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

August 10, 2022

BOSTON, Aug. 10, 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 June 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.

"We recently reported the completion of enrollment of the prespecified 200 subject run-in for NOR-212, our Phase 2b field efficacy study of HIL-214 in infants. We now look forward to resuming enrollment in NOR-212 following the prespecified data monitoring committee safety assessment expected later this quarter," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. "We are pleased that we remain on track with regards to achieving our key corporate milestones."

Second Quarter 2022 and Recent Business Highlights

Financial and Corporate

- In July 2022, HilleVax announced results from 5-year Phase 2 follow-up clinical trial supporting long-term immunogenicity of HIL-214.
- In May 2022, HilleVax commenced NOR-212 and completed enrollment of the prespecified 200 subject run-in.
- 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 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

- NOR-212 interim safety results from the first 200 subjects in the third quarter of 2022
- NOR-212 interim immunogenicity results from the first 200 subjects in the first half of 2023
- NOR-212 topline safety and clinical efficacy data in the second half of 2023

Second Quarter 2022 Financial Results

As of June 30, 2022, the company had cash and cash equivalents totaling $314.6 million.

Research and development expenses for the second quarter 2022 were $8.8 million, compared to $0.5 million for the second quarter 2021.

General and administrative expenses for the second quarter 2022 were $4.0 million, compared to $0.8 million for the second quarter 2021.

Other expenses for the second quarter 2022 were $41.1 million, compared to $0.5 million for the second quarter 2021. The increase in other expenses was primarily driven by changes in the fair value of convertible promissory notes and warrant liabilities.

Net loss for the second quarter 2022 was $53.9 million, compared to $1.7 million for the second 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 NOR-212 trial based on the prespecified safety assessment 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, including if the prespecified safety assessment by the clinical trial's data monitoring committee is unfavorable; 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; 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 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 8,826	$ 460	$ 15,037	$ 727
In-process research and development	—	—	2,500	—
General and administrative	3,982	753	6,585	1,951
Total operating expenses	12,808	1,213	24,122	2,678
Loss from operations	(12,808)	(1,213)	(24,122)	(2,678)
Total other income (expense)	(41,121)	(454)	(97,694)	(535)
Net loss	$ (53,929)	$ (1,667)	$ (121,816)	$ (3,213)
Net loss per share, basic and diluted	$ (2.03)	$ (0.34)	$ (7.30)	$ (0.66)
Weighted-average shares of common stock outstanding, basic and diluted	26,512,881	4,935,738	16,685,372	4,869,690

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

	June 30, 2022	**December 31, 2021**
Cash and cash equivalents	$ 314,612	$ 124,566
Total assets	341,232	127,159
Total liabilities	38,078	227,916
Total stockholders’ equity (deficit)	303,154	(100,757)
Total liabilities and stockholders’ equity (deficit)	341,232	127,159