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

November 10, 2022

BOSTON, Nov. 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 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 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; 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 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	17,892	39,675	42,014	42,353
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	$ (16,805)	$ (61,868)	$ (138,621)	$ (65,081)
Net loss per share, basic and diluted	$ (0.45)	$ (10.03)	$ (5.86)	$ (12.26)
Weighted-average shares of common stock outstanding, basic and diluted	37,323,626	6,166,500	23,640,388	5,306,710

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