UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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 5, 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
(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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 August 5, 2022, Ocugen, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2022. The Company has scheduled a conference call and webcast for 8:30 a.m. eastern time on August 5, 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 August 5, 2022.
99.2	Earnings Release Presentation issued August 5, 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 5, 2022

OCUGEN, INC.

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

Exhibit 99.1

Ocugen Provides Business Update & Second Quarter 2022 Financial Results

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

- *Dosing patients in U.S. Phase 2/3 COVAXIN™ (BBV152) clinical trial*
- *Completed dosing of patients in Cohort 1 of OCU400 gene therapy product candidate*
- *Expanding product pipeline with the regenerative medicine cell therapy program NeoCart®*

Malvern, Pa, August 5, 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 June 30, 2022, and provided a general business update.

"The second quarter was marked by several important milestones," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "On the vaccine front, we continued to work diligently with our co-development partner, Bharat Biotech, to ensure we execute our planned clinical and commercial objectives for COVAXIN™ – a whole-virion inactivated COVID-19 vaccine candidate."

"We are also excited and encouraged by the positive momentum of our investigational modifier gene therapy platform, with the potential to address many different gene mutations in the retina and look forward to bringing hope to patients for whom no treatment options exist," Dr. Musunuri added.

During the second quarter, Ocugen expanded its dynamic clinical product pipeline with the introduction of NeoCart®, an innovative Phase 3-ready cell therapy platform. The U.S. Food and Drug Administration (FDA) recently granted NeoCart® a Regenerative Medicine Advanced Therapy (RMAT) designation for the repair of full-thickness lesions of the knee cartilage in adults, and this candidate, if approved, offers the potential for a new therapeutic option in this area.

"With our diversified portfolio, Ocugen is well-positioned to advance our product development efforts and we look forward to sharing key data as these programs progress," Dr. Musunuri concluded.

Clinical and Business Updates

Vaccines

- **COVAXIN™ Development in the United States** — The Phase 2/3 immuno-bridging and broadening clinical trial, OCU-002, for COVAXIN™ is progressing well.
  - The Company is actively engaged in planning for the initiation of an adult safety clinical trial this year.
- **COVAXIN™ Data Published in Scientific Journals** — In June 2022, positive pediatric Phase 2/3 study results in children aged 2-18 years were published in *The Lancet Infectious Diseases*. A study published in *Nature Scientific Reports* in July shows that COVAXIN™ (BBV152) generated a persistent cell mediated memory immune response for up to 12 months. Additionally, a booster dose is safe and ensures persistent immunity to minimize breakthrough infections of COVID-19.

Gene Therapies

- **OCU400 Clinical Trial —** Dosing of subjects with retinitis pigmentosa in Cohort 1 was completed. Previously, the Company reported "first patient, first dose" in late March 2022.
  - The Independent Data and Safety Monitoring Board (DSMB) for the clinical trial recently completed a review of safety data based on dosing from Cohort 1 and recommends proceeding to dosing in Cohort 2. The Company expects to begin dosing in Cohort 2 this month.
- **OCU410 Development Program** — Ocugen is conducting IND-enabling studies as per discussions with the FDA. A clinical trial is scheduled to begin next year, and the Company is currently manufacturing materials to support the clinical trial.
- **Improved Patent Estate** — In June 2022, the Company announced that the United States Patent and Trademark Office issued U.S. Patent No. 11,351,225, which is directed to methods for preventing or treating an ocular disease or disorder associated with retinal degenerative disease. The patent covers the use of a nuclear hormone receptor gene,

such as nuclear receptor subfamily 2 group E member 3 (*NR2E3)*, RAR-related orphan receptor A (*RORA)*, Nuclear Protein 1, Transcriptional Regulator *(NUPR1)*, and Nuclear Receptor Subfamily 2 Group C Member 1 (*NR2C1)*, in treating retinal degenerative diseases as well as reducing the risk of developing such diseases.

Cell Therapies

- **Expansion of Product Candidate Pipeline with NeoCart®** — Ocugen added NeoCart®, a Phase 3-ready cell therapy platform technology to its diverse product candidate pipeline. The Company originally acquired NeoCart® as part of the Company's reverse merger with Histogenics Corporation in 2019. Ocugen is currently working with the FDA to finalize the Phase 3 protocol necessary to advance the clinical development program of NeoCart®. Also, the Company entered into a collaborative research agreement with Brigham and Women's Hospital, Harvard Medical School, to support NeoCart® development and explore expansion of the pipeline.

Other Business

- **At-the-Market Stock Issuance** — In June 2022, the Company announced it had entered into an At Market Issuance Sales Agreement relating to the sale of shares of Ocugen's common stock having an aggregate gross sales price of up to $160.0 million. Proceeds will be used for general corporate purposes.
- **Community Recognition** — In June 2022, the *Philadelphia Business Journal* named Ocugen among the region's "2022 Best Places to Work."

Second Quarter 2022 Financial Results

- The Company's cash, cash equivalents, and restricted cash totaled $115.0 million as of June 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 the second quarter of 2023. The Company had 216.1 million shares of common stock outstanding as of June 30, 2022.
- Research and development expenses for the three months ended June 30, 2022, were $9.0 million compared to $18.9 million for the three months ended June 30, 2021. Research and development expenses for the three months ended June 30, 2021, included a $15.0 million upfront payment to Bharat Biotech for the right and license to COVAXIN™ development, manufacturing, and commercialization in Canada.
- General and administrative expenses for the three months ended June 30, 2022, were $10.6 million compared to $6.8 million for the three months ended June 30, 2021.
- Ocugen reported a $0.09 net loss per share for the three months ended June 30, 2022, compared to a $0.13 net loss per share for the three months ended June 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 executive 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 using the following details:

Dial-in Numbers: (800) 715-9871 for U.S. callers and (646) 307-1963 for international callers
Conference ID: 7036957
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 forward-looking statements include, but are not limited to, statements about the potential for NeoCart® (autologous chondrocyte-derived neocartilage), if approved, to provide an innovative new option for the repair of full-thickness lesions of the knee cartilage in adults, as well as Ocugen's intention to begin dosing in Cohort 2 of the OCU400 clinical trial this month. 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

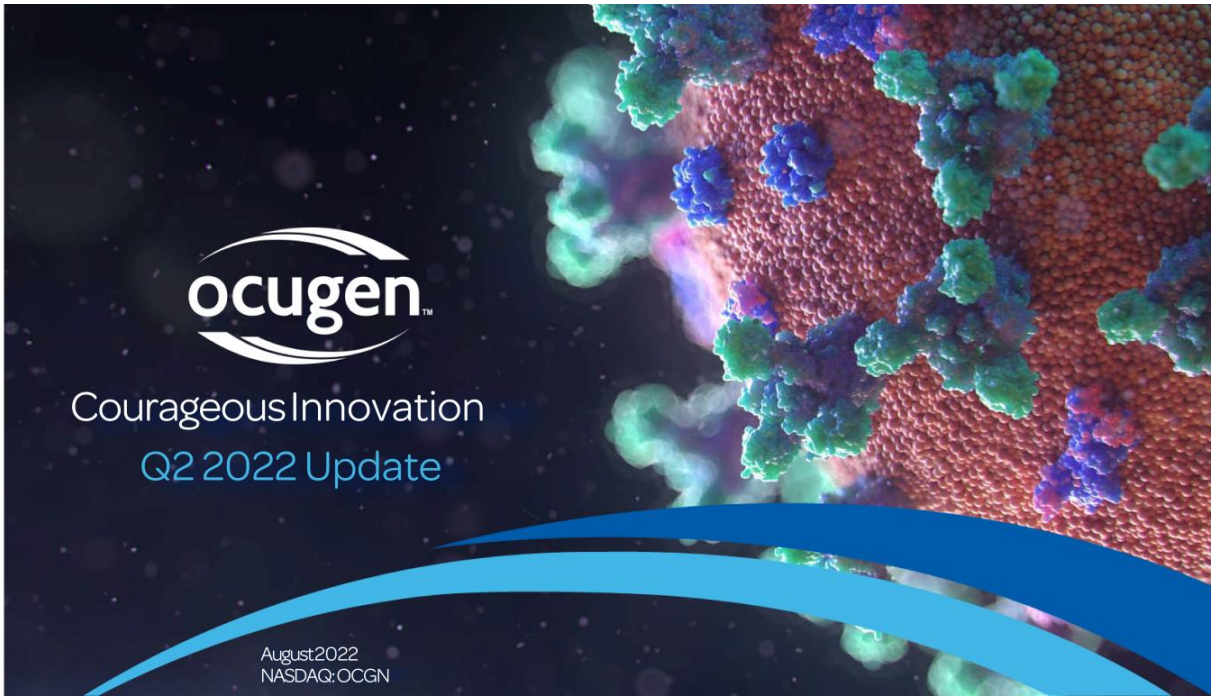
(Tables to follow)

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

	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 115,005	$ 94,958
Prepaid expenses and other current assets	7,564	7,688
Total current assets	122,569	102,646
Property and equipment, net	3,153	1,164
Restricted cash	—	151
Other assets	4,366	1,800
Total assets	$ 130,088	$ 105,761
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 5,921	$ 2,312
Accrued expenses	4,103	4,325
Operating lease obligations	314	363
Total current liabilities	10,338	7,000
Non-current liabilities		
Operating lease obligations, less current portion	3,892	1,231
Long term debt, net	1,750	1,712
Total liabilities	15,980	9,943
Stockholders' equity		
Convertible preferred stock	1	1
Common stock	2,163	1,995
Treasury stock	(48)	(48)
Additional paid-in capital	281,139	225,537
Accumulated other comprehensive income	10	—
Accumulated deficit	(169,157)	(131,667)
Total stockholders' equity	114,108	95,818
Total liabilities and stockholders' equity	$ 130,088	$ 105,761

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,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 9,007	$ 18,853	$ 16,922	$ 21,725
General and administrative	10,558	6,757	20,677	10,942
Total operating expenses	19,565	25,610	37,599	32,667
Loss from operations	(19,565)	(25,610)	(37,599)	(32,667)
Other income (expense), net	94	(342)	109	(362)
Net loss	$ (19,471)	$ (25,952)	$ (37,490)	$ (33,029)
Shares used in calculating net loss per common share — basic and diluted	215,862,977	195,572,189	210,806,330	190,960,775
Net loss per share of common stock — basic and diluted	$ (0.09)	$ (0.13)	$ (0.18)	$ (0.17)


ocugen
Courageous Innovation
Q2 2022 Update
August 2022
NASDAQ: OCGN

Cautionary Note on 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 forward-looking statements include, but are not limited to, statements about the potential for NeoCart® (autologous chondrocyte-derived neocartilage), if approved, to provide an innovative new option for the repair of full-thickness lesions of the knee cartilage in adults, as well as Ocugen's intention to begin dosing in Cohort 2 of the OCU400 clinical trial this month. 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.


We're Here to Make an Impact Through
Courageous Innovation
ocugen
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Path Forward for COVAXIN™ (BBV152)

Phase 2/3 **immuno-bridging and broadening** clinical trial, OCU-002, for COVAXIN™ is currently dosing subjects

Positive and compelling COVAXIN™ data published in the ***Lancet Infectious Diseases*** and ***Nature Scientific Reports***

Pre-commercialization efforts continue in Mexico:

- Emergency Use Authorization granted in Mexico
- An application for the use of COVAXIN™ in children ages 2-18 is still under review by regulatory authorities in Mexico

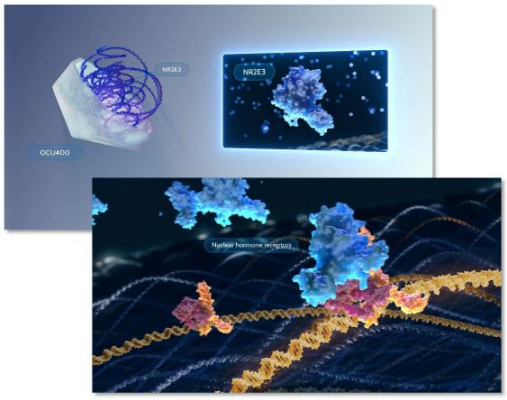
Lancet Infectious Diseases (Phase 2/3 Pediatric)

- 526 children enrolled
- 2-doses; 6 µg; 28 days apart
- Well tolerated and immunogenic
- Induced higher neutralizing antibody responses compared to adults

Booster Study (Adult)

- COVAXIN™ provides durable immunity against variants of concern
- Persistence of humoral and cell mediated immunity up to 12 months of vaccination
- No serious adverse events observed

Progress with Gene Therapy/Biological Programs (Ophthalmology)



Dosing on track in Phase 1/2 clinical trial studying OCU400 gene therapy for the treatment of retinitis pigmentosa resulting from genetic mutations of *NR2E3* and *RHO*

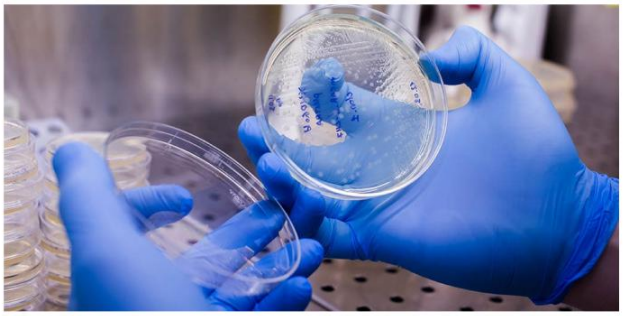
Data and Safety Monitoring Board (DSMB) recommends **proceeding to Cohort 2** based on safety data from Cohort 1 in OCU400. The Company expects to **begin dosing** in Cohort 2 this month.

Company aims to initiate **IND-enabling studies** for OCU410 gene therapy to support a future Phase 1/2 clinical trial in 2023

Expanded patent portfolio with the issuance of another gene therapy patent

Conducting **IND-enabling** study to support Phase 1/2a clinical trial for OCU200 (biological) next year

Introducing NeoCart®, Ocugen's Expansion into Restorative Cell Therapy



NeoCart® is a phase 3-ready **cell therapy platform technology** being developed for the repair of full-thickness lesions of the knee cartilage in adults

FDA granted **RMAT designation** to NeoCart®, which helps accelerate the timeline for market approval

Ocugen working with the FDA to finalize the **Phase 3 clinical trial protocol** necessary to advance development of NeoCart®

Financial Update

Financial Update

Statement of Operations	Three months ended June 30,	
	2022	2021
Research and development expense	$9.0	$18.9
General and administrative expense	10.6	6.8
Other income (expense), net	0.1	(0.3)
Net loss	$(19.5)	$(26.0)
Net loss per share of common stock – basic and diluted	$(0.09)	$(0.13)

Balance Sheet Data	June 30, 2022	December 31, 2021
Cash, cash equivalents, and restricted cash	$115.0	$95.1
Debt	$1.8	$1.7
Shares outstanding	216.1	199.4

Unaudited; in millions, except per share amounts

Questions & Answers

ocugen


ocugen
Thank you!
August 2022
NASDAQ: OCGN