



Altimune Announces Third Quarter 2023 Financial Results and Provides a Business Update

November 7, 2023 at 7:00 AM EST

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

Pemvidutide granted Fast Track designation for the treatment of 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, November 7, 2023, at 8:30 am EST

GAITHERSBURG, Md., Nov. 07, 2023 (GLOBE NEWSWIRE) -- [Altimune, Inc.](https://www.altimmune.com) (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three months ended September 30, 2023, and provided a business update.

"The next few months will be important as we receive the data from our 48-week MOMENTUM trial of pemvidutide in subjects with obesity as well as the results of our Phase 2 trial of HepTcell in CHB," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimune. "The rapidly expanding obesity market needs differentiated products that address not only excess body weight, but also risk factors for cardiovascular comorbidities, including elevated LDL-cholesterol and excess liver fat. We also were very pleased to receive Fast Track designation for our pemvidutide program in NASH, which demonstrates the unmet need for this critical liver disease. We believe that our liver fat reduction is class-leading and could result in unprecedented reductions of fibrosis and measures of NASH."

Recent Highlights and Anticipated Milestones

Pemvidutide

- *Top-line data readout from 48-week MOMENTUM Phase 2 obesity trial expected in Q4 2023*
 - Patient dosing (last subject last dose) was completed in September 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.
 - 391 subjects with obesity or overweight and 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.
- *Enrollment commenced in IMPACT Phase 2b NASH trial*
 - Informed by the positive results of the Phase 1b randomized, placebo-controlled trials of pemvidutide in subjects with non-alcoholic fatty liver disease (NAFLD), the FDA granted pemvidutide Fast Track designation for the treatment of NASH.
 - 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 to receive six monthly administrations.
 - 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 September 30, 2023

- Cash, cash equivalents and short-term investments totaled \$140.8 million as of September 30, 2023.
- Research and development expenses were \$18.4 million for the three months ended September 30, 2023, compared to \$20.3 million in the same period in 2022. The expenses for the quarter ended September 30, 2023 included \$10.4 million in direct costs related to development activities for pemvidutide and \$1.6 million in direct costs related to development activities for HepTcell.
- General and administrative expenses were consistent period-over-period at \$4.5 million for the three months ended September 30, 2023 and 2022.
- Interest income for the three months ended September 30, 2023 was \$1.9 million as compared to \$1.1 million in the same period in 2022, primarily due to an increase in interest income earned on cash equivalents and short-term investments.
- Net loss for the three months ended September 30, 2023 was \$20.7 million, or \$0.39 net loss per share, compared to a net loss of \$23.5 million, or \$0.48 net loss per share, in the same period in 2022.

Conference Call Information:

Date: Tuesday, November 7, 2023
Time: 8:30 am EST
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 patients with liver diseases and obesity. 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, 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.

Investor Contact:

Rich Eisenstadt

Chief Financial Officer
Phone: 240-654-1450
reisenstadt@altimmune.com

Media Contact:
Danielle Cantey
Evoke Canale
Phone: 619-826-4657
danielle.cantey@evokegroup.com

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

	September 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 86,855	\$ 111,097
Restricted cash	41	34
Total cash, cash equivalents and restricted cash	86,896	111,131
Short-term investments	53,924	73,783
Accounts receivable	876	173
Income tax and R&D incentive receivables	3,653	2,368
Prepaid expenses and other current assets	7,615	5,358
Total current assets	152,964	192,813
Property and equipment, net	765	1,081
Indefinite-lived intangible asset	12,419	12,419
Other assets	425	615
Total assets	\$ 166,573	\$ 206,928
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,046	\$ 4,804
Accrued expenses and other current liabilities	8,825	12,250
Total current liabilities	11,871	17,054
Other long-term liabilities	4,305	4,581
Total liabilities	16,176	21,635
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 52,858,920 and 49,199,845 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	5	5
Additional paid-in capital	590,206	568,399
Accumulated deficit	(434,690)	(377,884)
Accumulated other comprehensive loss, net	(5,124)	(5,227)
Total stockholders' equity	150,397	185,293
Total liabilities and stockholders' equity	\$ 166,573	\$ 206,928

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,	
	2023	2022	2023	2022
	\$	\$	\$	\$
Revenues	362	2	389	42
Operating expenses:				
Research and development	18,388	20,262	48,890	51,359

General and administrative	4,514	4,492	13,805	13,329
Total operating expenses	<u>22,902</u>	<u>24,754</u>	<u>62,695</u>	<u>64,688</u>
Loss from operations	(22,540)	(24,752)	(62,306)	(64,646)
Other income (expense):				
Interest expense	(29)	(64)	(33)	(191)
Interest income	1,884	1,053	5,387	1,402
Other income (expense), net	14	50	146	185
Total other income (expense), net	<u>1,869</u>	<u>1,039</u>	<u>5,500</u>	<u>1,396</u>
Net loss before income taxes	(20,671)	(23,713)	(56,806)	(63,250)
Income tax expense (benefit)	—	(197)	—	(197)
Net loss	<u>(20,671)</u>	<u>(23,516)</u>	<u>(56,806)</u>	<u>(63,053)</u>
Other comprehensive income — unrealized gain (loss) on short-term investments	56	(143)	103	(263)
Comprehensive loss	\$ (20,615)	\$ (23,659)	\$ (56,703)	\$ (63,316)
Net loss per share, basic and diluted	\$ (0.39)	\$ (0.48)	\$ (1.10)	\$ (1.37)
Weighted-average common shares outstanding, basic and diluted	53,633,354	49,286,535	51,495,957	45,881,547



Source: Altimune, Inc