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): August 31, 2022

HilleVax, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41365**	**85-0545060**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

75 State Street, Suite 100 - #9995 **Boston, Massachusetts** **(Address of principal executive offices)**	**02109** **(Zip Code)**

(617) 213-5054
(Registrant's telephone number, including area code)

(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:

☐ 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, $0.0001 par value per share	**HLVX**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Sec.230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Sec.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 Results of Operations and Financial Condition.

On August 31, 2022, HilleVax, Inc. (the "Company") announced that an independent safety data monitoring committee (the "DMC") completed a prespecified review of safety data from 203 subjects enrolled in the run-in portion of NEST-IN1 ("Norovirus Efficacy and Safety Trial for Infants" or "NOR-212"), the Company's Phase 2b trial for HIL-214. HIL-214 is the Company's investigational virus-like particle based vaccine candidate for the prevention of moderate-to-severe norovirus-related acute gastroenteritis in infants. Based on its review, the DMC recommended continuation of NEST-IN1 without modification, and enrollment has subsequently resumed. The Company also announced that it intended to report immunogenicity results from the first 200 subjects in NEST-INI in the fourth quarter of 2022 and remained on-track for topline safety and efficacy data from the full study in the second half of 2023.

NEST-IN1 is a Phase 2b, randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy, safety, and immunogenicity of HIL-214 in infants of approximately 5 months of age at the time of initial vaccination at sites in the United States and Latin America. The study is planned to enroll 3,000 subjects who will be randomized 1:1 to receive a two-dose regimen of either HIL-214 or placebo. The clinical trial protocol includes a prespecified 200 subject run-in to assess safety and immunogenicity. The primary objective of the trial is to evaluate the protective efficacy of HIL-214 against the first confirmed moderate or severe AGE event due to a HIL-214 vaccine strain, GI.1 or GII.4, (excluding certain co-infections) that occurs prior to each subject reaching 12 months of age. A key secondary endpoint is to evaluate the protective efficacy of HIL-214 against any GI or GII norovirus strain.

Forward-Looking Statements

The Company cautions you that statements contained in this current report regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to: the expected continuation of enrollment in the NEST-IN1 trial and the expected timing of data readouts from this trial. Actual results may differ from those set forth in this current report due to the risks and uncertainties inherent in the Company's business, including, without limitation: the Company currently depends entirely on the success of HIL-214, and the Company has not yet completed any clinical trials of HIL-214; potential delays in the commencement, enrollment, and completion of clinical trials and preclinical studies; the Company's dependence on third parties in connection with manufacturing, research and clinical and preclinical testing; unexpected adverse side effects or inadequate immunogenicity or efficacy of HIL-214 or any future vaccine candidates that may limit their development, regulatory approval, and/or commercialization; unfavorable results from clinical trials; results from prior clinical trials and studies not necessarily being predictive of future results; the Company's ability to maintain undisrupted business operations due to the COVID-19 pandemic, including delaying or disrupting the Company's clinical trials, manufacturing and supply chain; regulatory developments in the United States and foreign countries; any future impacts to the Company's business resulting from the conflict between Russia and Ukraine or other geopolitical developments outside the Company's control; and other risks described in the Company's prior press releases and the Company's filings with the Securities and Exchange Commission (the "SEC"), including under the heading "Risk Factors" in the Company's quarterly report on Form 10-Q and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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.

HilleVax, Inc.

Date: August 31, 2022

By: /s/ Paul S. Bavier
Name: Paul S. Bavier
Title: General Counsel and Chief Administrative Officer