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 3, 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 8.01 Other Events

On March 3, 2021, Ocugen, Inc. issued a press release announcing that its co-development partner, Bharat Biotech International Limited, announced the results of the first interim analysis of its Phase 3 clinical trial of COVAXIN, a whole virion inactivated COVID-19 vaccine candidate. A copy of this press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

The following exhibit is being filed herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Press Release of Ocugen, Inc. dated March 3, 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: March 3, 2021

OCUGEN, INC.

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

Exhibit 99.1

Ocugen's COVID-19 Vaccine Co-Development Partner, Bharat Biotech shares Phase 3 Interim Results of COVAXIN, Demonstrates Efficacy of 81%

- *Data from 25,800 participants in Phase 3 trial in India, received vaccine or placebo in a 1:1 ratio showed that the vaccine candidate was well tolerated and demonstrated 81% efficacy in preventing COVID-19 in those without prior infection after the second dose.*

- *Clinical trial to continue through to final analysis at 130 confirmed cases in order to gather further data and to evaluate the efficacy of COVAXIN in additional secondary study endpoints.*

Malvern, PA—March 03, 2021 (GLOBE NEWSWIRE) - Ocugen, Inc. (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 announced that its co-development partner, Bharat Biotech, announced the results of the first interim analysis of its Phase 3 study of COVAXIN, a whole virion inactivated COVID-19 vaccine candidate. COVAXIN demonstrated a vaccine efficacy of 81%.

"We are thrilled with the interim efficacy results of Bharat Biotech's Phase 3 trial of COVAXIN in India. These results, which in part suggest significant immunogenicity against the rapidly emerging UK variant, represent an additional step towards outlining the regulatory pathway for EUA and approval in the United States. COVAXIN, a whole virion based vaccine candidate, is designed to fill a significant unmet need in our national arsenal of vaccines against COVID-19," said Dr. Shankar Musunuri, Chairman of the Board, Chief Executive Officer, and Co-founder of Ocugen.

"Today's results from the interim analysis of Bharat Biotech's Phase 3 trial of COVAXIN mark a milestone in the development of another critical vaccine option for the US market. 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 ability of antibodies induced by COVAXIN to neutralize the UK variant of SARS-Cov-2," said Dr. Bruce Forrest, member of the vaccine scientific advisory board of Ocugen.

Interim Phase 3 Results as Reported by Bharat Biotech

Bharat Biotech's Phase 3 clinical trial enrolled 25,800 participants between 18-91 years of age, including 2,433 over the age of 60 and 4,500 with comorbidities. The primary endpoint of the Phase 3 clinical trial is based on the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 14 days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline.

The first interim analysis is based on 43 cases, of which 36 cases of COVID-19 were observed in the placebo group versus 7 cases observed in the COVAXIN group, resulting in a point estimate of vaccine efficacy of 80.6%.

The interim analysis included a preliminary review of the safety database, which showed that severe, serious, and medically attended adverse events occurred at low levels and were balanced between vaccine and placebo groups. The trial's conduct and monitoring are as per Good Clinical Practice guidelines and have been outsourced to IQVIA.

Analysis from the National Institute of Virology indicates that vaccine-induced antibodies can neutralize the UK variant strains and other heterologous strains, which has been published in bioRxiv.

Bharat Biotech expects to share further details of the trial results as additional data become available. An additional interim analysis is planned for 87 cases, and the final analysis is planned for 130 cases. All data from the second interim and final analyses will be shared via pre-publication servers as well as submitted to a peer-reviewed journal for publication.

About COVAXIN

COVAXIN, India's COVID-19 vaccine by Bharat Biotech, is developed in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). COVAXIN is a highly purified and inactivated vaccine that is manufactured using a vero cell manufacturing platform with an excellent safety track record of more than 300 million doses supplied.

In addition to generating strong immune response against multiple antigens, COVAXIN is shown to generate memory T cell responses, for its multiple epitopes, indicating longevity and a rapid antibody response to future infections. With published data demonstrating a safety profile superior to several other vaccines, COVAXIN is packaged in multi-dose vials that can be stored at 2-8^{o}C.

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.

About Bharat Biotech:

Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 123 countries, and World Health Organization (WHO) Pre-qualifications. Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution.

Having delivered more than 4 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis, Rabies, Chikungunya, Zika and the world's first tetanus-toxoid conjugated vaccine for Typhoid.

Bharat's commitment to global social innovation programs and public private partnerships resulted in the introduction of path breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC® and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The recent acquisition of the rabies vaccine facility, Chiron Behring, from GlaxoSmithKline (GSK) has positioned Bharat Biotech as the largest rabies vaccine manufacturer in the world. To learn more about Bharat Biotech visit www.bharatbiotech.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 that is the subject of this release), 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 emergency use authorization 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.

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