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, 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 November 8, 2024, Ocugen, Inc. (the "Company") issued a press release announcing certain financial results for the quarter ended September 30, 2024. The Company has scheduled a conference call and webcast for 8:30 a.m. Eastern Time on November 8, 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 November 8, 2024.
99.2	Earnings Release Presentation issued November 8, 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: November 8, 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 Third Quarter 2024 Financial Results

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

- *Subsequent to quarter-end, closed $30 million in debt financing*
- *OCU400 Phase 3 liMeliGhT clinical trial for retinitis pigmentosa (RP) on track to complete enrollment in 1H2025*
- *OCU410 is currently in Phase 2 of the Phase 1/2 ArMaDa clinical trial*
- *Data and Safety Monitoring Board (DSMB) for the OCU410ST GARDian clinical trial approved enrollment for the second phase of the Phase 1/2 clinical trial*
- *New data on Phase 1/2 clinical trials for OCU410, OCU410ST and OCU400 to be presented at upcoming Clinical Showcase*

MALVERN, Pa., November 8, 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, biologics, and vaccines, today reported third quarter 2024 financial results along with a general business update.

“I am very encouraged by the progress of our gene therapy programs and the clinical and regulatory milestones achieved in the third quarter of 2024, including the expansion of the OCU400 Phase 3 liMeLiGhT clinical trial into Canada,” said Dr. Shankar Musunuri, Chairman, CEO, and Co-founder of Ocugen. “With the recent equity and debt financings, we have sufficient cash-on-hand to continue supporting our robust ophthalmology pipeline and extend our cash runway into 1Q2026.”

As OCU400 is advancing through Phase 3 clinical development, the expanded access program (EAP) for adult patients with early to advanced RP makes it possible to reach a greater segment of the RP patient population—300,000 in the U.S., Canada, and Europe combined. Additionally, including Canadian patients in the OCU400 Phase 3 liMeliGhT trial may allow for broader commercialization with the U.S. and Europe. These accomplishments and consistent trial enrollment are bringing the Company even closer to providing a potential one-time treatment for life to patients living with RP.

Phase 2 of the OCU410 Phase 1/2 ArMaDa clinical trial is underway and will assess the safety and efficacy of OCU410 in a larger group of patients who are randomized into either of two treatment groups (medium- or high-dose) or a control group. OCU410 is being developed for geographic atrophy (GA), an advanced stage of dry age-related macular degeneration (dAMD). GA affects approximately 2-3 million people in the U.S. & EU. Current FDA-approved treatments address only the complement system and require approximately 6-12 intravitreal injections per year, whereas OCU410 addresses all four pathways linked with dAMD pathophysiology and is delivered through a single subretinal injection. There remains no approved product to treat GA in the EU.

Over a series of conferences during the third quarter 2024, Ocugen had the opportunity to provide an update on its three clinical-stage modifier gene therapies to significant investor audiences as well as industry decision-makers during meetings like the Cell & Gene Meeting on the Mesa hosted by the Alliance for Regenerative Medicine.

“It is imperative to continue educating our key stakeholders about the differentiated mechanism of action of our gene-agnostic modifier gene therapy platform,” said Dr. Musunuri. “Unlike other product candidates in development to treat blindness diseases, our approach leverages master gene regulators that reset the functional network—rather than targeting a single mutation—and restore overall health to the retina. Our data continues to support the potential to treat multiple disease mutations with a one-time therapy for life.”

While gene therapy remains the primary focus for the Company, Ocugen continues to pursue funding opportunities across the portfolio to ensure that its innovative platforms reach the people who need them.

A clinical showcase, providing updates from Ocugen’s ongoing gene therapy trials, will be held on November 12, 2024, and will include preliminary safety and efficacy data from the Phase 1/2 OCU410 ArMaDa clinical trial for geographic atrophy and Phase 1/2 OCU410ST GARDian clinical trial for Stargardt disease, along with RP and LCA data updates from the OCU400 Phase 1/2 clinical trial.

Ophthalmic Gene Therapies —First-in-class

- **OCU400** — Enrollment continues in the Phase 3 liMeliGhT clinical trial and Health Canada approved enrollment across a maximum of 5 sites in Canada. FDA approved EAP for the treatment of adult patients with RP who may benefit from the mechanism of action of OCU400.
- **OCU410** — Actively recruiting patients in Phase 2 of the Phase 1/2 ArMaDa clinical trial. Preliminary safety and efficacy update on OCU410 Phase 1/2 ArMaDa clinical trial will be shared at upcoming clinical showcase.
- **OCU410ST** — DSMB approved proceeding to Phase 2 of the Phase 1/2 GARDian clinical trial. Preliminary safety and efficacy update will be shared at upcoming clinical showcase.

Ophthalmic Biologic Product

- **OCU200 –** FDA cleared the investigational new drug application for the Phase 1 clinical trial evaluating OCU200. The Company is planning to initiate the OCU200 Phase I clinical trial this quarter.

Third Quarter 2024 Financial Results

- With the recent $30 million debt financing and $35 million equity financing in the third quarter, the cash runway now extends into 1Q2026.
- The Company's cash and restricted cash totaled $39.0 million as of September 30, 2024, compared to $39.5 million as of December 31, 2023.
- Total operating expenses for the three months ended September 30, 2024 were $14.4 million and included research and development expenses of $8.1 million and general and administrative expenses of $6.3 million. This compares to total operating expenses for the three months ended September 30, 2023 of $16.1 million that included research and development expenses of $7.0 million and general and administrative expenses of $9.1 million.

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: 9923172
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, 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. 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, expected cash runway into the first quarter of 2026, the ability to initiate new clinical programs; 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 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
Tiffany.Hamilton@ocugen.com

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

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash	$ 38,696	$ 39,462
Prepaid expenses and other current assets	1,977	3,509
Total current assets	40,673	42,971
Property and equipment, net	17,130	17,290
Restricted cash	305	—
Other assets	3,828	4,286
Total assets	$ 61,936	$ 64,547
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,494	$ 3,172
Accrued expenses and other current liabilities	12,475	13,343
Operating lease obligations	477	574
Current portion of long term debt	1,316	—
Total current liabilities	15,762	17,089
Non-current liabilities		
Operating lease obligations, less current portion	3,419	3,567
Long term debt, net	1,571	2,800
Other non-current liabilities	554	527
Total non-current liabilities	5,544	6,894
Total liabilities	21,306	23,983
Total stockholders' equity	40,630	40,564
Total liabilities and stockholders' equity	$ 61,936	$ 64,547

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,	
	2024	2023	2024	2023
Collaborative arrangement revenue	$ 1,136	$ 3,699	$ 3,291	$ 4,627
Total revenue	1,136	3,699	3,291	4,627
Operating expenses				
Research and development	8,108	7,048	23,836	31,794
General and administrative	6,280	9,082	20,372	26,839
Total operating expenses	14,388	16,130	44,208	58,633
Loss from operations	(13,252)	(12,431)	(40,917)	(54,006)
Other income (expense), net	282	714	743	1,898
Net loss	$ (12,970)	$ (11,717)	$ (40,174)	$ (52,108)

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Courageous Innovation

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

3Q 2024
Business Update
November 8, 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 fo 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 and expected cash runway into the first quarter 2026, 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 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 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.


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We're Driving Science in New Directions and Breaki
New Ground Through Courageous Innovation
First-In-Class Modifier Gene Therapy:
• OCU400 Phase 3 liMeliGhT Clinical Trial
◦ Retinitis pigmentosa
• OCU410 Phase 2 ArMaDa Clinical Trial
◦ Geographic atrophy
• OCU410ST Phase 1/2 GARDian Clinical Trial
◦ Stargardt disease

OCU400 Modifier Gene Therapy – A Paradigm Shift in Gene Therapy

- ✓ Health Canada approved initiation of OCU400 Phase 3 liMeliGhT trial for the treatment of retinitis pigmentosa (RP)
- ✓ Received FDA approval of expanded access program (EAP) for adult patients with RP

Upcoming anticipated catalysts:

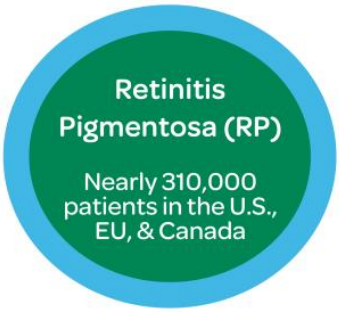
- *Clinical updates including Phase 3 recruitment for RP*
- *Phase 3 clinical trial is on track to complete enrollment in 1H2025*
- *New data updates from Phase 1/2 RP & LCA*

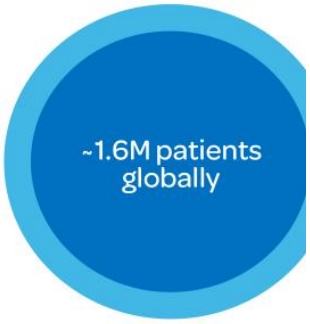
First Phase 3 gene therapy clinical trial to receive broad RP indication from FDA

OCU400 for the treatment of RP remains on track to meet 1H2026 Biologics License Application (BLA) and Marketing Authorization Application (MAA) filing targets.

OCU400: RP Market Opportunity

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





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

OCU410: A Single-Injection Approach to Address Unmet Need

- ✓ Dosing is underway in the OCU410 Phase 2 ArMaDa clinical trial, following the completion of Phase 1 low, medium, and high dose cohorts, which involved nine patients with geographic atrophy (GA)
  - *The Phase 2 trial is actively recruiting a larger patient group randomized into either of two treatment groups (medium or high dose) or control group*
  - *Plan to complete dosing by early 2025*

Upcoming anticipated catalyst: Preliminary safety and efficacy update from ongoing Phase 1/2 clinical trial

Dry AMD affects nearly 19 million people in the U.S. & EU

GA affects ~2-3 million people in the U.S. & EU – **a significant market opportunity**

OCU410 is positioned to transform the landscape of GA with its potential one-time therapy with a single sub-retinal injection—compared to other treatment options that require approximately 6-12 intravitreal injections annually.

OCU410 Program Overview—Phase 2

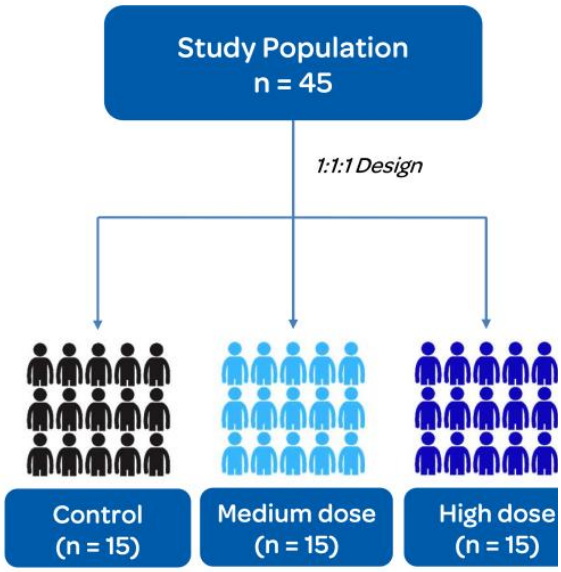
Study Objective and Modality

- Assess the safety and efficacy of OCU410 in subjects with GA secondary to dry age-related macular degeneration (dAMD)
- Single, unilateral subretinal injection using a modifier gene therapy platform

Overall Strategy

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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OCU410ST: Modifier Gene Therapy Addressing Shortcomings of Curr Approaches

- ✓ Data and Safety Monitoring Board (DSMB) approved enrollment for the second phase of the OCU410ST Phase 1/2 clinical trial

Upcoming anticipated catalyst: Preliminary safety and efficacy update from ongoing Phase 1/2 clinical trial

Stargardt disease affects ~100,000 people in the U.S. and Europe

The safety and tolerability profile of OCU410ST remains encouraging as clinical development progresses and continues to bring hope to patients who have no FDA-approved treatment available.

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OCU200: Biologic Program for the Treatment of Diabetic Macular Ede

- ✓ U.S. FDA cleared the IND for the Phase 1 clinical trial evaluating OCU200 for diabetic macular edema (DME)

Upcoming anticipated catalyst: Initiate Phase 1 clinical trial in the fourth quarter of 2024

Approximately 30 to 40% of DME patients are refractive to current anti-VEGF therapies

OCU200 has the potential to provide a new treatment option for the significant percentage of people living with DME, including non-responders to the current standard of care.

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Financial Update

Financial Update

Statement of Operations	Three months ended September 30,	
	2024	2023
Research and development expense	$8.1	$7.0
General and administrative expense	6.3	9.1
Other income (expense), net	0.3	0.7
Net loss	$(13.0)	$(11.7)

Balance Sheet Data	September 30, 2024	December 31, 2023 (audited)
Cash and restricted cash	$39.0*	$39.5
Debt	$2.9	$2.8

*Amount does not include $30.0 million in proceeds from debt financing transaction that closed on November 6, 2024

Questions & Answers

Near-Term Targeted Milestones

- OCU400 Phase 3 dosing and recruitment updates – 1H2026 BLA/MAA filing targets on track
- New data update from OCU400 Phase 1/2 RP & LCA
- Preliminary safety/efficacy update – OCU410 Phase 1/2 clinical trial (GA)
- Preliminary safety/efficacy update – OCU410ST Phase 1/2 clinical trial (Stargardt Disease)
- OCU200 Phase 1 Clinical trial initiation in 4Q 2024

Ocugen Vision

We're here to make an impact. At Ocugen, we approach drug development with a sense of urgency, resolve, ingenuity, and boldness. We consider patients in everything we do. **Courageous innovation** means driving science new directions and breaking new ground.