# 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): **December 22, 2020**

# 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) |

**5 Great Valley Parkway, Suite 160**
**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 December 22, 2020, Ocugen, Inc. (the "***Company***") issued a press release announcing that it has entered into a binding letter of intent with Bharat Biotech ("***Bharat***") to co-develop Bharat's COVID-19 vaccine candidate, COVAXIN™, an advanced stage whole-viron inactivated vaccine candidate currently in Phase III clinical trials, for the U.S. market. A copy of this press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and 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 December 22, 2020. |

**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: December 22, 2020

OCUGEN, INC.

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

**OCUGEN AND BHARAT BIOTECH TO CO-DEVELOP COVAXIN™, A WHOLE-VIRION INACTIVATED COVID-19 VACCINE, FOR THE US MARKET**

*Companies will co-develop inactivated vaccine candidate, COVAXIN™, to prevent COVID-19 infection in the US*

*Builds upon the promising safety and immunogenicity data in the Phase 1 and Phase 2 trials*

*Vaccine candidate is an inactivated ("traditional") type vaccine with potentially broad appeal*

Malvern, PA & Hyderabad, India December 22, 2020 (GLOBE NEWSWIRE) - Ocugen, Inc., (NASDAQ: OCGN), a leading biopharmaceutical company, and Bharat Biotech, a global leader in vaccine innovation, today announced that the companies have signed a binding letter of intent (LOI) to co-develop Bharat Biotech's COVID-19 vaccine candidate, COVAXIN™, an advanced stage whole-viron inactivated vaccine candidate, for the United States market.

COVAXIN™ has been evaluated in approximately 1,000 subjects in Phase 1 and Phase 2 clinical trials in India, with promising safety and immunogenicity data. The vaccine candidate is currently part of a Phase 3 clinical trial in India involving 26,000 volunteers.

Per the LOI, Ocugen will have US rights to the vaccine candidate and, in collaboration with Bharat Biotech, will be responsible for clinical development, registration, and commercialization for the US market. The companies have begun collaborating and will finalize details of the definitive agreement in the next few weeks. This collaboration leverages Ocugen's vaccine expertise, and its R&D and regulatory capabilities in the US.

In preparation for the development of COVAXIN™ in the US, Ocugen has assembled a Vaccine Scientific Advisory Board featuring leading academic and industry experts to evaluate the clinical and regulatory path to approval in the US market.

"COVAXIN™ utilizes a historically proven approach to vaccine design. The adjuvanted inactivated virus vaccine candidate elicited strong IgG responses against spike (S1) protein, receptor-binding domain (RBD) and the nucleocapsid (N) protein of SARS-CoV-2 along with strong cellular responses in Phase 1 and 2 clinical trials. COVAXIN™ offers a vaccine candidate that is different from other options currently available in the US market with potentially broader coverage against multiple protein antigens of the virus" said Harvey Rubin, M.D. Ph.D. of the University of Pennsylvania, a member of Ocugen's Vaccine Scientific Advisory Board.

David Fajgenbaum, M.D. of University of Pennsylvania's Division of Translational Medicine & Human Genetics, Director of the Center for Cytokine Storm Treatment & Laboratory, and member of Ocugen's Vaccine Scientific Advisory Board said, "The COVID-19 pandemic has caused unmatched devastation to individual patients and to the world. It is going to take the kind of unmatched collaboration and innovation that is occurring right now to effectively fight back. Vaccines such as COVAXIN™ that can potentially elicit a broad immune response and may limit future COVID-19 severity could be important to have in our arsenal."

"We are delighted to collaborate with Bharat Biotech to potentially bring COVAXIN™ to the US market. In the face of the coronavirus pandemic, it is incumbent upon all of us to find solutions that have the potential to save lives and restore normalcy to our day-to-day activities. We have been very pleased with the safety and immunogenicity demonstrated by the Phase 1 and Phase 2 trials of COVAXIN™ and are encouraged with the progress of the Phase 3 trials in India. We believe this unique yet traditional approach to vaccination holds great potential to appeal to a broad range of the population," said Dr. Shankar Musunuri, Chairman, CEO, and Co-Founder of Ocugen.

"The development and clinical evaluation of COVAXIN™ marks a significant milestone for vaccinology in India. COVAXIN™ has garnered interest from several countries worldwide for supplies and introduction and we are excited to collaborate with Ocugen to bring it to the US market," said Dr. Krishna Ella, Chairman & Managing Director of Bharat Biotech.

**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). This inactivated vaccine is developed and manufactured in Bharat Biotech's BSL-3 (Bio-Safety Level 3) bio containment facility. COVAXIN™ is a highly purified and inactivated vaccine, manufactured in a vero cell manufacturing platform with an excellent safety track record of more than 300 million doses supplied.

**About Ocugen, Inc.**
Ocugen, Inc. is a biopharmaceutical company focused on discovering, developing, and commercializing transformative therapies to cure blindness diseases. 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. For more information, please visit www.ocugen.com.

**About Bharat Biotech:**
Bharat Biotech has established an excellent track record of innovation with more than 140 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 116 countries and WHO Pre-qualifications. Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, the company 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 6 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 GSK has positioned Bharat 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 statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from our current expectations. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission (the "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:**
Ocugen, Inc.
Sanjay Subramanian
Chief Financial Officer
ir@ocugen.com

**Media Contact:**
For Ocugen:
LaVoieHealthScience
Lisa DeScenza
ldescenza@lavoiehealthscience.com
+1 978-395-5970

For Bharat Biotech:
Sheela Panicker
enright@enrightpr.com
+91 984-980-9594