
**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): **March 18, 2021**

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)

**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 March 18, 2021, Ocugen, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 2020. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. The Company has scheduled a conference call and webcast for 8:30 a.m. eastern time on March 18, 2021 to discuss these financial results and business updates.

The press release furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K contains a preliminary estimate of the Company's cash, cash equivalents, and restricted cash as of February 28, 2021. The preliminary estimate should not be viewed as a substitute for interim financial statements prepared in accordance with U.S. generally accepted accounting principles. The preliminary estimate is based on preliminary unaudited information and management estimates as of February 28, 2021, is not a comprehensive statement of the Company's financial results, and is subject to the completion of the Company's financial closing procedures. As a result, this preliminary estimate may differ from the actual results that will be reflected in the Company's financial statements when they are completed and publicly disclosed. Additional information and disclosures would be required for a more complete understanding of the Company's financial position as of February 28, 2021. The Company's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, the preliminary estimate.

The information disclosed under this Item 2.02, 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 exhibit is being furnished herewith:

(d) Exhibits

<u>Exhibit No.</u>	<u>Document</u>
99.1	<u>Press Release of Ocugen, Inc. dated March 18, 2021.</u>

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: March 18, 2021

OCUGEN, INC.

By: /s/ Shankar Musunuri

Name: Shankar Musunuri

Title: Chief Executive Officer and Chairman

Ocugen Provides Business Update and Full Year 2020 Financial Results

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

- COVID-19 vaccine candidate, COVAXIN™, demonstrates efficacy of 81% in Phase 3 interim results
- Emergency Use Authorization pathway with U.S. regulatory authorities in development for COVAXIN™
- European Commission grants orphan medicinal product designation for OCU400 for retinitis pigmentosa and leber congenital amaurosis and Ocugen is on track to submit an Investigational New Drug application for OCU400 in 2021
- On track to initiate four Phase 1/2 clinical trials encompassing Ocugen's ophthalmology pipeline in 2021 and 2022

MALVERN, PA — March 18, 2021 (GLOBE NEWSWIRE) — Ocugen, Inc. ("Ocugen") (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 full year 2020 financial results along with a general business update.

"We made strong progress toward our goal of offering a differentiated vaccine to save lives from COVID-19 and in our work toward curing blindness diseases. We are actively working with U.S. regulatory authorities to develop a plan around Emergency Use Authorization in the United States for COVAXIN™ and are preparing to file an Investigational New Drug application to initiate our first two clinical trials for OCU400 in the second half of this year. Proceeds from our recent registered direct offering provide the financial resources to drive our COVAXIN™ development efforts and ophthalmology pipeline forward," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen.

Business Highlights:

- Execution of Co-Development Agreement for COVAXIN™ in the U.S. Market – On February 2, 2021, Ocugen entered into a Co-Development, Supply and Commercialization Agreement with Bharat Biotech International Limited ("Bharat Biotech") for the development and commercialization of COVAXIN™ in the U.S. market. Upon receipt of Emergency Use Authorization ("EUA"), Bharat Biotech will supply a specified minimum number of doses of COVAXIN™ and then support the technology transfer for manufacturing for the U.S. market. Ocugen will share the profits from the sale of COVAXIN™ in the U.S. market with Bharat Biotech, with Ocugen retaining 45% of the profits.
- Steady Progress to Develop EUA Pathway in the United States for COVAXIN™ Supported by U.S. Leading Experts in Vaccines – Key members of Ocugen's management team and key advisors possess proven expertise and a track record of success in vaccine development and commercialization. Ocugen has established a vaccine scientific advisory board composed of leading academic and industry experts with extensive experience in the vaccine field. Collectively, the team is working with U.S. regulatory authorities to develop the regulatory pathway to EUA in the U.S. market.
- COVAXIN™ Demonstrates Efficacy of 81% in Phase 3 Interim Results – Interim results from Bharat Biotech's Phase 3 trial in India showed that COVAXIN™ was well tolerated and demonstrated 81% efficacy in preventing COVID-19 in those without prior infection after the second dose. In addition, COVAXIN™ has been shown to induce immune responses against multiple protein antigens of the virus potentially reducing the possibility of mutant virus escape. This breadth of immune responses has been demonstrated by the ability of antibodies induced by COVAXIN™ to neutralize the U.K. variant of SARS-CoV-2. This broad-antigen containing vaccine has the potential to be effective against new emerging variants.

- First Gene Therapy Candidate OCU400 On Track to Enter the Clinic in 2H21 – Based on Ocugen’s modifier gene therapy platform, Ocugen’s product candidate OCU400 represents a novel approach in that it has the potential to address multiple retinal diseases with one product. Ocugen is planning to file an Investigational New Drug application to initiate two Phase 1/2 clinical trials of OCU400 later this year for the treatment of two disease genotypes.
- European Commission (“EC”) Grants Orphan Medicinal Product Designation for OCU400 for Retinitis Pigmentosa (“RP”) and Leber Congenital Amaurosis (“LCA”) – Designation by the EC further supports the potential broad spectrum application of OCU400 to treat many IRDs. IRDs associated with RP and LCA diseases are caused by mutations in over 175 genes, and it is impractical to develop therapies that are specific to each gene.
- Capital Raised – Ocugen’s cash, cash equivalents, and restricted cash totaled approximately \$46.6 million as of February 28, 2021. Subsequent to December 31, 2020, Ocugen generated net proceeds of \$4.8 million under an at-the-market offering and net proceeds of \$21.2 million under a registered direct offering.

Full Year 2020 Financial Results:

- Ocugen’s cash, cash equivalents, and restricted cash totaled \$24.2 million as of December 31, 2020, compared to \$7.6 million as of December 31, 2019. The Company had 184.0 million shares of common stock outstanding as of December 31, 2020.
- Research and development expenses for the year ended December 31, 2020 were \$6.4 million compared to \$8.1 million for the year ended December 31, 2019. General and administrative expenses for the year ended December 31, 2020 were \$8.0 million compared to \$6.1 million for the year ended December 31, 2019. Ocugen reported a \$0.31 net loss per share for the year ended December 31, 2020 compared to a \$1.46 net loss per share for the year ended December 31, 2019.

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 2375087. 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. market. 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. 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, as well as risks associated with preliminary and interim data (including the Phase 3 interim data related to COVAXIN™), including the possibility of unfavorable new clinical trial data and further analyses of existing clinical trial data; 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 U.S. Food and Drug Administration ("FDA") will be satisfied with the design of and results from preclinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India; whether and when any biologics license and/or EUA applications may be filed in the United States for COVAXIN™; whether and when any such applications may be approved by the FDA; decisions by the FDA impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of COVAXIN™ in the United States, 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.

This press release contains a preliminary estimate of Ocugen's cash, cash equivalents, and restricted cash as of February 28, 2021. The preliminary estimate should not be viewed as a substitute for interim financial statements prepared in accordance with U.S. generally accepted accounting principles. The preliminary estimate is based on preliminary unaudited information and management estimates as of February 28, 2021, is not a comprehensive statement of Ocugen's financial results, and is subject to the completion of Ocugen's financial closing procedures. As a result, this preliminary estimate may differ from the actual results that will be reflected in Ocugen's financial statements when they are completed and publicly disclosed. Additional information and disclosures would be required for a more complete understanding of Ocugen's financial position as of February 28, 2021. Ocugen's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, the preliminary estimate.

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(tables to follow)

OCUGEN, INC.
CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	December 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 24,039,325	\$ 7,444,052
Prepaid expenses and other current assets	1,838,357	1,322,167
Asset held for sale	—	7,000,000
Total current assets	25,877,682	15,766,219
Property and equipment, net	632,967	222,464
Restricted cash	151,226	151,016
Other assets	714,477	667,747
Total assets	\$ 27,376,352	\$ 16,807,446
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 395,034	\$ 1,895,613
Accrued expenses	2,930,395	2,270,045
Short-term debt, net	234,119	—
Operating lease obligation	44,248	172,310
Other current liabilities	9,755	205,991
Total current liabilities	3,613,551	4,543,959
Non-current liabilities		
Operating lease obligation, less current portion	389,317	163,198
Long term debt, net	1,823,043	1,072,123
Other non-current liabilities	—	9,755
Total liabilities	5,825,911	5,789,035
Stockholders' equity		
Common stock	1,841,334	527,467
Treasury Stock	(47,864)	(47,864)
Additional paid-in capital	93,058,748	62,018,632
Accumulated deficit	(73,301,777)	(51,479,824)
Total stockholders' equity	21,550,441	11,018,411
Total liabilities and stockholders' equity	\$ 27,376,352	\$ 16,807,446

OCUGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Year ended December 31,	
	2020	2019
Revenues		
Collaboration revenue	\$ 42,620	\$ —
Total revenues	<u>42,620</u>	<u>—</u>
Operating expenses		
Research and development	6,353,287	8,085,522
In-process research and development	7,000,000	—
General and administrative	7,974,050	6,077,097
Total operating expenses	<u>21,327,337</u>	<u>14,162,619</u>
Loss from operations	<u>(21,284,717)</u>	<u>(14,162,619)</u>
Other income (expense)		
Change in fair value of derivative liabilities	—	(3,187,380)
Loss on debt conversion	—	(341,136)
Interest income	1,065	1,214
Interest expense	(720,963)	(1,767,836)
Other income (expense)	182,662	(784,873)
Total other income (expense)	<u>(537,236)</u>	<u>(6,080,011)</u>
Net loss	<u>\$ (21,821,953)</u>	<u>\$ (20,242,630)</u>
Deemed dividend related to Warrant Exchange	(12,546,340)	—
Net loss to common stockholders	<u>\$ (34,368,293)</u>	<u>\$ (20,242,630)</u>
Shares used in calculating net loss per common share — basic and diluted	<u>112,236,110</u>	<u>13,893,819</u>
Net loss per share of common stock — basic and diluted	<u>\$ (0.31)</u>	<u>\$ (1.46)</u>