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): May 09, 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)**	**(IRS Employer Identification No.)**
321 Harrison Avenue Boston, Massachusetts		**02118**
(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 2.02 Results of Operations and Financial Condition.

On May 9, 2024, HilleVax, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Press Release issued on May 9, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: May 9, 2024

By: /s/ Paul S. Bavier

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

Exhibit 99.1

HilleVax Reports First Quarter 2024 Financial Results and Highlights Recent Company Progress

Topline data from NEST-IN1 Phase 2B clinical study of HIL-214 in infants expected in mid-2024

$272.7 million of cash, cash equivalents and marketable securities as of March 31, 2024

BOSTON, May 9, 2024 – HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the quarter ended March 31, 2024, highlighted recent progress and outlined key upcoming milestones for HIL-214, the company's investigational virus-like particle (VLP) based vaccine for the prevention of moderate-to-severe norovirus-related acute gastroenteritis.

"We are excited to remain on track to report top-line data from our ongoing NEST-IN1 clinical trial in infants by mid-2024," said Rob Hershberg, MD, PhD, Chairman and CEO of HilleVax. "With positive results from NEST-IN1, we expect HIL-214 to rapidly progress into Phase 3 clinical trials in both infants and older adults, and we will provide clarity around those plans when we announce the NEST-IN1 data. HIL-214 remains the most advanced norovirus vaccine in clinical development and has the potential to address an enormous unmet medical need in both children and adults."

Recent Business Highlights

- In Q1 2024, HilleVax announced the appointment of Sean McLoughlin as Chief Operating Officer.

Upcoming Expected Milestones

- Topline safety and clinical efficacy data from NEST-IN1 in mid-2024.

First Quarter 2024 Financial Results

As of March 31, 2024 and December 31, 2023, the company had cash, cash equivalents and marketable securities totaling $272.7 million and $303.5 million, respectively.

Research and development expenses for the first quarter 2024 were $26.0 million, compared to $23.2 for the first quarter 2023. The increase was primarily due to the growth in the number of R&D employees.

General and administrative expenses for the first quarter 2024 were $8.5 million, compared to $5.8 million for the first quarter 2023. The increase was primarily due to the growth in the number of G&A employees.

Other income for the first quarter 2024 was $3.0 million, compared to $2.1 million for the first quarter 2023. The increase in the first quarter of 2024 compared to the first quarter of 2023 was primarily driven by accretion of marketable securities.

Net loss for the first quarter 2024 was $46.8 million, compared to $26.9 million for the first quarter 2023.

About HilleVax

HilleVax is a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines. Its most advanced program, HIL-214, is a virus-like particle (VLP) based vaccine candidate in development for the prevention of moderate-to-severe acute gastroenteritis (AGE) caused by norovirus infection. Globally, norovirus is estimated to result in over approximately 700 million cases of AGE and 200,000 deaths per year, resulting in direct and indirect healthcare system and societal costs of $10 billion in the United States and $60 billion globally. The burden of norovirus falls disproportionately on young children and older adults. For more information about HilleVax, visit the company's website at http://www.HilleVax.com.

Forward-Looking Statements

HilleVax cautions you that statements contained in this press release 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 potential opportunity for and benefits of HIL-214 and the expected timing of a data readout from the NEST-IN1 clinical trial, the advancement of HIL-214 to registration as the first norovirus vaccine, and longer-term market leadership plans. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: we currently depend entirely on the success of HIL-214, and we have not yet completed any clinical trials of HIL-214; potential delays in the commencement, enrollment, data readouts and completion of clinical trials and preclinical studies; our 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; and unstable market and economic conditions may adversely affect our business and financial condition and the broader economy and biotechnology industry; regulatory developments in the United States and foreign countries; any future impacts to our business resulting from military conflicts or other geopolitical developments outside our control; our reliance on intellectual property rights under our license agreements with Takeda Vaccines, Inc. and Kanghua Biological Products Co., Ltd.; our ability to obtain, maintain and enforce intellectual property protection for our vaccine candidates; we may use our capital resources sooner than we expect; and other risks described in our prior press releases and our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our 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 we undertake 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.

Contact:

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HilleVax, Inc.
Condensed Consolidated Statement of Operations Data
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 25,978	$ 23,164
In-process research and development	15,325	—
General and administrative	8,494	5,795
Total operating expenses	49,797	28,959
Loss from operations	(49,797)	(28,959)
Total other income	2,968	2,070
Net loss	$ (46,829)	$ (26,889)
Net loss per share, basic and diluted	$ (0.97)	$ (0.71)
Weighted-average shares of common stock outstanding, basic and diluted	48,460,185	37,753,522

HilleVax, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 272,743	$ 303,483
Total assets	314,175	344,434
Total liabilities	75,266	78,909
Total stockholders' equity	238,909	265,525
Total liabilities and stockholders' equity	314,175	344,434