HilleVax Reports First Quarter 2023 Financial Results and Highlights Recent Company Progress

May 12, 2023

BOSTON, May 12, 2023 (GLOBE NEWSWIRE) -- 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, 2023, 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.

"HilleVax has continued to make excellent progress on our HIL-214 program, including the recent completion of enrollment of over 3,000 subjects in our NEST-IN1 clinical trial," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. "We look forward to continuing to execute on our HIL-214 program and announcing top line safety and clinical efficacy data in the first quarter of 2024 for our NEST-IN1 clinical trial."

Recent Business Highlights

- In Q2 2023, HilleVax announced completion of enrollment of the NEST-IN1 (Norovirus Efficacy and Safety Trial for INfants) Phase 2b clinical trial with over 3,000 subjects enrolled in six countries.
- In Q2 2023, HilleVax announced the appointment of Nanette Cocero, Ph.D., MBA, to its Board of Directors.
- In Q4 2022, HilleVax announced positive immunogenicity results for the NEST-IN1 run-in cohort.

Upcoming Expected Milestones

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

First Quarter 2023 Financial Results

As of March 31, 2023, the company had cash and cash equivalents totaling $260.5 million.

Research and development expenses for the first quarter 2023 were $23.2 million, compared to $6.2 million for the first quarter 2022. The increase was primarily due to increased efforts in the advancement of the HIL-214 program and the growth in the number of R&D employees and their related activities.

General and administrative expenses for the first quarter 2023 were $5.8 million, compared to $2.6 million for the first quarter 2022. The increase was primarily due to the growth in the number of G&A employees and other administrative expenses related to operating as a public company.

Other income for the first quarter 2023 was $2.1 million, compared to $56.6 million of other expense for the first quarter 2022. The other income in the first quarter of 2023 was primarily driven by interest income on the company's cash and cash equivalents while the other expense in the first quarter of 2022 was primarily driven by changes in the fair value of convertible promissory notes and warrant liabilities.

Net loss for the first quarter 2023 was $26.9 million, compared to $67.9 million for the first quarter 2022.

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 timing of data readouts from the NEST-IN1 clinical 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; 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 March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 23,164	$ 6,211
In-process research and development	—	2,500
General and administrative	5,795	2,603
Total operating expenses	28,959	11,314
Loss from operations	(28,959)	(11,314)
Total other income (expense)	2,070	(56,573)
Net loss	$ (26,889)	$ (67,887)
Net loss per share, basic and diluted	$ (0.71)	$ (10.06)
Weighted-average shares of common stock outstanding, basic and diluted	37,753,522	6,748,668

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

	March 31, 2023	**December 31, 2022**
Cash and cash equivalents	$ 260,542	$ 279,401
Total assets	300,961	317,211
Total liabilities	57,900	49,982
Total stockholders' equity	243,061	267,229
Total liabilities and stockholders' equity	300,961	317,211