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): July 8, 2024

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.)**

321 Harrison Avenue **Boston, Massachusetts** **(Address of principal executive offices)**	**02118** **(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 Other Events.

On July 8, 2024, HilleVax, Inc. (the "Company") announced topline data from its NEST-IN1 Phase 2b clinical study of HIL-214 in infants. 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.

In the NEST-IN1 study there were 51 primary endpoint events with 25 in the vaccine arm (n=1,425) and 26 in the placebo arm (n=1,399) resulting in vaccine efficacy of 5% (95% confidence interval; -64%, 45%). The study did not meet its primary endpoint of efficacy against moderate or severe acute gastroenteritis ("AGE") events due to GI.1 or GII.4 norovirus genotypes. No clinical benefit was observed across secondary endpoints. HIL-214 exhibited a safety and immunogenicity profile consistent with what was observed in the prespecified analysis of the first 200 subjects in NEST-IN1 and in previously reported studies.

The Company plans to discontinue further development of HIL-214 in infants and is exploring the potential for continued development of HIL-214 and HIL-216, HilleVax's Phase 1 ready vaccine candidate, in adults.

Forward-Looking Statements

The Company cautions you that statements contained in this report regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on the Company's current beliefs and expectations and include, but are not limited to, the Company's plans to explore the potential for continued development of HIL-214 and HIL-216, HilleVax's Phase 1 ready vaccine candidate, in adults. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in the Company's business, including, without limitation: to-date the Company has depended primarily on the success of HIL-214, and the Company may be unable to identify a viable development path forward for HIL-214; if the Company does identify a development path forward for HIL-214, the Company may require additional capital and other resources, including partnerships or other strategic collaborations, and may be unable to secure partnerships, other strategic collaborations or other resources on acceptable terms or at all; topline results are based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the NEST-IN1 study and such topline data may not accurately reflect the complete results of a clinical trial; to the extent the Company pursues future studies, it may experience potential delays in the commencement, enrollment, data readouts and completion of clinical trials and preclinical studies; the Company depends 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, HIL-216 or any future vaccine candidates that may limit their development, regulatory approval, and/or commercialization; further unfavorable results from clinical trials; results from prior clinical trials and studies are not necessarily predictive of future results; the Company relies on intellectual property rights under its license agreements with Takeda Vaccines, Inc. and Kanghua Biological Products Co., Ltd.; the Company may be unable to obtain, maintain and enforce intellectual property protection for its vaccine candidates; the Company may use its capital resources sooner than it expects; and other risks described in the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's annual report on Form 10-K 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: July 8, 2024

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