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): **February 25, 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)

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 February 25, 2022, Ocugen, Inc. ("the Company") issued a press release announcing its financial results for the fourth quarter and the fiscal year ended December 31, 2021. The Company has scheduled a conference call and webcast for 8:30 a.m. eastern time on February 25, 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 February 25, 2022.
99.2	Earnings Release Presentation issued February 25, 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: February 25, 2022

OCUGEN, INC.

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

Exhibit 99.1

Ocugen Provides Business Update With Fourth Quarter and Full Year 2021 Financial Results

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

- *U.S. FDA lifts clinical hold on IND application for COVAXIN™ (BBV152), clearing the pathway for Phase 2/3 clinical trial in support of a BLA submission*
- *Engagement with U.S. FDA to advance pediatric EUA for COVAXIN™ included submission of a real-world safety database of more than 36 million vaccinated teens along with neutralization data against Omicron*
- *Comprehensive responses regarding COVAXIN™ submitted to Health Canada for the NOD*
- *OCU400 Phase 1/2 clinical trial initiated for the treatment of inherited retinal diseases caused by NR2E3 and RHO disease genotypes*

MALVERN, Pa. — February 25, 2022 (GLOBE NEWSWIRE) — Ocugen, Inc. (Ocugen) (NASDAQ: OCGN), a clinical-stage 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 fourth quarter and full year 2021 financial results along with a general business update.

"The fourth quarter capped a transformational year of growth for Ocugen as we saw major progress across our portfolio. The clinical hold for the COVAXIN™ development program was lifted, and we bolstered our pediatric Emergency Use Authorization submission to the U.S. Food and Drug Administration with a safety database of more than 36 million teens vaccinated with COVAXIN™. Our lead modifier gene therapy platform candidate, OCU400, received approval to initiate a Phase 1/2 clinical trial on target. I'm very pleased with the perseverance and commitment of the Ocugen team and the achievements they've made thus far. 2022 is poised to be another great year for the company. We're excited about commencing these clinical trials and will give periodic updates in the future," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen.

Business Updates

- COVAXIN™ in Phase 2/3 clinical trial for future Biologics License Application (BLA) submission — The FDA lifted its clinical hold on the COVAXIN™ IND application on February 18, 2022, and the Company expects to commence this immuno-bridging and broadening clinical trial as soon as possible.
- COVAXIN™ pediatric (2-18) Emergency Use Authorization (EUA) status — At the request of the FDA, Ocugen has shared real-world safety data from 36 million teenagers who had been vaccinated with COVAXIN™. Additionally, data (in-vitro) suggesting robust neutralization against Delta and Omicron variants were submitted to bolster the Company's pediatric EUA submission, which is currently under review by the FDA.
- COVAXIN™ review with Health Canada — Ocugen has submitted comprehensive responses to a Notice of Deficiency received in December 2021 from Health Canada regarding Ocugen's New Drug Submission (NDS) for COVAXIN™. Ocugen's responses are currently under review by Health Canada.
- Gene therapy clinical development progress — A Phase 1/2 clinical trial for OCU400 was initiated in January 2022, marking an advancement of Ocugen's modifier gene therapy program with updates for this multicenter, open-label, dose ranging study to be provided in the near future.
- Manufacturing site letter of intent (LOI) with Liminal BioSciences Inc. (Liminal) — In January 2022, Ocugen entered into a non-binding LOI with Liminal, a Canadian public company, for the acquisition of Liminal's manufacturing site in Belleville, Ontario. This manufacturing site, if acquired, would enable Ocugen to develop its internal manufacturing capabilities and expend its research and development capabilities to support its product candidate pipeline.
- Public offering of common stock — In February 2022, Ocugen announced an underwritten public offering of 16.0 million shares of its common stock for net proceeds of $50.0 million before estimated offering expenses. This public offering of common stock strengthens Ocugen's balance sheet and will be used to support Ocugen's product candidate development as well as general corporate expenses.

2021 Financial Results

- Ocugen's cash, cash equivalents, and restricted cash totaled $95.1 million as of December 31, 2021, compared to $24.2 million as of December 31, 2020. Ocugen had 199.4 million shares of common stock outstanding as of December 31, 2021.
- Fourth quarter — Research and development expenses for the three months ended December 31, 2021 were $7.1 million compared to $1.6 million for the three months ended December 31, 2020. General and administrative expenses for the three months ended December 31, 2021 were $7.5 million compared to $2.2 million for the three months ended December 31, 2020. Ocugen reported a $0.07 net loss per share for the three months ended December 31, 2021 compared to a $0.02 net loss per share for the three months ended December 31, 2020.
- Full year — Research and development expenses for the year ended December 31, 2021 were $35.1 million compared to $6.4 million for the year ended December 31, 2020. Research and development expenses for the year ended December 31, 2021 included a $15.0 million up-front payment to Bharat Biotech for the right and license to COVAXIN™ development, manufacturing, and commercialization in Canada. General and administrative expenses for the year ended December 31, 2021 were $22.9 million compared to $8.0 million for the year ended December 31, 2020. Ocugen reported a $0.30 net loss per share for the year ended December 31, 2021 compared to a $0.31 net loss per share for the year ended December 31, 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 4071887. 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 clinical-stage 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 International Limited's (Bharat Biotech) 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. Ocugen 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 Ocugen's progress in advancing the review of COVAXIN™ with the FDA, including with respect to its EUA submission for COVAXIN™ for pediatric use, and information about its non-binding LOI with Liminal to acquire Liminal's manufacturing site in Belleville, Ontario, and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements, including, among other things, the risk that Ocugen may not be able to successfully negotiate and execute definitive transaction agreements for the acquisition of Liminal's manufacturing site on acceptable terms, if at all, and the ultimate terms and timing for closing of the transactions contemplated thereby; the risk that Ocugen will not be able to successfully close the acquisition of Liminal's manufacturing site; risks associated with the planned development and refurbishing of the manufacturing site, including that the expected costs for such development will be greater than currently contemplated or that the planned development will take longer than expected or fail to be completed on a timely basis, if at all; and the risk that Ocugen will not be able to scale production for such site to adequately support manufacturing of its product candidates or the other products that are currently or may in the future be manufactured at such site. In addition, Ocugen's business is subject to numerous other risks and uncertainties, including, 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; the risk that Health Canada does not accept its NDS for COVAXIN™ or that Ocugen may not be able to adequately resolve the deficiencies noted by Health Canada with respect to its NDS, for which

Ocugen has provided responses that are currently under review by Health Canada; the risk that the FDA could make other decisions that adversely impact its ability to advance the development of COVAXIN™ in the United States even though the FDA's clinical hold on Ocugen's IND application for COVAXIN™ has been lifted; 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 is 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 Health Canada or otherwise sufficient to support its EUA submission, planned BLA submission, or its NDS; the size, scope, timing and outcome of any additional clinical trials or studies that Ocugen may be required to conduct to support an EUA or BLA; any additional chemistry, manufacturing, and controls information that Ocugen may be required to submit to the FDA or Health Canada; 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 Ocugen's 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 it files with the SEC. Any forward-looking statements that Ocugen makes in this press release speak only as of the date of this press release. Except as required by law, Ocugen assumes 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.

Ocugen Contact:
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Head, Investor Relations & Communications
+1 484 237 3398
ken.inchausti@ocugen.com

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

(tables to follow)

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

	As of December 31,	
	2021	2020
Assets		
Current assets		
Cash and cash equivalents	$ 94,958	$ 24,039
Advance for COVAXIN supply	4,988	—
Prepaid expenses and other current assets	2,700	1,839
Total current assets	102,646	25,878
Property and equipment, net	1,164	633
Restricted cash	151	151
Other assets	1,800	714
Total assets	$ 105,761	$ 27,376
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,312	$ 395
Accrued expenses and other current liabilities	4,325	2,941
Short-term debt, net	—	234
Operating lease obligations	363	44
Total current liabilities	7,000	3,614
Non-current liabilities		
Operating lease obligations, less current portion	1,231	389
Long term debt, net	1,712	1,823
Total liabilities	9,943	5,826
Stockholders' equity		
Convertible preferred stock	1	—
Common stock	1,995	1,841
Treasury Stock	(48)	(48)
Additional paid-in capital	225,537	93,059
Accumulated deficit	(131,667)	(73,302)
Total stockholders' equity	95,818	21,550
Total liabilities and stockholders' equity	$ 105,761	$ 27,376

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

	Three months ended December 31,		Year ended December 31,	
	2021	2020	2021	2020
Revenues				
Collaboration revenue	$ —	$ —	$ —	$ 43
Total revenues	—	—	—	43
Operating expenses				
Research and development	7,102	1,594	35,108	6,354
In-process research and development	—	—	—	7,000
General and administrative	7,470	2,214	22,920	7,974
Total operating expenses	14,572	3,808	58,028	21,328
Loss from operations	(14,572)	(3,808)	(58,028)	(21,285)
Other income (expense)				
Interest expense	(20)	(166)	(79)	(721)
Other income (expense)	11	184	(310)	184
Total other income (expense)	(9)	18	(389)	(537)
Loss before income taxes	(14,581)	(3,790)	(58,417)	(21,822)
Income tax benefit	—	—	(52)	—
Net loss and comprehensive income	$ (14,581)	$ (3,790)	$ (58,365)	$ (21,822)
Deemed dividend related to Warrant Exchange	—	—	—	(12,546)
Net loss to common stockholders	$ (14,581)	$ (3,790)	$ (58,365)	$ (34,368)
Shares used in calculating net loss per share attributable to common stockholders — basic and diluted	199,207,502	170,228,668	195,013,043	112,236,110
Net loss per share attributable to common stockholders — basic and diluted	$ (0.07)	$ (0.02)	$ (0.30)	$ (0.31)


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Business Update and Full Year and Q4 2021 Financial Results
NASDAQ: OCGN

Forward Looking Statement

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These and other risks and uncertainties are more fully described in Ocugen's periodic filings with the Securities and Exchange Commission (SEC), including the risk factors described in the section entitled "Risk Factors" in the quarterly a annual reports that it files with the SEC. Any forward-looking statements that Ocugen makes in this presentation speak only as of the this presentation. Except as required by law, Ocugen assumes 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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Transformation
Change
Improve
INNOVATION
PROCESS
DEVELOPED
STRATEGY
RISE
ADVANCEMENT
Innovation
Growth
EXPANSION
Progress
MODIFY
REFINEMENT
Evolve
CREATIVITY
Development
RESULTS
PROMOTE
Adapting
Build
Modification
IDEAS
PROGRESS
IMPROVE
RENEWAL
Metamorphosis
Strategies
Reorganization
ALTERATION
CHANG
REBUILDING
3

Forward Momentum for COVAXIN™ (BBV152)

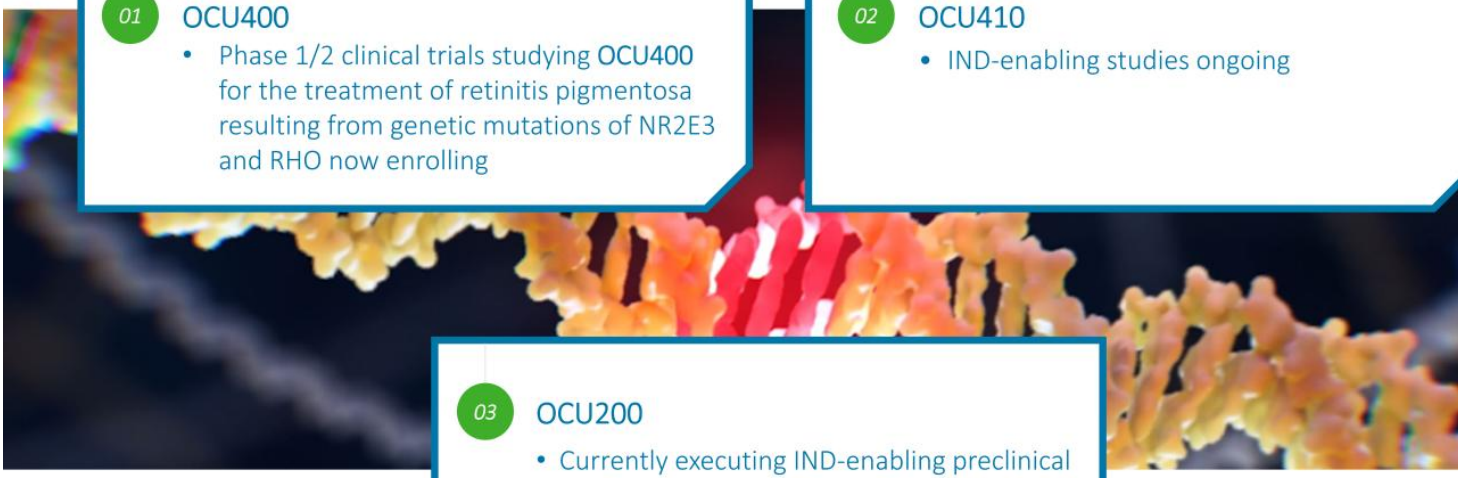
01

- U.S. FDA lifts clinical hold on IND submission of COVAXIN™, paving way for clinical trials supporting BLA
- Pediatric (2-18) Emergency Use Authorization submission updated with real-word safety, and Omicron data

02

- Comprehensive responses submitted to Health Canada against notice of deficiency
- Letter-of-Intent signed with Liminal BioSciences for acquisition of new Canada-based manufacturing facility;
- Tech transfer progressing with partner, JHS

Forward Momentum for Ocular Portfolio



01 OCU400

- Phase 1/2 clinical trials studying OCU400 for the treatment of retinitis pigmentosa resulting from genetic mutations of NR2E3 and RHO now enrolling

02 OCU410

- IND-enabling studies ongoing

03 OCU200

- Currently executing IND-enabling preclinical studies to support a Phase 1/2a clinical trial

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FINANCIAL UPDATE

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Financial Update

Statement of Operations	Three months ended December 31,		Year ended December 31,	
	2021	2020	2021	2020
Research and development expense	$7.1	$1.6	$35.1	
In-process research and development expense	—	—	—	
General and administrative expense	7.5	2.2	22.9	
Other income (expense), net	—	—	(0.4)	
Net loss	$(14.6)	$(3.8)	$(58.4)	$
Net loss to common stockholders	(14.6)	(3.8)	(58.4)	
Net loss per share of common stock — basic and diluted	$(0.07)	$(0.02)	$(0.30)	$

Balance Sheet Data	December 31,	
	2021	2020
Cash, cash equivalents, and restricted cash	$95.1	
Debt	$1.7	
Shares outstanding	199.4	

Unaudited; in millions, except per share amounts
Certain amounts may not add due to rounding

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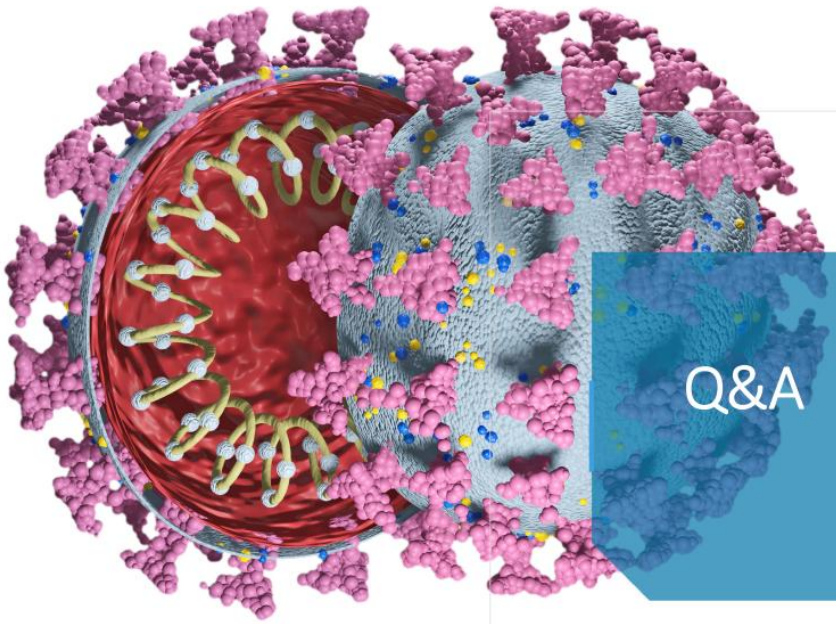

Q&A

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Business Update and Full Year and Q4 2021
Financial Results
NASDAQ: OCGN