Altimmune Announces Second Quarter 2024 Financial Results and Provides a Business Update

August 8, 2024 at 7:00 AM EDT

Recent presentations at major medical meetings provide further support for the differentiated profile of pemvidutide in obesity and metabolic dysfunction-associated steatohepatitis (MASH)

Enrollment progressing in Phase 2b IMPACT trial of pemvidutide in MASH with topline data expected in Q1 2025

Cash, cash equivalents and short-term investments of $164.9 million on June 30, 2024

Webcast to be held today, August 8, 2024, at 8:30 am ET

GAITHERSBURG, Md., Aug. 08, 2024 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the second quarter ended June 30, 2024, and provided a business update.

"During the second quarter, we continued to highlight the scientific evidence supporting the robust therapeutic potential of pemvidutide in metabolic diseases," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "The data presented at the European Association for the Study of the Liver (EASL) meeting highlighted the disease-modifying potential of pemvidutide in MASH and reinforces our confidence in achieving success on the MASH resolution and fibrosis improvement endpoints of our Phase 2b IMPACT trial. We also delivered two podium presentations at the American Diabetes Association (ADA) 84th Scientific Sessions that highlighted the robust reductions in body weight and serum lipids with pemvidutide treatment. In addition, we presented data demonstrating class-leading preservation of lean mass among incretin agents, an increasingly important consideration in the treatment of obesity. These data further exemplify the differentiation and broad utility we believe pemvidutide will bring to the rapidly evolving obesity marketplace. We continue to make progress toward expanding the development of pemvidutide in up to three additional indications where its dual GLP-1/glucagon agonism could provide benefit over currently available agents. In parallel with these efforts, our discussions with potential strategic partners continue to progress. We look forward to sharing further updates on each of these initiatives."

Recent Highlights and Anticipated Milestones:

Obesity:

- *On June 22 and 23, the Company presented data from its Phase 2 MOMENTUM obesity trial at the American Diabetes Association's (ADA) 84 th Annual Scientific Sessions*
  - At 48 weeks of treatment, subjects receiving pemvidutide achieved weight loss of up to 15.6% with weight loss continuing at the end of treatment.
  - A full analysis of body composition data showed class-leading lean mass preservation among incretin agents with only 21.9% of weight loss attributable to lean mass and 78.1% attributable to fat.
  - Treatment with pemvidutide also resulted in robust reductions of triglycerides (55.8%), total cholesterol (20.0%) and LDL cholesterol (17.4%) in subjects with elevated baseline lipids on the 2.4mg dose.
  - In addition, data from the Phase 1 first-in-human trial of pemvidutide demonstrated robust reductions in pro-inflammatory lipids associated with atherogenesis and cardiovascular risk.
- *End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) expected to take place in late Q3 2024*
  - The Company is seeking agreement from the Agency on the Phase 3 trial design and study endpoints that highlight the differentiation of pemvidutide in the treatment of obesity, including its ability to reduce serum lipids and liver fat content (LFC) and its class-leading preservation of lean mass among incretin agents.

Metabolic Dysfunction-Associated Steatohepatitis (MASH):

- *On June 5, Altimmune presented data at the EASL International Liver Congress™ 2024, supporting the disease-modifying potential and differentiated therapeutic profile of pemvidutide in MASH*
  - An analysis of data in our Phase 1 trial of metabolic-associated steatotic liver disease (MASLD) demonstrated that higher proportions of subjects receiving pemvidutide achieved FibroScan-aspartate aminotransferase (FAST) score, MRI-PDFF and alanine aminotransferase (ALT) responses than subjects receiving placebo, suggesting significant rates of MASH resolution and fibrosis improvement may be achieved in the IMPACT Phase 2b MASH trial.
  - A quantitative systems pharmacology (QSP) computational model predicted that GLP-1/glucagon dual agonism of pemvidutide would have more potent effects on MASH resolution and fibrosis improvement than GLP-1 therapy alone and that both endpoints would be achieved within the 24-week efficacy readout of the IMPACT trial.
  - Lipidomic profiling showed significant reductions in serum lipids associated with cardiovascular disease, reinforcing our belief in the disease-modifying potential of pemvidutide on MASH-associated cardiovascular co-morbidities.
- *On July 25, data from the previously reported 12-week clinical trial of pemvidutide in MASLD was published in the Journal of Hepatology*
  - The Phase 1 trial, which enrolled 94 subjects, evaluated three doses of pemvidutide versus placebo administered once weekly for 12 weeks.

- Pemvidutide-treated subjects achieved up to 68.5% relative reduction in LFC, an important predictor of MASH resolution and fibrosis improvement, compared to 4.4% in subjects receiving placebo, with up to 55.6% of pemvidutide-treated subjects achieving LFC normalization.
- LFC changes were accompanied by significant improvements in body weight and non-invasive markers of liver inflammation.
- The adverse event discontinuation rate was only 2.9% in subjects receiving pemvidutide with no severe or serious adverse events reported.

- *The Company continues to advance IMPACT, its biopsy-driven Phase 2b trial of pemvidutide in MASH*
  - The trial expects to enroll approximately 190 subjects with and without type 2 diabetes (T2D), randomized to receive 1.2mg or 1.8mg of pemvidutide or placebo.
  - The primary efficacy measures are MASH resolution or fibrosis improvement at Week 24.
  - The biopsy readout at Week 24 represents the earliest time point of any incretin-based MASH clinical trial.

Financial Results for the Three Months Ended June 30, 2024

- Altimmune had cash, cash equivalents and short-term investments totaling $164.9 million on June 30, 2024.
- Research and development expenses were $21.2 million for the three months ended June 30, 2024, compared to $13.3 million in the same period in 2023. The expenses for the quarter ended June 30, 2024, included $13.8 million in direct costs related to development activities for pemvidutide and $1.0 million in direct costs related to winddown and closing of our HepTcell program as announced on March 27, 2024.
- General and administrative expenses were $5.6 million for the three months ended June 30, 2024, compared to $4.8 million in the same period in 2023. The increase was primarily due to a $1.0 million increase in stock compensation expense caused by modifications of stock awards.
- Interest income for the three months ended June 30, 2024, was $2.2 million as compared to $1.8 million in the same period in 2023, primarily due to an increase in interest income earned on cash equivalents and short-term investments.
- Net loss for the three months ended June 30, 2024, was $24.6 million, or $0.35 net loss per share, compared to a net loss of $16.1 million, or $0.32 net loss per share, in the same period in 2023.

Conference Call Information:

Date:	Thursday, August 8, 2024
Time:	8:30 am 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, 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 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)

	June 30, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 57,128	$ 135,117
Restricted cash	41	41
Total cash, cash equivalents and restricted cash	57,169	135,158
Short-term investments	107,780	62,698
Accounts and other receivables	424	1,111
Income tax and R&D incentive receivables	2,588	3,742
Prepaid expenses and other current assets	3,225	6,917
Total current assets	171,186	209,626
Property and equipment, net	483	651
Other assets	1,677	363
Total assets	$ 173,346	$ 210,640
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,688	$ 2,070
Accrued expenses and other current liabilities	12,467	10,073
Total current liabilities	15,155	12,143
Other noncurrent liabilities	5,660	4,398
Total liabilities	20,815	16,541
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 71,046,267 and 70,677,400 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	7	7
Additional paid-in capital	673,081	665,427
Accumulated deficit	(515,365)	(466,331)
Accumulated other comprehensive loss, net	(5,192)	(5,004)

Total stockholders' equity	152,531	194,099
Total liabilities and stockholders' equity	$ 173,346	$ 210,640

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues	$ 5	$ 6	$ 10	$ 27
Operating expenses:				
Research and development	21,155	13,253	42,642	30,502
General and administrative	5,595	4,760	10,907	9,291
Total operating expenses	26,750	18,013	53,549	39,793
Loss from operations	(26,745)	(18,007)	(53,539)	(39,766)
Other income (expense):				
Interest expense	(1)	(2)	(2)	(4)
Interest income	2,182	1,835	4,595	3,503
Other income (expense), net	(76)	113	(88)	132
Total other income (expense), net	2,105	1,946	4,505	3,631
Net loss	(24,640)	(16,061)	(49,034)	(36,135)
Other comprehensive income — unrealized (loss) gain on short-term investments	(31)	(79)	(188)	47
Comprehensive loss	$ (24,671)	$ (16,140)	$ (49,222)	$ (36,088)
Net loss per share, basic and diluted	$ (0.35)	$ (0.32)	$ (0.69)	$ (0.72)
Weighted-average common shares outstanding, basic and diluted	70,924,371	50,691,558	70,863,042	50,410,184

Source: Altimmune, Inc