Altimmune Announces Second Quarter 2023 Financial Results and Provides a Business Update

August 10, 2023 at 7:00 AM EDT

Top-line 48-week results from the MOMENTUM Phase 2 obesity trial expected Q4 2023

Commenced enrollment in IMPACT Phase 2b trial of pemvidutide in non-alcoholic steatohepatitis (NASH)

Top-line results from the Phase 2 trial of HepTcell™ in chronic hepatitis B (CHB) expected Q1 2024

Webcast to be held today, August 10, 2023, at 8:30 am EDT

GAITHERSBURG, Md., Aug. 10, 2023 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three months ended June 30, 2023, and provided a business update.

"We are pleased to have commenced enrollment in our IMPACT Phase 2b biopsy-driven trial of pemvidutide in NASH," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "We believe our compelling Phase 1b data in subjects with nonalcoholic fatty liver disease (NAFLD) demonstrating class-leading improvements in liver fat and markers of liver inflammation support the prospects of achieving robust rates of NASH resolution and fibrosis improvement in our IMPACT trial. We are also eager to report our 48-week data from the MOMENTUM Phase 2 obesity trial next quarter. We believe the pemvidutide data showing significant weight loss, combined with robust reductions in liver fat content, serum lipids and blood pressure without cardiovascular safety signals could offer a differentiated product profile that meaningfully impacts patients with obesity and NAFLD or dyslipidemia, and patients with NASH."

Recent Highlights and Anticipated Milestones

Pemvidutide

- *Top-line data readout from 48-week MOMENTUM Phase 2 obesity trial expected in Q4 2023*
    - Dr. Louis Aronne, Professor of Metabolic Research and Professor of Clinical Medicine, Weil Cornell Medical School, a leading authority in obesity and obesity clinical trials, is serving as the Principal Investigator.
    - Approximately 320 subjects with obesity or overweight but without diabetes were randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 48 weeks in conjunction with diet and exercise.
    - In an interim 24-week data readout in March 2023, subjects receiving pemvidutide achieved robust reductions in body weight, waist circumference, serum lipids and blood pressure without arrhythmias, clinically meaningful heart rate increases or other safety signals.
    - Top-line data readout at 48 weeks will include subject disposition, weight loss, serum lipids, vital signs, adverse events and glycemic control.
- *Commenced enrollment in IMPACT Phase 2b NASH trial*
    - This Phase 2b biopsy-driven NASH trial is being conducted at approximately 60 sites in the U.S., with Dr. Stephen Harrison, Medical Director, Pinnacle Research, and Adjunct Professor of Medicine, Oxford University, serving as the principal investigator.
    - Approximately 190 subjects with and without diabetes are planned to be randomized 1:2:2 to 1.2 mg, 1.8 mg pemvidutide or placebo.
    - The key endpoints will be NASH resolution and fibrosis improvement after 24 weeks of treatment, with subjects followed for an additional 24 weeks for assessment of safety and additional biomarker responses.
    - Top-line results after 24 weeks of treatment are expected in the first quarter of 2025.

HepTcell™

- *Top-line data from Phase 2 clinical trial expected in Q1 2024*
    - The multicenter clinical trial, which is being conducted at 26 sites in North America, Europe and Southeast Asia, enrolled approximately 80 previously untreated subjects with inactive CHB and low levels of hepatitis B surface antigen (HBsAg).
    - Subjects were randomized 1:1 to HepTcell or placebo.
    - The primary endpoint is virological response, defined as a 1-log or greater reduction or clearance of HBsAg; secondary endpoints include changes in the levels of hepatitis B virus (HBV) DNA, pre-genomic RNA and other markers of virologic response.
    - Data readout is expected in the first quarter of 2024 after all subjects complete the 6-month course of treatment.

Financial Results for the Three Months Ended June 30, 2023

- Cash, cash equivalents and short-term investments totaled $160.0 million as of June 30, 2023.
- Research and development expenses were $13.3 million for the three months ended June 30, 2023, compared to $16.0 million in the same period in 2022. The expenses for the quarter ended June 30, 2023 included $5.6 million in direct costs related to development activities for pemvidutide and $1.8 million in direct costs related to development activities for HepTcell.
- General and administrative expenses were $4.8 million for the three months ended June 30, 2023, compared to $4.4 million in the same period in 2022. The change was primarily attributable to increased stock compensation and other labor related expenses.
- Interest income for the three months ended June 30, 2023 was $1.8 million as compared to $0.3 million in the same period in 2022.
- Net loss for the three months ended June 30, 2023 was $16.1 million, or $0.32 net loss per share, compared to a net loss of $20.1 million, or $0.42 net loss per share, in the same period in 2022.

Conference Call Information:

Date:	Thursday, August 10, 2023
Time:	8:30 am EDT
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 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 NASH. 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. Pemvidutide incorporates the EuPort™ domain, a proprietary technology that increases its serum half-life for weekly dosing while likely slowing the entry of pemvidutide into the bloodstream, which may improve its tolerability.

About HepTcell
HepTcell is a novel, investigational, immunotherapeutic comprised of nine synthetic peptides representing conserved T-cell epitopes on key HBV antigens formulated with IC31®, a TLR9-based adjuvant from Valneva SE. The HBV-directed peptides are designed to drive T cell responses against all HBV genotypes towards a functional cure for chronic HBV in patients of diverse genetic backgrounds.

About Altimmune
Altimmune is a clinical-stage biopharmaceutical company focused on developing innovative next-generation therapeutics for the treatment of obesity and liver diseases. The Company's lead product candidate, pemvidutide, is a GLP-1/glucagon dual receptor agonist that is being developed for the treatment of obesity and NASH. In addition, Altimmune is developing HepTcell™, an immunotherapeutic designed to achieve a functional cure for CHB. 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, the timing of the data readouts of the Phase 2 trial of HepTcell in CHB, the Phase 2 MOMENTUM trial of pemvidutide in obesity and the Phase 2b IMPACT trial of pemvidutide in NASH, 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, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 102,352	$ 111,097
Restricted cash	41	34
Total cash, cash equivalents and restricted cash	102,393	111,131
Short-term investments	57,602	73,783
Accounts receivable	136	173
Income tax and R&D incentive receivables	3,579	2,368
Prepaid expenses and other current assets	5,822	5,358
Total current assets	169,532	192,813
Property and equipment, net	882	1,081
Indefinite-lived intangible asset	12,419	12,419
Other assets	483	615
Total assets	$ 183,316	$ 206,928
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,035	$ 4,804
Accrued expenses and other current liabilities	7,402	12,250
Total current liabilities	11,437	17,054
Other long-term liabilities	4,165	4,581
Total liabilities	15,602	21,635
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 52,657,661 and 49,199,845 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	5	5
Additional paid-in capital	586,908	568,399
Accumulated deficit	(414,019)	(377,884)
Accumulated other comprehensive loss, net	(5,180)	(5,227)
Total stockholders' equity	167,714	185,293
Total liabilities and stockholders' equity	$ 183,316	$ 206,928

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,	
	2023	2022	2023	2022
Revenues	$ 6	$ 8	$ 27	$ 40
Operating expenses:				
Research and development	13,253	15,993	30,502	31,097
General and administrative	4,760	4,410	9,291	8,837
Total operating expenses	18,013	20,403	39,793	39,934
Loss from operations	(18,007)	(20,395)	(39,766)	(39,894)
Other income (expense):				
Interest expense	(2)	(65)	(4)	(127)
Interest income	1,835	328	3,503	349
Other income (expense), net	113	25	132	135

Total other income (expense), net	1,946	288	3,631	357
Net loss	(16,061)	(20,107)	(36,135)	(39,537)
Other comprehensive income — unrealized (loss) gain on short-term investments	(79)	(120)	47	(120)
Comprehensive loss	$ (16,140)	$ (20,227)	$ (36,088)	$ (39,657)
Net loss per share, basic and diluted	$ (0.32)	$ (0.42)	$ (0.72)	$ (0.90)
Weighted-average common shares outstanding, basic and diluted	50,691,558	47,502,599	50,410,184	44,150,835

Source: Altimmune, Inc