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 14, 2024**

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 14, 2024, Ocugen, Inc. (the "Company") issued a press release announcing certain financial results for the quarter ended March 31, 2024. The Company has scheduled a conference call and webcast for 8:30 a.m. Eastern Time on May 14, 2024, 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 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 14, 2024.
99.2	Earnings Release Presentation issued May 14, 2024.
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 14, 2024

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 2024 Financial Results

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

- *All three first-in-class modifier gene therapy product candidates currently in the clinic with OCU400 Phase 3 in progress*
- *OCU400 on track to meet 2026 Biologics License Application (BLA) and Market Authorization Application (MAA) approval targets*

MALVERN, Pa., May 14, 2024 (GLOBE NEWSWIRE) – Ocugen, Inc. (Ocugen or the Company) (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, and vaccines, today reported first quarter 2024 financial results along with a general business update.

“We’ve experienced several important clinical and regulatory milestones since the beginning of 2024 that we believe are leading the way to a new treatment paradigm for patients with blindness diseases,” said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. “It’s very encouraging to have FDA clearance and EMA support for the Phase 3 clinical trial of our lead modifier gene therapy candidate that offers a potential one-time treatment for life.”

With FDA clearance to begin the Phase 3 liMelihGT clinical trial, OCU400 becomes the first gene therapy to progress to late-stage trials with a broad retinitis pigmentosa (RP) indication. Until now, there has been only one marketed product to treat one of the 100 gene mutations associated with RP. The gene-agnostic mechanism of action for OCU400 provides hope for a much larger RP patient population. In the U.S. and Europe combined, RP affects nearly 300,000 people.

Ocugen expects to begin dosing patients in the Phase 3 liMeliGhT clinical trial in the second quarter of 2024. The Phase 3 trial will have a sample size of 150 participants—one arm of 75 participants with the *RHO* gene mutation and the other arm with 75 participants that are gene-agnostic. Luminance Dependent Navigation Assessment (LDNA) is the primary endpoint for the study and focuses on the proportion of responders, in treated and untreated groups, achieving an improvement of at least 2 Lux levels from baseline in the study eyes.

Leveraging a dual-track strategy, the Company plans to expand the Phase 3 OCU400 clinical trial in the second half of 2024 to include patients with Leber Congenital Amaurosis (LCA), contingent on favorable results from the Phase 1/2 study.

Modifier gene therapy has the potential to treat inherited retinal diseases as well as multifactorial blindness diseases affecting millions of patients. Leveraging the nuclear receptor RAR-related orphan receptor A (RORA), OCU410 is designed to regulate all four pathways involved with dry age-related macular degeneration (dAMD)—including lipid metabolism, inflammation, oxidative stress, and membrane attack complex (complement). Ocugen is developing OCU410 as a one-time gene therapy for the treatment of geographic atrophy (GA), an advanced stage of dAMD, affecting 2-3 million people in the U.S. and Europe combined. OCU410ST is being developed as a one-time gene therapy for the treatment of Stargardt disease, affecting approximately 100,000 people in the U.S. and Europe combined.

In April, dosing was complete in the second cohort (medium dose) of the Phase 1/2 ArMaDa clinical trial for OCU410. Dosing in the first cohort (low dose) of the Phase 1/2 GARDian trial for OCU410ST was completed earlier in the first quarter and in April 2024, the Data Safety and Monitoring Board approved the continuation to cohort 2 (medium dose).

“Our efforts in the first quarter of the year evidence the importance of our gene therapy programs and the need to operate the business to ensure their success,” said Dr. Musunuri. “We are opportunistic about Ocugen’s cell therapy and vaccine platforms, knowing that these technologies have great therapeutic and financial potential and are pursuing partnerships to support our entire pipeline.”

Ophthalmic Gene Therapies —First-in-class

- **OCU400** — Received FDA clearance of IND amendment to initiate OCU400 Phase 3 liMeliGhT clinical trial in RP. EMA provided acceptability of the U.S.-based trial for submission of Marketing Authorization Application (MAA). Currently, the multi-center Phase 3 clinical trial is in progress.

- **OCU410** — Currently in Phase 1/2 stage of clinical development with active patient enrollment. Dosing is complete in the second cohort (medium dose) in the dose-escalation phase of the study. Once the third cohort (high dose) is complete, the Company will move into the Phase 2 clinical trial—the expansion phase—in the third quarter of 2024.

- **OCU410ST** — Currently in Phase 1/2 stage of clinical development with active patient enrollment. Dosing is complete for Cohort 1 (low dose). Initiated enrollment in Cohort 2 (medium dose) in the dose-escalation phase of the study.

Regenerative Cell Therapies—First-in-class

- **NeoCart®** — Completed renovating an existing facility into a current Good Manufacturing Practice ("GMP") facility in accordance with the FDA's regulations. Intend to initiate the Phase 3 trial, contingent on adequate availability of funding.

Vaccines Portfolio—First-in-class

- **Mucosal Vaccine Platform** — NIAID is collaborating with Ocugen on clinical development of OCU500. Planning to submit IND by mid-2024 to initiate Phase 1 clinical trial.

Biologics

- **OCU200**— Continue to work with FDA to address comments to lift the clinical hold.

First Quarter 2024 Financial Results

- The Company's cash and cash equivalents totaled $26.4 million as of March 31, 2024, compared to $39.5 million as of December 31, 2023. The Company had 257.3 million shares of common stock outstanding as of March 31, 2024.

- Total operating expenses for the three months ended March 31, 2024 were $13.2 million and included research and development expenses of $6.8 million and general and administrative expenses of $6.4 million. This compares to total operating expenses for the three months ended March 31, 2023 of $18.5 million that included research and development expenses of $10.2 million and general and administrative expenses of $8.3 million.

- Ocugen reported a $0.05 net loss per common share for the three months ended March 31, 2024 compared to a $0.08 net loss per common share for the three months ended March 31, 2023.

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: 8699924
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 X 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, including, but not limited to, strategy, business plans and objectives for Ocugen's clinical programs, plans and timelines for the preclinical and clinical development of Ocugen's product candidates, including the therapeutic potential, clinical

benefits and safety thereof, expectations regarding timing, success and data announcements of current ongoing preclinical and clinical trials, the ability to initiate new clinical programs; Ocugen's financial condition, statements regarding qualitative assessments of available data, potential benefits, expectations for ongoing clinical trials, anticipated regulatory filings and anticipated development timelines, 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, including, but not limited to, the risks that preliminary, interim and top-line clinical trial results may not be indicative of, and may differ from, final clinical data; that unfavorable new clinical trial data may emerge in ongoing clinical trials or through further analyses of existing clinical trial data; that earlier non-clinical and clinical data and testing of may not be predictive of the results or success of later clinical trials; and that clinical trial data are subject to differing interpretations and assessments, including by regulatory authorities. These and other risks and uncertainties are more fully described in our annual and 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

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

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 26,375	$ 39,462
Prepaid expenses and other current assets	3,623	3,509
Total current assets	29,998	42,971
Property and equipment, net	17,654	17,290
Other assets	4,142	4,286
Total assets	$ 51,794	$ 64,547
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,731	$ 3,172
Accrued expenses and other current liabilities	12,434	13,343
Operating lease obligations	589	574
Current portion of long term debt	1,296	—
Total current liabilities	16,050	17,089
Non-current liabilities		
Operating lease obligations, less current portion	3,414	3,567
Long term debt, net	1,533	2,800
Other non-current liabilities	536	527
Total liabilities	21,533	23,983
Stockholders' equity		
Convertible preferred stock	1	1
Common stock	2,575	2,567
Treasury stock	(48)	(48)
Additional paid-in capital	325,799	324,191
Accumulated other comprehensive income	25	20
Accumulated deficit	(298,091)	(286,167)
Total stockholders' equity	30,261	40,564
Total liabilities and stockholders' equity	$ 51,794	$ 64,547

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

	Three months ended March 31,	
	2024	2023
Collaborative arrangement revenue	$ 1,014	$ 443
Total revenue	1,014	443
Operating expenses		
Research and development	6,826	10,172
General and administrative	6,404	8,306
Total operating expenses	13,230	18,478
Loss from operations	(12,216)	(18,035)
Other income (expense), net	292	709
Net loss	$ (11,924)	$ (17,326)
Shares used in calculating net loss per common share — basic and diluted	257,232,636	225,523,627
Net loss per share of common stock — basic and diluted	$ (0.05)	$ (0.08)

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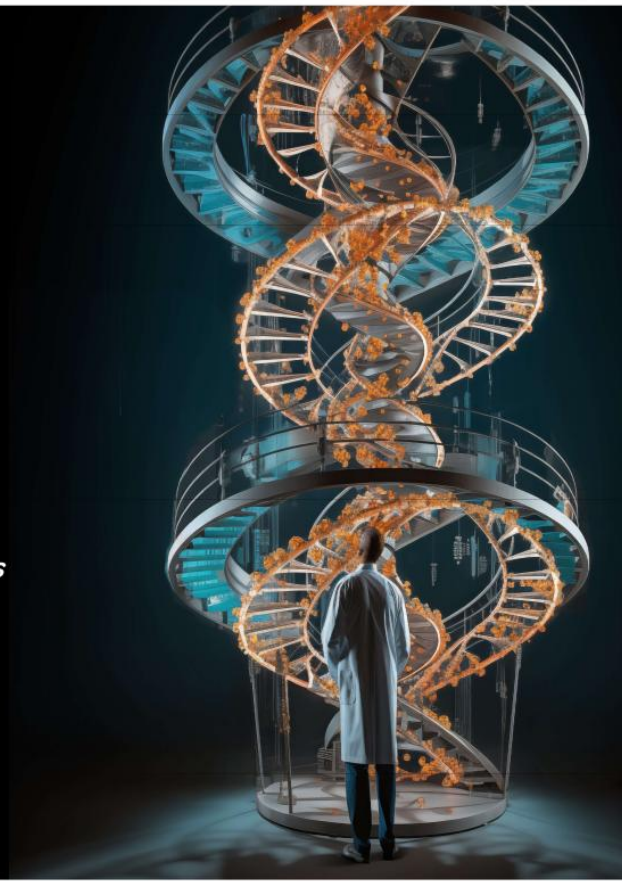
Courageous Innovation

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

1Q 2024
Business Update
May 14, 2024



Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including, but not limited to, strategy, business plans and objectives for Ocugen's clinical programs, plans and timelines for the preclinical and clinical development of Ocugen's product candidates, including the therapeutic potential, clinical benefits and safety thereof, expectations regarding timing, success and data announcements of current ongoing preclinical and clinical trials, t ability to initiate new clinical programs; Ocugen's financial condition, statements regarding qualitative assessments of available data, potential benefits, expectations for ongoing clinical trials, anticipated regulatory filings and anticipated development timelines, 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 ou current expectations, including, but not limited to, the risks that preliminary, interim and top-line clinical trial results may not be indicative of, and may differ from, final clinical data; that unfavorable new clinical trial data may emerge in ongoing clinical trials or through further analyses of existing clinical trial data; that earlier non-clinical and clinical data and testing of may not be predictive the results or success of later clinical trials; and that that clinical trial data are subject to differing interpretations and assessments, including by regulatory authorities. These and other risks and uncertainties are more fully described in our annual and periodic filin with the Securities and Exchange Commission (SEC), including the risk factors described in the section entitled "Risk Factors" in th quarterly and annual reports that we file with the SEC. Any forward-looking statements that we make in this presentation speak on 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.

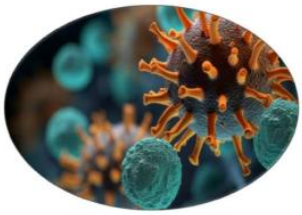
Through Courageous Innovation, We are Leveraging Our First-in-Class Platforms to Address Serious Unmet Medical Needs

Modifier Gene Therapy Platform
First-in-Class

- OCU400 Phase 3 liMeliGhT clinical trial (broad retinitis pigmentosa)
- OCU410 Ph1/2 ArMaDa clinical trial (geographic atrophy)
- OCU410ST Ph1/2 GARDian clinical trial (Stargard

Regenerative Cell Therapy Platform
First-in-Class

- Intend to initiate Phase 3 NeoCart® clinical trial, contingent on adequate availability of funding



Inhalation Vaccines Platform
First-in-Class

- Targeting OCU500 IND submission by mid-2024 to initiate Phase 1 clinical trial

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Modifier Gene Therapy – Creating a Paradigm Shift in Gene Therapy

- ✓ Received FDA clearance of IND amendment to initiate OCU400 Phase 3 clinical trial in retinitis pigmentosa (RP)
  - First gene therapy trial to receive broad RP indication from FDA
- ✓ EMA provided acceptability of the U.S.-based trial for submission of Marketing Authorization Application (MAA) of the OCU400 Phase 3 liMeliGhT clinical trial for RP
- ✓ Key Regulatory Approvals: Orphan Drug, Regenerative Medicine Advanced Therapy, Orphan Medicinal Product designations from both the FDA and the European Commission for treating inherited retinal diseases

Upcoming anticipated catalysts: Begin dosing patients in Phase 3 clinical trial for RP in 2Q 2024, followed by LCA Phase 3 clinical trial initiation in 2H 2024

Remain on track to meet 2026 BLA and MAA approval targets

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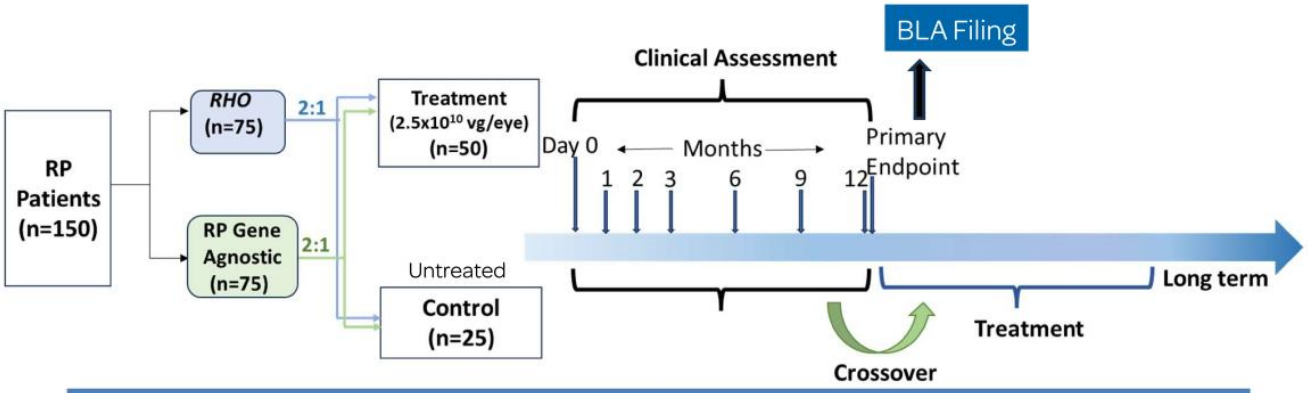
OCU400 Phase 3 Clinical Trial Design

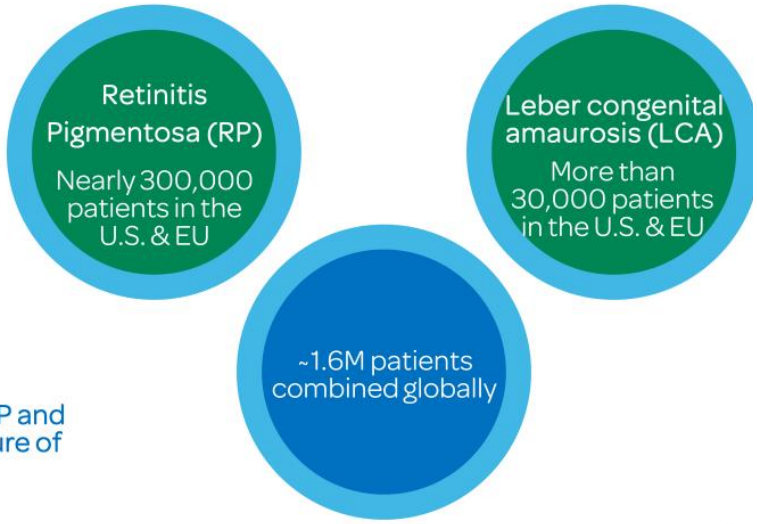


Study Design	
Population	• Patient with ≥8 years of age with Clinical and Molecular Diagnosis of Retinitis Pigmentosa
Key Eligibility Criteria	• BCVA ≤ 75 letters and ≥25 letters (ETDRS Chart) • Able to perform LDNA at ≤ 500 Lux but unable to pass the LDNA at ≤ 0.35 at the Screening visit • Presence of photoreceptors
Endpoints	
Primary	• Proportion of responder (**LDNA ≥ 2 Lux Level from Baseline- Study Eyes**) in treatment vs control arm
Secondary	• Proportion of responder EYES (**LDNA ≥ 2 Lux Level from Baseline**) in treatment vs control • Proportion of responder (LLVA score change of 0.3logMAR from Baseline) in treatment vs control

OCU400: RP & LCA Market Opportunity

OCU400 is designed to address the shortcomings of current gene therapy approaches—a broad spectrum, gene-agnostic approach to genetically diverse inherited retinal diseases and potential one-time therapy for life with a single sub-retinal injection

Preservation of vision is crucial for patients with RP and LCA due to the progressive and degenerative nature of these diseases



OCU410 and OCU410ST: Modifier Gene Therapy Continued Clinical Momentum

- ✓ OCU410 and OCU410ST modifier gene therapies leverage the nuclear receptor gene RAR-related orphan receptor A (RORA)
- ✓ Aim to provide a potential one-time therapy for life with a single sub-retinal injection
- ✓ Dosing underway for OCU410 and OCU410ST Phase 1/2 clinical trials

Clinical updates for both OCU410 and OCU410ST expected in 3Q 2024

OCU410 (dry-AMD): Modifier Gene Therapy Continued Clinical Momentum

- ✓ Dosing completion of subjects with GA in cohort 1 of OCU410 Phase 1/2 ArMaDa clinical trial
- ✓ Dosing completion of subjects with GA in cohort 2 of OCU410 Phase 1/2 ArMaDa clinical trial

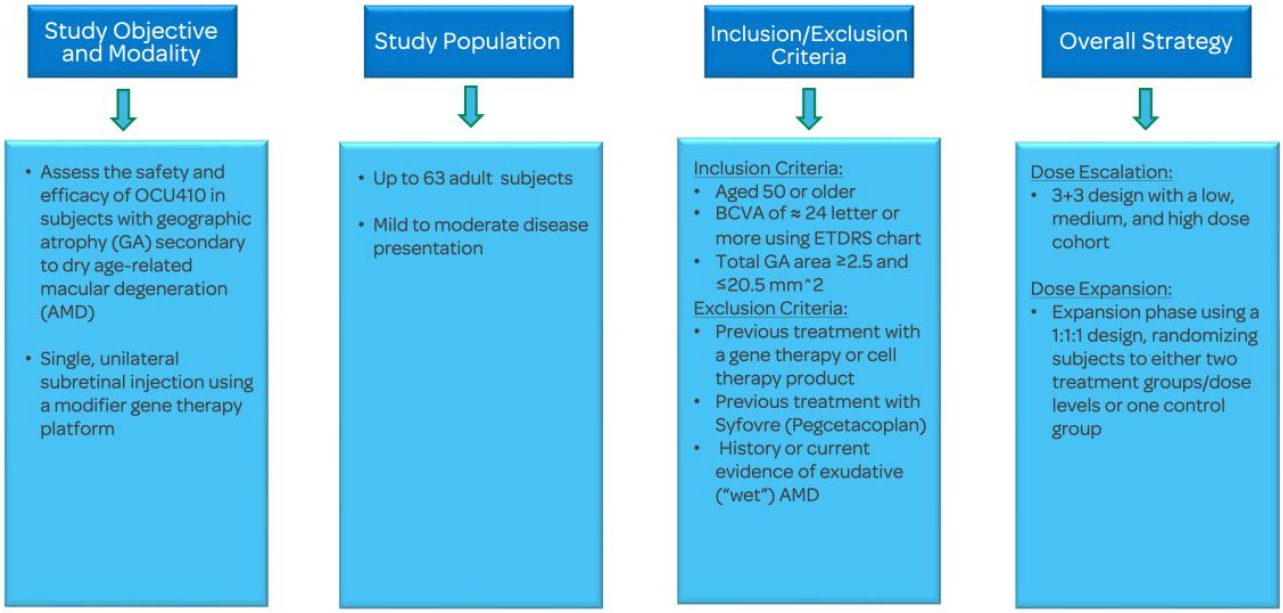
Upcoming anticipated catalyst: Clinical update from ongoing OCU410

Phase 1/2 trial anticipated in 3Q 2024

dry AMD affects nearly 19M people in the U.S. & EU
GA affects
~2-3M people in the U.S. & EU– a significant market opportunity

"We are very enthusiastic about the potential of OCU410 as a one-time therapy for life for the treatment of GA. OCU410 regulates multiple pathways involved with the disease including lipid metabolism, inflammation, oxidative stress, and membrane attack complex with a single sub-retinal injection." – Chief Medical Officer, Dr. Huma Qamar

OCU410 Program Overview



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OCU410ST (Stargardt Disease): Modifier Gene Therapy Clinical Momentum

- ✓ Dosing completion of subjects with Stargardt disease in cohort 1 of OCU410ST Phase 1/2 GARDian clinical trial
- ✓ DSMB approved to proceed dosing with the medium dose of OCU410ST in the dose-escalation phase of the study

Upcoming anticipated catalyst: Clinical update from ongoing OCU410ST Phase 1/2 trial anticipated 3Q 2024

No treatment options available for Stargardt disease patients. Stargardt affects ~100,000 in the U. and EU

"We are pleased to see the continued favorable safety and tolerability profile exhibited by OCU410ST, allowing us to evaluate a higher dose in patients with Stargardt retinal dystrophy. We recognize the high unmet medical need for Stargardt patients, as there are no current FDA-approved therapies for the indication, and we look forward to sharing the preliminary safety and efficacy data from our Phase 1 trial in the second half of 2024."

– Chief Medical Officer, Dr. Huma Qamar

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OCU410ST Program Overview

Study Objective and Modality

- Assess the safety and efficacy of OCU410ST in subjects with Stargardt disease
- Single, unilateral subretinal injection using a modifier gene therapy platform

Study Population

- Up to 42 subjects (30 adults and 12 pediatrics)
- Mild to moderate disease presentation

Inclusion/Exclusion Criteria

Adult Inclusion Criteria:
- Aged 18-65
- Total lesion area ≤18 mm^2
- BCVA of 50 ETDRS letters or less

Pediatric Inclusion Criteria:
- Aged 6-17
- Total lesion area ≤18 mm^2
- BCVA of 35 ETDRS letters or more

Exclusion Criteria:
- Previous treatment with a gene-therapy or cell therapy product
- Has genes that mimic Stargardt disease like ELOVL4 or PROM1

Overall Strategy

Dose Escalation:
- 3+3 design with a low, medium, and high dose cohort

Dose Expansion:
- Expansion phase using a 1:1:1 design, randomizing subjects to either two treatment groups/dose levels or one control group

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Financial Update

Financial Update

Statement of Operations	Three months ended March 31,	
	2024	2023
Research and development expense	$6.8	$10.2
General and administrative expense	6.4	8.3
Other income (expense), net	0.3	0.7
Net loss	$(11.9)	$(17.3)
Net loss per share of common stock – basic and diluted	$(0.05)	$(0.08)

Balance Sheet Data	March 31, 2024	December 31, 2023 (audited)
Cash and cash equivalents	$26.4	$39.5
Debt	$2.8	$2.8
Shares outstanding	257.3	256.6

Except as otherwise noted, all amounts are unaudited; in millions, except per share amounts
Certain amounts may not add due to rounding

Questions & Answers

2024 Near-Term Targeted Milestones

- Initiate OCU400 Ph3 clinical trial and recruit efficiently – in line with 2026 BLA/MAA approval target
- OCU400 Ph3 clinical updates
- Preliminary safety/efficacy updates – OCU410 Ph1/2 clinical trial (GA)
- Preliminary safety/efficacy updates – OCU410ST Ph1/2 clinical trial (Stargardt)
- Finalize partner for OCU400 – to maximize value for patients and shareholders

Ocugen™ Vision

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