# 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 18, 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<br>(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 February 18, 2022, Ocugen, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration lifted its clinical hold on the Company's Investigational New Drug application to evaluate the COVID-19 vaccine candidate, BBV152, known as COVAXIN™ outside the United States. 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 exhibits are being filed herewith:

**(d) Exhibits**

| Exhibit No. | Document |
|---|---|
| 99.1 | Press Release of Ocugen, Inc. dated February 18, 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 22, 2022

OCUGEN, INC.

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

**Exhibit 99.1**

# Ocugen, Inc. Announces U.S. FDA Lifts Clinical Hold on the Submission of Its Investigational New Drug Application for Its COVID-19 Vaccine Candidate COVAXIN™ (BBV152)

MALVERN, Pa., February 18, 2022 — Ocugen, Inc. (NASDAQ: OCGN), a clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing novel therapeutics and vaccines, announced that the U.S. Food and Drug Administration (FDA) has lifted its clinical hold on the Company's Investigational New Drug application (IND) to evaluate the COVID-19 vaccine candidate, BBV152, known as COVAXIN™ outside the United States.

COVAXIN™ is a whole-virion inactivated COVID-19 investigational vaccine candidate that uses the same vero cell manufacturing platform that has been used in the production of polio vaccines for decades.

"We are pleased to be able to move our clinical program for COVAXIN™ forward, which we hope will bring us closer to offering an alternative COVID-19 vaccine," said Dr. Shankar Musunuri, Chairman of the Board, Chief Executive Officer, and Co-Founder of Ocugen. "We firmly believe that managing this pandemic requires more than one approach to vaccines, so we are heartened to be able to continue developing our vaccine candidate."

**About COVAXIN™ (BBV152)**
COVAXIN™ (BBVI52) is an investigational vaccine candidate product in the U.S. It was developed by Bharat Biotech 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 more than 200 million doses having been administered to adults outside the U.S., COVAXIN™ is currently authorized under emergency use in 20 countries, and applications for emergency use authorization are pending in more than 60 other countries. The World Health Organization (WHO) recently added COVAXIN™ to its list of vaccines authorized for emergency use. And, as many as 110 countries have agreed to mutual recognition of COVID-19 vaccination certificates with India that includes vaccination using COVAXIN™. The trade name COVAXIN™ has not been evaluated by the FDA.

**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'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 our progress in advancing the review of COVAXIN™ with the U.S. Food and Drug Administration (FDA), including the risk that the FDA could make other decisions that adversely impact our ability to advance the development of COVAXIN™ in the United States, and the implications that previous clinical holds may have for our request for Emergency Use Authorization (EUA) of COVAXIN for pediatric use, including the timing and scope of any such authorization; 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 submission or planned Biologics License Applications (BLA) submission; 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; any additional chemistry, manufacturing, and controls 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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