# Altimmune Announces Third Quarter 2025 Financial Results and Business Updates

November 6, 2025 at 7:00 AM EST

*48-week Data from Phase 2b IMPACT Trial of Pemvidutide in MASH Expected Before Year End*

*End-of-Phase 2 Meeting with FDA for MASH Program Scheduled in Fourth Quarter*

*Executive Leadership Strengthened with Appointments of Chief Medical Officer, Chief Commercial Officer, and Chief Legal Officer*

*Cash, cash equivalents and short-term investments of $211 million as of September 30, 2025*

*Webcast to be held today, November 6, 2025, at 8:30 a.m. ET*

GAITHERSBURG, Md., Nov. 06, 2025 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a late clinical-stage biopharmaceutical company developing peptide-based therapeutics for liver and cardiometabolic diseases, today provided a corporate update and announced financial results for the quarter ended September 30, 2025.

“We have made a number of important advancements in the second half of 2025 and are approaching a major inflection point for the pemvidutide MASH program. Later this quarter we expect two milestones that will set the stage for 2026 and beyond, including our scheduled, in-person End-of-Phase 2 Meeting with the FDA which was granted to the Company based upon the strength of our 24-week IMPACT trial data. In addition, the 48-week data from the IMPACT trial is expected before year end and we look forward to assessing the longer treatment duration of pemvidutide in this MASH patient population,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. “At the End-of-Phase 2 meeting, we will seek alignment with the FDA on the proposed design of our Phase 3 MASH trial. One of the attributes of the design is the flexibility to adapt the trial pending the outcome of emerging regulatory discussions around approvable MASH endpoints, which could include the potential adoption of non-invasive tests (NITs) and AI-based biopsy readings.”

“Beyond MASH, we recently announced completion of patient recruitment and randomization in the RECLAIM trial of pemvidutide in alcohol use disorder (AUD), ahead of our expected enrollment timeline. Our ability to enroll this trial so quickly is a clear indication of the unmet need in AUD, a condition affecting millions of patients with currently approved therapies providing limited benefit. In addition to the clinical and regulatory progress, we are continuing to build the organization for our next phase of growth with several strategic additions to our management team, including the recent appointments of Dr. Christophe Arbet-Engels as Chief Medical Officer, Linda Richardson as Chief Commercial Officer and Robin Abrams as Chief Legal Officer. Christophe, Linda and Robin bring a wealth of expertise to our leadership team. They have already made significant contributions to our clinical, regulatory and organizational strategy and we are excited to continue benefiting from their deep experience.”

**Recent Highlights and Anticipated Milestones**

**Metabolic Dysfunction-Associated Steatohepatitis (MASH)**

- *End-of-Phase 2 Meeting with FDA scheduled for fourth quarter 2025*
  - During the in-person meeting, the Company is seeking alignment with the Agency on its proposed Phase 3 trial design and study endpoints
- *48-week data from Phase 2b IMPACT Trial to be reported in fourth quarter 2025*
  - The readout will include longer-term NIT and weight loss data
- *Late-breaking abstracts accepted at The Liver Meeting® 2025, hosted by the American Association for the Study of Liver Diseases (AASLD)*
  - A late-breaking oral presentation on the 24-week IMPACT data will be delivered by Dr. Mazen Noureddin, principal investigator of the trial, on November 11 at 11:45 a.m. ET
  - A late-breaking poster on AI-based digital pathology analysis of biopsy results to measure reductions in liver fibrosis will be presented on November 8 from 1:00-2:00 p.m. ET

**Alcohol Use Disorder (AUD)**

- *Announced early completion of enrollment in RECLAIM Phase 2 trial evaluating pemvidutide in AUD*
  - The RECLAIM trial is evaluating the safety and efficacy of pemvidutide versus placebo in approximately 100 patients with AUD over a 24-week treatment period
  - Enrollment was completed several months ahead of schedule, signaling significant interest from patients and providers in potential new AUD therapies
  - Topline results from the RECLAIM trial are expected in 2026
  - In August 2025, the Company was granted Fast Track Designation from the FDA for pemvidutide in AUD

**Alcohol-associated Liver Disease (ALD)**

- *Announced initiation of RESTORE, a Phase 2 trial of pemvidutide in ALD*
  - The RESTORE trial is a 48-week study evaluating the safety and efficacy of pemvidutide versus placebo in approximately 100 patients with ALD

**Corporate Updates**

- *Strengthened executive team with appointments of Christophe Arbet-Engels, M.D., Ph.D. as Chief Medical Officer, Linda Richardson as Chief Commercial Officer, and Robin Abrams, J.D., as Chief Legal Officer*
  - Dr. Arbet-Engels will lead the clinical development of pemvidutide, including the planned Phase 3 trial in MASH. He has more than 30 years of experience across industry, academia and private practice, including development, registration, launch and lifecycle management for multiple approved drugs
  - Ms. Richardson is an accomplished commercial leader who has overseen sales and marketing, commercial, corporate and business development at a variety of organizations and across a range of therapeutic areas, including metabolic disease, hepatology, cardiovascular and addiction medicine
  - Ms. Abrams is an experienced executive who has led legal, compliance and operations at multiple public biotech companies that were advancing late-stage clinical and recently approved commercial products in varied therapeutic areas

- *Strengthened Balance Sheet with Hercules Amendment*
  - The Company amended its previously announced debt facility with Hercules Capital, increasing the overall size from $100 million to $125 million and extending the interest-only period. The Company has drawn an additional $20 million upon execution of the amendment.

**Financial Results for the Three Months Ended September 30, 2025**

- Altimmune reported cash, cash equivalents and short-term investments totaling $210.8 million as of September 30, 2025, an increase of approximately 60% as compared to $131.9 million at December 31, 2024
- Research and development expenses were $15.0 million for the three months ended September 30, 2025, compared to $19.8 million in the same period in 2024, with the decrease related to the timing of CRO development costs. The expenses for the quarter ended September 30, 2025, included $9.2 million in direct costs related to pemvidutide development activities
- General and administrative expenses were $5.9 million and $5.0 million for the three months ended September 30, 2025 and 2024, respectively. The increase was primarily attributable to increases in professional fees and non-cash stock-based compensation
- Interest income was $2.4 million for the three months ended September 30, 2025
- Net loss for the three months ended September 30, 2025, was $19.0 million, or $0.21 net loss per share, compared to a net loss of $22.8 million, or $0.32 net loss per share, in the same period in 2024

**Conference Call Information:**

| | |
|---|---|
| Date: | November 6, 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 with balanced 1:1 glucagon/GLP-1 dual receptor agonist activity, in development for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), alcohol use disorder (AUD) and alcohol-associated liver disease (ALD). The activation of glucagon receptors results in direct effects on the liver, including reductions in liver fat, inflammation and fibrosis, while GLP-1 receptors mediate metabolic effects such as appetite suppression and weight loss.

The FDA granted Fast Track designations to pemvidutide for the treatment of MASH and AUD, both areas of significant unmet medical need. The 48-week readout from the ongoing IMPACT Phase 2b MASH trial is expected in fourth quarter 2025. Phase 2 trials in AUD (RECLAIM) and ALD (RESTORE) were initiated in May 2025 and July 2025, respectively, and are currently ongoing.

**About Altimmune**
Altimmune is a late clinical-stage biopharmaceutical company developing novel peptide-based therapeutics for liver and cardiometabolic diseases. The Company's lead product candidate is pemvidutide, a glucagon/GLP-1 dual receptor agonist for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), alcohol use disorder (AUD) and alcohol-associated liver disease (ALD). For more information, please visit www.altimmune.com.

**Follow @Altimmune, Inc. on LinkedIn**
**Follow @AltimmuneInc on X**

**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 and ALD, and the prospects for receiving regulatory approval or commercializing or selling any product or drug candidates, financial results, 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.

**Investor Contact:**
Lee Roth
Burns McClellan
Phone: 646-382-3403
lroth@burnsmc.com

**Media Contact:**
Savannah Valade
Real Chemistry
altimmune@realchemistry.com

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

| | September 30, 2025 | December 31, 2024 |
|---|---|---|
| | (Unaudited) | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 61,236 | $ 36,926 |
| Restricted cash | 42 | 42 |
| Total cash, cash equivalents and restricted cash | 61,278 | 36,968 |
| Short-term investments | 149,540 | 94,965 |
| Accounts and other receivables | 845 | 544 |
| Income tax and R&D incentive receivables | 547 | 2,573 |
| Prepaid expenses and other current assets | 4,405 | 2,204 |
| Total current assets | 216,615 | 137,254 |
| Property and equipment, net | 337 | 413 |
| Other assets | 1,495 | 1,639 |
| Total assets | $ 218,447 | $ 139,306 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,804 | $ 211 |
| Accrued expenses and other current liabilities | 7,802 | 10,257 |
| Total current liabilities | 12,606 | 10,468 |
| Term loan, noncurrent | 14,445 | — |
| Other noncurrent liabilities | 5,795 | 5,330 |
| Total liabilities | 32,846 | 15,798 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock, $0.0001 par value; 200,000,000 shares authorized; 95,598,665 and 72,352,701 shares issued and outstanding as of September 30, 2025 and December 31 2024, respectively | 10 | 7 |
| Additional paid-in capital | 812,732 | 689,864 |
| Accumulated deficit | (622,125) | (561,390) |
| Accumulated other comprehensive loss, net | (5,016) | (4,973) |
| Total stockholders' equity | 185,601 | 123,508 |

| | | |
|---|---|---|
| Total liabilities and stockholders' equity | $ 218,447 | $ 139,306 |

**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, | |
|---|---|---|---|---|
| | **2025** | **2024** | **2025** | **2024** |
| Revenues | $ 5 | $ 5 | $ 15 | $ 15 |
| Operating expenses: | | | | |
| Research and development | 14,960 | 19,803 | 48,023 | 62,445 |
| General and administrative | 5,904 | 4,969 | 17,588 | 15,876 |
| Total operating expenses | 20,864 | 24,772 | 65,611 | 78,321 |
| Loss from operations | (20,859) | (24,767) | (65,596) | (78,306) |
| Other income (expense): | | | | |
| Interest expense | (495) | (6) | (760) | (8) |
| Interest income | 2,426 | 1,910 | 5,103 | 6,505 |
| Other income (expense), net | (86) | 18 | (163) | (70) |
| Total other income (expense), net | 1,845 | 1,922 | 4,180 | 6,427 |
| Net loss before income taxes | (19,014) | (22,845) | (61,416) | (71,879) |
| Income tax expense (benefit) | — | — | (681) | — |
| Net loss | (19,014) | (22,845) | (60,735) | (71,879) |
| Other comprehensive income — unrealized gain (loss) on short-term investments | 23 | 347 | (43) | 159 |
| Comprehensive loss | $ (18,991) | $ (22,498) | $ (60,778) | $ (71,720) |
| Net loss per share, basic and diluted | $ (0.21) | $ (0.32) | $ (0.74) | $ (1.01) |
| Weighted-average common shares outstanding, basic and diluted | 89,418,028 | 71,084,787 | 82,198,581 | 70,927,222 |

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


Source: Altimmune, Inc