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

August 14, 2023

BOSTON, Aug. 14, 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 June 30, 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 in our HIL-214 program following completion of enrollment of our NEST-IN1 clinical trial in late April 2023. Due to issues relating solely to the logistical complexity of processing diarrheal samples from various geographies, we are adjusting our guidance to read out top line clinical data on all subjects in our NEST-IN1 clinical trial to mid-2024," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. "We remain committed to potentially bringing the first vaccine to market to address the global unmet need associated with norovirus infections."

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.

Upcoming Expected Milestones

- Topline safety and clinical efficacy data from NEST-IN1 in mid-2024.

Second Quarter 2023 Financial Results

As of June 30, 2023, the company had cash, cash equivalents and marketable securities totaling $244.1 million.

Research and development expenses for the second quarter 2023 were $23.0 million, compared to $8.8 million for the second quarter 2022. The increase was primarily due to increased activities for the development of HIL-214 and the growth in the number of R&D employees.

General and administrative expenses for the second quarter 2023 were $7.2 million, compared to $4.0 million for the second quarter 2022. The increase was primarily due to the growth in the number of G&A employees.

Other income for the second quarter 2023 was $2.3 million, compared to $41.1 million of other expense for the second quarter 2022. The other income in the second quarter of 2023 was primarily driven by interest income on the company's cash, cash equivalents and marketable securities, while the other expense in the second quarter of 2022 was primarily driven by changes in the fair value of convertible promissory notes and warrant liabilities.

Net loss for the second quarter 2023 was $27.9 million, compared to $53.9 million for the second 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 potential opportunity for and benefits of HIL-214 and the expected timing of a data readout 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, data readouts 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; and unstable market and economic conditions 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 22,953	$ 8,826	$ 46,117	$ 15,037
In-process research and development	—	—	—	2,500
General and administrative	7,231	3,982	13,026	6,585
Total operating expenses	30,184	12,808	59,143	24,122
Loss from operations	(30,184)	(12,808)	(59,143)	(24,122)
Total other income (expense)	2,282	(41,121)	4,352	(97,694)
Net loss	$ (27,902)	$ (53,929)	$ (54,791)	$ (121,816)
Net loss per share, basic and diluted	$ (0.74)	$ (2.03)	$ (1.45)	$ (7.30)
Weighted-average shares of common stock outstanding, basic and diluted	37,951,735	26,512,881	37,853,176	16,685,372

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 244,050	$ 279,401
Total assets	286,522	317,211
Total liabilities	67,759	49,982
Total stockholders' equity	218,763	267,229
Total liabilities and stockholders' equity	286,522	317,211