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): **May 1, 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.

On May 5, 2023, Ocugen, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023. The Company has scheduled a conference call and webcast for 8:30 a.m. Eastern Time on May 5, 2023 to discuss these financial results and business updates. The Company will use presentation materials in connection with the conference call and webcast, which presentation materials will be posted on the Company's website at www.ocugen.com. Copies of the press release and presentation materials are furnished herewith as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K (this "Report") and incorporated herein by reference.

The information disclosed under Item 2.02 of this Report, including Exhibit 99.1 and Exhibit 99.2, 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 (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On May 1, 2023, the Company received a notification letter (the “Bid Price Letter”) from The Nasdaq Stock Market LLC (“Nasdaq”) notifying the Company that, for the last 30 consecutive business days, the closing bid price for the Company’s common stock has been below the minimum $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (“Rule 5550(a)(2)”). The Bid Price Letter is a notice of deficiency, not delisting, and does not currently affect the listing or trading of the Company’s shares of common stock on The Nasdaq Capital Market.

The Company has 180 days, or until October 30, 2023, to comply with Rule 5550(a)(2) by maintaining a closing bid price of at least $1.00 per share for 10 consecutive business days. Additionally, the Company may be eligible for a second 180-day period to satisfy Rule 5550(a)(2), if, as of October 30, 2023, the Company continues to have a market value of publicly held shares of at least $1 million, meets all other initial listing standards of The Nasdaq Capital Market (with the exception of the bid price requirement), and provides written notice of its intention to cure the deficiency during such second compliance period.

The Company intends to monitor closely the closing bid price of its common stock and to consider plans for regaining compliance with Rule 5550(a)(2). While the Company plans to review all available options, there can be no assurance that it will be able to regain compliance with the applicable rules during the 180-day compliance period, any subsequent extension period, or at all.

Forward-Looking Statements

In addition to historical information, this Report contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act, and Section 21E of the Exchange Act. Such forward-looking statements include statements regarding the Company’s intent or ability to regain compliance with Nasdaq’s minimum bid price requirement and other statements that are not statements of historical fact. In some cases these statements may be identified by words like “anticipate,” “assume,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “future,” “will,” “should,” “would,” “seek,” and similar terms or phrases. Important factors that could cause the Company’s actual results to differ materially from those indicated in the forward-looking statements are more fully discussed in the Company’s periodic filings with the Securities and Exchange Commission (the "SEC"), including the risk factors described under the heading “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC and other documents subsequently filed with or furnished to the SEC. Any forward-looking statement made in this Report speaks only as of the date hereof. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments, or otherwise.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are being furnished herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Press Release of Ocugen, Inc. dated May 5, 2023.
99.2	Earnings Release Presentation issued May 5, 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: May 5, 2023

OCUGEN, INC.

By: /s/ Shankar Musunuri

Name: Shankar Musunuri

Title: Chairman, Chief Executive Officer, & Co-Founder

Exhibit 99.1

Ocugen Provides Business Update with First Quarter 2023 Financial Results

Conference Call and Webcast Today at 8:30 a.m. ET

- *Announced Positive Preliminary Safety and Efficacy Results from the Phase 1/2 Trial of OCU400 for the Treatment of Retinitis Pigmentosa (RP) and Leber Congenital Amaurosis (LCA)*
- *Received Orphan Drug Designation (ODD) from the FDA for OCU410ST for the Treatment of ABCA4-Associated Retinopathies Including Stargardt, Retinitis Pigmentosa (RP19), and Cone-Rod Dystrophy 3 (CORD3) Diseases*
- *Submitted Multiple Proposals for Federal Funding of Ocugen's Inhaled Vaccines for COVID-19 and Flu*

MALVERN, Pa., May 5, 2023 (GLOBE NEWSWIRE) — Ocugen, Inc. (Ocugen or the Company) (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, biologics, and vaccines, today reported first quarter 2023 financial results along with a general business update.

"I am excited about our pipeline achievements to date — especially those for our modifier gene therapy platform," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "The preliminary positive efficacy and safety results from our Phase 1/2 trial of OCU400 support the potential for this first-in-class therapeutic approach to be a viable gene-agnostic treatment for RP and LCA patients. Based on proof-of-concept data, we are getting ready to introduce two more programs with the modifier concept into the clinic —including OCU410 for dry age-related macular degeneration."

OCU410ST recently received broad ODD from the FDA for the treatment of *ABCA4*-associated retinopathies including Stargardt, RP19, and CORD3 diseases. This designation acknowledges the potential for OCU410ST to fulfill a significant unmet medical need and represents a noteworthy milestone in our effort to develop innovative treatments for inherited retinal diseases.

Ocugen remains dedicated to our potentially first-in-class ophthalmic programs targeting blindness diseases and vaccines to support public health. Since the beginning of the year, the Company has been leading advocacy efforts and pursuing government funding to potentially bring its inhaled vaccines for COVID-19 and flu to patients and healthcare professionals searching for next generation options. Given the FDA's recent cancellation of emergency use authorizations issued to monovalent vaccines, Ocugen will now focus its efforts solely on the development of the inhaled mucosal vaccine platform, starting with quadrivalent flu and bivalent COVID-19.

"We will continue to deliver on our corporate goals and scientific programs throughout 2023 and look forward to providing updates across our comprehensive portfolio in the coming months," concluded Dr. Musunuri.

Ophthalmic Gene Therapies

- **OCU400** — Preliminary safety and efficacy results among RP patients treated in the first two cohorts of the Phase 1/2 trial indicate positive trend in multi-luminance mobility testing and best-corrected visual acuity scores for OCU400 treated eyes. Received FDA approval to enroll pediatric patients in the ongoing Phase 1/2 trial; dosing to be initiated in the second quarter of 2023. Phase 3 adult trial to be initiated near the end of 2023.
- **OCU410** — Ocugen intends to submit an Investigational New Drug ("IND") application for OCU410 in the second quarter of 2023 to initiate a Phase 1/2 trial.
- **OCU410ST** — FDA granted ODD to OCU410ST for the treatment of *ABCA4*-associated retinopathies including Stargardt, RP19, and CRD3 diseases. Ocugen intends to submit an IND application for OCU410ST in the second quarter of 2023 to initiate a Phase 1/2 trial.

Ophthalmic Biologic Product

- **OCU200** — Submitted an IND application to the FDA in February 2023 to initiate a Phase 1 trial targeting diabetic macular edema. In April, the IND was placed on clinical hold by the FDA as part of its request for additional information related to chemistry, manufacturing, and controls prior to initiating the Phase 1 trial. The company plans to respond to the FDA promptly to get FDA clearance to initiate the Phase 1 trial.

Regenerative Cell Therapies

- **NeoCart®** — Renovations continue on cGMP manufacturing facility for NeoCart, with completion planned for the fourth quarter of 2023.

Vaccines Portfolio

- **OCU500/OCU510/OCU520** — Intend to submit an IND application to the FDA in late 2023/early 2024. Continuing to work with government agencies to obtain government funding.
- **COVAXIN™** — Ocugen has concluded that the development of COVAXIN in North America is not commercially viable as a result of the FDA's recent decision around monovalent vaccines.

First Quarter 2023 Financial Results

- The Company's cash, cash equivalents, and investments totaled $76.7 million as of March 31, 2023 compared to $90.9 million as of December 31, 2022. The Company estimates that its current cash, cash equivalents, and investments will enable it to fund its operations into the first quarter of 2024. The Company had 226.4 million shares of common stock outstanding as of March 31, 2023.
- Total operating expenses for the three months ended March 31, 2023 were $17.8 million and included research and development expenses of $9.6 million and general and administrative expenses of $8.2 million. This compares to total operating expenses for the three months ended March 31, 2022 of $18.0 million that included research and development expenses of $7.9 million and general and administrative expenses of $10.1 million.
- Ocugen reported a $0.07 net loss per common share for the three months ended March 31, 2023 compared to a $0.09 net loss per common share for the three months ended March 31, 2022.

Conference Call and Webcast Details

Ocugen has scheduled a conference call and webcast for 8:30 a.m. ET today to discuss the financial results and recent business highlights. Ocugen's senior management team will host the call, which will be open to all listeners. There will also be a question-and-answer session following the prepared remarks.

Attendees are invited to participate on the call or webcast using the following details:

Dial-in Numbers: (800) 715-9871 for U.S. callers and (646) 307-1963 for international callers
Conference ID: 4613996
Webcast: Available on the events section of the Ocugen investor site

A replay of the call and archived webcast will be available for approximately 45 days following the event on the Ocugen investor site.

About Ocugen, Inc.
Ocugen, Inc. is a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies and vaccines that improve health and offer hope for patients across the globe. We are making an impact on patient's lives through courageous innovation—forging new scientific paths that harness our unique intellectual and human capital. Our breakthrough modifier gene therapy platform has the potential to treat multiple retinal diseases with a single product, and we are advancing research in infectious diseases to support public health and orthopedic diseases to address unmet medical needs. Discover more at www.ocugen.com and follow us on Twitter and LinkedIn.

Cautionary Note on Forward-Looking Statements
This press release 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 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 press release speak only as of the date of this press release. Except as required by law, we assume no obligation to

update forward-looking statements contained in this press release whether as a result of new information, future events, or otherwise, after the date of this press release.

Contact:
Tiffany Hamilton
Head of Communications
IR@ocugen.com

(Tables to follow)

OCUGEN, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands)
(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 68,259	$ 77,563
Marketable securities	8,462	13,371
Prepaid expenses and other current assets	7,680	7,558
Total current assets	84,401	98,492
Property and equipment, net	7,952	6,053
Other assets	3,946	4,087
Total assets	$ 96,299	$ 108,632
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 8,092	$ 8,062
Accrued expenses and other current liabilities	5,823	9,900
Operating lease obligations	512	498
Current portion of long term debt	1,256	—
Total current liabilities	15,683	18,460
Non-current liabilities		
Operating lease obligations, less current portion	3,449	3,587
Long term debt, net	1,058	2,289
Other non-current liabilities	309	244
Total liabilities	20,499	24,580
Stockholders' equity		
Convertible preferred stock	1	1
Common stock	2,265	2,217
Treasury stock	(48)	(48)
Additional paid-in capital	303,073	294,874
Accumulated other comprehensive income	25	26
Accumulated deficit	(229,516)	(213,018)
Total stockholders' equity	75,800	84,052
Total liabilities and stockholders' equity	$ 96,299	$ 108,632

OCUGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(Unaudited)

	Three months ended March 31,	
	2023	**2022**
Operating expenses		
Research and development	$ 9,558	$ 7,915
General and administrative	8,193	10,119
Total operating expenses	17,751	18,034
Loss from operations	(17,751)	(18,034)
Other income (expense), net	1,253	15
Net loss	$ (16,498)	$ (18,019)
Shares used in calculating net loss per common share — basic and diluted	225,523,627	205,693,498
Net loss per common share — basic and diluted	$ (0.07)	$ (0.09)


ocugen
Q1 2023
Business Update
May 5, 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 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 Accomplishments to Date — A Strong Start to the Year

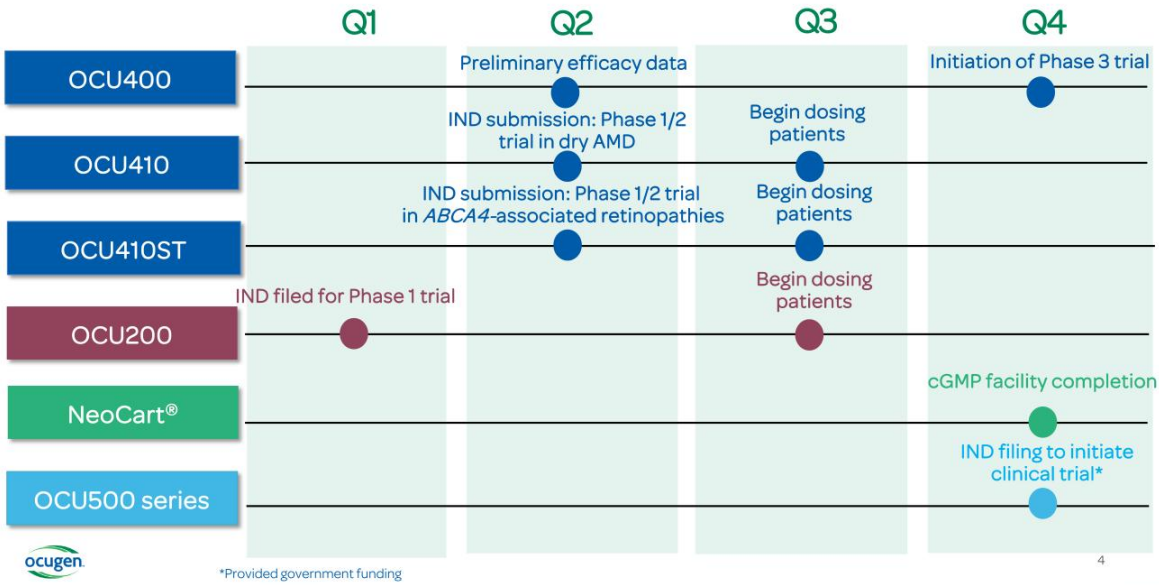
Modifier Gene Therapy

- ✓ Announced **positive** preliminary safety and efficacy results from Phase 1/2 trial of OCU400
- ✓ FDA **approved** enrollment of pediatric patients in ongoing Phase 1/2 trial of OCU400
- ✓ **Orphan Drug Designation** granted to OCU410ST for the treatment of *ABCA4*-associated retinopathies

Vaccines

- ✓ Submitted multiple proposals for federal funding of Ocugen's inhaled vaccines platform for COVID-19 and flu

2023: Several Significant Milestones Expected

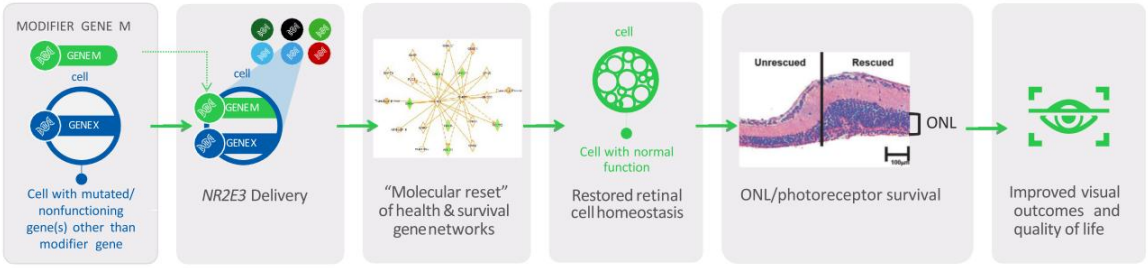


*Provided government funding

Modifier Gene Therapy: A Broader Reach

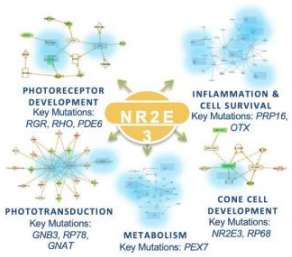
Gene modifier therapy can potentially address multiple genetic defects with a single product utilizing a gene agnostic approach.

In patients with IRDs, this could mean:



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

- Favorable safety and tolerability profile related to OCU400 investigational product candidate
- Initial clinical data from low- and medium-dose cohorts indicates a positive trend in MLMT and BCVA scores for OCU400-treated eyes
- 100% of treated eyes showed a stable or improved MLMT score trend
- 71% of OCU400 treated eyes in low- and medium-dose cohorts experienced ≥1 Lux luminance level improvement in mobility test from baseline
- 67% of OCU400 treated eyes in the low-dose cohort at 9-month follow-up experienced ≥ 2 Lux luminance level improvement in mobility test from baseline
- 43% of OCU400 treated eyes demonstrated 8-11 letters of improvement in BCVA score compared to none of the untreated eyes
- Ocugen believes these preliminary data 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.

MLMT, Multi-Luminance Mobility Test
BCVA, Best Corrected Visual Acuity

Study Overview

Primary Endpoint: Safety

Safety of subretinal administration of OCU400

Exploratory Endpoint: Efficacy

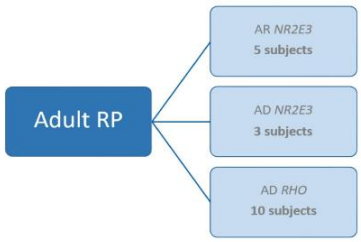
Multi-Luminance Mobility Test (MLMT)

Best Corrected Visual Acuity (BCVA)

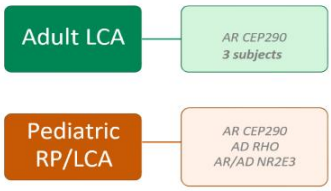
Clinical Trials.gov Identifier: **NCT05203939**

Enrollment Status

COMPLETED



ENROLLING



Multi-Luminance Mobility Test			
	Total Subjects for analyses (N=7); pooled analyses Subjects with 9-months follow-up : Cohort 1, N=3 Subjects with 6 months follow-up: N=1 from Cohort 1 and N=3 from Cohort 2		Total Subject for analyses (N=3) Cohort 1 with 9 month follow-up
	Improvement ≥ 1 Lux	Improvement ≥ 2 Lux	Improvement ≥ 2 Lux
Treated Eye	71.4%	28.6%	66.7%
Untreated Eye	28.6%	0.0%	0.0%

- *100% of treated eyes showed stability or improved MLMT scores*
- *71% of treated eyes improved by at least 1 Lux Level in pooled analyses vs ONLY 29% of untreated eyes*
- *29 % of treated eyes improved by at least 2 Lux Level in pooled analyses vs 0 % of untreated eyes*
- *67 % of treated eyes improved by at least 2 Lux Level in cohort 1 subjects with 9 months follow -up vs 0 % of untreated eyes*

MLMT is used as efficacy measure to assess visual function

Best Corrected Visual Acuity (BCVA) Score		
	Total Subjects for analyses (N=7) Subjects with 9-months follow-up : Cohort 1, N=3 Subjects with 6 months follow-up: N=1 from Cohort 1 and N=3 from Cohort 2	
	Improvement ≥ 8 Letters	
Treated Eye	42.9%	
Untreated Eye	0.0%	

OCU400: Expected Pathway to Clinical Development & Potential Approval

- Ocugen plans to meet with regulatory agencies in 3Q to potentially finalize Phase 3 clinical program and overall package
- Continuing to enroll LCA and pediatric patients in Phase 1/2 trial

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

OCU410ST: Received ODD for the Treatment of *ABCA4*-Associated Retinopathies Including 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)

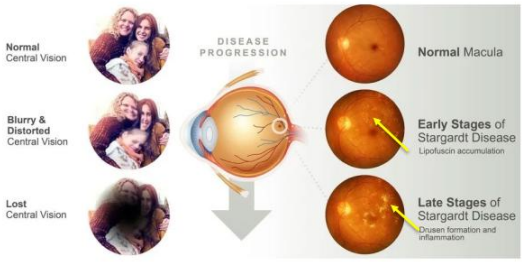
No treatment options exist

- 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

Plan to submit IND for initiation of Phase 1/2 clinical trial in 2Q 2023



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

dAMD

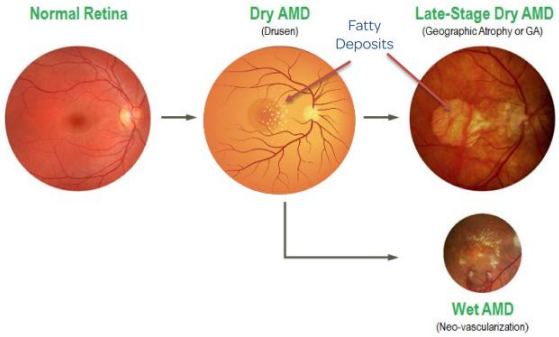
Limited options, presenting significant unmet medical need

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

Recently approved therapy for geographic atrophy (GA)—advanced form of dAMD–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

Plan to submit IND for initiation of Phase 1/2 clinical trial in 2Q 2023



OCU500 Series: Next-Generation Vaccine Candidates Using Inhalation Technology

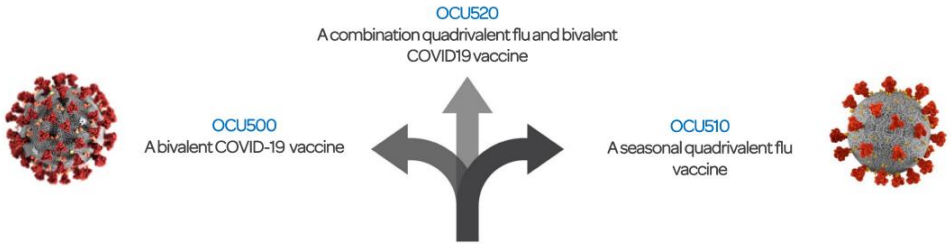
Current focus solely on the development of our inhaled mucosal vaccine platform based on chAd vector

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:

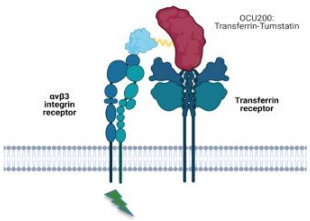
- Legislative advocacy for next-generation mucosal vaccine development
- Multiple proposal submissions for federal funding of Ocugen's inhaled vaccines platform for COVID-19 and flu
- Ongoing dialogue with several government agencies regarding the development of the inhaled vaccines platform



Pipeline Updates

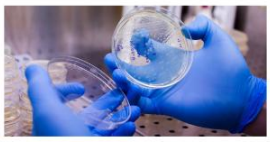
OCU200

- IND submitted. The Company plans to respond promptly to get FDA clearance to initiate Phase 1 trial.



NeoCart®

- Renovations continue on cGMP manufacturing facility for NeoCart



- Completion planned for 4Q 2023

Financial Update

Financial Update

Statement of Operations	Three months ended March 31,	
	2023	2022
Research and development expense	$9.6	$7.9
General and administrative expense	8.2	10.1
Other income (expense), net	1.3	-
Net loss	$(16.5)	$(18.0)
Net loss per share of common stock – basic and diluted	$(0.07)	$(0.09)

Balance Sheet Data	March 31, 2023	December 31, 2022
Cash, cash equivalents, and investments	$76.7	$90.9
Debt	$2.3	$2.3
Shares outstanding	226.4	221.6

Unaudited; in millions, except per share amounts

Questions & Answers


ocugen™
Thank you!
May 2023
NASDAQ: OCGN