



Altimmune Announces Second Quarter 2022 Financial Results and Provides a Business Update

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Topline data from 12-week Phase 1b trial in subjects with obesity/overweight and non-alcoholic fatty liver disease (NAFLD) expected mid-September 2022

GAITHERSBURG, Md., Aug. 11, 2022 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three and six months ended June 30, 2022, and provided a business update.

"We continue to advance the development of pemvidutide, our GLP-1/glucagon dual receptor agonist, and look forward to reporting important readouts from our ongoing clinical trials during the coming months," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "We expect to announce top line data from our 12-week trial in subjects with obesity/overweight and NAFLD in mid-September 2022, followed by 24-week data from an extension of that trial in Q4 2022. Enrollment in our Phase 2 MOMENTUM obesity trial has been very robust. As of August 10, 167 subjects have been randomized, and approximately 25 additional subjects are being randomized each week. At this rate, we expect to complete the randomization of all 320 subjects in September 2022. We have also made the decision to conduct the interim analysis of this trial when approximately 50%, or 160 study participants, complete 24 weeks of treatment, which we expect will occur in Q1 2023. While we had planned to conduct an interim analysis on approximately 100 subjects at year end 2022, it is our current belief that an interim analysis on 50% of the subjects would be more meaningful."

"We believe that pemvidutide has the potential to deliver weight loss equaling or exceeding 20% after only 48 weeks of treatment. In addition, we believe that pemvidutide will have a highly differentiated product profile compared to other obesity products in development— including, no dose titration, faster weight loss and robust reductions in lipids. If achieved, we believe these features would translate into greater ease of administration, improved adherence to therapy, and greater potential for cardiovascular benefit," Dr. Garg added.

Recent Highlights and Anticipated Milestones:

Pemvidutide¹ (ALT-801)

- *Topline data from 12-week Phase 1b trial in subjects with obesity/overweight and NAFLD expected mid-September 2022*
 - This trial is being conducted in the U.S., with Dr. Stephen A. Harrison, Director, Pinnacle Research and University of Oxford, serving as Principal Investigator.
 - The trial is fully enrolled and has randomized and dosed a total of 94 subjects, of whom approximately 29% have type 2 diabetes. Treatments included 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo in a 1:1:1:1 ratio administered weekly for 12 weeks.
 - The topline data will include:
 - liver fat assessment by MRI-PDFF
 - weight loss
 - adverse events (AEs leading to discontinuation, rates of gastrointestinal AEs, severe and serious AEs)
 - laboratory parameters, including liver function tests and glucose
 - serum lipids
 - hemoglobin A1c
 - heart rate and blood pressure
- *Topline data from a 12-week extension to the Phase 1b trial expected in Q4 2022*
 - This extension trial provides 12 weeks of additional treatment to subjects who completed the 12-week Phase 1b trial in subjects with obesity/overweight and NAFLD. This extension allows subjects to receive a total of 24 weeks of treatment.
 - The principal readouts are weight loss and the safety of pemvidutide at 24 weeks of treatment.
- *Enrollment is over 50% complete in 48-week Phase 2 MOMENTUM obesity trial – 24-week interim analysis of 160 subjects expected in Q1 2023*
 - This Phase 2 trial is being conducted at approximately 25 sites in the U.S., with Dr. Lou Aronne, Professor of Clinical Medicine, Weill Cornell Medical College, a leading authority in obesity and obesity clinical trials, serving as the Principal Investigator.
 - The trial is expected to enroll approximately 320 non-diabetic subjects with obesity/overweight with at least one co-morbidity. Subjects are being 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.
 - The primary endpoint is the relative (percent) change in body weight at 48 weeks compared to baseline. Additional

readouts include metabolic and lipid profiles, cardiovascular measures and glucose homeostasis.

- As of August 10, 2022, 167 subjects have been randomized and approximately 25 additional subjects are being randomized each week. Based on the current rate of enrollment, Altimmune expects to complete the randomization of all 320 subjects in September 2022.
- A 24-week interim analysis on approximately 50%, or 160 subjects, is planned in Q1 2023.

- *Enrollment ongoing in Phase 1b trial of diabetic subjects with obesity and overweight*

- This 12-week trial will evaluate the effects of pemvidutide on glucose control in approximately 48 subjects with type 2 diabetes.
- Completion of enrollment is expected in September 2022, and data readout is expected in Q1 2023.

¹proposed INN

HepTcell

- *Enrollment continuing in the Phase 2 clinical trial in chronic hepatitis B*

- Endpoints include virological markers of hepatitis B infection and functional cure.
- Data readout is expected in H2 2023.

Financial Results for the Three Months Ended June 30, 2022

- Altimmune had cash, cash equivalents and short-term investments totaling \$184.8 million at June 30, 2022.
- Revenue was minimal for the three months ended June 30, 2022 compared to \$0.1 million in the same period in 2021. The change in revenue quarter over quarter was primarily due to the discontinuation of development activities for the T-COVID and NasoShield programs.
- Research and development expenses were \$16.0 million for the three months ended June 30, 2022, compared to \$13.3 million in the same period in 2021. The expenses for the quarter ended June 30, 2022 included \$8.7 million in direct costs related to development activities for pemvidutide and \$1.4 million in direct costs related to development activities for HepTcell. In addition, approximately \$1.9 million of expense was a non-cash expense associated with the achievement of the Phase 2 development milestone for pemvidutide.
- General and administrative expenses were \$4.4 million for the three months ended June 30, 2022, compared to \$3.7 million in the same period in 2021. The change was primarily attributable to increased labor and labor-related expenses, including stock compensation.
- Net loss for the three months ended June 30, 2022 was \$20.1 million, or \$0.42 net loss per share, compared to a net loss of \$24.8 million, or \$0.60 net loss per share, in the same period in 2021. Net loss for the three months ended June 30, 2021 included an \$8.1 million impairment loss relating to a write-down of the construction-in-progress associated with the construction of the Lonza facility, which was to manufacture AdCOVID.

Conference Call Information:

Date: Thursday, August 11

Time: 8:30 am Eastern Time

Webcast: The conference call will be webcast live on Altimmune's Investor Relations website at <https://ir.altimmune.com/investors>.

Dial-in: Participants who would like to join the call may 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. By combining GLP-1 and glucagon activity in a single peptide, pemvidutide has the potential to achieve weight loss equaling or exceeding 20% after only 48 weeks of treatment. Pemvidutide incorporates the EuPort™ domain, a proprietary technology that increases its serum half-life for weekly dosing while slowing the entry of pemvidutide into the bloodstream, which may improve its tolerability. In a 12-week Phase 1 clinical trial, pemvidutide-treated subjects demonstrated striking reductions in body weight, liver fat and serum lipids commonly associated with cardiovascular disease.

About HepTcell

HepTcell is a novel, investigational, immunotherapeutic comprised of nine synthetic peptides representing conserved hepatitis B (HBV) sequences 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 the development of novel peptide-based 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 chronic hepatitis B. 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 NAFLD trials, diabetic subject trial, drug-drug interaction trial, and the Phase 2 obesity clinical trial of pemvidutide, the timing of the data readouts for the Phase 2 clinical trial of HepTcell, and the prospects for regulatory approval, use, 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. (the "Company") 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: potential impacts from the ongoing conflict in Ukraine and the COVID-19 pandemic, such as 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 annual report on Form 10-K for the fiscal year ended December 31, 2021 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 data)

	June 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 135,858	\$ 190,301
Restricted cash	34	34
Total cash, cash equivalents and restricted cash	135,892	190,335
Short-term investments	48,898	—
Accounts receivable	195	429
Income tax and R&D incentive receivables	5,900	5,410
Prepaid expenses and other current assets	4,619	7,952
Total current assets	195,504	204,126
Property and equipment, net	1,236	1,448
Intangible assets, net	12,419	12,419
Other assets	747	872
Total assets	\$ 209,906	\$ 218,865
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,872	\$ 2,034
Contingent consideration	—	6,090
Accrued expenses and other current liabilities	10,973	10,152
Total current liabilities	13,845	18,276
Other long-term liabilities	1,526	1,454
Total liabilities	15,371	19,730
Commitments and contingencies (Note 14)		
Stockholders' equity:		

Common stock, \$0.0001 par value; 200,000,000 shares authorized; 46,372,105 and 40,993,768 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively

	5	4
Additional paid-in capital	532,398	497,342
Accumulated deficit	(332,708)	(293,171)
Accumulated other comprehensive loss, net	(5,160)	(5,040)
Total stockholders' equity	194,535	199,135
Total liabilities and stockholders' equity	\$ 209,906	\$ 218,865

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues	\$ 8	\$ 137	\$ 40	\$ 975
Operating expenses:				
Research and development	15,993	13,272	31,097	25,150
General and administrative	4,410	3,659	8,837	7,480
Impairment loss on construction-in-progress	—	8,070	—	8,070
Total operating expenses	20,403	25,001	39,934	40,700
Loss from operations	(20,395)	(24,864)	(39,894)	(39,725)
Other income (expense):				
Interest expense	(65)	(22)	(127)	(34)
Interest income	328	33	349	75
Other income (expense), net	25	26	135	(7)
Total other income (expense), net	288	37	357	34
Net loss	(20,107)	(24,827)	(39,537)	(39,691)
Other comprehensive income — unrealized (loss) gain on short-term investments	(120)	1	(120)	6
Comprehensive loss	\$ (20,227)	\$ (24,826)	\$ (39,657)	\$ (39,685)
Net loss per share, basic and diluted	\$ (0.42)	\$ (0.60)	\$ (0.90)	\$ (0.99)
Weighted-average common shares outstanding, basic and diluted	47,502,599	41,356,643	44,150,835	40,142,561



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Source: Altimune, Inc