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

November 9, 2023

BOSTON, Nov. 09, 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 September 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 is advancing our HIL-214 clinical development program to potentially bring the first norovirus vaccine to market," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. "We have continued to progress the NEST-IN1 clinical trial and remain on track to report topline data by mid-2024."

Recent Business Highlights

- In Q3 2023, HilleVax announced the closing of an underwritten public offering of 9,200,000 shares of its common stock at a price of $12.50 per share for gross proceeds of $115.0 million.
- In Q3 2023, HilleVax initiated three clinical trials supporting the advancement of HIL-214, including NOR-109, a Phase 1 clinical trial of HIL-214 in Japanese infants, NOR-206, a Phase 2 clinical trial co-administering HIL-214 with other standard infant vaccinations, and NOR-215, a Phase 2 serology study of HIL-214 in adults. As of October 2023, HilleVax has completed enrollment of subjects in all three clinical trials.
- 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.

Upcoming Expected Milestones

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

Third Quarter 2023 Financial Results

As of September 30, 2023 and December 31, 2022, the company had cash, cash equivalents and marketable securities totaling $324.4 million and $279.4 million, respectively. The increase was due to $107.4 million of net proceeds received from the issuance of common stock in an underwritten public offering.

Research and development expenses for the third quarter 2023 were $27.3 million, compared to $13.3 million for the third 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 third quarter 2023 were $6.6 million, compared to $4.6 million for the third quarter 2022. The increase was primarily due to the growth in the number of G&A employees.

Other income for the third quarter 2023 was $2.1 million, compared to $1.1 million for the third quarter 2022. The increase in other income in the third quarter of 2023 compared to the third quarter of 2022 was primarily driven by higher interest rates increasing interest income on the company's cash, cash equivalents and marketable securities.

Net loss for the third quarter 2023 was $31.8 million, compared to $16.8 million for the third 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 September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 27,308	$ 13,315	$ 73,425	$ 28,352
In-process research and development	—	—	—	2,500
General and administrative	6,603	4,577	19,629	11,162
Total operating expenses	33,911	17,892	93,054	42,014
Loss from operations	(33,911)	(17,892)	(93,054)	(42,014)
Total other income (expense)	2,096	1,087	6,448	(96,607)
Net loss	$ (31,815)	$ (16,805)	$ (86,606)	$ (138,621)
Net loss per share, basic and diluted	$ (0.81)	$ (0.45)	$ (2.26)	$ (5.86)
Weighted-average shares of common stock outstanding, basic and diluted	39,039,553	37,323,626	38,252,981	23,640,388

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

	September 30, 2023	**December 31, 2022**
Cash, cash equivalents and marketable securities	$ 324,410	$ 279,401
Total assets	366,969	317,211
Total liabilities	68,339	49,982
Total stockholders’ equity	298,630	267,229
Total liabilities and stockholders’ equity	366,969	317,211