### **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): November 15, 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)

D 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))

Se	curities registered pursuant to Section 12(b) of the Ac	t:
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  $\Box$ 

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.  $\Box$ 

#### Item 8.01 Other Events.

Attached as Exhibit 99.1 hereto and incorporated herein by reference is a presentation that Ocugen, Inc. will post on its website on November 15, 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

Exhibit No.

99.1
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Document
Ocugen, Inc. Presentation.
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: November 15, 2021

OCUGEN, INC.

By: /s

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

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# 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," "belivers," "potential," "proposed," "continue," "estimates," "anticipates," "expects, ""plans," "Intends," "may," "acuuld, "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 submission. 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 include information 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 prosibility 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 will be published in scientific journal publications and there and when data from Bhard Biotech's clinical trial so will be published in scientific journal publications and the bear onducted by Bhart Biotech in India, will be accepted by the U.S. food and Drug Administration ("FDA") or otherwise sufficient to support our Emergency Use Autorization ("FUA") or Investigational New Submits dational information to the FDA in support of our IND submissions, the extent and significance of any such changes; the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to su

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### Ocugen: A Diversified Portfolio Designed to Serve Unmet Needs



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Vaccine development with a COVID-19 vaccine candidate.

Modifier gene therapies designed to cure multiple rare and broad diseases with one product.

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 | Manufacturing | Medical | Regulatory | Commercial

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Strong balance sheet

## Pipeline Overview

	Asset/Program	Maindication	
Vaccine	COVAXIN™ (BBV152) Whole-Virion Inactivated Vaccine	COVID-19	Adult-Phase 3* Peds-Phase 2/3*
		Gene mutation-associated retinal degeneration**	
		NR2E3 Mutation	IND Enabling
Modifier Gene	OCU400 *** AAV-hNR2E3	RHO Mutation	IND Enabling
Therapy Platform		CEP290 Mutation	IND Enabling
		PDE6B Mutation	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

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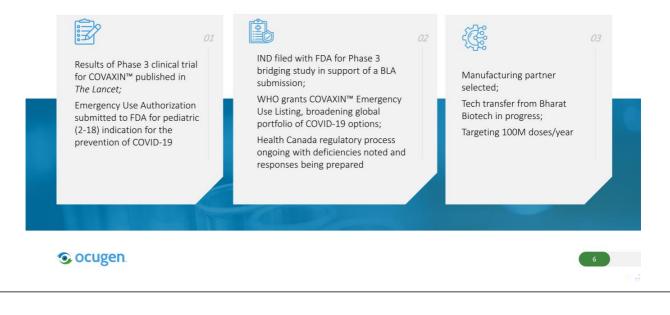
\*\* No approved therapies exist
 https://www.aao.org/eve-health/diseases/amd-treatment
 https://www.aao.org/eve-health/diseases/amd-treatment
 \*\*\* Orphan designation in the US
 Broad orphan medicinal product designation in the EU for the treatment of both retinitis pigmentosa (RP) and Leber Congenital amaurosis (LCA)

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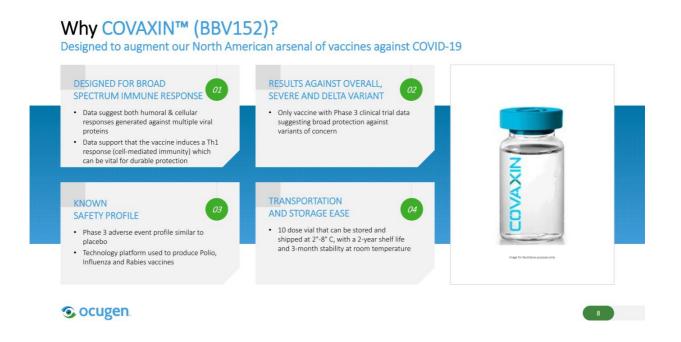
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### Forward Momentum for COVAXIN<sup>™</sup> (BBV152)

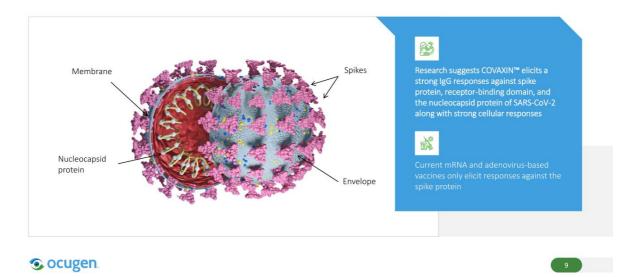


## Product Profile

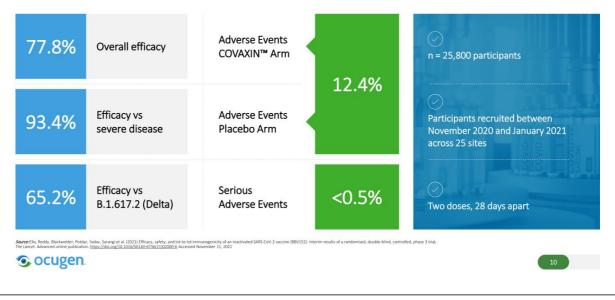
Whole virion inactivated SARS-Cc concentration & Adjuvant: 6µg +		
		AXIII AXIII
Proposed indication	Target population	6
Prevention of COVID-19 caused by SARS-CoV-2	Pediatric: 2-18 years of age Adult: 18 years of age and older	Imper for Australian surgeous only
_@		<b>(</b>
Dose Level and Regimen	Presentation	Potential Shelf Life
0.5mL per dose suspension 2 Doses: Day 0 & Day 28	Ten doses per vial	Approximately two years at 2°- 8°C and three months at room temp (25°C)



## Why COVAXIN™ (BBV152)? Broad Spectrum Response



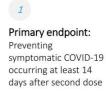
# Why COVAXIN™ (BBV152)? The Only COVID-19 Vaccine Candidate with Clinical Results Against Delta Variant



## Summary of Efficacy and Safety Results from Phase 3 Clinical Trial

Descentes		Vaccine efficacy		
Parameter	BBV152	Placebo	Total	(95% CI)
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)





Secondary endpoint: Efficacy in subgroups based on age (18 - 59)years;  $\geq 60$  years)

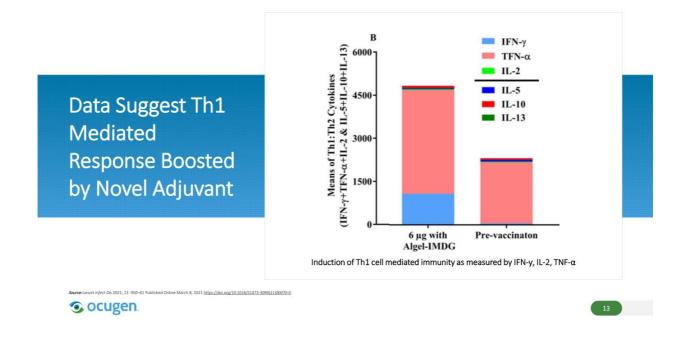
Source: Ela, Reddy, Blackwelder, Fotdar, Yadav, Sarangi et al. (2021) Efficacy, safety, and lot to-loi immunogenicity of an inactivated SARS CoV-2 vaccine (BBV152): interim results of a randomised, double-blind, controlled, phase 3 trial; The Loncet: Advanced online publication. <a href="https://doi.org/10.1016/S0140-573621102006-6">https://doi.org/10.1016/S0140-573621102006-6</a> Accessed November 11, 2021

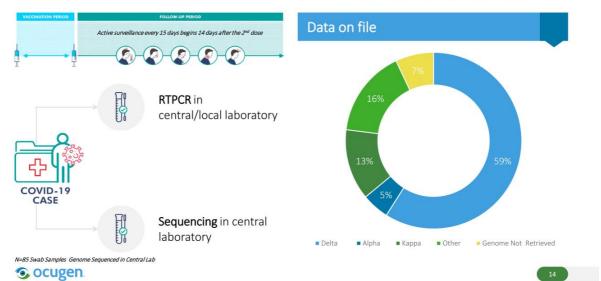




### The Role of the Adjuvant in COVAXIN<sup>™</sup> (BBV152)







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

## 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)	
В.1.617.1 (Карра)	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.1.1419 (n = 1), B. 1.353 (n = 1), B. 1.353 (n = 1), B. 1.153 (n = 1), B. 1.153 (n = 1), B. 1.353 (n = 1), B. 1.351 and B.1.518 (n = 1 cases). 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.

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



# COVAXIN<sup>™</sup> (BBV152) May Help Reduce *Transmission Rate* from Breakthrough Infections

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<u>~150-fold</u> 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-vaccinate

Ct values	All cases	BBV152	Placebo mean	Mean ratio of BBV152/ Placebo (95% Cl)
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:Ela, Redøy, Blackwelder, Potdar, Yudav, Sarangi et al. (2021) Efficacy, safety, and lot-to-lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): interim results of a randomised, double-blind, controlled, phase 3 trial; The Loncet: Advanced online publication. https://bioiorg/10.1016/S0149-073622102000-6 Accessed November 11, 2021

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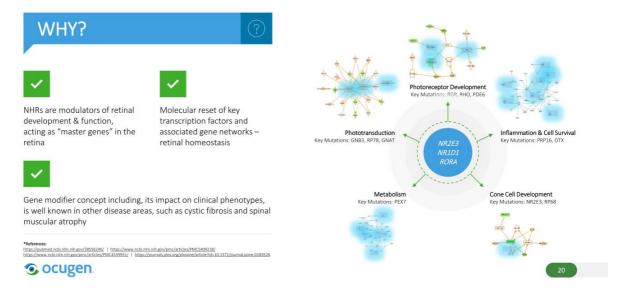




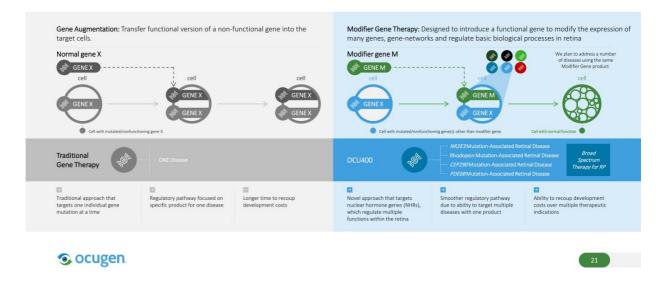
## Forward Momentum for OCU400/OCU410



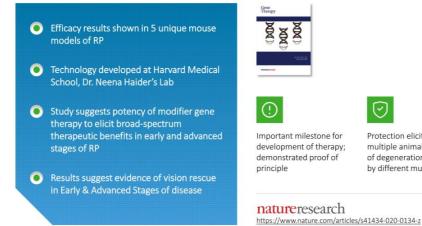
## Our Focus: Nuclear Hormone Receptor Genes (NHRs)



### Our Vision: Modifier Gene Therapy vs Traditional Gene Augmentation



### Our Proof of Principle: Published in Nature Gene Therapy



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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

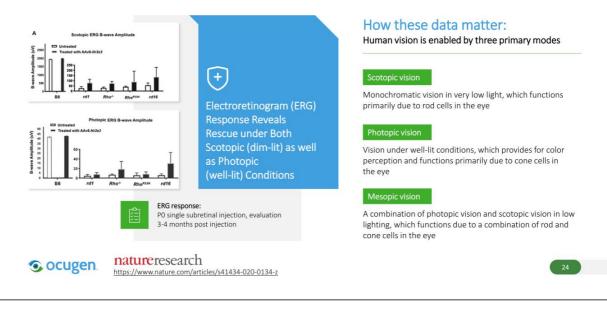
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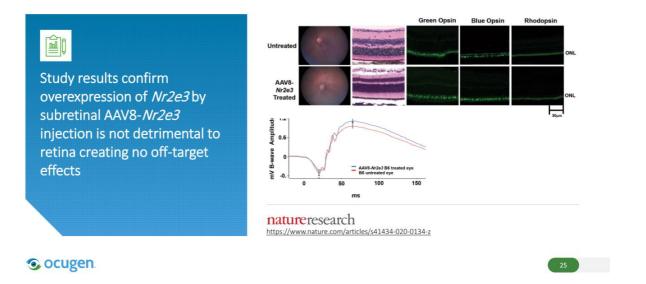
# Data Show How OCU400 Stops Disease Progression and Rescues Vision in Both Early and Advanced Stages

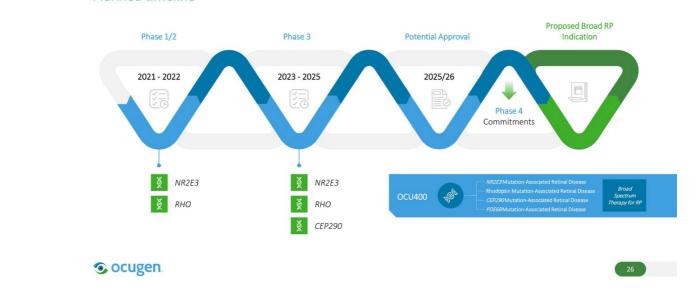


### OCU400 Demonstrates Improved Vision Signals in Retina



## OCU400 Demonstrated Safety in Mouse Model



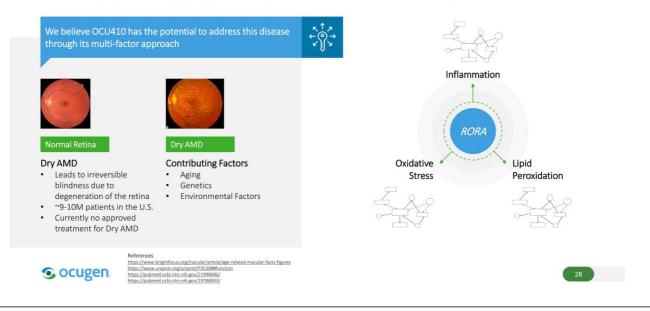


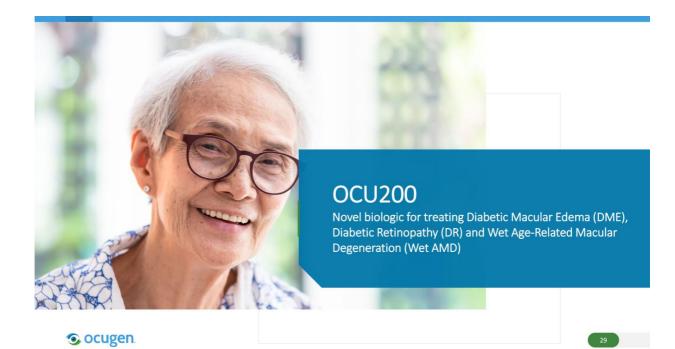
# OCU400 – Clinical and Regulatory Strategy Planned timeline

## OCU400 – Competitive Overview

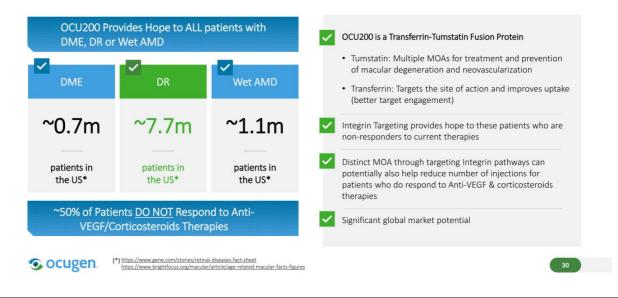
One product for many IRDs (including broad RP indication)       Image: Control of the	
(including broad RP indication)       Image: Constraint of the coular disease space       Image: Consten disease space       Image: Consten disease space	ReNeuron
disease space     Image: Constraint of the space       POC data in RP models with different genetic mutations     Image: Constraint of the space       Potentially longer benefit due to an example of the space     Potentially limited due to loss of retinal	mited
genetic mutations Potentially longer benefit due to Potentially limited due to loss of retinal	
Potentially longer benefit due to Potentially limited due to loss of retinal	
Expected long-term outcome promotion of homeostasis cells over time Not established	ed
Target Patient Population     Large     Small (specific to mutation)     Variable	
Developmental cost Low High (No economies of scale) High	

## OCU410 (AAV-RORA): Dry Age-Related Macular Degeneration

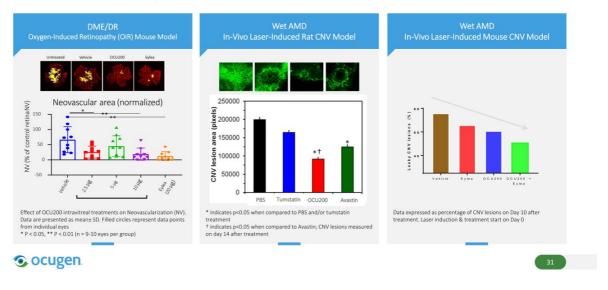




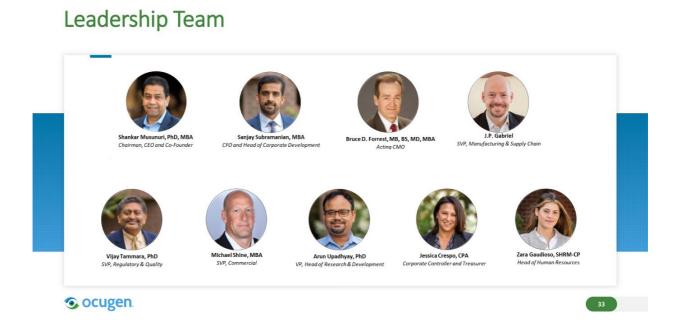
### OCU200: Potential to Treat DME, DR & Wet AMD



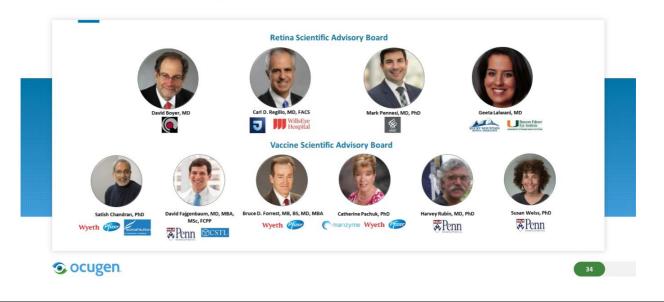
# OCU200 Demonstrated Superior Efficacy Compared to Existing Anti-VEGF Therapies







## Scientific Advisory Boards



## Forward Momentum for Ocugen

