HilleVax Reports Second Quarter 2024 Financial Results and Highlights Recent Company Progress

August 8, 2024

$245.0 million of cash, cash equivalents and marketable securities as of June 30, 2024

The company is exploring the potential for continued development of its HIL-214 and HIL-216 norovirus vaccine candidates in adults

BOSTON, Aug. 08, 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 quarter ended June 30, 2024 and highlighted recent progress.

Recent Business Highlights

- In Q3 2024, HilleVax announced that the NEST-IN1 clinical study did not meet its primary or secondary efficacy endpoints and that the company would discontinue further development of HIL-214 in infants.
- In Q3 2024, HilleVax announced a workforce reduction of approximately 40% of its workforce to reduce operating expenses while maintaining core capabilities as the company explores the potential for continued development of its HIL-214 and HIL-216 norovirus candidates as well as business development-related activities for these vaccine candidates.

Second Quarter 2024 Financial Results

As of June 30, 2024 and December 31, 2023, the company had cash, cash equivalents and marketable securities totaling $245.0 million and $303.5 million, respectively.

Research and development expenses for the second quarter 2024 were $26.6 million, compared to $23.0 for the second quarter 2023. The increase was primarily due to the growth in the number of R&D employees.

General and administrative expenses for the second quarter 2024 were $8.1 million, compared to $7.2 million for the second quarter 2023. The increase was primarily due to the growth in the number of G&A employees.

Other income for the second quarter 2024 and second quarter 2023 was $2.3 million.

Net loss for the second quarter 2024 was $40.7 million, compared to $27.9 million for the second quarter 2023.

About HilleVax

HilleVax is a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines. Its initial programs, HIL-214 and HIL-216, are virus-like particle (VLP) based vaccine candidates 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

The company 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 the company's current beliefs and expectations and include, but are not limited to, the company's plans to explore continued development efforts on, and advance the development of, HIL-214 and HIL-216 in adults and the potential opportunity for and benefits of HIL-214 and HIL-216, and intended objectives and benefits of the workforce reduction. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the company's business, including, without limitation: to-date the company has depended primarily on the success of HIL-214, and the company may be unable to identify a viable development path forward for HIL-214 or HIL-216; if the company does identify a development path forward for its vaccine candidates, the company may require additional capital and other resources, including business development partnerships or other strategic collaborations, and the company may be unable to secure partnerships, other strategic collaborations or other resources on acceptable terms or at all; topline results are based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the NEST-IN1 study and such topline data may not accurately reflect the complete results of a clinical trial; to the extent the company pursues future studies, the company may experience potential delays in the commencement, enrollment, data readouts and completion of clinical trials and preclinical studies; the company depends 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, HIL-216 or any future vaccine candidates that may limit their development, regulatory approval, commercialization and/or business development potential; further unfavorable results from clinical trials; results from prior clinical trials and studies are not necessarily predictive of future results; the company relies on intellectual property rights under its license agreements with Takeda Vaccines, Inc. and Kanghua Biological Products Co., Ltd.; the company may be unable to obtain, maintain and enforce intellectual property protection for its vaccine candidates; the company may use its capital resources sooner than it expects; and other risks described in the company's prior press releases and the company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the company's 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 the company undertakes 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,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 26,601	$ 22,953	$ 52,579	$ 46,117
In-process research and development	—	—	15,325	—
General and administrative	8,127	7,231	16,621	13,026
Impairment charges	8,235	—	8,235	—
Total operating expenses	42,963	30,184	92,760	59,143
Loss from operations	(42,963)	(30,184)	(92,760)	(59,143)
Total other income	2,295	2,282	5,263	4,352
Net loss	$ (40,668)	$ (27,902)	$ (87,497)	$ (54,791)
Net loss per share, basic and diluted	$ (0.83)	$ (0.74)	$ (1.79)	$ (1.45)
Weighted-average shares of common stock outstanding, basic and diluted	49,179,109	37,951,735	48,819,729	37,853,176

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

	June 30, 2024	**December 31, 2023**
Cash, cash equivalents and marketable securities	$ 245,040	$ 303,483
Total assets	276,931	344,434
Total liabilities	72,001	78,909
Total stockholders' equity	204,930	265,525
Total liabilities and stockholders' equity	276,931	344,434