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): **July 2, 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 July 2, 2021, Ocugen, Inc. (the "Company") issued a press release announcing that its co-development partner, Bharat Biotech International Limited, shared positive results of its Phase 3 study 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.

(d) Exhibits

The following exhibit is being filed herewith:

Exhibit No.	Document
99.1	Press Release of Ocugen, Inc., dated July 2, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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: July 6, 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 Results Demonstrating 77.8% Protection against Overall Disease

- *Efficacy analysis demonstrates COVAXIN™ to be 93.4% protective against severe symptomatic COVID-19*
- *Efficacy data demonstrates 65.2% protection against the SARS-CoV-2, B.1.617.2 Delta variant*
- *Adverse events reported were similar to placebo, with 12.4% of subjects experiencing commonly known side effects and less than 0.5% of subjects feeling serious adverse events*

MALVERN, PA, and HYDERABAD, INDIA, July 2, 2021 - 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, shared positive results of its Phase 3 study of COVAXIN™, a whole virion inactivated COVID-19 vaccine candidate. COVAXIN™ demonstrated a vaccine efficacy in mild, moderate, and severe COVID-19 disease of 77.8% with efficacy against severe COVID-19 disease alone of 93.4%.

"As we brace ourselves for the potential next wave of COVID-19 outbreaks from the Delta variant, reporting of the final efficacy analysis from this Phase 3 study comes at a crucial time. We expect these efficacy and safety outcomes, along with demonstrated efficacy against emerging variants of concern, will support our initiatives to bring COVAXIN™ to the US and Canadian markets," said Dr. Shankar Musunuri, Chairman of the Board, Chief Executive Officer and Co-Founder of Ocugen.

"With the Delta variant becoming a dominant strain of COVID-19 in the United States, we believe that the Phase 3 efficacy results reported by Bharat Biotech demonstrate that COVAXIN™ has the potential to become an important option to expand protection against this emerging variant. Combining these data with the only Delta-variant results from a controlled Phase 3 clinical trial, evidence continues to support a favorable benefit-risk profile for COVAXIN™," said Dr. Bruce Forrest, Acting Chief Medical Officer and a member of the vaccine scientific advisory board of Ocugen.

Phase 3 Results as Reported by Bharat Biotech

Bharat Biotech's Phase 3 clinical trial enrolled 25,798 participants across 25 sites and between 18-98 years of age in India, including 2,750 over the age of 60 and 7,065 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 safety and efficacy readouts from Phase III clinical trials present a comprehensive data package for COVAXIN™. This has been a great journey of science leading to translational product development to combat this deadly pandemic," added Dr. Krishna Ella, Chairman & Managing Director, Bharat Biotech. "We continue our efforts towards additional studies on variants of concern. Our commitment to data transparency has been sustained with 10 publications within the past year, and we will share our findings with regulators worldwide."

COVAXIN™ demonstrated overall efficacy of 77.8% (95% CI; 65.2-86.4), achieving its primary endpoint. One hundred and thirty positive COVID-19 cases were observed: 24 in the vaccine group and 106 in the placebo group. Sixteen severe cases were observed: one in the vaccine group and 15 in the placebo group, achieving an efficacy of 93.4% (95% CI; 57.1-99.8) with respect to severe COVID-19 infection.

In the Phase 3 trial conducted by Bharat Biotech, subjects vaccinated with COVAXIN™ achieved greater protection against emerging B.1.617.2 (delta) and B.1.351 (beta) variants than those who had previous natural infections. Results showed an efficacy rate of 65.2% (95% CI; 33.1-83.0).

Adverse events reported were low, with 12.4% of subjects experiencing commonly known side effects and less than 0.5% of subjects feeling serious adverse events, side effects that keep many from considering taking current vaccines. Both adverse events and severe adverse events reported in the vaccine group were reported at similar rates to the placebo group.

Ocugen recently announced that it will pursue submission of a Biologics License Application (BLA) for its COVID-19 vaccine candidate, COVAXIN™ in the United States and has initiated discussions with Health Canada for regulatory approval.

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. It is a two-dose vaccine given four weeks apart.

In addition to generating strong immune response against multiple antigens, COVAXIN™ has been 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 available data for several other vaccines, COVAXIN™ is packaged in multi-dose vials that can be stored at 2-8^{o}C.

Based on the more than 30 million doses supplied in India and other countries, COVAXIN™ has an excellent safety record. COVAXIN™ is currently being administered under emergency use authorizations in 13 countries, and applications for emergency use authorization are pending in more than 60 additional countries.

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.

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 the 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 introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The acquisition of the rabies vaccine facility, Chiron Behring, from GlaxoSmithKline (GSK) has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer. 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 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 we will be able to provide the U.S. Food and Drug Administration (FDA) with sufficient additional information regarding the design of and results from preclinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India in order for those trials to support a biologics license application (BLA); the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to support a BLA; any additional chemistry, manufacturing and controls information that we may be required to submit the timing of our BLA filing; whether and when an application for authorization under interim order for emergency use will be filed in Canada; whether and when any such applications may be approved by Health Canada; whether developments with respect to 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.

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

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

Media contact for Bharat Biotech:
Sheela Panicker | +91 9849809594 | enright@enrightpr.com
Shilpa Suryawanshi | +91 9833738595 | shilpa.suryawanshi@perfectrelations.com