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): March 17, 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 2.02 Results of Operations and Financial Condition.

On March 17, 2023, HilleVax, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2022. 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 March 17, 2023
104	Cover Page Interactive Data File (embedded within the Ingline 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: March 17, 2023

By: /s/ Paul S. Bavier

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

HILLEVAX

HilleVax Reports Full Year 2022 Financial Results and Highlights Recent Company Progress

BOSTON, March 17, 2023 – HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the year ended December 31, 2022, highlighted recent program 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.

"2022 was a momentous year for HilleVax where the company achieved many important milestones including the initiation and execution of our Phase 2b clinical trial NEST-IN1 and the completion of our initial public offering," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. "We look forward to completing enrollment of our NEST-IN1 clinical trial in 2023 and announcing top line safety and clinical efficacy data in the first quarter of 2024."

Recent Business Highlights

- In Q4 2022, HilleVax announced positive immunogenicity results for the NEST-IN1 run-in cohort.
- In Q3 2022, HilleVax announced the positive recommendation by the safety data monitoring committee to continue enrollment of the remaining 2,800 subjects in the NEST-IN1 clinical trial after the evaluation of safety data from the prespecified 200 subject run-in.

Upcoming Expected Milestones

- Topline safety and clinical efficacy data from NEST-IN1 in the first quarter of 2024.

Full Year 2022 Financial Results

As of December 31, 2022, the company had cash and cash equivalents totaling $279.4 million.

Research and development expenses for the fourth quarter 2022 were $17.6 million and $45.9 million for the full year ended December 31, 2022, compared to $8.4 million for the fourth quarter 2021 and $10.0 million for the full year ended December 31, 2021.

General and administrative expenses for the fourth quarter 2022 were $5.5 million and $16.7 million for the full year ended December 31, 2022, compared to $2.7 million for the fourth quarter 2021 and $5.8 million for the full year ended December 31, 2021.

Other income for the fourth quarter 2022 was $1.9 million, compared to $26.3 million of other expense for the fourth quarter 2021. The other income in the fourth quarter of 2022 was primarily driven by interest income on the company's cash and cash equivalents while the other expense in the fourth quarter of 2021 was primarily driven by changes in the fair value of convertible promissory notes and warrant liabilities and interest expense on outstanding convertible debt.

Other expense for the full year ended December 31, 2022 was $94.7 million, compared to $49.0 million for the full year ended December 31, 2021. The other expense in 2022 was primarily driven by changes in the fair value of convertible promissory notes and warrant liabilities and interest expense on our convertible promissory notes, offset by interest income on the company's cash and cash equivalents. The other expense in 2021 was primarily driven by changes in the fair value of convertible promissory notes and warrant liabilities and interest expense on outstanding convertible debt.

Net loss for the fourth quarter 2022 was $21.2 million and $159.8 million for the full year ended December 31, 2022, compared to $37.3 million for the fourth quarter 2021 and $102.4 million for the full year ended December 31, 2021.

About HilleVax

HilleVax is a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines. Its initial 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 over $4 billion in direct health system costs and $60 billion in societal costs per year. 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 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 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, 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; our ability to maintain undisrupted business operations due to the COVID-19 pandemic or other epidemic diseases, including delaying or disrupting our 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 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 the conflict between Russia and Ukraine or other geopolitical developments outside our control; our reliance on intellectual property rights under our license agreement with Takeda Vaccines, Inc.; 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 17,556	$ 8,391	$ 45,908	$ 10,014
In-process research and development	—	(10)	2,500	37,656
General and administrative	5,543	2,692	16,705	5,756
Total operating expenses	23,099	11,073	65,113	53,426
Loss from operations	(23,099)	(11,073)	(65,113)	(53,426)
Total other income (expense)	1,911	(26,254)	(94,696)	(48,982)
Net loss	$ (21,188)	$ (37,327)	$ (159,809)	$ (102,408)
Net loss per share, basic and diluted	$ (0.56)	$ (5.70)	$ (5.89)	$ (18.22)
Weighted-average shares of common stock outstanding, basic and diluted	37,553,735	6,546,410	27,147,314	5,619,182

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

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 279,401	$ 124,566
Total assets	317,211	127,159
Total liabilities	49,982	227,916
Total stockholders' equity (deficit)	267,229	(100,757)
Total liabilities and stockholders' equity (deficit)	317,211	127,159