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

May 9, 2024 at 7:00 AM EDT

Enrollment ongoing in IMPACT Phase 2b trial of pemvidutide in Metabolic Dysfunction-Associated Steatohepatitis (MASH), with top line results expected in Q1 2025

Cash, cash equivalents and short-term investments of $182.1 million at March 31, 2024

Webcast to be held today, May 9, 2024, at 8:30 am ET

GAITHERSBURG, Md., May 09, 2024 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the first quarter ended March 31, 2024, and provided a business update.

“As the obesity therapeutics space evolves, increasing attention is being placed on agents that are able to drive weight loss while addressing the quality of that weight loss and the comorbidities of obesity. With significant weight loss, preservation of lean mass and reductions in serum lipids and liver fat achieved in our clinical trials, we believe that pemvidutide could differentiate itself from other therapies in this competitive market. With these promising data, we are preparing for our End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), which is expected to occur late in the third quarter. This meeting is expected to provide further clarity regarding the Phase 3 pemvidutide obesity registrational program, and we look forward to our upcoming interactions with the Agency,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. “Further, we continue to advance IMPACT, our Phase 2b trial of pemvidutide in MASH, with top line results expected in the first quarter of 2025.”

Recent Highlights and Anticipated Milestones:

- *In March 2024, Altimmune reported additional data from the Phase 2 MOMENTUM trial of pemvidutide in obesity, demonstrating significant weight loss with class-leading preservation of lean mass*
  - Body composition analysis from MOMENTUM showed 74.5% of weight loss came from body fat and only 25.5% of weight loss came from lean mass in pemvidutide-treated subjects.
  - This analysis demonstrated a preferential reduction of visceral over subcutaneous fat in the pemvidutide group.
  - Analyses of the MOMENTUM body composition and other new data to be presented at scientific meetings later this year.
- *Preparations underway for an End-of-Phase 2 meeting with FDA*
  - The Company plans to present a comprehensive data package, including data from the MOMENTUM Phase 2 trial of pemvidutide in obesity.
  - The meeting is currently expected to take place in late Q3 2024.
- *The Company has continued to advance enrollment in IMPACT, a biopsy-driven Phase 2b trial of pemvidutide in MASH*
  - The Company expects to enroll approximately 190 subjects with and without diabetes, randomized to receive one of two doses of pemvidutide or placebo.
  - The primary efficacy measures of the trial are MASH resolution or fibrosis improvement with topline data expected in Q1 2025.
  - The primary efficacy readout will be at 24 weeks of treatment, which is the earliest time point for any incretin-based therapy in MASH.

Financial Results for the Three Months Ended March 31, 2024

- Altimmune had cash, cash equivalents and short-term investments totaling $182.1 million at March 31, 2024.
- Research and development expenses were $21.5 million for the three months ended March 31, 2024, compared to $17.2 million in the same period in 2023. The expenses for the quarter ended March 31, 2024 included $13.5 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 $5.3 million for the three months ended March 31, 2024, compared to $4.5 million in the same period in 2023. The increase was primarily due to a $0.6 million increase in stock compensation and other labor related expenses.
- Interest income for the three months ended March 31, 2024 was $2.4 million as compared to $1.7 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 March 31, 2024 was $24.4 million, or $0.34 net loss per share, compared to a net loss of $20.1 million, or $0.40 net loss per share, in the same period in 2023.

Conference Call Information:

Date:	Thursday, May 9, 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, leading to rapid reductions in levels of liver fat and serum lipids. In clinical trials, once-weekly pemvidutide has shown compelling weight loss, robust reductions in triglycerides, LDL cholesterol, liver fat content and blood pressure with a clean safety profile to date. The U.S. FDA has granted Fast Track designation to pemvidutide for the treatment of MASH. Pemvidutide has recently completed the MOMENTUM Phase 2 obesity trial and is being studied in the 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)

	March 31, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 78,978	$ 135,117
Restricted cash	41	41
Total cash, cash equivalents and restricted cash	79,019	135,158
Short-term investments	103,046	62,698
Accounts and other receivables	307	1,111
Income tax and R&D incentive receivables	2,272	3,742
Prepaid expenses and other current assets	2,871	6,917
Total current assets	187,515	209,626
Property and equipment, net	544	651
Other assets	299	363
Total assets	$ 188,358	$ 210,640
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,760	$ 2,070
Accrued expenses and other current liabilities	7,573	10,073
Total current liabilities	11,333	12,143
Noncurrent liabilities	4,088	4,398
Total liabilities	15,421	16,541
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 70,899,134 and 70,677,400 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	7	7
Additional paid-in capital	668,816	665,427
Accumulated deficit	(490,725)	(466,331)
Accumulated other comprehensive loss, net	(5,161)	(5,004)
Total stockholders' equity	172,937	194,099
Total liabilities and stockholders' equity	$ 188,358	$ 210,640

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

	Three Months Ended March 31,	
	2024	2023
Revenues	$ 5	$ 21
Operating expenses:		
Research and development	21,487	17,249
General and administrative	5,312	4,531
Total operating expenses	26,799	21,780
Loss from operations	(26,794)	(21,759)
Other income (expense):		
Interest expense	(1)	(2)
Interest income	2,413	1,668
Other income (expense), net	(12)	19
Total other income (expense), net	2,400	1,685
Net loss	(24,394)	(20,074)
Other comprehensive income — unrealized (loss) gain on short-term investments	(157)	126
Comprehensive loss	$ (24,551)	$ (19,948)
Net loss per share, basic and diluted	$ (0.34)	$ (0.40)
Weighted-average common shares outstanding, basic and diluted	70,801,713	50,125,685



Source: Altimmune, Inc