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): **November 9, 2021**

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)

263 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 November 9, 2021, Ocugen, Inc. ("the Company") issued a press release announcing its financial results for the quarter ended September 30, 2021. The Company has scheduled a conference call and webcast for 8:30 a.m. eastern time on November 9, 2021 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.

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 9, 2021.
99.2	Earnings Release Presentation issued November 9, 2021.
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: November 9, 2021

OCUGEN, INC.

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

Exhibit 99.1

Ocugen Provides Business Update and Third Quarter 2021 Financial Results

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

- *Emergency Use Authorization application filed with the U.S. FDA for the COVID-19 vaccine candidate, COVAXIN™ (BBV152), for children aged 2 – 18 years*
- *Investigational New Drug application filed with the U.S. FDA for COVAXIN™ (BBV152)*
- *Investigational New Drug application filed with the U.S. FDA for breakthrough modifier gene therapy candidate, OCU400*
- *Collaboration with CanSinoBIO expanded to include OCU410 for chemistry, manufacturing, and controls development and manufacturing*

MALVERN, Pa. — November 9, 2021 (GLOBE NEWSWIRE) — Ocugen, Inc. (Ocugen or the Company) (NASDAQ: OCGN), a biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19, today reported third quarter 2021 financial results along with a general business update.

"We've been relentless in our efforts to launch our innovative medicines onto regulatory pathways here in the United States. The submission of COVAXIN for Emergency Use Authorization for pediatrics is another example of Ocugen contributing to public health efforts to curb the pandemic, giving parents another option for protecting their children. Two Investigational New Drug submissions within a span of two weeks is a phenomenal achievement resulting from the work of international teams aligned around serving people with serious diseases. Our capabilities in the areas of R&D, clinical development, manufacturing, and commercial continue to expand with our workforce nearly doubling since the last quarter to deliver for the future. I'm really proud of the teams for their commitment to meeting our mission," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen.

Business Highlights

FORWARD MOMENTUM FOR COVAXIN™ AND OPHTHALMIC PIPELINE

- The Company filed an Emergency Use Authorization (EUA) application with the U.S. Food and Drug Administration (FDA) for the use of the COVID-19 vaccine candidate, COVAXIN™ (BBV152), for children aged 2 – 18 years. The Company believes its vaccine candidate has the potential to fulfill an unmet need in the national arsenal of COVID-19 vaccines. The inactivated virus platform has been used for decades in vaccines for pediatric populations.
- The Company also filed an Investigational New Drug (IND) application with the FDA to initiate a Phase 3 clinical trial evaluating COVAXIN™ (BBV152) in support of an upcoming Biologics License Application (BLA) submission. The observer-blind, immuno-bridging study of the whole-virion, inactivated SARS-CoV-2 vaccine candidate in healthy adults, if allowed to proceed, will help demonstrate that the Phase 3 data from the studies conducted by Bharat Biotech International Limited (Bharat Biotech) in India will be applicable to the U.S. population. Under the IND, the Company will also initiate a safety-bridging study, if required.
- The Company filed an IND application with the FDA for OCU400 for the Phase 1/2 study to assess the safety of OCU400 (*NR2E3*) in patients with a mutation in *NR2E3* and *RHO* mutation-associated retinal degeneration. If allowed to proceed, the Company is planning to initiate this clinical trial in the United States around the end of 2021.
- In September 2021, the Company entered into a Development and Commercial Supply Agreement with Bharat Biotech, pursuant to which Bharat Biotech will supply the Company with clinical trial materials and commercial supplies of COVAXIN™ finished drug product prior to the completion of the Company's technology transfer to Jubilant HollisterStier.
- In September 2021, the Company and CanSino Biologics, Inc. ("CanSinoBIO") expanded their current collaboration on the development of OCU400 to now include OCU410. With that, CanSinoBIO will be responsible for the chemistry, manufacturing, and controls (CMC) development and manufacture of clinical supplies of both products and be responsible for the costs associated with such activities.

Third Quarter 2021 Financial Results

- Ocugen's cash, cash equivalents, and restricted cash totaled $107.5 million as of September 30, 2021, compared to $24.2 million as of December 31, 2020. Ocugen had 198.9 million shares of common stock outstanding as of September 30, 2021.
- Research and development expenses for the three months ended September 30, 2021 were $6.3 million compared to $1.5 million for the three months ended September 30, 2020. General and administrative expenses for the three months ended September 30, 2021 were $4.5 million compared to $1.7 million for the three months ended September 30, 2020. Ocugen reported a $0.05 net loss per share for the three months ended September 30, 2021 compared to a $0.07 net loss per share for the three months ended September 30, 2020, which includes the in-process research and development expense of $7.0 million related to the reduction of the carrying value of an asset that was previously recorded as held for sale.

Conference Call and Webcast Details

Ocugen has scheduled a conference call and webcast for 8:30 a.m. eastern time 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.

The call can be accessed by dialing (844) 873-7330 (U.S.) or (602) 563-8473 (international) and providing the conference ID 8198297. To access a live audio webcast of the call on the "Investors" section of the Ocugen website, please click here. A replay of the webcast will be archived on Ocugen's website for approximately 45 days following the call.

About Ocugen, Inc.
Ocugen, Inc. is a biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19. Our breakthrough modifier gene therapy platform has the potential to treat multiple retinal diseases with one drug – "one to many" and our novel biologic product candidate aims to offer better therapy to patients with underserved diseases such as wet age-related macular degeneration, diabetic macular edema, and diabetic retinopathy. We are co-developing Bharat Biotech's COVAXIN™ vaccine candidate for COVID-19 in the U.S. and Canadian markets. For more information, please visit www.ocugen.com.

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 information about qualitative assessments of available data, potential benefits, expectations for clinical trials, and anticipated timing of clinical trial readouts and regulatory submissions, including with respect to our belief that COVAXIN™ has the potential to fulfill an unmet need in the national arsenal of COVID-19 vaccines, our plans to initiate the Phase 1/2 study for OCU400, if authorized to proceed, near the end of 2021, and our belief that the results from the Phase 3 study for COVAXIN™, if allowed to proceed, will help demonstrate that the Phase 3 data from the studies conducted by Bharat Biotech Bharat Biotech in India will be applicable to the U.S. population. This information involves risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, including whether the FDA will authorize COVAXIN™ for administration as a vaccine for pediatric uses against COVID-19 pursuant to the EUA we submitted with the FDA and the timing and scope of any such authorization, as well as risks associated with preliminary and interim data, including the possibility of unfavorable new clinical trial data and further analyses of existing clinical trial data; the risk that the results of in-vitro studies will not be duplicated in human clinical trials; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when data from Bharat Biotech's clinical trials will be published in scientific journal publications and, if so, when and with what modifications; whether the data and results from the preclinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India, will be accepted by the FDA or otherwise sufficient to support our EUA or IND submissions, as applicable; whether the FDA will accept our IND submissions without any changes, or if we are required to submit additional information to the FDA in support of our IND submissions, the extent and significance of any such changes; the size, scope, timing, and outcome of any additional trials or studies that we may be required to conduct to support an EUA or BLA for COVAXIN™; any additional CMC information that we may be required to submit to the FDA; whether and when a BLA for COVAXIN™ will be submitted to or approved by the FDA; whether

developments with respect to the COVID-19 pandemic will affect the regulatory pathway available for vaccines in the United States, Canada, or other jurisdictions; market demand for COVAXIN™ in the United States or Canada; decisions by the FDA or Health Canada impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of COVAXIN™ in the United States or Canada, including development of products or therapies by other companies. 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.

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Please submit investor-related inquiries to: IR@ocugen.com

(tables to follow)

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

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 107,349	$ 24,039
Advance for COVAXIN supply	4,988	—
Prepaid expenses and other current assets	1,113	1,839
Total current assets	113,450	25,878
Property and equipment, net	1,052	633
Restricted cash	151	151
Other assets	1,659	714
Total assets	$ 116,312	$ 27,376
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,095	$ 395
Accrued expenses and other current liabilities	3,962	2,941
Short-term debt, net	—	234
Operating lease obligation	172	44
Total current liabilities	6,229	3,614
Non-current liabilities		
Operating lease obligation, less current portion	1,280	389
Long term debt, net	1,693	1,823
Total liabilities	9,202	5,826
Stockholders' equity		
Convertible preferred stock	1	—
Common stock	1,990	1,841
Treasury stock	(48)	(48)
Additional paid-in capital	222,253	93,059
Accumulated deficit	(117,086)	(73,302)
Total stockholders' equity	107,110	21,550
Total liabilities and stockholders' equity	$ 116,312	$ 27,376

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,	
	2021	2020	2021	2020
Revenues				
Collaboration revenue	$ —	$ —	$ —	$ 43
Total revenues	—	—	—	43
Operating expenses				
Research and development	6,281	1,478	28,006	4,760
In-process research and development	—	7,000	—	7,000
General and administrative	4,508	1,704	15,450	5,760
Total operating expenses	10,789	10,182	43,456	17,520
Loss from operations	(10,789)	(10,182)	(43,456)	(17,477)
Other income (expense)				
Interest income	5	—	15	—
Interest expense	(19)	(292)	(59)	(555)
Other income (expense)	(4)	—	(336)	—
Total other income (expense)	(18)	(292)	(380)	(555)
Loss before income taxes	(10,807)	(10,474)	(43,836)	(18,032)
Income tax benefit	(52)	—	(52)	—
Net loss and comprehensive loss	$ (10,755)	$ (10,474)	$ (43,784)	$ (18,032)
Deemed dividend related to Warrant Exchange	—	—	—	(12,546)
Net loss to common stockholders	$ (10,755)	$ (10,474)	$ (43,784)	$ (30,578)
Shares used in calculating net loss per common share — basic and diluted	198,790,980	141,591,218	193,599,525	92,764,157
Net loss per share of common stock — basic and diluted	$ (0.05)	$ (0.07)	$ (0.23)	$ (0.33)


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Forward Looking Statement

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Forward Momentum for COVAXIN™ (BBV152)

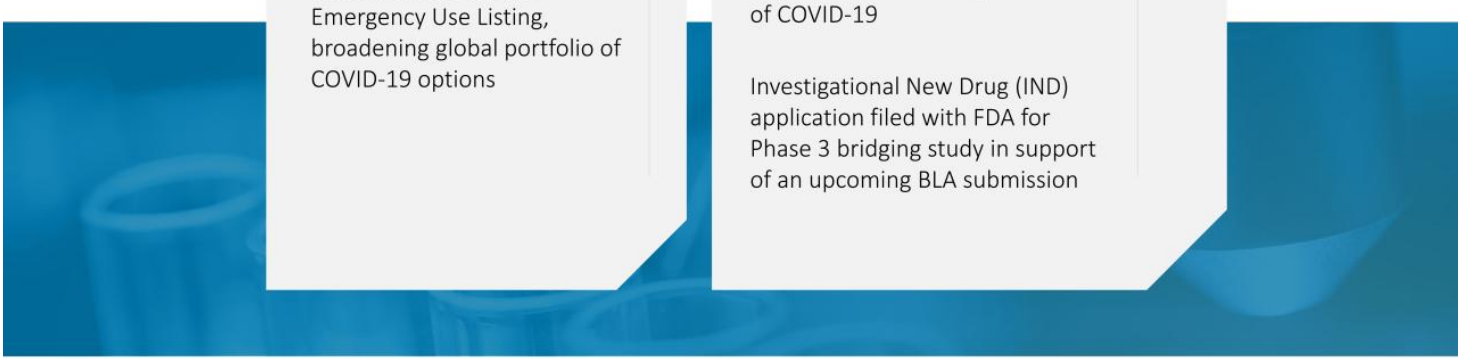
01

WHO grants COVAXIN™ Emergency Use Listing, broadening global portfolio of COVID-19 options

02

Emergency Use Authorization submitted to FDA for pediatric (2-18) indication for the prevention of COVID-19

Investigational New Drug (IND) application filed with FDA for Phase 3 bridging study in support of an upcoming BLA submission



Investigational New Drug application (IND) to evaluate COVAXIN™ (BBV152) among U.S. participants

OCU-002
A Phase 3, Observer-Blind, Immuno-bridging, and Broadening (BB) Study of a Whole, Inactivated SARS-CoV-2 Vaccine (BBV152) in Healthy Adults

Development phase: 3

Number of subjects: A few hundred participants

Primary objective: Demonstrate immuno-bridging comparing US based participants following second dose of BBV152 to those who received two doses in BBV152 Phase 3 efficacy trial in India

Secondary objectives:
Immunogenicity of two doses of BBV152 over time in 18-65 and greater than 65 age groups

Immuno-broadening effects in participants

BBV152 Phase 3 clinical trial conducted in India by Bharat Biotech

- n = 25,800 participants
- Participants recruited between November 2020 and January 2021 across 25 sites
- Two doses, 28 days apart

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Forward Momentum for Ocular Portfolio

01 OCU400

- Submitted IND for the treatment of retinitis pigmentosa resulting from genetic mutations, NR2E3 and RHO

02 OCU410

- Preclinical data shows OCU410 plays role in regulation genes associated with Dry-AMD pathogenesis
- IND-enabling studies ongoing

03 OCU200

- Currently executing IND-enabling preclinical studies to support a Phase 1 clinical trial

04 Manufacturing capacity

- Successfully completed manufacturing at commercial scale (200L) at CanSinoBio to support clinical studies
- Expanded manufacturing agreement to include support for OCU410

FINANCIAL UPDATE

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Financial Update

Statement of Operations	Three months ended	
	September 30, 2021	September 30, 2020
Research and development expense	$(6.3)	$(1.5
In-process research and development expense	–	(7.0
General and administrative expense	(4.5)	(1.7
Other income (expense), net	–	(0.3
Net loss	$(10.8)	$(10.5
Net loss per share of common stock – basic and diluted	$(0.05)	$(0.07

Balance Sheet Data	September 30, 2021	September 30, 2020
Cash, cash equivalents, and restricted cash	$107.5	$24.
Debt	$1.7	$2.
Shares outstanding	198.9	184.

Unaudited; in millions, except per share data

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Q&A

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