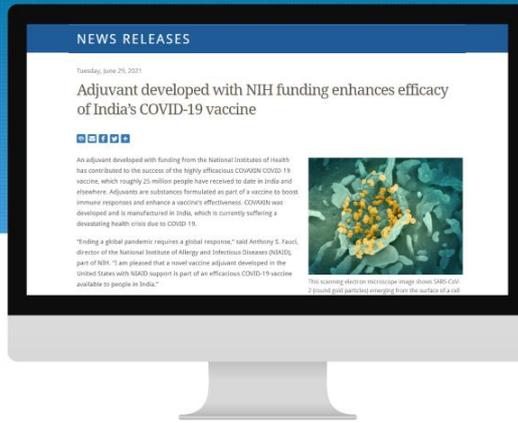
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Secondary endpoint:
Efficacy in subgroups based on age (18 – 59 years; ≥60 years)

Source: Efficacy, safety, and lot to lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): a double-blind, randomised, controlled phase 3 trial; Elio, Reddy, Blackwelder, Potdar, et al.; medRxiv 2021.06.30.21259439; accessed July 7, 2021



The Role of the Adjuvant in COVAXIN™ (BBV152)



Source: National Institutes of Health; June 29, 2021. <https://www.nih.gov/news-events/news-releases/adjuvant-developed-nih-funding-enhances-efficacy-indias-covid-19-vaccine>; accessed July 12, 2021



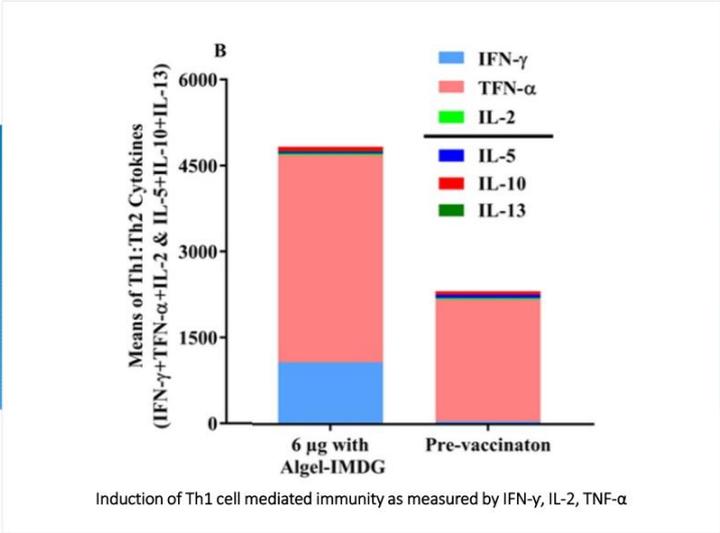
Expert commentary suggests adjuvant provides additional enhancement to elicit immune responses supporting broad protection

Adjuvatisation helps to optimise COVID-19 vaccine candidate

Overall, Algel-IMDG-adjuncted BBV152 was safe, immunogenic, and able to induce Th1-biased T-cell responses, and could therefore be a potentially superior vaccine over the alum-adjuncted inactivated COVID-19 vaccines.

Source: Adjuvatisation helps to optimize COVID-19 vaccine candidate; Jing Xin, L. Feng Cai, Z. Lancet Infect Dis 2021; Published Online March 8, 2021; [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00094-3/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00094-3/fulltext); accessed Sept 7, 2021

Data Suggest Th1 Mediated Response Boosted by Novel Adjuvant

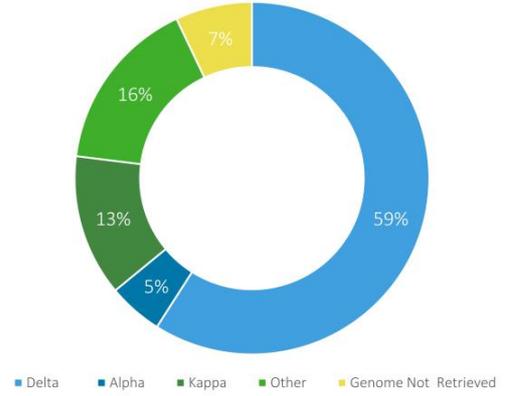
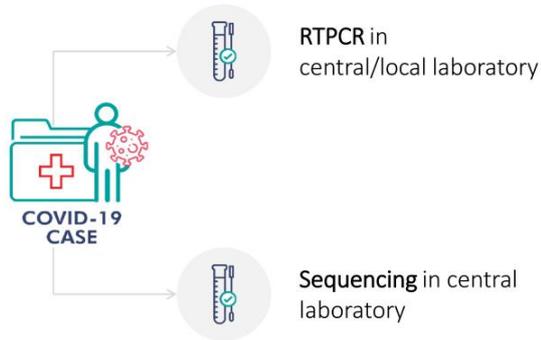


Source: *Lancet Infect Dis* 2021; 21: 950-61 Published Online March 8, 2021 [https://doi.org/10.1016/S1473-3099\(21\)00070-0](https://doi.org/10.1016/S1473-3099(21)00070-0)

COVAXIN™ (BBV152) Phase 3 Trial: 90% of Infections by Variants



Data on file



N=85 Swab Samples Genome Sequenced in Central Lab



COVAXIN™ (BBV152) Efficacy Against Variants in Phase 3 Trial

Variants (VOC/VOI)	Total number of cases n/N	BBV152 n/N	Placebo n/N	Vaccine efficacy % (CI)*
B.1.617.2 (Delta)	50/16973	13/8471	37/8502	65.2 (33.1 – 83.0)
B.1.617.1 (Kappa)	11/16973	1/8471	10/8502	90.1 (30.4 – 99.8)
B.1.1.7 (Alpha)	4/16973	1/8471	3/8502	--
Other	14/16973	3/8471	11/8502	73.0 (-2.2 – 95.2)
Completed genome not retrieved	6/16973	0/8471	6/8502	--
All variant related severe COVID-19	4/16973	0/8471	4/8502	--

Data include per protocol population only. Efficacy estimates were only reported for at least 10 symptomatic cases. In those participants who met the definition for symptomatic COVID-19 and were PCR positive an additional nasopharyngeal swab for genotyping was collected. Other pangolin lineages detected include D614G (n=7), B.1.36 (n = 3), B.1.1.419 (n = 1), B. 1.153 (n = 1), B. 1.351 and B.1.618 (n = 1 each in placebo). The > 1 lower bound of 95%CI for mean ratio indicates a statistical significance. In breakthrough symptomatic Delta variant infections, the viral load in the vaccine arm was significantly lower than the placebo arm.



Source: *Lancet Infect Dis* 2021; 21: 950–61 Published Online March 8, 2021 [https://doi.org/10.1016/S1473-3099\(21\)00070-0](https://doi.org/10.1016/S1473-3099(21)00070-0)

COVAXIN™ (BBV152) May Help Reduce *Transmission Rate* from Breakthrough Infections



~150-fold reduction in viral load in nasopharyngeal swabs of COVAXIN™ vaccinated individual compared to placebo



Similar virus nasopharyngeal swabs load in unvaccinated or Pfizer- or Moderna-vaccinated

Ct values	All cases	BBV152	Placebo mean	Mean ratio of BBV152/ Placebo (95% CI)
B.1.617.2 (Delta) – E gene	20.11	25.55	18.20	1.42 (1.28, 1.57)
B.1.617.2 (Delta) – ORF gene	22.97	28.29	21.09	1.35 (1.24, 1.46)

Source: Efficacy, safety, and lot to lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): a double-blind, randomised, controlled phase 3 trial; Ella, Reddy, Blackwelder, Potdar, et al. <https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v1> | <https://www.medrxiv.org/content/10.1101/2021.08.18.2126237v1>



Extensive Publication Portfolio of the COVAXIN™ (BBV152) Clinical Development Journey



Publications found at ocugen.com





MODIFIER GENE THERAPY PLATFORM

Breakthrough Technology Designed to Address Multiple
Diseases with One Product and Approach Complex Diseases
Through Multiple Factors

Forward Momentum for OCU400



01

Successfully completed manufacturing at commercial scale (200L) at CanSinoBio to support clinical studies



02

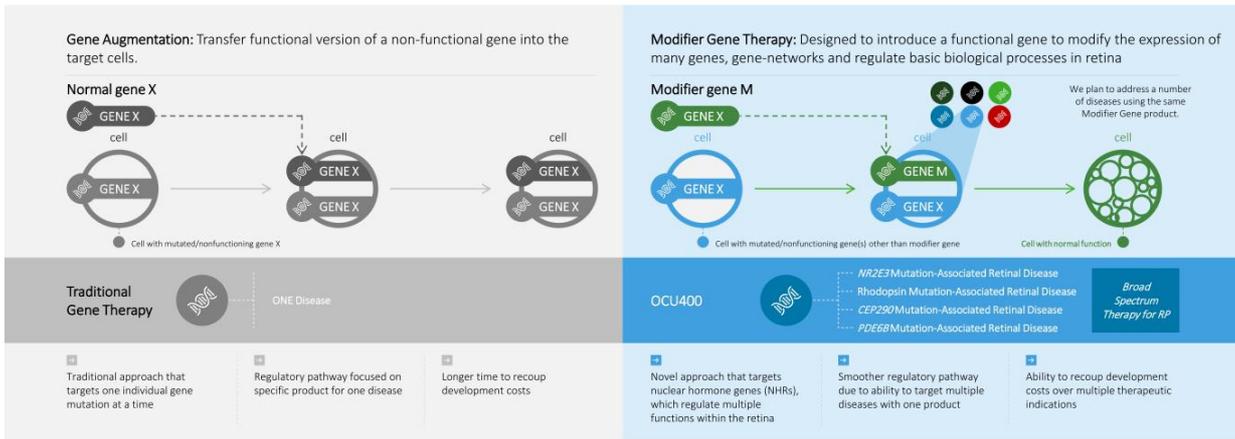
Preclinical tox studies in-progress



03

On target to file IND in 2H21 and launch Phase 1/2a clinical trials within Q4 2021

Our Vision: Modifier Gene Therapy vs Traditional Gene Augmentation



OCU400's target: Nuclear Hormone Receptor Genes (NHRs)

WHY?



NHRs are modulators of retinal development & function, acting as "master genes" in the retina



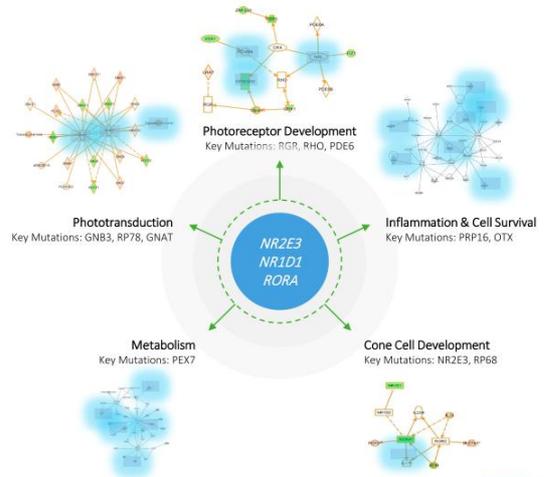
Molecular reset of key transcription factors and associated gene networks – retinal homeostasis



Gene modifier concept including, its impact on clinical phenotypes, is well known in other disease areas, such as cystic fibrosis and spinal muscular atrophy

*References:

<https://pubmed.ncbi.nlm.nih.gov/28556246/> | <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5409218/>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4339951/> | <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0183326>



Our Proof of Principle: 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 suggests potency of modifier gene therapy to elicit broad-spectrum therapeutic benefits in early and advanced stages of RP
- Results suggest evidence of vision rescue in Early & Advanced Stages of disease



Important milestone for development of therapy; demonstrated proof of principle



Protection elicited in multiple animal models of degeneration caused by different mutations

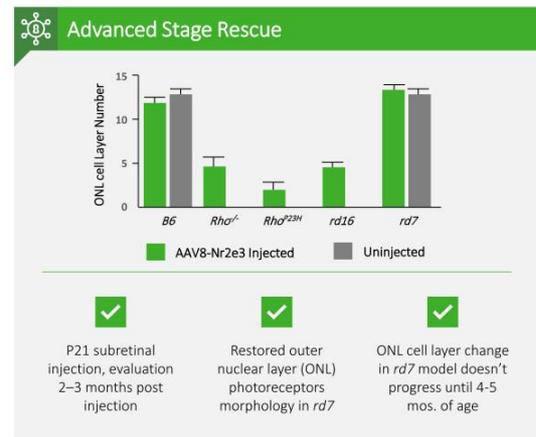
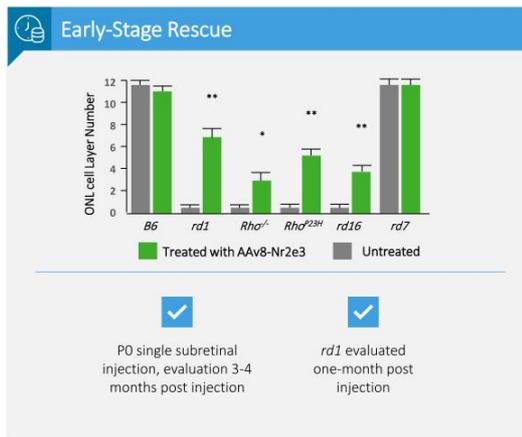


Potential to represent first broad-spectrum therapy and to provide rescue even after disease onset

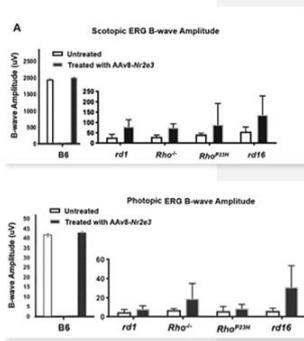
natureresearch

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

Data Show How OCU400 Stops Disease Progression and Rescues Vision in Both Early and Advanced Stages



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

How these data matter:

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

Scotopic vision

Monochromatic vision in very low light, which functions primarily due to rod cells in the eye

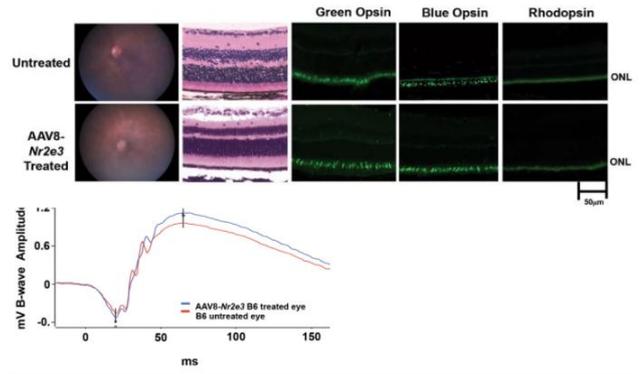
Mesopic vision

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

OCU400 Demonstrated Safety in Mouse Model



Study results confirm overexpression of *Nr2e3* by subretinal AAV8-*Nr2e3* injection is not detrimental to retina creating no off-target effects



nature research

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

OCU400 – Clinical and Regulatory Strategy

Planned timeline



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

 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



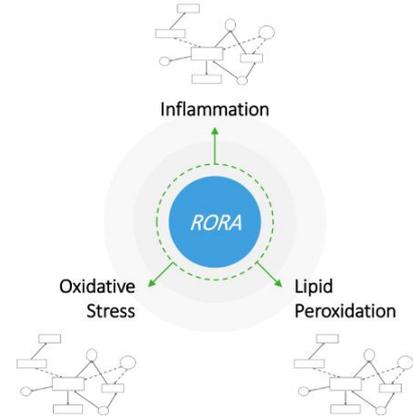
Dry AMD

Dry AMD

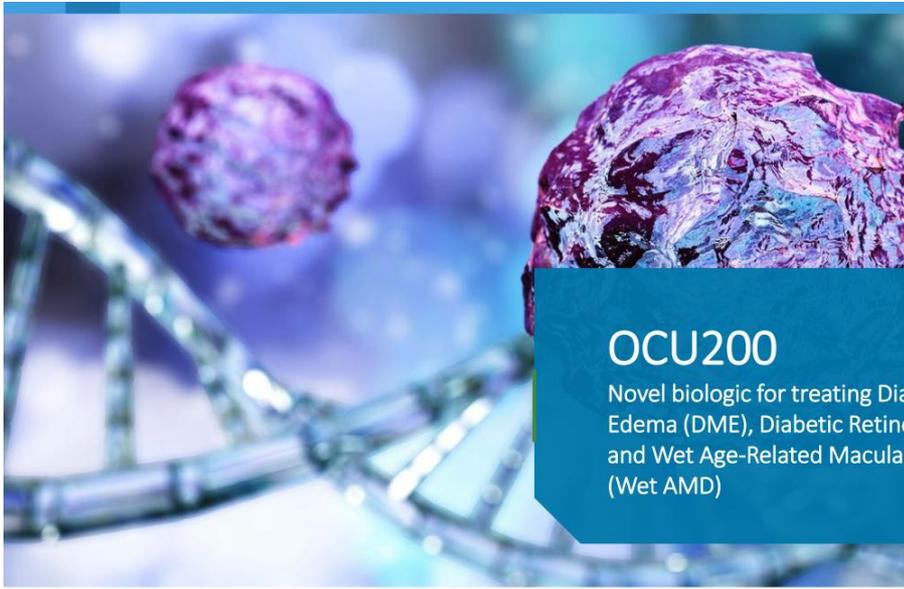
- Leads to irreversible blindness due to degeneration of the retina
- ~9-10M patients in the U.S.
- Currently no approved treatment for Dry AMD

Contributing Factors

- Aging
- Genetics
- Environmental Factors



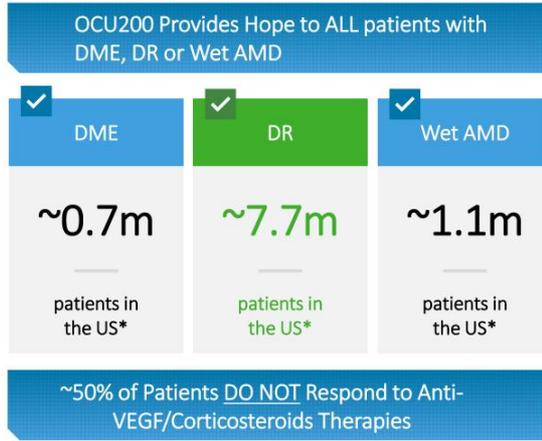
References
<https://www.brightfocus.org/macular/article/age-related-macular-facts-figures>
<https://www.uniprot.org/uniprot/P35398#function>
<https://pubmed.ncbi.nlm.nih.gov/21998696/>
<https://pubmed.ncbi.nlm.nih.gov/19786043/>



OCU200

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

OCU200: Potential to Treat DME, DR & Wet AMD

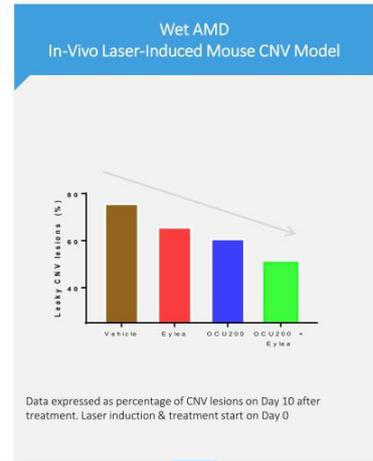
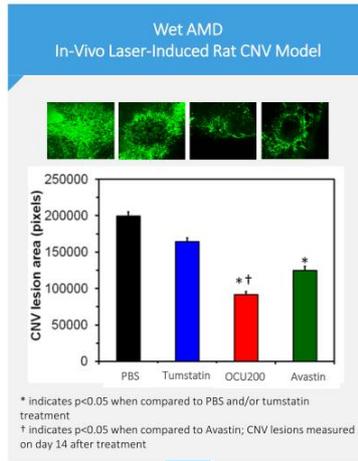
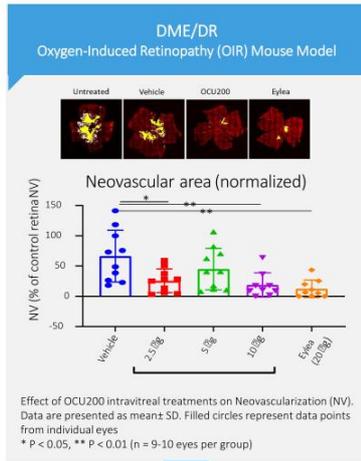


- ✓ OCU200 is a Transferrin-Tumstatin Fusion Protein
 - Tumstatin: Multiple MOAs for treatment and prevention of macular degeneration and neovascularization
 - Transferrin: Targets the site of action and improves uptake (better target engagement)
- ✓ Integrin Targeting provides hope to these patients 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



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

OCU200 Demonstrated Superior Efficacy Compared to Existing Anti-VEGF Therapies





Leadership and Scientific Advisors

Leadership Team



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



Sanjay Subramanian, MBA
CFO and Head of Corporate Development



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



J.P. Gabriel
SVP, Manufacturing & Supply Chain



Vijay Tammarra, PhD
SVP, Regulatory & Quality



Michael Shine, MBA
SVP, Commercial



Arun Upadhyay, PhD
VP, Head of Research & Development



Jessica Crespo, CPA
Corporate Controller and Treasurer



Zara Gaudio, SHRM-CP
Head of Human Resources

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



Forward Momentum for Ocugen

COVAXIN™ (BBV152)

- » Published phase 3 clinical trial suggests demonstration of efficacy against COVID-19 and variants of concern and interest
- » Rolling submission to Health Canada completed; Bharat Biotech submission to the World Health Organization (WHO) under review; Discussions with FDA ongoing
- » Manufacturing partner selected; Tech transfer from Bharat Biotech in progress; Targeting 100M doses/year

OCU400

- » 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 and launch Phase 1/2a clinical trials within Q4 2021



Taking Science to New Heights for Patients

September 2021
NASDAQ: OCGN

