#### **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): December 15, 2021

#### OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

**Delaware** (State or Other Jurisdiction of Incorporation)

 $\ \square$  Pre–commencement communications pursuant to Rule 13e–4(c) under the Exchange Act (17 CFR 240.13e–4(c))

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)

 $\ensuremath{\text{N/A}}$  (Former Name or Former Address, if Changed Since Last Report)

Che	k 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))

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 chapter).	Rule 405 of the Securities Act of 1933 (§230.405	5 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this
Emerging growth company $\square$		
If an emerging growth company, indicate by check mark if the registrant has elected not to u the Exchange Act. $\square$	ise the extended transition period for complying v	with any new or revised financial accounting standards provided pursuant to Section 13(a) of

#### 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 December 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.	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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 15, 2021

OCUGEN, INC.

By:

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



### 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," "roposed," "continue," "estimates," "anticipates," "aphs," "plans," "intend," "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 dates are not met due to impacts from the ongoing COVID-19 pandemic, as well as risks associated with preliminary and interim date, 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 will be published in scientific journal publications and, if so, when and with what modifications; whether the data and results from precinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India, will be accepted by the U.S. Food and Drug Administration ("FDA") or otherwise sufficient to support our Emergency Use Authorization



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



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

Strong balance sheet



## Pipeline Overview

	Asset/Program	Mark Indication	
Vaccine	COVAXIN™ (BBV152) Whole-Virion Inactivated Vaccine	COVID-19	Adult-Phase 3* Peds-Phase 2/3*
		Gene mutation-associated retinal degeneration**	
		NR2E3 Mutation	Phase 1/2
Modifier Gene Therapy Platform  OCU410 AAV-hRORA		RHO Mutation	Phase 1/2
	The second control of	CEP290 Mutation	
		PDE6B Mutation	To be submitted
	V-1-1-1-1-1-1-1	Dry Age-Related Macular Degeneration (Dry AMD)**	Preclinical
		Diabetic Macular Edema	Preclinical
Novel Biologic	OCU200 Transferrin – Tumstatin	Diabetic Retinopathy	Preclinical
	Had and a section of the section of	Wet Age-Related Macular Degeneration (Wet AMD)	Preclinical



\*\* No approved therapies exist <a href="https://www.aao.org/eye-health/diseases/ard-treatment">https://www.aao.org/eye-health/diseases/ard-treatment</a> the US Broad orphan medicinal product designation in the EU for the treatment of both retinitis pigmentosa (RP) and Leber Congenital amaurosis (LCA)



ocugen.

### Forward Momentum for COVAXIN™ (BBV152)







### **Product Profile**

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



Prevention of COVID-19 caused



Target population

Pediatric: 2-18 years of age
Adult: 18 years of age and olde





Dose Level and Regimen

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



Presentation

Ten doses per vial

Potential 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



- 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

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

#### RESULTS AGAINST OVERALL, SEVERE AND DELTA VARIANT



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

#### **TRANSPORTATION** AND STORAGE EASE



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



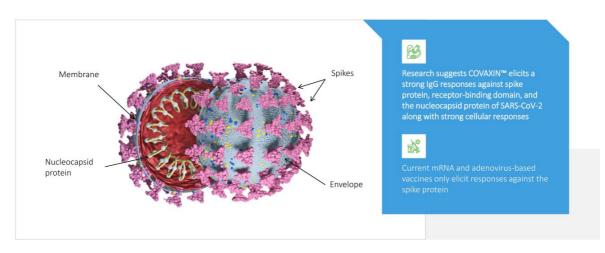


KNOWN

SAFETY PROFILE



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





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



Rounce Ella, Reddy, Blackwelder, Potdar, Yadav, Sarang et al. (2021) Efficacy, safety, and lot-to-lot immunogenicity of an circulated SARS-CoV-2 vaccine (BBV152): interim results of a randomised, double-blind, controlled, phase 3 trial, the content Advanced colline obalisation. https://doi.org/10.10.1016/3014-0576321730000-05. Accessed November 11. 2021





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

		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)



#### Primary endpoint:

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



#### Secondary endpoint:

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

Source: Ella, Reddy, Blackwelder, Potdar, Yadav, Sarangi et al. (2021) Efficacy, safety, and lot-to-lof immunogenicity of a raintwisted SARS-CoV-2 vaccine (BBV152): Interim results of a raindomised, double-blind, controlled, phase 3 tria-7 he forner. Advanced solline publication, https://doi.org/10.1016/S019-06-3621/S02000-06-Accessed November 11, 2021



### The Role of the Adjuvant in COVAXIN™ (BBV152)



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

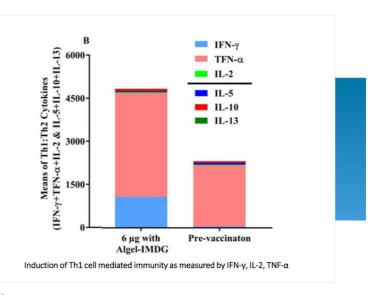
Adjuvantation helps to optimise COVID-19 vaccine candidate

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

Source: Adjuvantation 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/PIIS1473-3099/2100094-3/fulltest:-accessed Sent 7, 2021



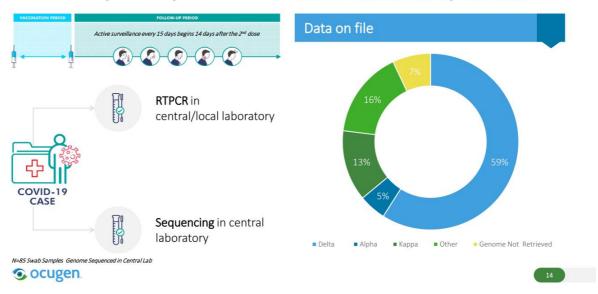
Data Suggest Th1 Mediated Response Boosted by Novel Adjuvant



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



### 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)
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	201
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), 8.1.36 (n = 3), 8.1.1419 (n = 1), 8.1.153 (n = 1), 8.1.351 and 8.1618 (n = 1 each in placebo, 1 he > 1 lower bound of 95%Cl 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.



ource: Lancet Infect Dis 2021; 21: 950–61 Published Online March 8, 2021 https://doi.org/10.1016/\$1473-3099(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

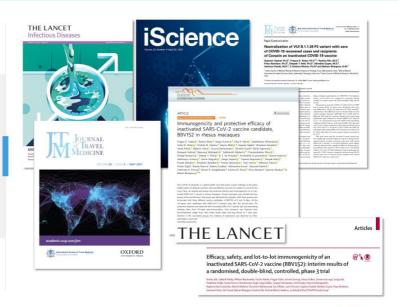
Similar virus nasopharyngeal swabs load in unvaccinated or Pfizer- or Moderna-vaccinated

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 Ella, Reddy, Blackwelder, Potdar, Yadav, 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 tria The Lancet. Advanced online publication. https://doi.org/10.1016/S0140-6736/21/202006\_6 Accessed November 11, 2021



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



Publications found at ocugen.com





### **MODIFIER GENE THERAPY PLATFORM**

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

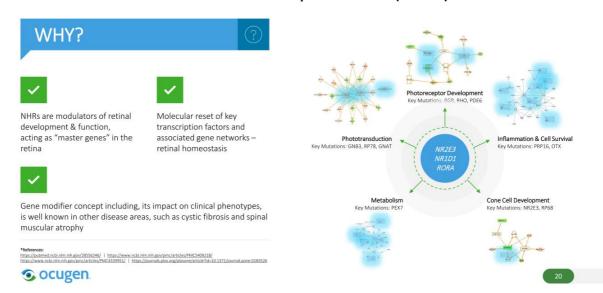


### Forward Momentum for OCU400/OCU410

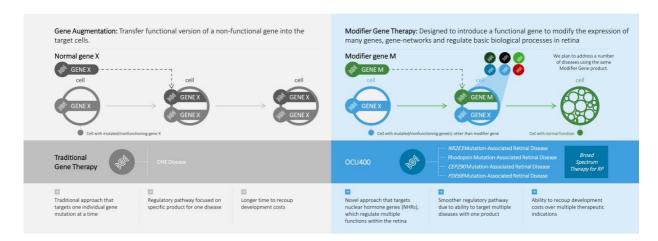




### Our Focus: Nuclear Hormone Receptor Genes (NHRs)



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





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

- 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









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

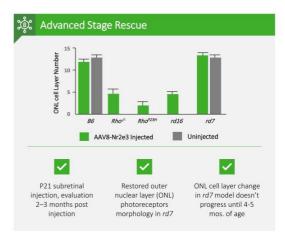
natureresearch

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

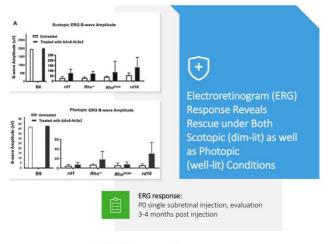








### OCU400 Demonstrates Improved Vision Signals in Retina



#### How these data matter:

Human vision is enabled by three primary modes

#### Scotopic vision

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

#### Photopic vision

Vision under well-lit conditions, which provides for color perception and functions primarily due to cone cells in the eve

#### 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

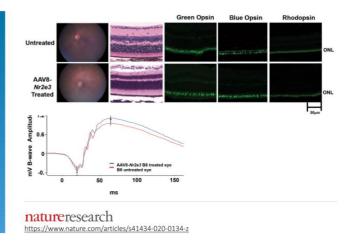


natureresearch https://www.nature.com/articles/s41434-020-0134-z

### 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





# OCU400 – Clinical and Regulatory Strategy Planned timeline





## OCU400 – Competitive Overview

	OCU400	Traditional Gene Therapy		
Features	<b>⊙</b> ocugen	Reche Biogen OMITAGE.	≯astellas jCyte ReNeuron	
One product for many IRDs including broad RP indication)	<b>Ø</b>	8	Limited	
Technology established in the ocular disease space	<b>Ø</b>	<b>Ø</b>	8	
POC data in RP models with different genetic mutations	<b>⊘</b>	8	8	
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	



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







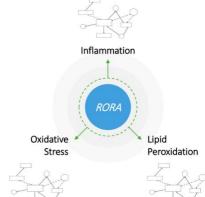
#### Dry AMD

- 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**

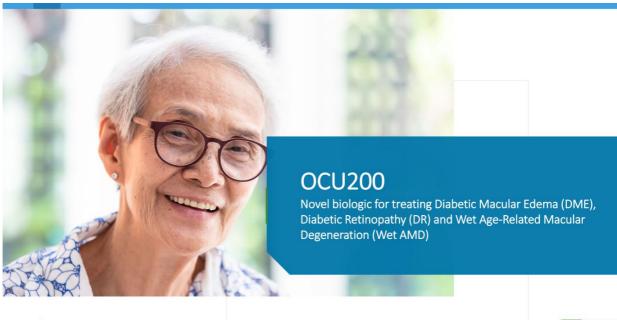
- AgingGenetics
- Environmental Factors





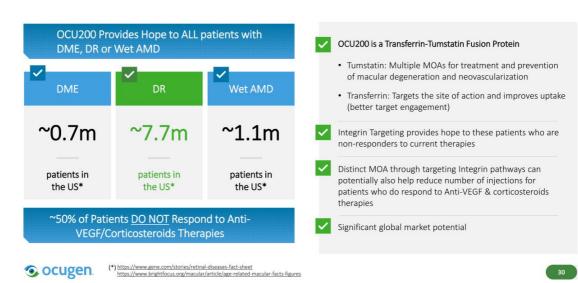




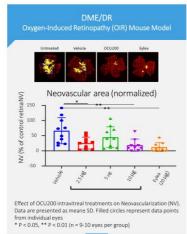


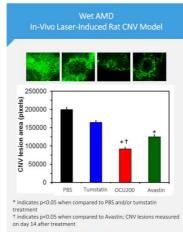
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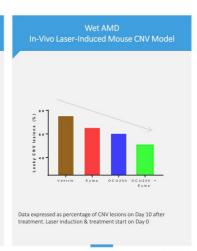
### OCU200: Potential to Treat DME, DR & Wet AMD



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











## Leadership Team





















## Scientific Advisory Boards



ocugen.

### Forward Momentum for Ocugen



Emergency Use Authorization submitted to FDA for pediatric (2-18) indication for the prevention of COVID-19

IND filed with FDA for Phase 3 bridging study in support of a BLA submission; WHO grants COVAXIN™ Emergency Use Listing, broadening global portfolio of COVID-19 options

Health Canada regulatory process ongoing with deficiencies noted and responses being prepared



IND accepted by FDA for clinical trials studying OCU400 for the treatment of retinitis pigmentosa resulting from genetic mutations of NR2E3 and RHO

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

Expanded manufacturing agreement with CanSinoBio to include support for OCU410  $\,$ 



