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 28, 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 February 28, 2023, Ocugen, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and the fiscal year ended December 31, 2022. The Company has scheduled a conference call and webcast for 8:30 a.m. eastern time on February 28, 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 and incorporated herein by reference.

The information disclosed under Item 2.02 of this Current Report on Form 8-K, 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, 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 February 28, 2023.
99.2	Earnings Release Presentation issued February 28, 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: February 28, 2023

OCUGEN, INC.

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

Exhibit 99.1

Ocugen Provides Business Update with Fourth Quarter and Full Year 2022 Financial Results

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

- *Completed retinitis pigmentosa patient enrollment in OCU400 Phase 1/2 clinical trial*
- *Continued progress for programs targeting eye diseases with the submission of an IND application for OCU200*
- *Expanded portfolio now includes inhaled vaccines for COVID-19, seasonal flu, and a combination COVID-19+seasonal flu vaccine*

MALVERN, Pa., Feb. 28, 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 fourth quarter and full year 2022 financial results along with a general business update.

"We continue to grow and advance as a diversified biotechnology organization as reflected in our accomplishments of 2022," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "Our pipeline has been expanded to appropriately address the current challenges and gaps in the fight against COVID-19, application of OCU410 to address Stargardt (a rare eye disease), and our novel approach to address dry age-related macular degeneration (dAMD)—a disease affecting vision in over 266 million people worldwide.

"Following FDA concurrence in the fourth quarter of 2022 on a confirmatory Phase 3 clinical trial design for NeoCart®, we are developing internal capabilities to move our regenerative medicine asset, NeoCart®, into the clinic next year."

"The FDA has granted expanded orphan drug designations to OCU400 for the treatment of retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA)," said Dr. Musunuri. "These broad, gene-agnostic designations are encouraging at this stage in the development of OCU400."

"During our first decade, we have built a strong foundation for addressing the diseases and conditions we aim to treat. We delivered on our promise to file an OCU200 IND in the first quarter of 2023 and look forward to delivering on important milestones in 2023, especially regarding preliminary efficacy data for gene therapy product OCU400, as we progress toward realizing our long-term vision to address unmet medical needs through courageous innovation," Dr. Musunuri concluded.

Business Updates

Ophthalmic Gene Therapies

- **OCU400** — Established the high dose as the maximum tolerable dose, completed retinitis pigmentosa patient enrollment, and continuing to enroll patients with LCA to receive the high dose. Ocugen intends to initiate a Phase 3 clinical trial near the end of 2023.
- **OCU410 and OCU410ST** — Executing IND-enabling studies and intend to submit IND applications in the second quarter of 2023 to initiate Phase 1/2 clinical trials in dry AMD (geographic atrophy) and Stargardt disease.

Ophthalmic Biologic Product

- **OCU200** — Submitted an IND application on February 27, 2023 to initiate a Phase 1 clinical trial targeting diabetic macular edema.

Regenerative Cell Therapies

- **NeoCart®** — Received concurrence from the FDA on the confirmatory Phase 3 clinical trial design. Ocugen intends to initiate the Phase 3 clinical trial in the first half of 2024. Ocugen is renovating its facility to accommodate cGMP manufacturing of NeoCart® for clinical trials and beyond.

Vaccines Portfolio

- **OCU500 Series** — Developing a novel mucosal vaccine platform which includes OCU500, a bivalent COVID-19 inhaled vaccine; OCU510, a seasonal quadrivalent flu inhaled vaccine; and OCU520 a combination quadrivalent seasonal flu and bivalent COVID-19 inhaled vaccine.
- **COVAXIN™ (BBV152)** — Completed enrollment in Phase 2/3 immuno-bridging and broadening clinical trial in fourth quarter 2022.

Financial Results

- Fourth quarter — Research and development expenses for the three months ended December 31, 2022, were $17.2 million compared to $7.1 million for the three months ended December 31, 2021. General and administrative expenses for the three months ended December 31, 2022, were $6.9 million compared to $7.5 million for the three months ended December 31, 2021. Ocugen reported a $0.10 net loss per common share for the three months ended December 31, 2022, compared to a $0.07 net loss per common share for the three months ended December 31, 2021.
- Full year — Research and development expenses for the year ended December 31, 2022, were $49.8 million compared to $35.1 million for the year ended December 31, 2021. General and administrative expenses for the year ended December 31, 2022, were $35.1 million compared to $22.9 million for the year ended December 31, 2021. Ocugen reported a $0.38 net loss per common share for the year ended December 31, 2022, compared to a $0.30 net loss per common share for the year ended December 31, 2021.
- Ocugen's cash, cash equivalents, restricted cash, and investments totaled $90.9 million as of December 31, 2022, compared to $95.1 million as of December 31, 2021. 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 221.6 million shares of common stock outstanding as of December 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: 8912239
Webcast: Available on Ocugen's 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, biologics, 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.

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)

	As of December 31,	
	2022	2021
Assets		
Current assets		
Cash and cash equivalents	$ 77,563	$ 94,958
Marketable securities	13,371	—
Prepaid expenses and other current assets	7,558	7,688
Total current assets	98,492	102,646
Property and equipment, net	6,053	1,164
Restricted cash	—	151
Other assets	4,087	1,800
Total assets	$ 108,632	$ 105,761
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 8,062	$ 2,312
Accrued expenses and other current liabilities	9,900	4,325
Operating lease obligations	498	363
Total current liabilities	18,460	7,000
Non-current liabilities		
Operating lease obligations, less current portion	3,587	1,231
Long term debt, net	2,289	1,712
Other non-current liabilities	244	—
Total liabilities	24,580	9,943
Stockholders' equity		
Convertible preferred stock	1	1
Common stock	2,217	1,995
Treasury stock	(48)	(48)
Additional paid-in capital	294,874	225,537
Accumulated other comprehensive income	26	—
Accumulated deficit	(213,018)	(131,667)
Total stockholders' equity	84,052	95,818
Total liabilities and stockholders' equity	$ 108,632	$ 105,761

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

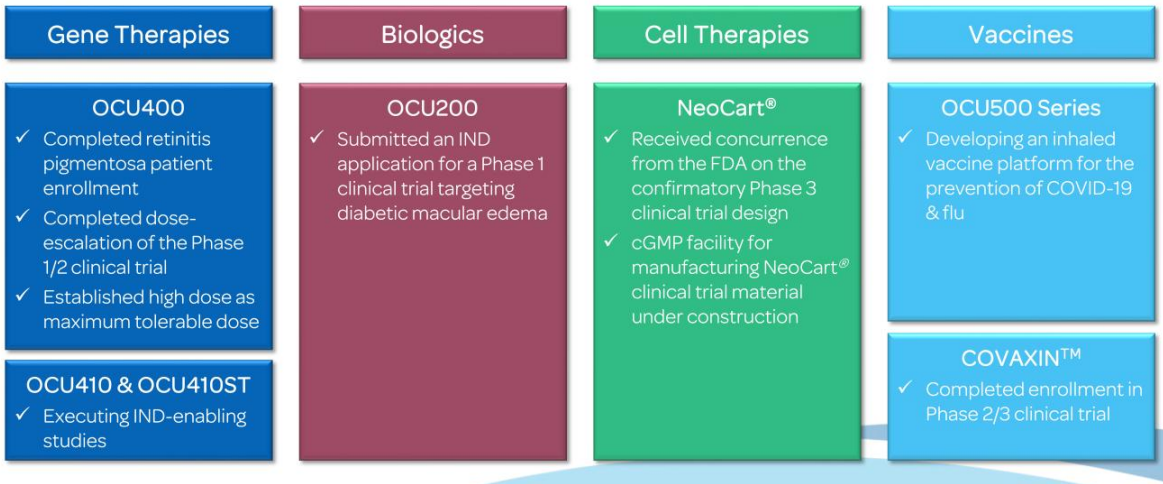
	Three months ended December 31,		Year ended December 31,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 17,213	$ 7,102	$ 49,757	$ 35,108
General and administrative	6,937	7,470	35,111	22,920
Total operating expenses	24,150	14,572	84,868	58,028
Loss from operations	(24,150)	(14,572)	(84,868)	(58,028)
Other income (expense), net	2,211	(9)	3,517	(389)
Loss before income taxes	(21,939)	(14,581)	(81,351)	(58,417)
Income tax benefit	—	—	—	(52)
Net loss	$ (21,939)	$ (14,581)	$ (81,351)	$ (58,365)
Shares used in calculating net loss per common share — basic and diluted	220,072,823	199,207,502	214,600,051	195,013,043
Net loss per common share — basic and diluted	$ (0.10)	$ (0.07)	$ (0.38)	$ (0.30)


ocugen
Q4 & Full Year 2022
Business Update
February 28, 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.

Accomplishments – 2022 & YTD



OCU400: Phase 1/2 Clinical Trial Progressing as Planned, Developing a Novel Gene Therapy in Ophthalmic Areas of High Unmet Need

FDA granted expanded Orphan Drug Designations for all retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA) mutations

Despite its prevalence, RP and LCA patients have limited treatment options

- US: RP & LCA affect 110K and 15K people, respectively
- Worldwide: conditions affect approximately 1.6M people

Current approved and in-development gene therapies focus on individual gene

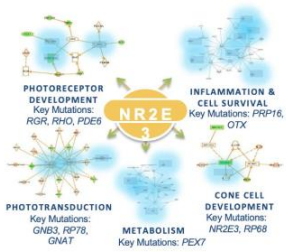
- More than 125 mutated genes associated with RP and LCA
- Developing a single therapy to treat each mutation is infeasible

OCU400 addresses shortcomings of current gene therapy approaches

- Broad-spectrum, gene-agnostic approach to genetically diverse inherited retinal diseases
- Therapy with a ***single*** sub-retinal injection, using NHRs

Dose escalation and recruitment of RP patients completed

- High dose established as Maximum Tolerable Dose (MTD)
- Continue to enroll patients with LCA
- Intend to initiate a Phase 3 trial near the end of 2023.



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

OCU200: Submitted an IND with the US FDA Yesterday to Initiate a Phase 1 Clinical Trial Targeting Diabetic Macular Edema (DME)

OCU200 is our novel biologics candidate for sight-threatening conditions

- A recombinant fusion protein of tumstatin and transferrin
- Potential to address diabetic macular edema (DME), diabetic retinopathy (DR), wet AMD

High prevalence of DME, DR and wet AMD patients

- DME: 21M worldwide
- DR: 162M worldwide
- Wet AMD: 30M worldwide

Limited treatment options available for the above patients

- Current therapies target only one pathway, either angiogenesis or inflammation
- Up to 50% of patient populations experience limited or no response to current treatments

OCU200 potentially addresses shortcomings of current treatments

- Intended to targets multiple causative pathways such as angiogenesis, oxidation, inflammation
- Potential to offer better treatment options for ***all*** patients

Company submitted an IND application on February 27, 2023

- Initially targeting DME

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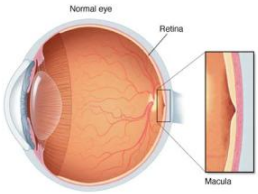
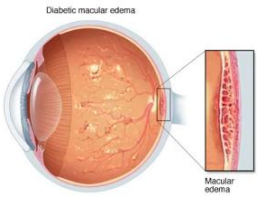




Diabetic Macular Edema: bulges protrude from the blood vessels, leading to leakage of fluid and blood into the retina; leakage results in swelling (or "edema"), promoting vision loss.

NeoCart®: US FDA Agreed to Proposed Control and Overall Design for Phase 3 Trial to Evaluate Safety and Efficacy Compared to Chondroplasty Standard of Care

NeoCart is a regenerative cell therapy technology

- Combines bioengineering and cell processing to enhance autologous cartilage repair
- Potential to accelerate healing and reduce pain through reconstructing damaged knee cartilage

High prevalence of knee cartilage damage, with progression to osteoarthritis (OA)

- Arthroscopic knee procedures: over 1M annually*
- OA: 528M diagnosed worldwide
- Cell therapy global revenue forecast: $45B+, with North America expected to hold largest share**

Current therapies to treat cartilage damage in the knee suboptimal

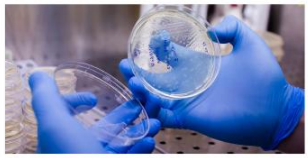
- Varying outcomes due to variable cellular responses
- Current standard of care suffers from one or more of the following: pain, reduced knee function, failure to address cartilage damage, donor tissue availability, open surgery

NeoCart potentially addresses shortcomings of current treatments

- Treat pain at the source, improve function and potentially prevent progression to OA
- Potential for improved efficacy, long-term benefits, accelerated discovery, predictable outcomes

Program advancing on several fronts

- Received FDA concurrence on confirmatory trial design of Phase 3 (initiate 1H2024)
- Renovating facility to accommodate cGMP manufacturing for clinical trials



*The Journal of Bone & Joint Surgery: June 1, 2011 - Volume 93 - Issue 11 - p 994-1000
**https://www.biospace.com/article/cell-therapy-market-size-cagr-trends-forecast-report-2022-2030/

OCU500 Series: Next-Generation Vaccine Candidates Using Inhalation Technology to Potentially Overcome Durability and Transmission Challenges

COVID-19 and flu infections continue to be a public health concern

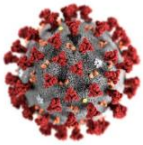
- COVID-19: 1M+ US cases in the last 30 days; 5M+ WW cases with 47K deaths in the last 28 days
- Flu: 50%+ of U.S. population 6-months and older received a shot for the 2022 to 2023 flu season, totaling 170M doses

Limitations of current COVID-19 vaccines

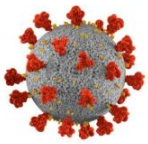
- Lack of durability: immunity wanes significantly over time, requiring repeated boosters
- Inability to stop transmission: breakthrough infections prevalent, increasing potential for mutations

Inhalation vaccine advantages

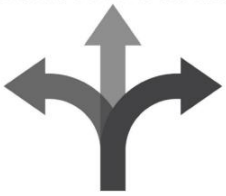
- Potential to generate rapid mucosal immunity in respiratory pathways, limiting infection and transmission
- COVID-19 preclinical studies demonstrated vaccine induced high neutralizing and effector responses



OCU520
A combination quadrivalent flu and bivalent COVID19 vaccine

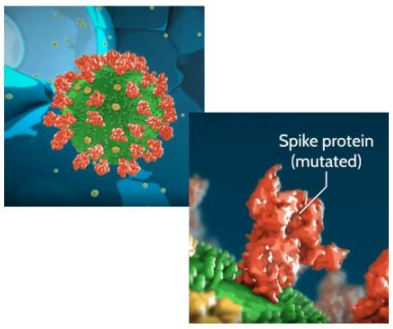


OCU500
A bivalent COVID-19 vaccine



OCU510
A seasonal quadrivalent flu vaccine

COVAXIN™ (BBV152): Final Data and Analysis Expected Mid-Year 2023 for Our Injectable COVID-19 Vaccine

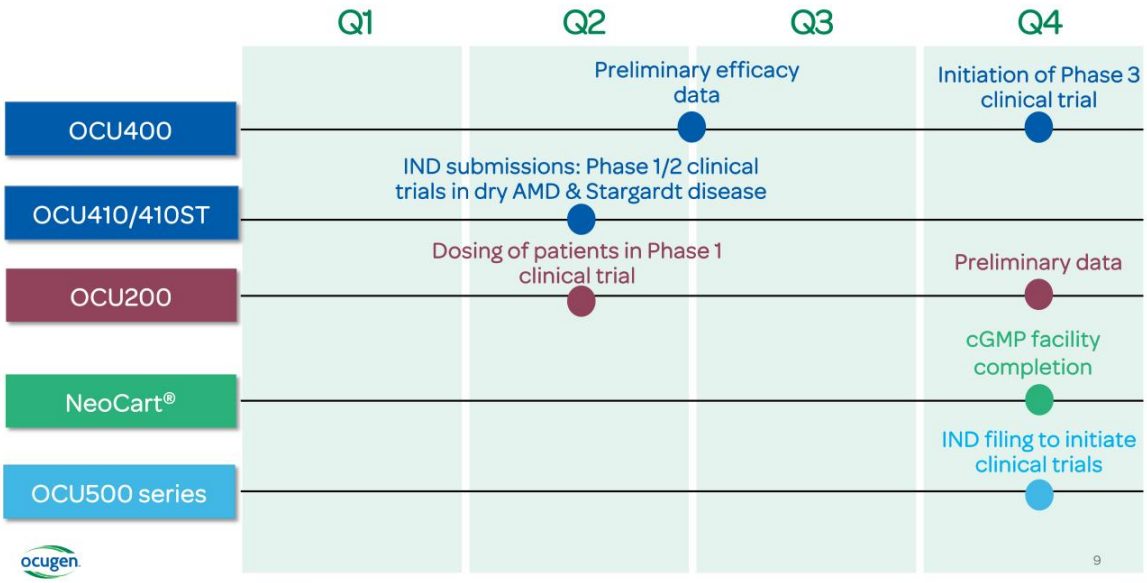


Enrollment completed for Phase 2/3 immuno-bridging and broadening clinical trial in December 2022

Topline data highlights, reported in January 2023, include the following:

- Safety: well-tolerated with no related serious adverse events (no thrombotic, myocarditis, pericarditis cases)
- Efficacy: immunogenicity demonstrated
- Final data and analysis: anticipated mid-year 2023

2023: Several Significant Milestones Expected



Financial Update

Financial Update

Statement of Operations	Three months ended December 31,		Year ended December 31,	
	2022	2021	2022	2021
Research and development expense	$17.2	$7.1	$49.8	$35.1
General and administrative expense	6.9	7.5	35.1	22.9
Other income (expense), net	2.2	–	3.5	(0.4)
Net loss	$(21.9)	$(14.6)	$(81.4)	$(58.4)
Net loss per share of common stock – basic and diluted	$(0.10)	$(0.07)	$(0.38)	$(0.30)

Balance Sheet Data	As of December 31,	
	2022	2021
Cash, cash equivalents, restricted cash, and investments	$90.9	$95.1
Debt	$2.3	$1.7
Shares outstanding	221.6	199.4

Unaudited; in millions, except per share amounts

Questions & Answers

ocugen


ocugen™
Thank you!
February 2023
NASDAQ: OCGN