
**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): **August 21, 2023**

OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-36751
(Commission
File Number)

04-3522315
(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))
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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 August 21, 2023, Ocugen, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2023. The Company has scheduled a conference call and webcast for 8:30 a.m. eastern time on August 22, 2023 to discuss these financial results and business updates. A copy of the press release is furnished herewith as Exhibit 99.1 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, 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 August 21, 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: August 21, 2023

OCUGEN, INC.

By: /s/ Shankar Musunuri

Name: Shankar Musunuri

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

Ocugen Provides Business Update with Second Quarter 2023 Financial Results

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

- *Investigational New Drug (IND) Applications Cleared for Novel Gene Therapies for Geographic Atrophy Secondary to AMD and for Stargardt Disease*
 - *OCU400 Clinical Study Results Update Expected This Quarter*

MALVERN, Pa., August 21, 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 second quarter 2023 financial results along with a general business update.

“We continue to advance our pipeline to provide solutions for patients living with serious diseases but without effective treatment options,” said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. “It remains our plan to start dosing patients across all of our ophthalmology programs by the end of the year and we are very enthusiastic about the FDA clearance of our INDs for OCU410 and OCU410ST for a form of Geographic Atrophy and Stargardt disease, respectively.”

During important meetings in the second quarter of 2023, including The Association for Research in Vision and Ophthalmology (ARVO) 2023 Annual Meeting and BIO International, the Company continued to educate key stakeholders about the science behind its innovative modifier gene therapy platform and next-generation inhalation vaccine candidates aimed at enhancing durability and reducing transmission.

This quarter, Ocugen plans to share updated data results on OCU400 from its Phase 1/2 clinical trial in patients with retinitis pigmentosa. The Company also continues to have ongoing conversations with government agencies towards obtaining support of its inhaled vaccines for COVID-19 and flu.

“We remain dedicated to our mission to develop cutting-edge therapies with a commitment to ensuring global market access,” said Dr. Musunuri. “We are executing plans consistent with our long-term strategy of delivering multiple products to market targeting unmet medical needs utilizing first-in-class platform technologies in gene therapies, cell therapies and vaccines.”

Ophthalmic Gene Therapies

- **OCU400** — Phase 3 adult trial to be initiated near the end of 2023/early 2024, subject to the outcome of the ongoing Phase 1/2 trial and discussions with the FDA on the proposed Phase 3 trial plan.
- **OCU410 and OCU410ST** — IND applications to initiate Phase 1/2 trials for both OCU410 and OCU410ST were cleared by the FDA and the Company plans to initiate Phase 1/2 trials by the end of 2023.

Regenerative Cell Therapies

- **NeoCart®** — Manufacturing facility construction for NeoCart is on target to be completed by the end of 2023, as planned. The Company plans to initiate the Phase 3 trial in the second half of 2024.

Vaccines Portfolio

- **Inhaled Mucosal Vaccine Platform** — The Company is continuing the internal development of its inhaled mucosal vaccine platform to achieve IND readiness and intends to submit an IND application in 2024, provided it receives government funding. The Company has submitted multiple proposals to obtain government funding and is continuing discussions with relevant government agencies regarding developmental support for its inhaled mucosal vaccine platform.

Second Quarter 2023 Financial Results

- The Company’s cash, cash equivalents, and investments totaled \$70.6 million as of June 30, 2023, compared to \$90.9 million as of December 31, 2022. The Company had 256.5 million shares of common stock outstanding as of June 30, 2023.

- Total operating expenses for the three months ended June 30, 2023 were \$23.7 million and included research and development expenses of \$14.2 million and general and administrative expenses of \$9.6 million. Research and development expenses for the three months ended June 30, 2023 included a non-recurring, non-cash expense of \$4.4 million as a result of the impairment of the short-term asset for the advanced payment for the supply of COVAXIN as well as the associated loss on the disposal of related fixed assets. This compares to total operating expenses for the three months ended June 30, 2022 of \$19.6 million that included research and development expenses of \$9.0 million and general and administrative expenses of \$10.6 million.
- Ocugen reported a \$0.10 net loss per common share for the three months ended June 30, 2023 compared to a \$0.09 net loss per common share for the three months ended June 30, 2022.

Conference Call and Webcast Details

Ocugen has scheduled a conference call and webcast for 8:30 a.m. ET tomorrow 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: 6803433

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 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 include, but are not limited to, statements regarding our clinical development activities and related anticipated timelines. 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:

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(Tables to follow)

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

	June 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	\$ 70,578	\$ 77,563
Marketable securities	—	13,371
Prepaid expenses and other current assets	2,874	7,558
Total current assets	73,452	98,492
Property and equipment, net	11,720	6,053
Other assets	3,804	4,087
Total assets	\$ 88,976	\$ 108,632
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 3,881	\$ 8,062
Accrued expenses and other current liabilities	7,787	9,900
Operating lease obligations	526	498
Current portion of long term debt	1,266	—
Total current liabilities	13,460	18,460
Non-current liabilities		
Operating lease obligations, less current portion	3,308	3,587
Long term debt, net	1,472	2,289
Other non-current liabilities	455	244
Total liabilities	18,695	24,580
Stockholders' equity		
Convertible preferred stock	1	1
Common stock	2,566	2,217
Treasury stock	(48)	(48)
Additional paid-in capital	320,181	294,874
Accumulated other comprehensive income	22	26
Accumulated deficit	(252,441)	(213,018)
Total stockholders' equity	70,281	84,052
Total liabilities and stockholders' equity	\$ 88,976	\$ 108,632

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

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	\$ 14,169	\$ 9,007	\$ 23,727	\$ 16,922
General and administrative	9,564	10,558	17,757	20,677
Total operating expenses	23,733	19,565	41,484	37,599
Loss from operations	(23,733)	(19,565)	(41,484)	(37,599)
Other income (expense), net	808	94	2,061	109
Net loss	\$ (22,925)	\$ (19,471)	\$ (39,423)	\$ (37,490)
Shares used in calculating net loss per common share — basic and diluted	238,311,498	215,862,977	231,952,888	210,806,330
Net loss per share of common stock — basic and diluted	\$ (0.10)	\$ (0.09)	\$ (0.17)	\$ (0.18)