

**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): November 10, 2022

HilleVax, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-41365
(Commission
File Number)

85-0545060
(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 2.02 Results of Operations and Financial Condition.

On November 10, 2022, HilleVax, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 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 Statement and Exhibits**(d) Exhibits**

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99.1	Press Release issued on November 10, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 10, 2022

By: /s/ Paul S. Bavier

Name: Paul S. Bavier

Title: General Counsel and Chief Administrative Officer



HilleVax Reports Third Quarter 2022 Financial Results and Highlights Recent Company Progress

BOSTON, November 10, 2022 – HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the quarter ended September 30, 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.

“Following completion of the 200 subject run-in, we began enrollment of the remaining 2,800 subjects in our Phase 2b NEST-IN1 clinical trial during the third quarter and remain on-track for topline safety and efficacy data from the full clinical trial in the second half of 2023,” said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. “We look forward to announcing immunogenicity results from the first 200 subjects later this quarter and continued progress to topline safety and efficacy data in our NEST-IN1 clinical trial.”

Third Quarter 2022 and Recent Business Highlights

- In August 2022, HilleVax announced the positive recommendation by the data safety monitoring committee to continue enrollment of the remaining 2,800 subjects in the company’s Phase 2b NEST-IN1 clinical trial after the evaluation of safety data from the prespecified 200 subject run-in.
- In August 2022, HilleVax announced the acceleration of reporting of immunogenicity results from the first 200 subjects in NEST-IN1 to the fourth quarter of 2022 from the first half of 2023.
- In July 2022, HilleVax announced results from a 5-year Phase 2 follow-up clinical trial supporting the long-term immunogenicity of HIL-214.

Upcoming Expected Milestones

- Interim immunogenicity results from the first 200 subjects enrolled in NEST-IN1 in the fourth quarter of 2022.
- Topline safety and clinical efficacy data from NEST-IN1 in the second half of 2023.

Third Quarter 2022 Financial Results

As of September 30, 2022, the company had cash and cash equivalents totaling \$292.1 million.

Research and development expenses for the third quarter 2022 were \$13.3 million, compared to \$0.9 million for the third quarter 2021.

General and administrative expenses for the third quarter 2022 were \$4.6 million, compared to \$1.1 million for the third quarter 2021.

Other income for the third quarter 2022 was \$1.1 million, compared to \$22.2 million of other expense for the third quarter 2021. The other income in 2022 was primarily driven by interest income on the Company's cash and cash equivalents while 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 third quarter 2022 was \$16.8 million, compared to \$61.9 million for the third quarter 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 uninterrupted business operations due to the COVID-19 pandemic, including delaying or disrupting our clinical trials, manufacturing and supply chain; 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; 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 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 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 13,315	\$ 896	\$ 28,352	\$ 1,623
In-process research and development	—	37,666	2,500	37,666
General and administrative	4,577	1,113	11,162	3,064
Total operating expenses	<u>17,892</u>	<u>39,675</u>	<u>42,014</u>	<u>42,353</u>
Loss from operations	(17,892)	(39,675)	(42,014)	(42,353)
Total other income (expense)	1,087	(22,193)	(96,607)	(22,728)
Net loss	<u>\$ (16,805)</u>	<u>\$ (61,868)</u>	<u>\$ (138,621)</u>	<u>\$ (65,081)</u>
Net loss per share, basic and diluted	<u>\$ (0.45)</u>	<u>\$ (10.03)</u>	<u>\$ (5.86)</u>	<u>\$ (12.26)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>37,323,626</u>	<u>6,166,500</u>	<u>23,640,388</u>	<u>5,306,710</u>

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

	September 30, 2022	December 31, 2021
Cash and cash equivalents	\$ 292,060	\$ 124,566
Total assets	322,076	127,159
Total liabilities	34,883	227,916
Total stockholders' equity (deficit)	287,193	(100,757)
Total liabilities and stockholders' equity (deficit)	322,076	127,159