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): **August 22, 2023**

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)

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 ☐

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 2.02 Results of Operations and Financial Condition.

Ocugen, Inc. (the "Company") held a conference call and webcast earlier today to discuss its financial results for the quarter ended June 30, 2023, along with a general business update. The presentation materials used in connection with the conference call and webcast will be posted on the Company's website at www.ocugen.com. A copy of the presentation materials is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information disclosed under Item 2.02 of this Current Report on Form 8-K, 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 Company 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 filed herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Earnings Release Presentation issued August 22, 2023.
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: August 22, 2023

OCUGEN, INC.

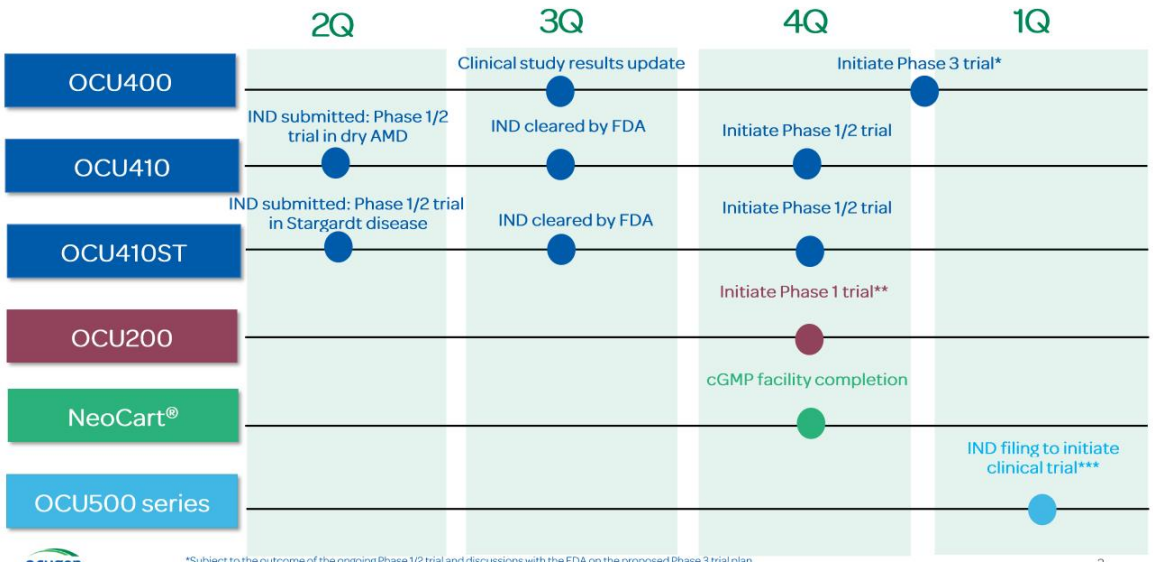
By: /s/ Shankar Musunuri
Name: Shankar Musunuri
Title: Chairman, Chief Executive Officer & Co-Founder


ocugen
2Q 2023
Business Update
August 22, 2023
NASDAQ: OCGN

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.

2023/2024: Updated Anticipated Timing on Milestones

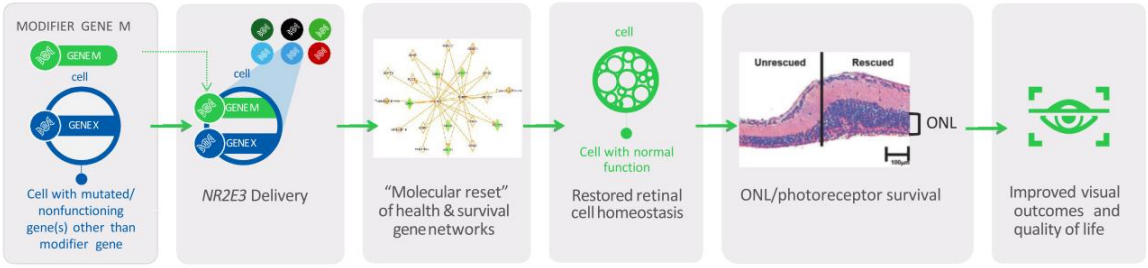


*Subject to the outcome of the ongoing Phase 1/2 trial and discussions with the FDA on the proposed Phase 3 trial plan
**Subject to FDA clearance of IND
***Provided government funding

Modifier Gene Therapy: A Broader Reach

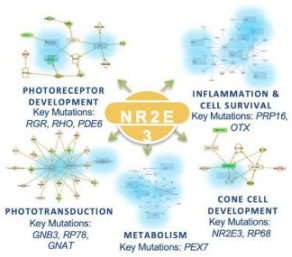
Gene modifier therapy can potentially address multiple genetic defects with a single product utilizing a gene agnostic approach.

In patients with IRDs, this could mean:



Ocugen Announced Positive Preliminary Safety and Efficacy Results from the Ongoing Phase 1/2 Trial of OCU400

- Continuing to enroll adult LCA patients to receive the medium dose based on the nature of the disease for this subset of the population
- Phase 3 adult trial to be initiated near the end of 2023/early 2024, subject to the outcome of the ongoing Phase 1/2 trial and discussions with the FDA on the proposed Phase 3 trial plan
- Preliminary data announced in April supports the potential of the modifier gene therapy platform in the gene-agnostic treatment of complex and heterogenous inherited retinal diseases



Nuclear Hormone Receptors (NHRs): intracellular receptors that regulate gene expression, acting as a master regulator of genes in the retina.

OCU400: Expected Pathway to Clinical Development & Potential Approval

Both FDA & EMA granted broad orphan drug designation for RP & LCA

OCU410 for the Treatment of Dry Age-related Macular Degeneration (AMD)

Targets all four hallmark conditions of dry AMD: lipid metabolism, inflammation, oxidative stress, and complement activation

Limited options for AMD, presenting significant unmet medical need

- US: 10M
- Worldwide: condition affects more than 266M people

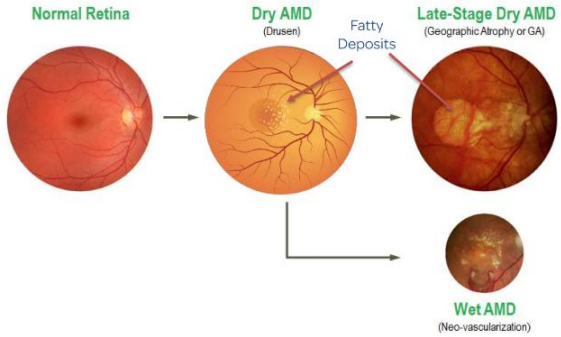
First approved therapy for geographic atrophy (GA)—advanced form of AMD–has limitations

- Frequent intravitreal injections (N ~6-12 doses per year); Patient compliance
- Limited effect of GA lesion growth rate
- Approximately 12% of patients experience neovascular AMD when the drug is administered every month for two years

Latest therapy for GA approved on August 4, 2023

- Only approved GA treatment with a statistically significant reduction ($p<0.01$) in the rate of GA progression at the 12-month primary endpoint across two Phase 3 clinical trials

IND application to initiate a Phase 1/2 trial was cleared by the FDA and the Company plans to initiate the Phase 1/2 trial by the end of 2023



OCU410ST: Received ODD for the Treatment of *ABCA4*-Associated Retinopathies—Stargardt, Retinitis Pigmentosa 19 (RP19) and Cone-rod Dystrophy 3 (CORD3)

ABCA4-associated retinopathies—Genetic Rare Disease

- *ABCA4* gene produces an ATP-binding cassette (ABC) superfamily transmembrane protein involved in clearance of all-trans-retinal aldehyde, a byproduct of the retinoid cycle, from photoreceptor cells
- Mutation in *ABCA4* gene results in Stargardt disease. Different *ABCA4* alleles have been identified to cause other retinopathies such as cone-rod dystrophy type 3 (CORD 3), retinitis pigmentosa type 19 (RP 19)

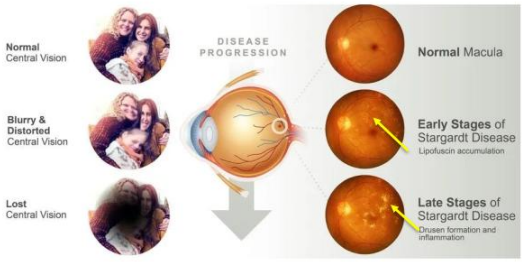
No treatment options exist

- US: 44,000 patients

Modifier gene therapy platform addresses shortcomings of current approaches

- AAV delivery platform delivers the *RORA* (RAR Related Orphan Receptor A)
- Broad-spectrum, gene-agnostic approach
- Potential one-time, curative therapy with a single sub-retinal injection

IND application to initiate a Phase 1/2 trial was cleared by the FDA and the Company plans to initiate the Phase 1/2 trial by the end of 2023



OCU500 Series: Next-Generation Vaccine Technology

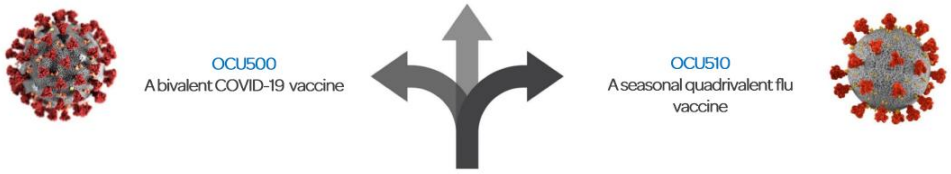
Inhaled mucosal vaccine platform based on ChAd vector

Inhalation technology as a differentiator

- Multiple preclinical studies using Ocugen's vector demonstrated vaccine-induced high neutralizing and effector responses
- Clinical studies using a similar vector administered via the inhalation platform showed mucosal antibodies, systemic antibodies, and durable immune response up to 1 year with 1/5 of the dose compared to the same vaccine given via intramuscular administration
- The inhaled method offers the potential for broad, durable protection from severe disease and reduction in transmission

Alignment with American Pandemic Preparedness Plan to transform U.S. capabilities to rapidly and effectively respond to existing and emerging infectious diseases via:

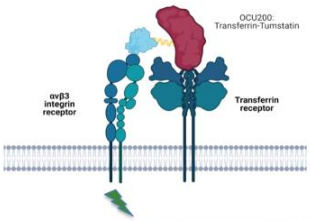
- Legislative advocacy for next-generation mucosal vaccine development
- Multiple proposal submissions for federal funding of Ocugen's inhaled vaccines platform for COVID-19 and flu
- Ongoing dialogue with several government agencies regarding the development of the inhaled vaccines platform



Pipeline Updates

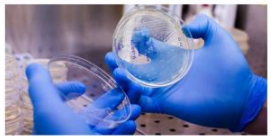
OCU200

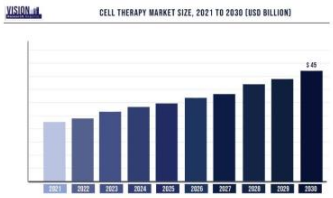
- Providing FDA with the requested information related to chemistry, manufacturing and controls to release the clinical hold
- Plan to initiate Phase 1 trial in 4Q 2023



NeoCart®

- Manufacturing facility construction for NeoCart is on target to be completed by the end of 2023, as planned
- Plan to initiate Phase 3 trial in 2H 2024





Financial Update

Financial Update

Statement of Operations	Three months ended June 30,	
	2023	2022
Research and development expense	$14.2*	$9.0
General and administrative expense	9.6	10.6
Other income (expense), net	0.8	0.1
Net loss	$(22.9)	$(19.5)
Net loss per share of common stock – basic and diluted	$(0.10)	$(0.09)

Balance Sheet Data	June 30, 2023	December 31, 2022
Cash, cash equivalents, and investments	$70.6	$90.9
Debt	$2.7	$2.3
Shares outstanding	256.5	221.6

*Includes a non-recurring, non-cash expense of $4.4 million

Unaudited; in millions, except per share amounts
Certain amounts may not add due to rounding

Questions & Answers

ocugen


ocugen™
Thank you!
August 2023
NASDAQ: OCGN