HilleVax Reports Full Year 2023 Financial Results and Highlights Recent Company Progress

March 20, 2024

Topline data from NEST-IN1 Phase 2B clinical study of HIL-214 in infants expected in mid-2024

Enrollment for NEST-IN1 study completed in Q2 2023

$303.5 million of cash, cash equivalents and marketable securities as of December 31, 2023

BOSTON, March 20, 2024 (GLOBE NEWSWIRE) -- HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the year ended December 31, 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.

"Over the past year, we made significant progress with HIL-214, our vaccine candidate for the prevention of moderate-to-severe norovirus related acute gastroenteritis. We have continued to progress the NEST-IN1 clinical trial and remain on track to report topline data by mid-2024," said Rob Hershberg, MD, PhD, Chairman and Chief Executive Officer of HilleVax. "We have also made good progress on our manufacturing activities for HIL-214 in support of continued development in subsequent registrational trials for infants and older adults."

Recent Business Highlights

- In Q1 2024, HilleVax announced the appointment of Sean McLoughlin as Chief Operating Officer.
- 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.

Full Year 2023 Financial Results

As of December 31, 2023 and December 31, 2022, the company had cash, cash equivalents and marketable securities totaling $303.5 million and $279.4 million, respectively. The increase was due to $107.8 million of net proceeds received from the issuance of common stock in an underwritten public offering.

Research and development expenses for the fourth quarter 2023 were $33.3 million and $106.7 million for the full year ended December 31, 2023, compared to $17.6 million for the fourth quarter 2022 and $45.9 million for the full year ended December 31, 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 fourth quarter 2023 were $7.0 million and $26.7 million for the full year ended December 31, 2023, compared to $5.5 million for the fourth quarter 2022 and $16.7 million for the full year ended December 31, 2022. The increase was primarily due to the growth in the number of G&A employees.

Other income for the fourth quarter 2023 was $3.3 million, compared to $1.9 million for the fourth quarter 2022. The increase in other income in the fourth quarter of 2023 compared to the fourth quarter of 2022 was primarily driven by higher interest rates increasing interest income on our cash, cash equivalents and marketable securities.

Other income for the full year ended December 31, 2023 was $9.8 million, compared to $94.7 million of other expense for the full year ended December 31, 2022. The other income in 2023 was primarily driven by interest income on our cash, cash equivalents and marketable securities. Other expense in 2022 was primarily driven by changes in the fair value of convertible promissory notes and warrant liabilities and interest expense on our convertible promissory notes, offset by interest income on the company's cash and cash equivalents.

Net loss for the fourth quarter 2023 was $37.0 million and $123.6 million for the full year ended December 31, 2023, compared to $21.2 million for the fourth quarter 2022 and $159.8 million for the full year ended December 31, 2022.

About HilleVax

HilleVax is a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines. Its most advanced 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 direct and indirect healthcare system and societal costs of $10 billion in the United States and $60 billion globally. 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, the advancement of HIL-214 to registration as the first norovirus vaccine, and longer-term market leadership plans. 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 military conflicts or other geopolitical developments outside our control; our reliance on intellectual property rights under our license agreements with Takeda Vaccines, Inc. and Kanghua Biological Products Co., Ltd.; 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 December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 33,258	$ 17,556	$ 106,683	$ 45,908
In-process research and development	—	—	—	2,500
General and administrative	7,033	5,543	26,662	16,705
Total operating expenses	40,291	23,099	133,345	65,113
Loss from operations	(40,291)	(23,099)	(133,345)	(65,113)
Total other income (expense)	3,331	1,911	9,779	(94,696)
Net loss	$ (36,960)	$ (21,188)	$ (123,566)	$ (159,809)
Net loss per share, basic and diluted	$ (0.78)	$ (0.56)	$ (3.04)	$ (5.89)
Weighted-average shares of common stock outstanding, basic and diluted	47,557,423	37,553,735	40,598,482	27,147,314

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 303,483	$ 279,401
Total assets	344,434	317,211
Total liabilities	78,909	49,982

Total stockholders’ equity	265,525	267,229
Total liabilities and stockholders’ equity	344,434	317,211