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): **November 8, 2022**

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 November 8, 2022, Ocugen, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022. The Company has scheduled a conference call and webcast for 8:30 a.m. eastern time on November 8, 2022 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 November 8, 2022.
99.2	Earnings Release Presentation issued November 8, 2022.
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: November 8, 2022

OCUGEN, INC.

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

Exhibit 99.1

Ocugen Provides Business Update & Third Quarter 2022 Financial Results

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

- *Initiated dosing in the third and final cohort of U.S. Phase 1/2 OCU400 gene therapy clinical trial*
- *Expanded product pipeline with OCU500—Ocugen's mucosal COVID-19 vaccine and OCU410ST for Stargardt disease*
- *Completed enrollment of U.S. Phase 2/3 COVAXIN™ (BBV152) clinical trial*

Malvern, Pa, November 8, 2022 (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 financial results for the quarter ended September 30, 2022, and provided a general business update.

"We achieved several important milestones in the third quarter of 2022," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "We expanded our vaccines pipeline by adding a second asset to combat COVID-19, OCU500, through our exclusive license agreement with Washington University to develop, manufacture, and commercialize a mucosal vaccine in the United States, Europe, and Japan."

"Our modifier gene therapy platform has significant potential to address multiple blindness diseases," said Dr. Musunuri. "The OCU400 clinical trial is on track, and we are also pleased to announce the addition of OCU410ST to our pipeline as a potential therapy for Stargardt disease—an orphan disease."

"We continue to deliver on our near-term commitments as we advance our longer-term strategy and goal of bringing solutions to patients with debilitating diseases for whom no appropriate treatment options exist. We are passionate about this goal and anticipate achieving multiple milestones across our programs next year," Dr. Musunuri concluded.

Business Updates

Vaccines

- **COVAXIN™ —** enrollment was completed, and dosing continues, in the Phase 2/3 immuno-bridging and broadening clinical trial. No safety concerns have been identified to date and efficacy is being continuously monitored. Top line data is expected in early 2023.
- **OCU500 —** a novel adenovirus-vectored mucosal vaccine, specifically designed to block COVID-19 infection at the portal of virus entry and that could prevent transmission as well as provide protection against new variants. This approach represents a potential universal booster, regardless of previous COVID-19 vaccination. Obtaining mucosal immunity has been published as a potential way to prevent infection and transmission, thus limiting the origin of new variants. Mucosal vaccines similar to the Company's approach are already authorized in China and India. Ocugen intends to work closely with government agencies tasked with pandemic preparedness and response to initiate clinical trials.

Gene Therapies

- **OCU400**
  - Dosing of subjects with *NR2E3* and *RHO*-related retinitis pigmentosa in Cohort 2 was completed. Based on a review of safety data by the independent Data and Safety Monitoring Board for the clinical trial, dosing has begun in Cohort 3, and enrollment is expected to be completed by the end of the year.
  - The current clinical trial will also start enrolling patients with Leber congenital amaurosis associated with *CEP290* mutations.
- **OCU410 and OCU410ST —** Filings of Investigational New Drug (IND) applications for both dry age-related macular degeneration and Stargardt disease are planned for Q2 2023.

Biologicals

- **OCU200 —** Ocugen is currently executing IND-enabling studies. The filing of an IND application targeting DME is planned for Q1 2023.

Cell Therapies

- **NeoCart® —** Ocugen continues to work with the U.S. Food and Drug Administration to finalize the Phase 3 protocol necessary for the clinical development program of NeoCart®. Ocugen is building its own manufacturing suites to prepare for a NeoCart® clinical trial and as part of an overall research and development expansion.

Third Quarter 2022 Financial Results

- The Company's cash, cash equivalents, and restricted cash totaled $101.6 million as of September 30, 2022, compared to $95.1 million as of December 31, 2021. The Company believes that its current cash and cash equivalents balance will enable it to fund its operations into Q4 2023. The Company had 216.7 million shares of common stock outstanding as of September 30, 2022.
- Research and development expenses for the three months ended September 30, 2022, were $15.6 million compared to $6.3 million for the three months ended September 30, 2021. General and administrative expenses for the three months ended September 30, 2022, were $7.5 million compared to $4.5 million for the three months ended September 30, 2021.
- Ocugen reported a $0.10 net loss per share for the three months ended September 30, 2022, compared to a $0.05 net loss per share for the three months ended September 30, 2021.

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: 3481499

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)

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 101,602	$ 94,958
Prepaid expenses and other current assets	5,895	7,688
Total current assets	107,497	102,646
Property and equipment, net	4,517	1,164
Restricted cash	—	151
Other assets	4,225	1,800
Total assets	$ 116,239	$ 105,761
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 6,460	$ 2,312
Accrued expenses	8,004	4,325
Operating lease obligations	443	363
Total current liabilities	14,907	7,000
Non-current liabilities		
Operating lease obligations, less current portion	3,764	1,231
Long term debt, net	2,265	1,712
Total liabilities	20,936	9,943
Stockholders' equity		
Convertible preferred stock	1	1
Common stock	2,168	1,995
Treasury stock	(48)	(48)
Additional paid-in capital	284,231	225,537
Accumulated other comprehensive income	30	—
Accumulated deficit	(191,079)	(131,667)
Total stockholders' equity	95,303	95,818
Total liabilities and stockholders' equity	$ 116,239	$ 105,761

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 15,622	$ 6,281	$ 32,544	$ 28,006
General and administrative	7,497	4,508	28,174	15,450
Total operating expenses	23,119	10,789	60,718	43,456
Loss from operations	(23,119)	(10,789)	(60,718)	(43,456)
Other income (expense), net	1,197	(18)	1,306	(380)
Loss before income taxes	(21,922)	(10,807)	(59,412)	(43,836)
Income tax benefit	—	(52)	—	(52)
Net loss	$ (21,922)	$ (10,755)	$ (59,412)	$ (43,784)
Shares used in calculating net loss per common share — basic and diluted	216,591,011	198,790,980	212,755,746	193,599,525
Net loss per share of common stock — basic and diluted	$ (0.10)	$ (0.05)	$ (0.28)	$ (0.23)


ocugen
Q3 2022
Business Update
November 8, 2022
NASDAQ: OCGN

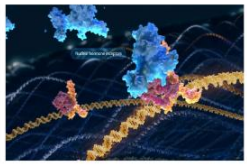
Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, which are based on the beliefs and assumptions of Ocugen, Inc. and on information currently available to management. All statements contained in this presentation other than statements of historical fact are forward-looking statements. 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. 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.

Q3 2022 Accomplishments – Progress Toward Long-Term Strategy

OCU500 Licensing Agreement for a Mucosal COVID-19 Vaccine

- Acquired rights to Develop, Manufacture and Commercialize in **U.S., Europe, and Japan**
- An important addition to Ocugen's COVID-19 **vaccine portfolio**
- **Represents a potential universal booster**, regardless of previous COVID-19 vaccination



Modifier Gene Therapy Platform

- Introduction of **OCU410ST** to potentially treat **Stargardt disease**
- Provided a deeper dive at **2022 American Academy of Ophthalmology Meeting** and **Ocugen R&D Day**

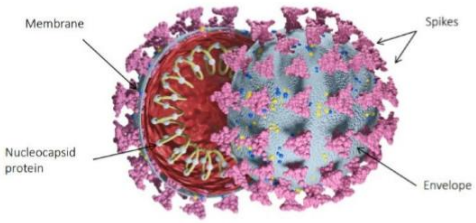
OCU500: Mucosal Vaccine

- **Potential to generate rapid local immunity** in the nose, mouth, upper airways, and lungs - where SARS-CoV-2 enters and infects the body
- Generates neutralizing IgG, mucosal IgA, and T cell responses to **help reduce transmission rate**
- Mucosal immunity has been demonstrated as a potential way to prevent infection and spread, thus **limiting the origin of new variants**

Other features include:

- Non-invasive
- Needle-free administration
- Potential for increased compliance
- Scalable manufacturing
- Stored and shipped at standard refrigerated conditions
- Potential to develop multi-strain and variant specific versions

COVAXIN™ (BBV152)



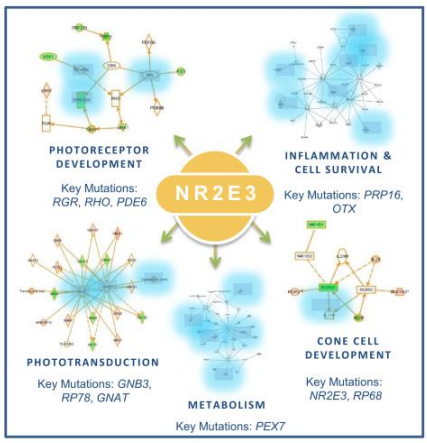
Enrollment completed for Phase 2/3 immuno-bridging and broadening clinical trial

- No safety concerns identified to date
- Topline data expected in early 2023
- Successfully completed demonstration batch as part of the technology transfer

OCU400

Data and Safety Monitoring Board Recommended Proceeding to Enroll Subjects in Cohort 3

- The Company expects to complete Cohort 3 enrollment by the end of 2022
- Current study will also begin enrolling patients with **Leber congenital amaurosis (LCA) CEP290 mutations**
  - LCA is a rare eye disease associated with mutations in more than 25 genes
- By the end of the Phase 1/2 study, data will be collected and analyzed from dosed RP & LCA patients before initiating Phase 3



OCU410 & OCU410ST

Utilizes AAV delivery platform for the retinal delivery of the RORA (RAR Related Orphan Receptor A) gene

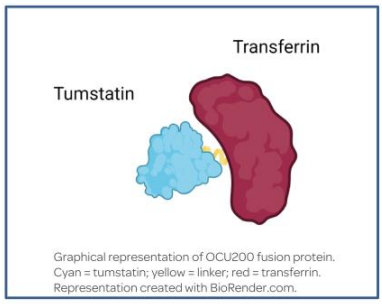
OCU410

- Being developed for the treatment of dry AMD
- Successfully completed cGMP manufacturing in support of clinical trials
- Currently conducting IND-enabling toxicology studies
- Planning to file IND application in Q2 2023 to initiate Phase 1/2 clinical trial

OCU410ST

- Being developed to potentially treat Stargardt disease, an orphan disease
- Planning to file IND application in Q2 2023 to initiate Phase 1/2 clinical trial

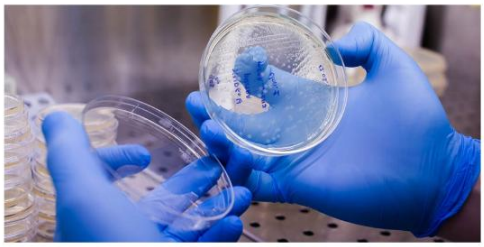
OCU200



Graphical representation of OCU200 fusion protein.
Cyan = tumstatin; yellow = linker; red = transferrin.
Representation created with BioRender.com.

- Novel Transferrin-Tumstatin fusion protein
- Currently executing IND-enabling studies
- Designed to treat severely sight-threatening diseases like Diabetic Macular Edema (DME), diabetic retinopathy, and wet AMD
- Planning to submit an IND application in Q1 2023 to initiate Phase 1 clinical trial targeting DME

NeoCart® - Ocugen's Expansion into Regenerative Cell Therapy



- NeoCart® shows **potential to accelerate healing** and reduce pain, rebuilding damaged knee cartilage and limiting the progression towards osteoarthritis
- Working with the FDA to finalize the **Phase 3 clinical trial protocol** necessary to advance development of NeoCart®
- Building our own manufacturing suites to prepare for the study


We're Here to Make
an Impact Through
Courageous Innovation
ocugen
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Financial Update

Financial Update

Statement of Operations	Three months ended September 30,	
	2022	2021
Research and development expense	$15.6	$6.3
General and administrative expense	7.5	4.5
Other income (expense), net	1.2	–
Net loss	$(21.9)	$(10.8)
Net loss per share of common stock – basic and diluted	$(0.10)	$(0.05)

Balance Sheet Data	September 30, 2022	December 31, 2021
Cash, cash equivalents, and restricted cash	$101.6	$95.1
Debt	$2.3	$1.7
Shares outstanding	216.7	199.4

Unaudited; in millions, except per share amounts

Questions & Answers


ocugen
Thank you!
November 8, 2022
NASDAQ: OCGN
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