



Altimune Announces Third Quarter 2024 Financial Results and Provides a Business Update

November 12, 2024 at 7:00 AM EST

Enrollment completed in Phase 2b IMPACT trial of pemvidutide in metabolic dysfunction-associated steatohepatitis (MASH); top-line efficacy data expected in Q2 2025

Successful completion of the obesity End-of-Phase 2 meeting with the FDA

Company plans to submit Investigational New Drug (IND) applications for pemvidutide in up to three additional indications beginning Q4 2024

Cash, cash equivalents and short-term investments of \$139.4 million on September 30, 2024

Webcast to be held today, November 12, 2024, at 8:30 a.m. ET

GAITHERSBURG, Md., Nov. 12, 2024 (GLOBE NEWSWIRE) -- [Altimune, Inc.](#) (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the third quarter ended September 30, 2024, and provided a business update.

"In the third quarter, we reached several important milestones, most notably the completion of enrollment in the Phase 2b IMPACT trial of pemvidutide in MASH, positioning us to report top-line efficacy data in the second quarter of 2025," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimune. "Further, we successfully completed our End-of-Phase 2 meeting with the FDA for the pemvidutide Phase 3 obesity program, gaining agreement on the design of the pivotal studies as well as the measures of efficacy and safety."

Dr. Garg continued, "The Phase 3 program is designed to leverage the key attributes of pemvidutide, including the effects of balanced GLP-1/glucagon dual agonism in subjects with overweight and obesity. The program will include four pivotal trials with a primary efficacy endpoint of weight loss and will evaluate the effects of pemvidutide on principal co-morbidities of obesity, including elevated serum lipids and excess liver fat. The program will also assess the preservation of lean mass and its impact on subjects at risk for loss of physical function and other complications of sarcopenia."

"At the 60th Annual Meeting of the European Association for the Study of Diabetes, we presented compelling data from our Phase 2 MOMENTUM trial of pemvidutide in obesity, which highlighted its class-leading preservation of lean mass and preferential reduction in visceral adipose tissue, both of which are important differentiators for pemvidutide," said Scott Harris, M.D., Chief Medical Officer of Altimune. "We also remain on-track to submit an IND application this quarter for the first of up to three additional indications for pemvidutide, with the trial expected to initiate in the first half of 2025."

Dr. Garg concluded, "The data we have generated to date, coupled with the multiple key inflection points on the horizon, give us confidence that 2025 will be a transformational year for pemvidutide, and for Altimune."

Recent Highlights and Anticipated Milestones:

Metabolic Dysfunction-Associated Steatohepatitis (MASH):

- *The Company completed patient enrollment in IMPACT, a biopsy-driven Phase 2b trial of pemvidutide in MASH*
 - The IMPACT trial 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 MASH therapy to achieve both fibrosis improvement and significant weight loss at 24 weeks of treatment.
 - Top-line efficacy data is expected in Q2 2025.

Obesity:

- *Completed End-of-Phase 2 Meeting for the obesity program with the FDA*
 - Agreement was reached on the plan for four Phase 3 clinical trials that leverage the key attributes of pemvidutide including balanced GLP-1/glucagon dual agonism.
 - Each of the four studies is designed to assess the ability of pemvidutide treatment to drive meaningful weight loss and address co-morbidities in specific subpopulations of patients with overweight or obesity.
 - Data from these studies are expected to form the basis for a registrational package to support FDA approval of pemvidutide in obesity.
- *The Company presented data from a body composition sub-study from the Phase 2 MOMENTUM trial at the 60th Annual Meeting of the European Association for the Study of Diabetes (EASD)*
 - In an MRI evaluation of subjects with overweight and obesity treated with pemvidutide for 48 weeks, the lean loss ratio was 21.9%.
 - Lean mass preservation was greater in subjects aged 60 years and older, in whom the lean loss ratio was further reduced to 19.9%.
 - In addition to the preservation of lean mass, visceral adipose tissue (VAT) was reduced by 28.3% in the 2.4mg cohort at Week 48. Reduction of VAT is important as VAT is closely associated with cardiovascular risk.

Additional Indications for Pemvidutide:

- *The Company plans to submit IND applications for pemvidutide in up to three additional indications*
 - The first of these IND applications will be submitted in Q4 2024, with remaining IND applications expected to be submitted in the first half of 2025.
 - Preparations for the first trial are underway, with initiation planned for H1 2025.

Corporate Update:

- *On November 11, 2024, the Company announced the appointment of life sciences industry veteran Greg Weaver as Chief Financial Officer*

Financial Results for the Three Months Ended September 30, 2024:

- Altimmune had cash, cash equivalents and short-term investments totaling \$139.4 million on September 30, 2024.
- Research and development expenses were \$19.8 million for the three months ended September 30, 2024, compared to \$18.4 million in the same period in 2023. The expenses for the quarter ended September 30, 2024, included \$12.4 million in direct costs related to development activities for pemvidutide and \$0.8 million in direct costs related to additional research and discovery projects.
- General and administrative expenses were \$5.0 million for the three months ended September 30, 2024, compared to \$4.5 million in the same period in 2023. The increase was primarily due to a \$0.4 million increase in professional fees.
- Interest income was consistent period-over-period at \$1.9 million for each of the three months ended September 30, 2024 and 2023.
- Net loss for the three months ended September 30, 2024, was \$22.8 million, or \$0.32 net loss per share, compared to a net loss of \$20.7 million, or \$0.39 net loss per share, in the same period in 2023.

Conference Call Information:

Date: November 12, 2024
 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 and MASH. For more information, please visit www.altimmune.com.

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Forward-Looking Statement

Any statements made in this press release relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters, including without limitation, the timing of the IMPACT trial data readout, the timing of the planned End-of-Phase 2 FDA meeting, the timing of the planned IND submissions for pemvidutide, the timing of key milestones for any of 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)

	September 30, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 31,474	\$ 135,117
Restricted cash	42	41
Total cash, cash equivalents and restricted cash	31,516	135,158
Short-term investments	107,906	62,698
Accounts and other receivables	428	1,111
Income tax and R&D incentive receivables	2,912	3,742
Prepaid expenses and other current assets	2,997	6,917
Total current assets	145,759	209,626
Property and equipment, net	446	651
Other assets	1,659	363
Total assets	\$ 147,864	\$ 210,640
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,133	\$ 2,070
Accrued expenses and other current liabilities	7,505	10,073
Total current liabilities	8,638	12,143
Other noncurrent liabilities	5,849	4,398
Total liabilities	14,487	16,541
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 71,124,407 and 70,677,400 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	7	7
Additional paid-in capital	676,425	665,427
Accumulated deficit	(538,210)	(466,331)
Accumulated other comprehensive loss, net	(4,845)	(5,004)
Total stockholders' equity	133,377	194,099
Total liabilities and stockholders' equity	\$ 147,864	\$ 210,640

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues	\$ 5	\$ 362	\$ 15	\$ 389
Operating expenses:				
Research and development	19,803	18,388	62,445	48,890
General and administrative	4,969	4,514	15,876	13,805
Total operating expenses	24,772	22,902	78,321	62,695
Loss from operations	(24,767)	(22,540)	(78,306)	(62,306)
Other income (expense):				
Interest expense	(6)	(29)	(8)	(33)
Interest income	1,910	1,884	6,505	5,387
Other income (expense), net	18	14	(70)	146
Total other income (expense), net	1,922	1,869	6,427	5,500
Net loss	(22,845)	(20,671)	(71,879)	(56,806)
Other comprehensive income — unrealized gain on short-term investments	347	56	159	103
Comprehensive loss	\$ (22,498)	\$ (20,615)	\$ (71,720)	\$ (56,703)
Net loss per share, basic and diluted	\$ (0.32)	\$ (0.39)	\$ (1.01)	\$ (1.10)
Weighted-average common shares outstanding, basic and diluted	71,084,787	53,633,354	70,927,222	51,495,957

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



Source: Altimune, Inc