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

June 8, 2022

Initiated Phase 2b Clinical Trial of HIL-214 Vaccine Candidate for the Prevention of Norovirus-Related Acute Gastroenteritis in Infants (NOR-212)

Completed Upsized Initial Public Offering Raising $230 Million in Gross Proceeds

BOSTON, June 08, 2022 (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, 2022, highlighted recent program progress, and outlined key upcoming milestones for HIL-214, the company's virus-like particle (VLP) based vaccine candidate for the prevention of moderate-to-severe norovirus-related acute gastroenteritis.

"HilleVax achieved significant milestones this year, including the initiation of NOR-212, a Phase 2b clinical trial of HIL-214 in infants, as well as completion of enrollment of the 200 subject safety run-in for the trial. We look forward to resuming enrollment following the prespecified data monitoring committee safety assessment expected in the third quarter," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. "Through the completion of our recent initial public offering (IPO), we also secured the capital needed to fund the Phase 2b clinical trial and prepare HIL-214 for Phase 3."

First Quarter 2022 and Recent Business Highlights

Financial and Corporate

- In May 2022, HilleVax dosed the first subjects in NOR-212, the first ever field efficacy clinical trial of a norovirus vaccine candidate in infants.
- In May 2022, HilleVax completed enrollment of the prespecified 200 subject run-in for NOR-212.
- In May 2022, HilleVax completed its IPO, raising $230 million in aggregate gross proceeds, before deducting underwriting discounts and commissions and offering expenses, and began trading on The Nasdaq Global Select Market.
- In April 2022, HilleVax entered into a Loan and Security Agreement (Loan Agreement) with Hercules Capital, Inc. providing for term loans of up to $75 million in the aggregate, of which $5 million has been borrowed.

Upcoming Expected Milestones

- Phase 2b interim safety results from first 200 subjects in the third quarter of 2022
- Phase 2b interim immunogenicity results from first 200 subjects in the first half of 2023
- Phase 2b topline safety and clinical efficacy results in the second half of 2023

First Quarter 2022 Financial Results

As of March 31, 2022, the company had cash and cash equivalents totaling $111.3 million, which does not include gross proceeds of $230.0 million from the IPO or the $5.0 million drawn under the Loan Agreement.

Research and development expenses for the first quarter 2022 were $6.2 million, compared to $0.3 million for the first quarter 2021.

General and administrative expenses for the first quarter 2022 were $2.6 million, compared to $1.2 million for the first quarter 2021.

Other expenses for the first quarter 2022 were $56.6 million, compared to $0.1 million for the first quarter 2021. The increase in other expense was driven by changes in the fair value of convertible promissory notes and warrant liabilities.

Net loss for the first quarter 2022 was $67.9 million, compared to $1.5 million for the first 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. 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 NOR-212 trial; and projected cash runway and expectations regarding the sufficiency of existing capital to support our operating

plan. 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, including delaying or disrupting our clinical trials, manufacturing and supply chain; regulatory developments in the United States and foreign countries; 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 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.

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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,	
	2022	**2021**
Operating expenses:		
Research and development	$ 6,211	$ 267
In-process research and development	2,500	—
General and administrative	2,603	1,198
Total operating expenses	11,314	1,465
Loss from operations	(11,314)	(1,465)
Total other income (expense)	(56,573)	(81)
Net loss	$ (67,887)	$ (1,546)
Net loss per share, basic and diluted	$ (10.06)	$ (0.32)
Weighted-average shares of common stock outstanding, basic and diluted	6,748,668	4,802,907

HilleVax, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands, except share and par value data)
(unaudited)

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 111,252	$ 124,566
Total assets	114,696	$ 127,159
Total liabilities	283,068	227,916
Total stockholders’ deficit	(168,372)	(100,757)
Total liabilities and stockholders’ deficit	114,696	127,159