Altimmune Announces Second Quarter 2025 Financial Results and Business Update

August 12, 2025 at 7:00 AM EDT

Positive data from the IMPACT Phase 2b trial reinforces the potential for pemvidutide to be a highly differentiated MASH therapy

Pemvidutide is the first product candidate to achieve statistically significant MASH resolution and weight loss at 24 weeks

New data from the IMPACT trial demonstrates potentially class-leading improvements in corrected T1 (cT1), an important marker of liver inflammation and fibrosis

End-of-Phase 2 Meeting with FDA expected in Q4 2025

Cash, cash equivalents and short-term investments of $183.1 million as of June 30, 2025

Webcast to be held today, August 12, 2025, at 8:30 a.m. ET

GAITHERSBURG, Md., Aug. 12, 2025 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a late clinical-stage biopharmaceutical company developing peptide-based therapeutics for liver and cardiometabolic diseases, today announced financial results for the second quarter ended June 30, 2025 and provided a business update.

"Pemvidutide demonstrated rapid and robust MASH effects, meaningful weight loss and impressive safety and tolerability in the recently reported results from the IMPACT Phase 2b trial," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "We are preparing for an End-of-Phase 2 Meeting with the FDA which will position us well for Phase 3 development. In addition, we look forward to reporting the full 48-week data in the fourth quarter and providing further updates as we continue to advance pemvidutide."

Dr. Scott Harris, Chief Medical Officer of Altimmune, commented, "The improvements in cT1 observed in the IMPACT trial were potentially class-leading among MASH clinical trials to-date. Reductions in cT1 are correlated with MASH resolution and fibrosis improvement. These new data along with the previously reported results from non-invasive tests of fibrosis, further strengthen the potential therapeutic value of pemvidutide."

Recent Highlights and Anticipated Milestones

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

- *Reported positive 24-week top-line data from the IMPACT Phase 2b trial*
  - Statistically significant MASH resolution without worsening of fibrosis was observed in up to 59.1% of patients receiving pemvidutide
  - Fibrosis improvement without worsening of MASH was observed in up to 34.5% of pemvidutide-treated patients
  - Statistically significant improvements were observed across multiple objective measures of fibrosis, including supplemental AI-based analyses and non-invasive tests (NITs) of liver fibrosis, Enhanced Liver Fibrosis (ELF) score and Vibration-Controlled Transient Elastography (VCTE)
  - Statistically significant weight loss of up to 6.2% at 24 weeks with a trajectory of continuing weight loss
  - Potential for best-in-class tolerability without dose titration
    - Fewer adverse event-related discontinuations with pemvidutide vs placebo
    - Less than 1% treatment discontinuations due to adverse events in pemvidutide-treated patients
- *New data on corrected T1 (cT1) imaging demonstrates potentially class-leading improvements in pemvidutide-treated patients*
  - cT1 is a highly reproducible MRI-based imaging method that measures the magnitude of liver inflammation and fibrosis. Decreases in cT1 relaxation time of 80 milliseconds (ms) or greater have been correlated with improvements in liver inflammation and fibrosis in clinical studies.
  - In an analysis of imaging data from the IMPACT trial, mean decreases from baseline in cT1 relaxation time were 145.0 ms and 147.9 ms in the pemvidutide 1.2 mg and 1.8 mg groups, respectively, compared with a decrease of 27.5 ms in placebo ($p < 0.001$ for both)
- *The IMPACT trial is ongoing with data on weight loss, NITs and safety at 48 weeks of treatment expected in the fourth quarter of 2025*
- *End-of-Phase 2 Meeting with FDA targeted for fourth quarter of 2025*

Alcohol Use Disorder (AUD)

- *Announced in May 2025 the initiation of RECLAIM, a Phase 2 trial evaluating the safety and efficacy of pemvidutide in AUD*
  - RECLAIM is a randomized, placebo-controlled trial expected to enroll approximately 100 subjects, randomized 1:1, to receive either 2.4 mg pemvidutide or placebo weekly for 24 weeks
  - The primary endpoint of the trial is the change from baseline in the average number of heavy drinking days per

week at 24 weeks
  - Key secondary endpoints include the proportion of subjects achieving a 2-level reduction in World Health Organization (WHO) risk drinking level and absolute change from baseline in average levels of phosphatidylethanol (PEth) a serum biomarker of alcohol intake

Alcohol-Associated Liver Disease (ALD)

- *Announced in July 2025 the initiation of RESTORE, a Phase 2 trial evaluating the safety and efficacy of pemvidutide in ALD*
  - RESTORE is a randomized, placebo-controlled trial expected to enroll approximately 100 subjects, randomized 1:1 to receive either 2.4 mg pemvidutide or placebo weekly for 48 weeks
  - The primary endpoint of the trial is the change from baseline in liver stiffness measurement (LSM), as measured by VCTE, at week 24
  - Key secondary endpoints include the change from baseline in LSM at week 48, changes in ELF score at weeks 24 and 48, and changes in alcohol consumption and body weight at both 24 and 48 weeks

Corporate Update

- *Jerry Durso appointed by Altimmune Board of Directors to succeed Mitchel Sayare, Ph.D. as Chairman*
  - Appointment is part of the Board's ongoing succession planning. It recognizes Mr. Durso's extensive commercial and corporate development expertise and aligns with Altimmune's planned advancement into Phase 3 development of pemvidutide in MASH.
  - Dr. Sayare to continue to serve on the Board as an Independent Director

Financial Results for the Three Months Ended June 30, 2025

- Altimmune reported cash, cash equivalents and short-term investments totaling $183.1 million as of June 30, 2025, a 39% increase as compared to $131.9 million at December 31, 2024
- Research and development expenses were $17.2 million for the three months ended June 30, 2025, compared to $21.2 million in the same period in 2024, the decrease resulting from timing of clinical trial costs. The expenses for the quarter ended June 30, 2025, included $11.2 million in direct costs related to pemvidutide development activities
- General and administrative expenses were consistent period-over-period at $5.7 million and $5.6 million for the three months ended June 30, 2025 and 2024, respectively
- Interest income was $1.1 million for the three months ended June 30, 2025
- Net loss for the three months ended June 30, 2025, was $22.1 million, or $0.27 net loss per share, compared to a net loss of $24.6 million, or $0.35 net loss per share, in the same period in 2024

Conference Call Information:

Date:	August 12, 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 1:1 GLP-1/glucagon dual receptor agonist in development for the treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH), Alcohol Use Disorder (AUD), Alcohol-Associated Liver Disease (ALD) and obesity. 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 the ongoing IMPACT Phase 2b trial, at Week 24, once-weekly pemvidutide demonstrated statistically significant MASH resolution without worsening of fibrosis, positive trends in liver fibrosis stage improvement without worsening of MASH, statistically significant reductions in non-invasive tests of fibrosis, weight loss, and liver fat content, and improvements in blood pressure. In a post-hoc AI-based analysis of the biopsies from the IMPACT trial, pemvidutide achieved a statistically significant reduction in liver fibrosis. In earlier trials, pemvidutide also demonstrated class-leading lean mass preservation and robust reductions in triglycerides and LDL cholesterol. Pemvidutide was well tolerated in the IMPACT trial, demonstrating potentially best-in-class tolerability among drugs in development for MASH with very low rates of discontinuation due to adverse events. The U.S. FDA granted Fast Track designation to pemvidutide for the treatment of MASH. The ongoing IMPACT Phase 2b MASH trial 48-week readout is expected in Q4 2025. In addition, RECLAIM, a Phase 2 trial in AUD and RESTORE, a Phase 2 trial in ALD, were initiated in May 2025 and July 2025, respectively.

About Altimmune

Altimmune is a late clinical-stage biopharmaceutical company focused on developing novel peptide-based therapeutics for liver and cardiometabolic diseases. The Company's lead program is pemvidutide, a GLP-1/glucagon dual receptor agonist for the treatment of MASH, Alcohol Use Disorder (AUD), Alcohol-Associated Liver Disease (ALD) and obesity. 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 pemvidutide, an investigational product candidate, and other business and financial matters including without limitation, clinical trial study design, status, correspondence, results and data, including the ongoing RECLAIM, RESTORE and IMPACT Trials, the timing of key milestones for the Company's clinical assets, future plans or expectations for pemvidutide for the treatment of MASH, AUD, ALD and obesity, and the prospects for receiving regulatory approval or commercializing or selling any product or drug candidates, and the impact of the changes to our leadership and governance structure, 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, quarterly report on Form 10-Q and the Company's 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)

	June 30, 2025	December 31, 2024
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 183,105	$ 36,926
Restricted cash	42	42
Total cash, cash equivalents and restricted cash	183,147	36,968
Short-term investments	—	94,965
Accounts and other receivables	321	544
Income tax and R&D incentive receivables	557	2,573
Prepaid expenses and other current assets	4,397	2,204
Total current assets	188,422	137,254
Property and equipment, net	364	413
Other assets	1,564	1,639
Total assets	$ 190,350	$ 139,306
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 851	$ 211
Accrued expenses and other current liabilities	8,369	10,257
Total current liabilities	9,220	10,468
Term loan, noncurrent	14,332	—

Other noncurrent liabilities	5,431	5,330
Total liabilities	28,983	15,798
Commitments and contingencies		
Stockholders' equity:		
Stockholders' equity:	9	7
Additional paid-in capital	769,508	689,864
Accumulated deficit	(603,111)	(561,390)
Accumulated other comprehensive loss, net	(5,039)	(4,973)
Total stockholders' equity	161,367	123,508
Total liabilities and stockholders' equity	$ 190,350	$ 139,306

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenues	$ 5	$ 5	$ 10	$ 10
Operating expenses:				
Research and development	17,236	21,155	33,063	42,642
General and administrative	5,691	5,595	11,684	10,907
Total operating expenses	22,927	26,750	44,747	53,549
Loss from operations	(22,922)	(26,745)	(44,737)	(53,539)
Other income (expense):				
Interest expense	(264)	(1)	(265)	(2)
Interest income	1,132	2,182	2,677	4,595
Other income (expense), net	(92)	(76)	(77)	(88)
Total other income (expense), net	776	2,105	2,335	4,505
Net loss before income taxes	(22,146)	(24,640)	(42,402)	(49,034)
Income tax expense (benefit)	—	—	(681)	—
Net loss	(22,146)	(24,640)	(41,721)	(49,034)
Other comprehensive income — unrealized loss on short-term investments	(36)	(31)	(66)	(188)
Comprehensive loss	$ (22,182)	$ (24,671)	$ (41,787)	$ (49,222)
Net loss per share, basic and diluted	$ (0.27)	$ (0.35)	$ (0.53)	$ (0.69)
Weighted-average common shares outstanding, basic and diluted	81,477,548	70,924,371	78,529,028	70,863,042

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

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