Altimmune Announces Fourth Quarter and Full Year 2024 Financial Results and Provides a Business Update

February 27, 2025 at 7:00 AM EST

Top-line data from Phase 2b IMPACT trial of pemvidutide in metabolic dysfunction-associated steatohepatitis (MASH) to be reported in Q2 2025

Investigational New Drug (IND) applications in two additional indications have received FDA clearance, with Phase 2 trials to commence mid-2025

Company to hold virtual R&D Day on March 13, 2025. Program will include KOL presentations on pemvidutide development in obesity, MASH and additional indications

Two pharmaceutical industry veterans added to Company Board of Directors

Cash, cash equivalents and short-term investments of $131.9 million on December 31, 2024

Webcast to be held today, February 27, 2025, at 8:30 a.m. ET

GAITHERSBURG, Md., Feb. 27, 2025 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the fourth quarter and full year ended December 31, 2024, and provided a business update.

"2024 was a year of important progress for Altimmune as we continued to advance pemvidutide in multiple indications," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "As announced previously, we completed enrollment of the IMPACT Phase 2b trial of pemvidutide in MASH and are on track to report top-line data in the second quarter of 2025. IMPACT was one of the fastest enrolling biopsy-driven Phase 2b MASH trials, which we believe reflects the attractiveness of pemvidutide to patients and providers, specifically the compound's potent reduction of both liver fat and body weight. Based on the totality of the data generated to date, including multiple non-invasive biomarkers of liver inflammation and fibrosis, we are confident that pemvidutide will achieve statistically significant improvements in biopsy endpoints, both MASH resolution and fibrosis improvement, at trial readout. We anticipate holding an end-of-Phase 2 meeting with FDA by the end of 2025 to gain alignment on the registrational Phase 3 program."

Dr. Garg continued, "In-line with our previously stated plan, we submitted INDs for two additional indications in Q4 2024, and I am excited to report that both have received FDA clearance, and we are on track to initiate Phase 2 efficacy studies mid-2025. We look forward to providing information on these additional indications and our development plans during the upcoming virtual R&D Day on March 13. We believe that these indications reinforce our vision for the broad therapeutic utility of pemvidutide."

Recent Highlights and Anticipated Milestones

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

- *IMPACT, the Company's biopsy-driven Phase 2b trial of pemvidutide in MASH, is on track for top-line data readout in Q2 2025*
  - IMPACT is evaluating the efficacy and safety of pemvidutide in approximately 190 subjects with biopsy-confirmed MASH.
  - With a successful readout from IMPACT, pemvidutide would be the first incretin to achieve statistical significance on MASH resolution and fibrosis improvement at only 24 weeks of treatment, and the first therapy in any class to achieve these endpoints along with meaningful weight loss at this timepoint.

Additional Indications for Pemvidutide

- *The Company submitted IND applications for pemvidutide in two additional indications at the end of 2024, both of which have been cleared by FDA*
  - Phase 2 trials in additional indications are expected to initiate in mid-2025.

R&D Day March 13, 2025

- *Altimmune will hold a virtual R&D Day on Thursday, March 13, 2025 at 12:00pm Eastern Time*
  - The program will feature presentations on pemvidutide development from Company management and key opinion leaders in obesity, MASH and the two additional indications which will be disclosed during the event.
  - Details of the R&D Day, including registration information, are available at https://investorday.altimmune.com. Additional information related to the event will be posted to this site.

Corporate Update

- *The Company strengthened its Board of Directors with the appointments of pharmaceutical industry veterans Teri Lawver and Jerry Durso*
  - Ms. Lawver has nearly 30 years of experience spanning pharmaceuticals, medical devices and consumer health

technology. She most recently served as Executive Vice President and Chief Commercial Officer of Dexcom. Previously she served for over 20 years at Johnson & Johnson in various leadership roles, including as Global Vice President for the Cardiovascular & Metabolism therapeutic area and Worldwide Vice President for the Immunology business at Janssen Pharmaceuticals.

- Mr. Durso brings more than 30 years of leadership experience in the life sciences industry, most recently serving as Chief Executive Officer at Intercept Pharmaceuticals where he built a successful rare liver disease franchise and ultimately led the Company through its acquisition by Alfasigma. Prior to Intercept, he spent over two decades in a variety of leadership roles at Sanofi, including Chief Commercial Officer for its U.S. Pharmaceuticals business.

Financial Results for the Three Months Ended December 31, 2024

- Altimmune reported cash, cash equivalents and short-term investments totaling $131.9 million on December 31, 2024.
- Research and development expenses were $19.8 million for the three months ended December 31, 2024, compared to $16.9 million in the same period in 2023. The expenses for the quarter ended December 31, 2024, included $13.6 million in direct costs related to development activities for pemvidutide.
- General and administrative expenses were $5.1 million for the three months ended December 31, 2024, compared to $4.3 million in the same period in 2023. The increase was primarily due to a $0.5 million increase in stock compensation.
- Interest income was $1.6 million for the three months ended December 31, 2024, compared to $2.0 million for the same period in 2023.
- Net loss for the three months ended December 31, 2024, was $23.2 million, or $0.33 net loss per share, compared to a net loss of $31.6 million, or $0.54 net loss per share, in the same period in 2023. The net loss for 2023 included the $12.4 million noncash impairment charge related to the discontinuation of development of HepTcell.

Financial Results for the Year Ended December 31, 2024

- Research and development expenses were $82.2 million for the year ended December 31, 2024, compared to $65.8 million in the same period in 2023. The expenses for the year ended December 31, 2024, included $53.3 million in direct costs related to development activities for pemvidutide and $1.3 million in initial costs for additional research and discovery projects.
- General and administrative expenses were $21.0 million for the year ended December 31, 2024, compared to $18.1 million in the same period in 2023. The increase was primarily due to a $2.7 million increase in stock compensation and other labor-related expenses, including the $1.0 million increase in stock compensation expense caused by modifications of stock awards.
- Interest income was $8.1 million for the year ended December 31, 2024, compared to $7.4 million for the same period in 2023.
- Net loss for the year ended December 31, 2024, was $95.1 million, or $1.34 net loss per share, compared to a net loss of $88.4 million, or $1.66 net loss per share, in the same period in 2023. The net loss for 2023 included the $12.4 million noncash impairment charge related to the discontinuation of development of HepTcell.

Conference Call Information:

Date:	February 27, 2025
Time:	8:30 a.m. Eastern Time
Webcast:	To listen, the conference call will be webcast live on Altimmune's Investor Relations website at https://ir.altimmune.com/investors.
Dial-in:	To participate or dial-in, register here to receive the dial-in numbers and unique PIN to access the call.

Following the conclusion of the call, the webcast will be available for replay on the Investor Relations (IR) page of the Company's website at www.altimmune.com. The Company has used, and intends to continue to use, the IR portion of its website as a means of disclosing material non-public information and for complying with disclosure obligations under Regulation FD.

About Pemvidutide

Pemvidutide is a novel, investigational, peptide-based GLP-1/glucagon dual receptor agonist in development for the treatment of obesity and MASH. Activation of the GLP-1 and glucagon receptors is believed to mimic the complementary effects of diet and exercise on weight loss, with GLP-1 suppressing appetite and glucagon increasing energy expenditure. Glucagon is also recognized as having direct effects on hepatic fat metabolism, which is believed to lead to rapid reductions in levels of liver fat and serum lipids. In clinical trials to date, once-weekly pemvidutide has demonstrated compelling weight loss with class-leading lean mass preservation, and robust reductions in triglycerides, LDL cholesterol, liver fat content and blood pressure. The U.S. FDA has granted Fast Track designation to pemvidutide for the treatment of MASH. Pemvidutide recently completed the MOMENTUM Phase 2 obesity trial and is being studied in the ongoing IMPACT Phase 2b MASH trial.

About Altimmune

Altimmune is a clinical-stage biopharmaceutical company focused on developing innovative next-generation peptide-based therapeutics. The Company is developing pemvidutide, a GLP-1/glucagon dual receptor agonist for the treatment of obesity, MASH and other indications. For more information, please visit www.altimmune.com.

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Forward-Looking Statement

Any statements made in this press release related to the development or commercialization of product candidates and other business matters, including without limitation, trial results and data, the timing of key milestones for our clinical assets, and the prospects for the utility of, regulatory approval, commercializing or selling any product or drug candidates, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Altimmune, Inc. may identify forward-looking statements. The Company cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time. Important factors that may cause actual results to differ materially from the results discussed in the forward looking statements or historical experience include risks and uncertainties, including risks relating to: delays in regulatory review, manufacturing and supply chain interruptions, access to clinical sites, enrollment, adverse effects on healthcare systems and disruption of the global economy; the reliability of the results of studies relating to human safety and possible adverse effects resulting from the administration of the Company's product candidates; the Company's ability to manufacture clinical trial materials on the timelines anticipated; and the success of future product advancements, including the success of future clinical trials. Further information on the factors and risks that could affect the Company's business, financial conditions and results of operations are contained in the Company's filings with the U.S. Securities and Exchange Commission, including under the heading "Risk Factors" in the Company's most recent annual report on Form 10-K and our other filings with the SEC, which are available at www.sec.gov.

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ALTIMMUNE, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per-share amounts)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,926	$ 135,117
Restricted cash	42	41
Total cash, cash equivalents and restricted cash	36,968	135,158
Short-term investments	94,965	62,698
Accounts and other receivables	544	1,111
Income tax and R&D incentive receivables	2,573	3,742
Prepaid expenses and other current assets	2,204	6,917
Total current assets	137,254	209,626
Property and equipment, net	413	651
Other assets	1,639	363
Total assets	$ 139,306	$ 210,640
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 211	$ 2,070
Accrued expenses and other current liabilities	10,257	10,073
Total current liabilities	10,468	12,143
Other noncurrent liabilities	5,330	4,398
Total liabilities	15,798	16,541
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 72,352,701 and 70,677,400 shares issued and outstanding as of December 31, 2024 and 2023, respectively	7	7

Additional paid-in capital	689,864	665,427
Accumulated deficit	(561,390)	(466,331)
Accumulated other comprehensive loss, net	(4,973)	(5,004)
Total stockholders' equity	123,508	194,099
Total liabilities and stockholders' equity	$ 139,306	$ 210,640

ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per-share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Revenues	$ 5	$ 37	$ 20	$ 426
Operating expenses:				
Research and development	19,781	16,909	82,226	65,799
General and administrative	5,090	4,332	20,966	18,137
Impairment loss on intangible asset	—	12,419	—	12,419
Total operating expenses	24,871	33,660	103,192	96,355
Loss from operations	(24,866)	(33,623)	(103,172)	(95,929)
Other income (expense):				
Interest expense	(1)	(2)	(9)	(35)
Interest income	1,569	1,964	8,074	7,351
Other income (expense), net	118	20	48	166
Total other income (expense), net	1,686	1,982	8,113	7,482
Net loss	(23,180)	(31,641)	(95,059)	(88,447)
Other comprehensive income Ñ unrealized gain on short-term investments	(128)	120	31	223
Comprehensive loss	$ (23,308)	$ (31,521)	$ (95,028)	$ (88,224)
Net loss per share, basic and diluted	$ (0.33)	$ (0.54)	$ (1.34)	$ (1.66)
Weighted-average common shares outstanding, basic and diluted	71,260,875	58,442,779	71,003,399	53,246,937

This press release was published by a CLEAR® Verified individual.



Source: Altimmune, Inc