UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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): February 21, 2024

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)

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

(Address, including zip code, and telephone number, including area code, of principal executive office)

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 \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.

Item 7.01 Regulation FD Disclosure Attached as Exhibit 99.1 hereto and incorporated herein by reference is a presentation that Ocugen, Inc. will present at an in-person Clinical Showcase at the Nasdaq Market Site in Times Square, New York City on February 21, 2024, and may use from time to time in presentations or discussions with investors, analysts, and other parties. The information in this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are being furnished 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 21, 2024

OCUGEN, INC.

By:

/s/ Shankar Musunuri Name: Shankar Musunuri Title: Chairman, Chief Executive Officer, & Co-Founder



Courageous Innovation

Dedicated to Bringing Game-Changing Gene & Cell Therapies and Vaccines to Market and Working Even Harder to Provide Access to Patients Globally

> Clinical Showcase February 21, 2024



Forward Looking Statements

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 statements include, but are not limited to, statements regarding our clinical development activities and related anticipated timelines. Such statements are subject to numerous important factors, risks, and uncertainties that may cause actual events or results to differ materially from our current expectations. 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 this presentation whether as a result of new information, future events, or otherwise, after the date of this presentation.



Agenda

Opening: Dr. Shankar Musunuri, Chairman, CEO & Co-founder, Ocugen Modifier Gene Therapy Platform & Program Update: Dr. Arun Upadhyay, CSO & Head of R&D, Ocugen Modifier Gene Therapy Market Potential: Mike Shine, SVP Commercial, Ocugen

Q&A

10-minute Break

Panel: Modifier Gene Therapy & OCU400 in the Clinic

Moderated by Swayampakula Ramakanth, PhD, Managing Director of Equity Research at H.C. Wainwright

- Dr. Lejla Vajzovic, Associate Professor of Ophthalmology with Tenure, Director of Duke Vitreoretinal Fellowship Program at Duke Eye Center and Duke University School of Medicine
- Dr. Byron Lam, Professor of Ophthalmology, Dr. Mark J. Daily, Endowed Chair in Ophthalmology at the University of Miami
- Dr. Neena Haider, inventor of modifier gene therapy, CEO & CSO Shifa Precision, faculty at Harvard Medical School OCU400
- Phase 1/2 clinical trial participant who has completed 12 months of therapy



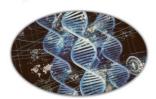
We're Here to Make an Impact Through Courageous Innovation



Through Courageous Innovation, We are Leveraging Our First-in-Class **Platforms to Address Serious Unmet Medical Needs**

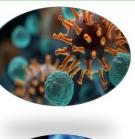
Modifier Gene Therapy Platform First-in-Class

- Therapeutic Focus: inherited retinal diseases and . larger blindness diseases with unmet need
- Differentiator: master gene regulator; gene-agnostic . approach
- Pipeline: .
 - OCU400 (Ph1/2): RP* & LCA**; Orphan drug designation from FDA/EMA, RMAT from FDA - Ph3 target: March/April 2024
 - OCU410 (Ph1/2): dry AMD
 - OCU410ST (Ph1/2): Stargardt; Orphan drug designation from FDA





*RP, retinitis pigmentosa **LCA, Leber congenital amaurosis





Inhalation Vaccines Platform First-in-Class

- Therapeutic Focus: Flu and COVID-19
- 2 Differentiator: inhalation for improved durability and transmission control
 - Pipeline: OCU500 (Preclin): COVID-19 vaccine (NIH/NIAID Nextgen Collaboration – Ph1 planned for early 2024)
 - o OCU510 (Preclin): flu quadrivalent
 - o OCU520 (Preclin): COVID-19 + flu combo

Regenerative Cell Therapy Platform First-in-Class

- Therapeutic Focus: articular cartilage lesions .
- Differentiator: 3-D scaffold
- . Pipeline:
 - NeoCart (Ph3): articular cartilage defects in the knee

- Ph3 target: 2H2024
- $\circ~$ Completed cGMP facility construction
- $_{\odot}\,$ RMAT designation from FDA

Execution of High Value Gene Therapies Will Increase Valuation

H.C.WAINWRIGHT&CO.

Entering a Year of Execution; New \$7 PT; Reiterate Buy

1.040 +168.73%

Past 3 Months



Noble Sector RESEARCH REPORT

Raising Price Target to \$8 Based On Clinical Progress

Key Gene Therapy Milestones Achieved in 2023

- First gene therapy program to get alignment with FDA for broad RP indication in Ph3
- Initiated dosing in OCU410 Ph1/2 clinical trial (dry AMD/GA)
- Initiated dosing in OCU410ST Ph1/2 clinical trial (Stargardt)

Key Gene Therapy Target Milestones for 2024

- Initiate OCU400 Ph3 clinical trial and recruit efficiently in line with 2026 BLA approval target
- Continue to provide OCU400 Ph3 clinical updates
- Provide preliminary safety/efficacy updates from OCU410 Ph1/2 clinical trial in GA patients
- Provide preliminary safety/efficacy updates from OCU410ST Ph1/2 clinical trial in Stargardt patients
- Finalize big Pharma partner for OCU400 to maximize value for patients and shareholders

20th Century Disruptive Biotechnologies

- Penicillin
- Polio vaccine
- Recombinant DNA
- Production of monoclonal antibodies
- Genetically engineered bacteria

21st Century Biotechnology Innovations

- Human Genome fully sequenced
- Gene and cell therapies/CRISPR
- First commercial gene therapies
- mRNA vaccines

Ocugen's Modifier Gene Therapy (MGT) - First Broad Mutation Agnostic and Multifactorial Gene Therapy

- Current gene therapy/CRISPR: Costly, mutation-specific and typically addresses ultra rare patient groups
- · Ocugen MGT: Potential to treat broad cohorts of patients with inherited retinal diseases with a single therapy

7

• Being studied in diseases that affect millions (dry AMD) as a potential one-time therapy for life



Ocugen's Modifier Gene Therapy is a First-in-Class Platform Technology Designed to Restore Homeostasis and Preserve Vision

Modifier Gene Therapy Platform First-in-Class

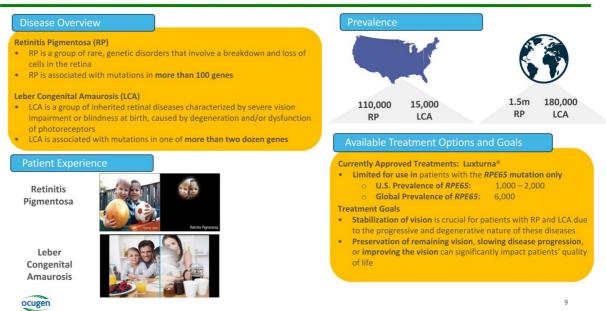
- Therapeutic Focus: Inherited retinal diseases and larger blindness
 diseases with unmet need
- Differentiator: "<u>Master Gene Regulator</u>"; gene-agnostic approach
 OCU400 (*NR2E3*) has been shown in humans (Ph 1/2) to improve vision in patients with *RHO gene* mutations.
 - OCU410 (*RORA*) has been shown to beneficially modify the four pathways which directly contribute to dry Age-Related Macular Degeneration (dry AMD) in multiple animal models
- Pipeline:
 - OCU400 (Ph1/2): RP* & LCA**; Orphan drug designation from FDA/EMA and RMAT from FDA
 - Ph3 start target: March/April 2024
 - o OCU410 (Ph1/2) underway: GA
 - \circ OCU410ST (Ph1/2) underway: Stargardt Disease \circ Received orphan drug designation from FDA



*RP, retinitis pigmentosa **LCA, Leber congenital amaurosis



Retinitis Pigmentosa: Inherited Retinal Disease with a High Unmet Need



FDA & EMA granted expanded Orphan Drug Designations for all RP and LCA mutations

FDA granted RMAT designation for RP indication associated with NR2E3 and RHO mutations

OCU400 addresses shortcomings of current gene therapy approaches

- Broad-spectrum, gene-agnostic approach to genetically diverse inherited retinal diseases
- Consists of human Nuclear Hormone Receptor gene, NR2E3, with potential to preserve/improve/restore retina function
- Being developed as one-time, curative therapy with a *single* sub-retinal injection

Phase 3 trial to initiate in March/April 2024

- FDA has agreed to trial design and primary endpoint
 Favorable design based on Ph 1/2 results
- First gene agnostic / multi mutation Ph 3 RP trial
- Ph3 study duration- 1 yr. from patient dosing





Ph 1/2 Safety and Efficacy Summary

- OCU400 continued to be generally safe and well-tolerated in subjects across different mutations and dose levels
- Efficacy measurements suggest *positive trends* in Best-Corrected Visual Acuity (BCVA) and Multi-Luminance Mobility Testing (MLMT), and Low-Luminance Visual Acuity (LLVA) among treated eyes
- 89% (16/18) of subjects demonstrated *preservation or improvement* in the treated eye either on *BCVA or LLVA or MLMT* scores from baseline
- 78% (14/18) of subjects *demonstrated* **stabilization** or **improvement** in treated eyes in MLMT scores from baseline
- 80% (8/10) of RHO mutation subjects experienced either stabilization or increase in MLMT scores from baseline
- Treatment effect in RHO patients supports the gene-agnostic mechanism of action of OCU400





A PHASE 3, MULTI-CENTER, RANDOMIZED STUDY TO ASSESS THE EFFICACY, SAFETY AND TOLERABILITY OF SUBRETINAL OCU400 GENE THERAPY FOR THE TREATMENT OF RETINITIS PIGMENTOSA

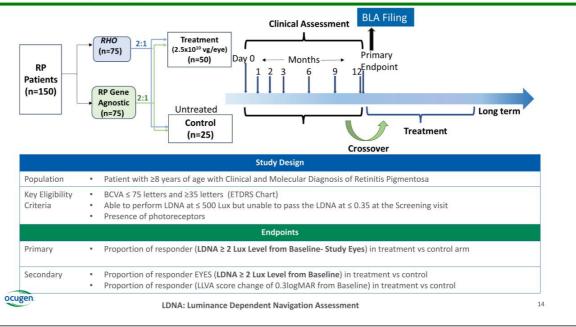


RP and LCA—Unmet need and Treatment Benefit Target

- IRDs, such as RP and LCA, are a group of heterogenous genetic disorders that affect the retina, the light-sensitive tissue at the back of the eye
- They often lead to a gradual loss of vision over time and can ultimately result in blindness
- <u>Stabilization of vision is crucial</u> for patients with RP and LCA due to the progressive and degenerative nature of these diseases
- **Preservation of remaining vision, slowing disease progression, or improving the vision** can significantly impact patients' quality of life. Such outcomes not only can enhance the quality of life for affected individuals but also provide hope that future treatments that could ultimately lead to vision restoration.
- Comprehensive care, early diagnosis, and access to emerging therapies are essential components of a *strategy to stabilize vision in RP and LCA patients*



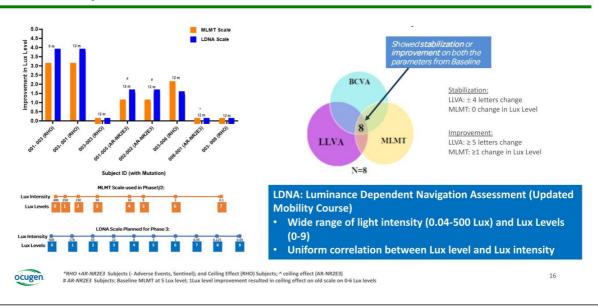
Phase 3 Study Design



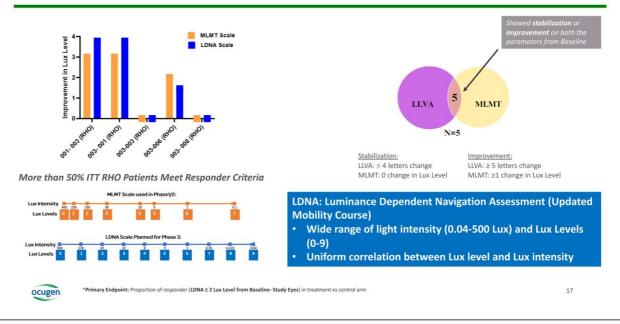
Phase 3 Study: Statistical Considerations

Population	Each arm will enroll 75 participants
	 In each arm, participants (N=75) will be randomized 2:1 to the Treatment group (2.5 x vg/eye of OCU400) and Untreated Control group
	• This sample size is needed to achieve the targeted level of statistical power in each arm (RHO and Gene Agnostic).
Assumptions	The response rates are expected to be:
	 0.50 for the active treatment (OCU400) based on Phase 1/2 Study results in Inter Treat population
	 and 0.1 for untreated control based on prior studies and to account for patient random positive response
Power	• >90%
Hypothesis	 The Primary efficacy hypothesis is that the response rate is higher with treatment grou compared to control in the RHO subgroup
	 The conditional efficacy hypothesis is that the response rate is higher with treatment compared to control in the Gene Agnostic subgroup.

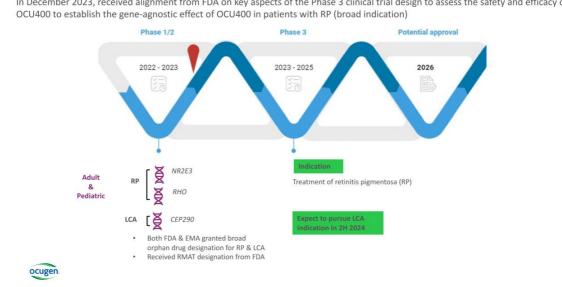
Phase 1/2 Patients Population Meeting "Intent to Treat Population" Criteria for Phase 3 Study*



OCU400: Demonstrate Gene Agnostic Effect in RHO Patients



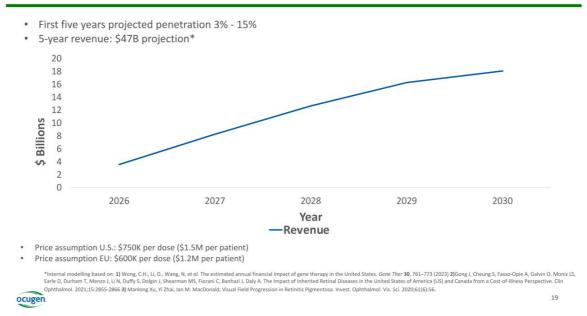
OCU400: Expected Pathway to Clinical Development & Potential Approval



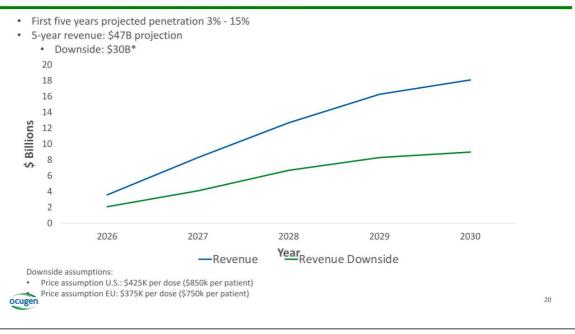
18

In December 2023, received alignment from FDA on key aspects of the Phase 3 clinical trial design to assess the safety and efficacy of

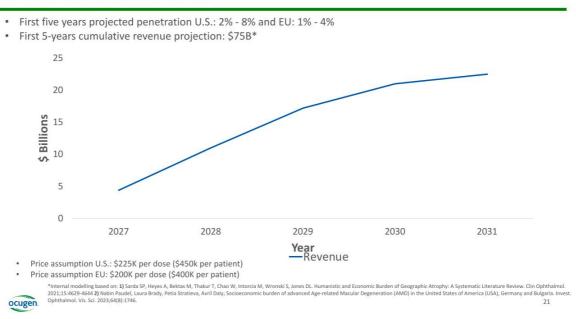
OCU400 RP - U.S. & EU Market Potential



OCU400 RP – U.S. & EU Market Potential



OCU410 GA Market Potential



Ocugen[™] Vision

Fully integrated, patient-centric biotech company focused on vaccines in support of public health and gene and cell therapies targeting unmet medical needs through **Courageous Innovation**



Swayampakula Ramakanth, PhD

Dr. Ramakanth is a Managing Director of Equity Research at H.C. Wainwright whose research focuses on the healthcare sector. His research covers companies operating in oncology, wound health, medical devices, spine health and AI Drug Discovery. Dr. Ramakanth possesses over twenty years of experience as a Life Sciences Equity Analyst as well as seven years of biotechnology industry experience. Prior to joining H.C. Wainwright, Dr. Ramakanth worked as a Junior Analyst at both Jefferies and Merrill Lynch covering large cap pharmaceuticals. Dr. Ramakanth was also a Junior Analyst at both First Albany and Rodman & Renshaw where he focused on biotechnology companies. He also conducted bench research and directed a preclinical drug development group at Regeneron Pharmaceuticals, Inc. His educational background includes a Ph.D. in Pharmacology/Toxicology from the University of Utah, an MBA from Rutgers University, an M.S. in Pharmaceutics from Auburn University, and a B. Pharm (Hons.) from BITS, India. Dr. Ramakanth also completed a post-doctoral fellowship at the University of Texas MD Anderson Cancer Center.



Neena Haider, PhD

Dr. Haider is the founder of Shifa Precision, a world-renowned geneticist, and visionary scientist who has brought multiple gene therapies to the clinic. She has served/serves in numerous leadership roles and steering committees at institutions including Harvard Medical School, National Institute of Health (NIH), the U.S. Congress, National Science Foundation (NSF) and NASA. Dr. Haider is an internationally recognized scientist who has authored approximately 50 research articles, reviews, and book chapters. Her work has been cited over 3,000 times and appears in textbooks in other countries. Dr. Haider understands the needs and gaps in the current healthcare system and built Shifa Precision as a solution to actualize personalized precision medicine and developed precision therapies to achieve better health outcomes for all. Dr. Haider has a strong interest and commitment to the education of young scientists, supporting and creating a diverse and inclusive environment, and to mentor and nurture the growth of young students. She has chaired a task force on mentoring, invited as a speaker for a workshop on resilience for the BIPOC community, and developed a Positive Mindful Wellness workshop and Science of Mindfulness course at HMS. Dr. Haider continues to teach at Harvard Medical School and to train young scholars how to become mindful innovators.



Byron L. Lam, MD

Dr. Lam is the Mark J. Daily Professor at the Bascom Palmer Eye Institute, University of Miami Miller School of Medicine. Dr. Lam is a clinical scientist with expertise and translational research experience in the areas of hereditary retinal disease, neuro-ophthalmology, and ophthalmic epidemiology. His research focus includes gene therapy, clinical visual function testing, ophthalmic molecular imaging, and biomarkers. In addition to clinical studies, Dr. Lam has performed numerous clinical trials including Leber hereditary optic neuropathy and hereditary retinal disease. Dr. Lam serves on the editorial board of the American Journal of Ophthalmology. He is the author of the textbook *Electrophysiology of Vision: Clinical Testing and Applications*.



Lejla Vajzovic, MD, FASRS

Dr. Vajzovic is a vitreoretinal surgeon and tenured Associate Professor of Ophthalmology at Duke University School of Medicine with expertise in adult and pediatric retinal diseases and surgery. She serves as a principal investigator for numerous national clinical trials in early to late stages of development. Her research interests span from pediatric to adult retinal diseases such as dry and wet age-related macular degeneration, diabetic retinopathy and venous occlusive diseases, as well as vitreoretinal surgical diseases. She is a co-director of the Duke Pediatric Retina and Optic Nerve Center, and directs the Duke Center for Artificial and Regenerative Vision, where she performs gene-therapy delivery, and devices implantation to restore vision to individuals with total blindness. An influential educator, she organizes and directs several highly successful national and international courses, including the first-of-its-kind Advances in Pediatric Retina Course at Duke and the international Duke fellows and general Advances in Vitreous Surgery Course. She is director of prestigious Duke Vitreoretinal Surgical Fellowship and director of Duke Eye Center's Continuing Medical Education program. In addition, she serves as a Retina Society **American Academy of Ophthalmology (AAO)** Council Representative and American Society of Retina Specialist (ASRS) Research and Safety in Therapeutics Committee Member. She is elected member of the Retina Society, Macula Society and Club Jules Gonin Society.



