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): **November 5, 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 November 5, 2021, Ocugen, Inc. (the "Company") issued a press release announcing that it had submitted a request to the U.S. Food and Drug Administration for Emergency Use Authorization of the Company's COVID-19 vaccine candidate, BBV152, known as COVAXIN™ outside the United States, for children ages 2 to 18 years. 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 November 5, 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: November 5, 2021

OCUGEN, INC.

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

Exhibit 99.1

Ocugen, Inc. Announces Submission of Emergency Use Authorization Request to the US FDA for Investigational COVID-19 Vaccine COVAXIN ™ (BBV152) for Children Ages 2-18 Years

- *COVAXIN™ (BBV152) was recently awarded Emergency Use Listing by the World Health Organization*
- *Pediatric EUA submission based on immuno-bridging clinical trial in children, ages 2-18, demonstrating comparable neutralizing antibody response as seen in a large adult Phase 3 clinical trial conducted in India*
- *COVAXIN™ (BBV152) uses same Vero Cell manufacturing platform as other childhood vaccines, including the inactivated polio vaccine*
- *COVAXIN™ (BBV152) elicited antibody titers against multiple antigens (S1, RBD, and N); and provided durable immunity against COVID-19 in Phase 3 adult trial in India*
- *No serious adverse events or hospitalizations were observed in Phase 2/3 pediatric study of COVAXIN™ (BBV152), including no events of special interest such as Guillain-Barre Syndrome, anaphylactic reactions, myocarditis, pericarditis, and vaccine-induced thrombotic thrombocytopenia.*

MALVERN, Pa., – November 5, 2021 – Ocugen, Inc. (NASDAQ: OCGN), a biopharmaceutical company focused on discovering, developing, and commercializing novel therapeutics and vaccines, announced today that it has submitted a request to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of Ocugen's COVID-19 vaccine candidate BBV152, known as COVAXIN™ outside of the U.S., for pediatric use. The vaccine candidate was developed by the company's partner, Bharat Biotech, and was studied in an immuno-bridging clinical trial conducted in India with children 2-18 years of age.

COVAXIN™ (BBV152) is a whole-virion, inactivated vaccine, manufactured using a Vero Cell manufacturing platform, as has been used in the production of the inactivated polio vaccine for the past 35 years, as well as of other traditional childhood vaccines.

The submission is based on results of a Phase 2/3 pediatric clinical trial conducted by Bharat Biotech in India with 526 children 2-18 years of age, which bridged immunogenicity data to a large, Phase 3 safety and efficacy clinical trial in nearly 25,800 adults in India.

About the Data to Support the EUA

A Phase 2/3, open-label, multicenter study was conducted in India from May 2021 to July 2021, to evaluate the safety, reactogenicity and immunogenicity, of the whole-virion inactivated SARS-CoV-2 Vaccine (COVAXIN™ BBV152) in healthy volunteers 2-18 years of age.

COVAXIN™ (BBV152) was evaluated in three age groups: 2-6 years, 6-12 years and 12-18 years. All participants received two doses of the whole virion inactivated SARS-CoV-2 virus vaccine 28 days apart.

The neutralizing antibody responses against wild-type strain in the pediatric age group of 2-18 years were equivalent to those seen in adults, ages 18+ years, in Bharat Biotech's large Phase 3 efficacy and safety trial. More than 90 percent of the seroconversion rates were observed for antibody titers against S1, RBD, N proteins and wild-type neutralizing antibodies. These results suggest similar protection in children, ages 2-18, to that demonstrated in adults older than 18 years.

Among the 526 study subjects in the pediatric clinical trial, no serious adverse effects, such as deaths, hospitalizations, myocarditis, pericarditis, Guillain-Barre syndrome, vaccine-induced thrombotic thrombocytopenia or anaphylactic reactions were reported in the study. These were also not observed in the surveillance data collected in India following the administration of over 59 million doses of COVAXIN™ (BBV152) in adults. All other adverse events were mild or moderate in nature and were generally resolved within 24 hours.

"Filing for Emergency Use Authorization in the U.S. for pediatric use is a significant step toward our hope to make our vaccine candidate available here and help combat the COVID-19 pandemic," said Dr. Shankar Musunuri, Chairman of the Board, Chief Executive Officer, and Co-Founder of Ocugen. "Our research suggests that people are seeking more choices when selecting a vaccine, especially for their children. Having a new type of vaccine available will enable people to discuss with their child's physician the best approach for them to lower their child's risk of contracting COVID-19. The inactivated virus platform has been used for decades in vaccines for the pediatric population and, if authorized, we hope to offer another vaccine option to protect children as young as 2 years."

About COVAXIN™ (BBV152)

COVAXIN™ (BBV152) 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 100 million doses having been administered to adults outside the U.S., COVAXIN™ is currently authorized under emergency use in 17 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. The trade name COVAXIN™ has not been evaluated by the FDA.

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. 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, including with respect to our hope that COVAXIN™, if authorized under the EUA, would be available to children as young as two years of age. 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, including whether the FDA will authorize COVAXIN™ for administration as a vaccine for pediatric uses against COVID-19 pursuant to the EUA we submitted with the FDA and the timing and scope of any such authorization, 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 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; 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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