
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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): **September 14, 2022**

OCUGEN, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-36751
(Commission
File Number)

04-3522315
(I.R.S. Employer
Identification Number)

**11 Great Valley Parkway
Malvern, Pennsylvania 19355
(484) 328-4701**

(Address, including zip code, and telephone number, including area code, of principal executive office)

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))
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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 September 14, 2022, Ocugen, Inc. issued a press release announcing the publication of a comprehensive review of BBV152, known as COVAXIN™, in *Frontiers in Immunology*. A copy of the 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

<u>Exhibit No.</u>	<u>Document</u>
99.1	Press Release of Ocugen, Inc. dated September 14, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 14, 2022

OCUGEN, INC.

By: /s/ Shankar Musunuri

Name: Shankar Musunuri

Title: Chief Executive Officer and Chairman

OCUGEN ANNOUNCES PUBLICATION OF A COMPREHENSIVE REVIEW OF BBV152 IN FRONTIERS IN IMMUNOLOGY

- *Data include the persistence of immune responses and protection against variants of concern, especially Delta and Omicron*
- *Ocugen has North American commercialization rights for BBV152, commercialized as COVAXIN™*

Malvern, Pa, September 14, 2022 (GLOBE NEWSWIRE) — Ocugen, Inc. (Ocugen or the Company) (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies and vaccines, today announced the publication “A comprehensive review of BBV152 vaccine development, effectiveness, safety, challenges, and prospects” appeared in *Frontiers in Immunology*. BBV152, commercialized as COVAXIN™, is developed and manufactured by Ocugen’s partner Bharat Biotech, a global leader in vaccine innovation based in Hyderabad, India. BBV152 is currently authorized by the World Health Organization, authorized under Emergency Use Authorization in 28 countries, and accepted as a COVID-19 vaccine to travel into over 85 countries. It is under clinical investigation by Ocugen in the United States for use in adults aged 18 years and older.

This review by Dotiwala and Upadhyay provides a detailed analysis of the immunogenicity, safety, and efficacy of BBV152—a whole virus inactivated vaccine and an important tool in the fight to control the COVID-19 pandemic. Additionally, BBV152 has a broader impact on public health, as it induces high neutralization efficacy against different SARS-CoV-2 variants of concern.

“Unfortunately, the COVID-19 pandemic is not yet over, despite the introduction of effective vaccines and a greater understanding of COVID-19 pathogenesis and transmission dynamics,” said David Fajgenbaum, MD, MBA, MSc, Assistant Professor of Medicine, Translational Medicine & Human Genetics, University of Pennsylvania, and Ocugen Vaccine Scientific Advisory Board member. “This study demonstrates durability through immune memory and a broader immune response with BBV152 and provides further evidence that additional vaccine options—including those built on a traditional vaccine platform—are needed.”

Findings include:

- 77.8% and 93.4% protection from symptomatic COVID-19 disease and severe symptomatic COVID-19 disease respectively.
- Studies in pediatric populations show superior immunogenicity (geometric mean titer ratio of 1.76 compared to an adult) with a seroconversion rate of >95%.
- Reactogenicity and safety profiles were comparable across all pediatric age groups between 2-18 yrs.

The study concludes that BBV152 is a suitable alternative to mRNA vaccines.

About Ocugen, Inc.

Ocugen, Inc. is a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies and vaccines that improve health and offer hope for patients across the globe. We are making an impact on patient’s lives through courageous innovation—forging new scientific paths that harness our unique intellectual and human capital. Our breakthrough modifier gene therapy platform has the potential to treat multiple retinal diseases with a single product, and we are advancing research in infectious diseases to support public health and orthopedic diseases to address unmet medical needs.

Discover more at www.ocugen.com and follow us on Twitter and LinkedIn.

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 (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.

Contact:

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