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): April 25, 2023

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)**	**(IRS Employer Identification No.)**

75 State Street **Suite 100** **Boston, Massachusetts**	**02109**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 617 213-5054

(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, par value $0.0001 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 (§ 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 April 25, 2023, HilleVax, Inc. (the "Company") announced that it completed enrollment of its NEST-IN1 clinical trial (**N**orovirus **E**fficacy and **S**afety **T**rial for **IN**fants), with over 3,000 subjects enrolled in six countries. NEST-IN1 is the Company's ongoing Phase 2b trial for HIL-214, its investigational virus-like particle (VLP) based vaccine candidate for the prevention of moderate-to-severe norovirus-related acute gastroenteritis (AGE) in infants. Topline safety and clinical efficacy data from NEST-IN1 are expected in the first quarter of 2024.

NEST-IN1 is a randomized, double-blind, placebo-controlled trial in infants of approximately 5 months of age at time of initial vaccination at sites in the United States and Latin America. Subjects were randomized 1:1 to receive either HIL-214 or placebo. In the vaccine arm, subjects received HIL-214 (50/150 µg GI.1/GII.4 VLP combination with 500 µg alum) in a two-dose regimen delivered 28 to 56 days apart. In the control arm, subjects received saline placebo at the corresponding timepoints. The primary objective of NEST-IN1 is to evaluate the protective efficacy of HIL-214 against moderate or severe AGE events associated with GI.1 or GII.4 norovirus strains (excluding certain co-infections) during a pre-determined surveillance period that begins one month after the administration of the second dose of HIL-214. A key secondary endpoint is the evaluation of the protective efficacy of HIL-214 against any GI or GII norovirus strain. Other secondary endpoints include the evaluation of safety and immunogenicity of HIL-214.

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 expected timing of data readouts from the NEST-IN1 clinical trial. 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: 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 or other epidemic diseases, including delaying or disrupting the Company's clinical trials, manufacturing and supply chain; unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may adversely affect the Company's business and financial condition and the broader economy and biotechnology industry; 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; the Company's reliance on intellectual property rights under the Company's license agreement with Takeda Vaccines, Inc.; the Company's ability to obtain, maintain and enforce intellectual property protection for the Company's vaccine candidates; the Company may use its capital resources sooner than the Company expects; and other risks described in the Company's prior press releases and 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 t-hat 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.

SIGNATURES

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: April 25, 2023

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