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): **April 20, 2022**

OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36751**	**04-3522315**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 hereto and incorporated herein by reference is a presentation that Ocugen, Inc. will post on its website on April 20, 2022 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).

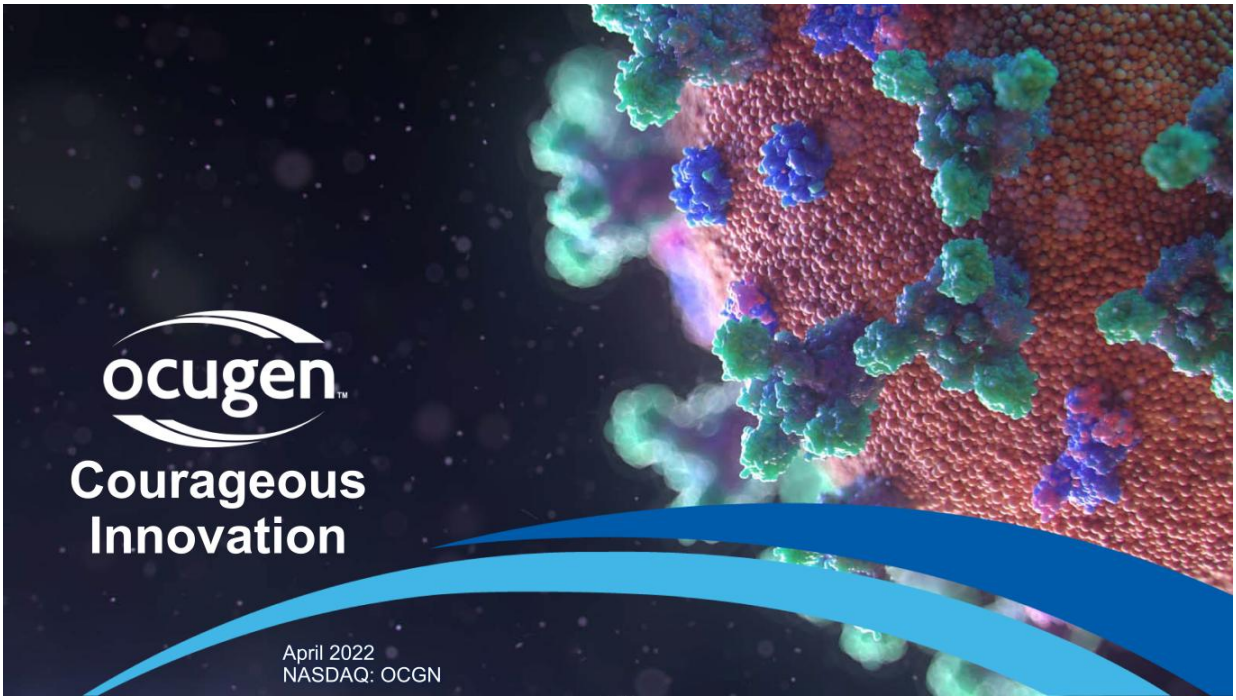
SIGNATURE

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: April 20, 2022

OCUGEN, INC.

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


ocugen™
Courageous Innovation
April 2022
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 the data and results from preclinical 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 Investigational New Drug applications (“IND”) or planned Biologics License Applications (“BLA”), as applicable; whether and when we are able to resolve the clinical hold on our Phase 2/3 immuno-bridging and broadening clinical trial for COVAXIN ™; the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to support a for COVAXIN™, including our Phase 2/3 immuno-bridging and broadening clinical trial and planned safety-bridging clinical trial; any additional chemistry, manufacturing, and controls information that we may be required to submit; whether and when a BLA for COVAXIN™ will be submitted to the FDA; whether and when a BLA may be approved by the FDA, whether a New Drug Submission application may be approved by Health Canada, and whether the additional information that we provide to Health Canada will be sufficient to support an approval by Health Canada of COVAXIN™ and any delays associated therewith; our ability to successfully commercialize COVAXIN™ in Mexico for adults over the age of 18 pursuant to our agreement with Bharat Biotech, and whether and when we will obtain Emergency Use Authorization approval for COVAXIN™ in Mexico for children between 2 and 18 years of age; the 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, Mexico 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, Canada or Mexico; decisions by the FDA, Health Canada or the Federal Commission for Protection against Sanitary Risks in Mexico impacting labeling, manufacturing processes, safety, and/or other matters that could affect the availability or commercial potential of COVAXIN™ in the United States, Canada or Mexico, 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.

.

We're Here to Make an Impact Through *Courageous Innovation*

Mission

At Ocugen, we are developing novel solutions to medical challenges, approaching healthcare innovation with purpose and agility to deliver new options for people facing disease.

Vision

We are fostering a future where no one feels hopeless in the face of disease. From genetic disorders to new diseases, our expertise and tenacity are creating choices – for people and for global communities.

Pioneering a breakthrough modifier gene therapy for several genetic forms of vision impairment

Innovating a novel biologic to treat eye diseases that can lead to vision loss for millions of people

Co-developing a COVID-19 vaccine

Pipeline Overview

	Asset/Program	Indication	Status
Vaccine	**COVAXIN™ (BBV152)** Whole-Virion Inactivated Vaccine	**COVID-19**	• EUA for adults in Mexico; EUA for 2–18 year olds under review* • US Phase 2/3 clinical trial* (Temporarily paused dosing/clinical hold) • Health Canada NDS under review*
Modifier Gene Therapy Platform	**OCU400 ***** AAV-hNR2E3	**Gene mutation-associated retinal degeneration****	
		NR2E3 Mutation	Phase 1/2
		RHO Mutation	Phase 1/2
		CEP290 Mutation	To be submitted
		PDE6B Mutation	To be submitted
	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

* Based on Bharat Biotech-sponsored clinical trials in India

** No approved therapies exist

*** ORPHAN DRUG DESIGNATION in the US; Broad ORPHAN MEDICINAL PRODUCT DESIGNATION by the EC for the treatment of retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA)

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

COVAXIN™ (BBV152)

A Whole-Virion Inactivated COVID-19 Vaccine Candidate
Licensed from Bharat Biotech (BBIL) for the US and Canadian Markets

Product Profile

COVAXIN™ (BBV152): Whole Virion Inactivated SARS-CoV-2 Antigen & Adjuvant: 6ug/SHD + Algel-IMDG (TLR7/8 Agonist)

Proposed indication

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

Target population

Pediatric: 2-18 years of age

Adult: 18 years of age and older

Dose Level and Regimen

6 ug per 0.5 mL suspension;
2 Doses: Day 0 & Day 28

Presentation

Ten doses per vial

Expected Shelf Life

Two years in storage conditions of 2°- 8°C and stable for six 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

- Adult and pediatric phase 2/3 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 SHOW PREVENTION OF SEVERE COVID-19 DISEASE

- Phase 3 data suggest prevention of hospitalizations caused by COVID-19
- Booster dose provides robust neutralizing antibody responses against Omicron and Delta variants

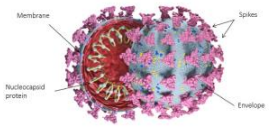
Image for illustrative purposes only

KNOWN SAFETY PROFILE USING VERO CELL PLATFORM

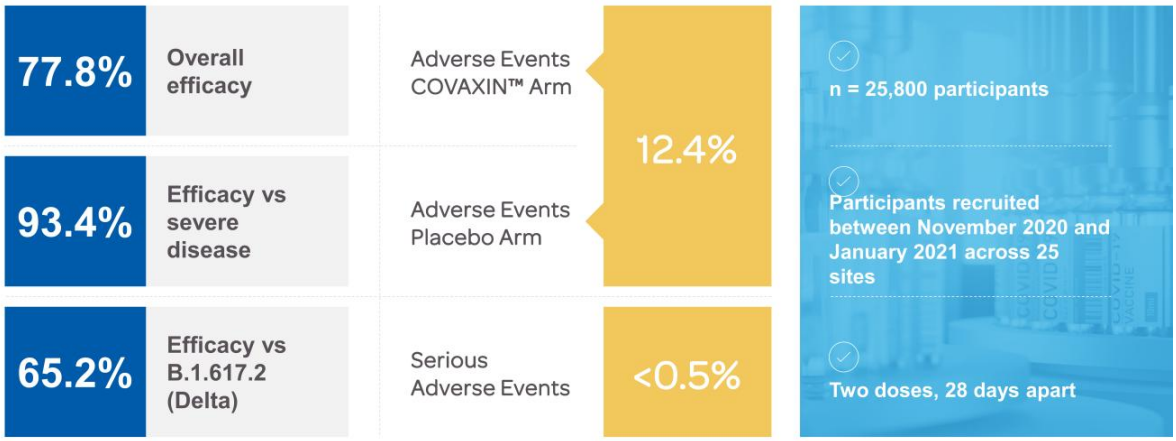
- Data demonstrate strong safety profile within adult and pediatric populations
- Technology platform used to produce Polio, Influenza and Rabies vaccines

TRANSPORTATION AND STORAGE EASE

- 10 dose vial that can be stored and shipped at 2°- 8° C with a 2-year shelf life and 6-month stability at room temperature



Why COVAXIN™ (BBV152)? Phase 3 Clinical Trial Highlights



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 trial; *The Lancet*. Advanced online publication. https://doi.org/10.1016/S0140-6736(21)00500-8 Accessed November 11, 2021

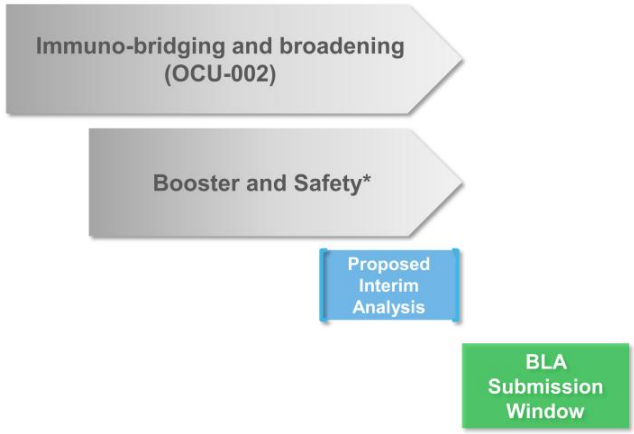
Pathway for COVAXIN™ (BBV152) development

NCT: 05258669

OCU-002

A Phase 2/3, Observer-Blind, Immuno-bridging, and Broadening Study of a Whole, Inactivated Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) Vaccine (BBV152) in Healthy Adults

Study Type	Interventional (Clinical Trial)
Estimated Enrollment	400 participants
Allocation	Randomized
Intervention Model	Parallel assignment
Intervention Model Description	1:1 randomization ratio
Primary Purpose	Prevention



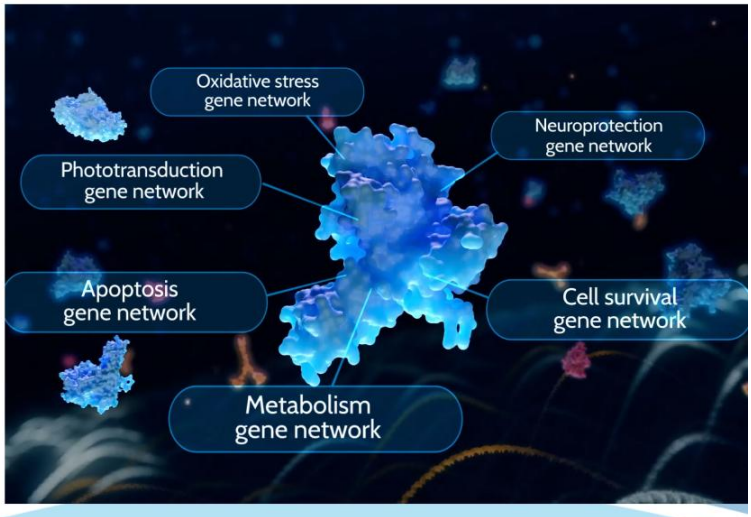
*Protocol to be submitted

MODIFIER GENE THERAPY PLATFORM

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

Our Focus: Nuclear Hormone Receptor Genes (NHRs)

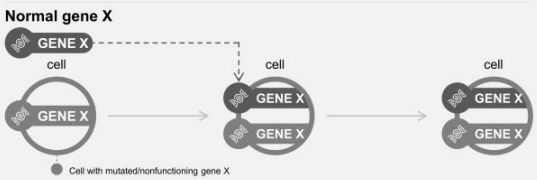
- NHRs are modulators of retinal development & function, acting as “master genes” in the retina
- Molecular reset of key transcription factors and associated gene networks – retinal homeostasis
- Gene modifier concept including, its impact on clinical phenotypes, is well known in other disease areas, 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.0183526

Our Vision:
Modifier Gene Therapy vs Traditional Gene Augmentation

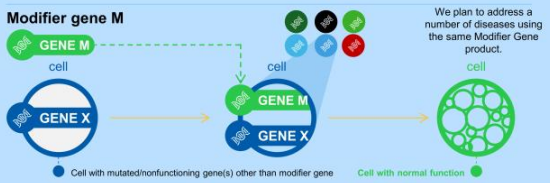
Gene Augmentation: Transfer functional version of a non-functional gene into the target cells.



Traditional Gene Therapy — ONE Disease

- 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: Designed to introduce a functional gene to modify the expression of many genes, gene-networks and regulate basic biological processes in retina.



OCU400

- *NR2E3* Mutation-Associated Retinal Disease
- *Rhodopsin* Mutation-Associated Retinal Disease
- *CEP290* Mutation-Associated Retinal Disease
- *PDE6B* Mutation-Associated Retinal Disease

Broad Spectrum Therapy for RP

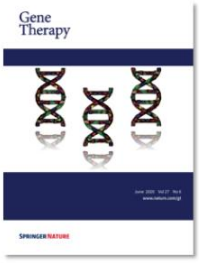
- Novel approach that targets nuclear hormone genes (NHRs), which regulate multiple functions within the retina
- Smoother regulatory pathway due to ability to target multiple diseases with one product
- Ability to recoup development costs over multiple therapeutic indications

Our Proof of Principle:

- 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

ocugen

Published in Nature Gene Therapy



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

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

OCU400 – Pathway to Phase 3 Clinical Trials

Just 30 days to receive FDA clearance for Phase 1/2 gene therapy clinical trial

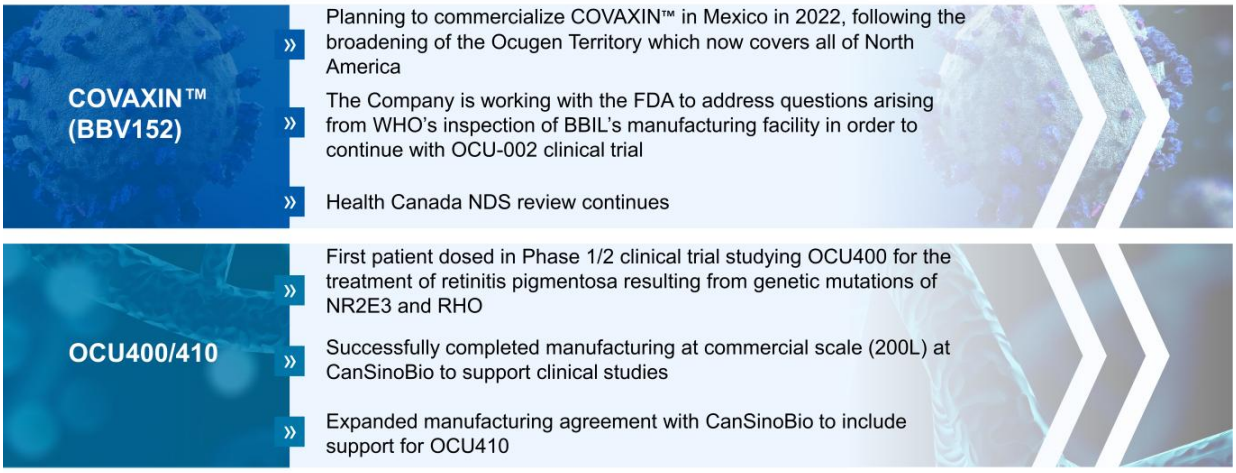
OCU400

*A Phase 1/2 Study to Assess the Safety and Efficacy of **OCU400** for Retinitis Pigmentosa Associated With NR2E3 (Nuclear Receptor Subfamily 2 Group E Member 3) and RHO (Rhodopsin) Mutations*

Study Type	Interventional (Clinical Trial)
Estimated Enrollment	18 participants
Allocation	Non-randomized
Intervention Model:	Sequential assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment

- NCT: 05203939
- Seven clinical trial sites being activated
- Escalation study involving low, medium, high doses
- First patient dosed by end of Q1 2022
- Periodic updates available starting in Q3 2022
- Enrollment concludes by YE 2022

Summary of activities at Ocugen



Experienced Leadership

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

Jessica Crespo, CPA
Chief Accounting Officer
& SVP, Finance

Bruce Forrest, MD
Acting Chief Medical Officer

J.P. Gabriel
SVP, Technical Operations

Zara Gaudioso, SHRM-CP
AVP, Human Resources,
Chief of Staff

Nirdosh Jagota, PhD
SVP, Regulatory Affairs,
Compliance and Safety

Huma Qamar, MD, MPH, CMI
AVP, Clinical Development

Mike Shine
SVP, Commercial

Arun Upadhyay, PhD
SVP, Research & Development


ocugen
Thank you!
April 2022
NASDAQ: OCGN