



Altimune Reports Fourth Quarter and Full Year 2021 Financial Results and Provides a Corporate Update

March 15, 2022 at 7:01 AM EDT

Data readouts from multiple clinical trials expected during the next 6 to 12 months

Strong cash position of \$190.3 million as of December 31, 2021

GAITHERSBURG, Md., March 15, 2022 (GLOBE NEWSWIRE) -- Altimune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the fourth quarter and full year ended December 31, 2021 and provided a corporate update.

"We expect the next 12 months to be a period of intense execution with value-creating data readouts from multiple clinical trials. We are extremely pleased with the progress of our pemvidutide (ALT-801) program as we showed double-digit weight loss after 12 weeks of treatment, good tolerability without the use of dose titration, and pronounced decreases in serum lipids commonly associated with cardiovascular disease. We also observed a remarkable reduction in liver fat content to undetectable levels after only 6 weeks of pemvidutide treatment in subjects with hepatic steatosis, or fatty liver," said Vipin K. Garg, Ph.D., President and Chief Executive Officer at Altimune. "In addition to our ongoing 12-week Phase 1b NAFLD trial, we expect to initiate a 48-week Phase 2 trial of pemvidutide in obesity, the MOMENTUM trial, in the next few weeks and look forward to sharing data from both of these trials later this year. In addition, we expect to read out our HepTcell trial in the first half of 2023."

Recent Highlights and Anticipated Milestones:

Pemvidutide¹ (ALT-801)

- *Enrollment in Phase 1b nonalcoholic fatty liver disease (NAFLD) trial is over 90% complete, and data readout is expected in Q3 2022*
 - The 12-week trial is being conducted at 15 sites in the U.S., with Dr. Stephen A. Harrison serving as Principal Investigator. The trial will be comprised of 72 non-diabetic and diabetic subjects across four treatment arms (pemvidutide 1.2, 1.8, 2.4 mg and placebo).
 - The primary efficacy readouts of this trial are liver fat reduction and weight loss.
 - A 52-week biopsy driven Phase 2 non-alcoholic steatohepatitis (NASH) trial is expected to follow the conclusion of the NAFLD trial.
- *Received U.S. Food and Drug Administration (FDA) clearance of pemvidutide investigational new drug application (IND) for obesity – Initiation of the Phase 2 MOMENTUM trial of pemvidutide in obesity expected in the first quarter of 2022*
 - The trial is expected to enroll approximately 320 non-diabetic subjects with either obesity or overweight with at least one obesity-related complication. Subjects will be randomized 1:1:1:1 to receive either 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 48 weeks.
 - The primary endpoint of the MOMENTUM trial is the relative (percent) change in body weight at 48 weeks compared to baseline, with additional readouts including metabolic and lipid profiles, cardiovascular measures and glucose homeostasis.
 - An interim analysis is planned to assess changes in body weight after 24 weeks of treatment, with an expected readout in Q4 2022.
- *Initiated a double-blind, placebo-controlled 12-week extension to the ongoing NAFLD Phase 1b Trial*
 - This extension will allow subjects to receive up to a total of 24 weeks of pemvidutide or placebo and provide a readout on weight loss at 24 weeks.
 - Topline data from the extension trial expected in Q4 2022.
- *Completed 6-month and 9-month toxicology studies of pemvidutide in rats and non-human primates*
 - No significant findings, including no ALT or blood glucose elevations, were reported.
 - Toxicology results support 24-week NAFLD extension and 48-week obesity studies.
- *Initiated a 12-week Phase 1 trial to characterize effects of pemvidutide on glucose control in diabetic population*
 - This represents a follow-on to the evaluation of a pre-diabetic population in our first-in-human trial in which reductions of insulin resistance and maintenance of glucose control were observed.

- Results of a drug-drug interaction trial of pemvidutide expected in the first half of 2022

HepTcell

- Enrollment ongoing for the Phase 2 clinical trial in chronic hepatitis B subjects, with study readout expected H1 2023
 - Readouts from this trial are expected to include virological markers of hepatitis B infection and functional cure.

Financial Results for the Three Months Ended December 31, 2021

- Altimmune had cash, cash equivalents, short-term investments and restricted cash totaling \$190.3 million at December 31, 2021.
- Revenue was \$3.3 million for the three months ended December 31, 2021 compared to \$2.3 million in the same period in 2020. The increase in revenue quarter over quarter was primarily due to the receipt of prior period rate adjustments under the Company's U.S. government contract for NasoShield, partially offset by the discontinuation of development work under prior programs.
- Research and development expenses were \$20.2 million for the three months ended December 31, 2021, compared to \$9.0 million in the same period in 2020. The change was primarily the result of the increased costs related to the development of pemvidutide and an increase in the contingent liability for stock-based milestone payments associated with the acquisition of pemvidutide, partially offset by the discontinuation of development work for prior clinical programs.
- General and administrative expenses were generally consistent period-over-period with \$3.8 million recognized for the three months ended December 31, 2021 and \$4.1 million in the same period in 2020.
- Net loss for the three months ended December 31, 2021 was \$23.9 million, or \$0.57 net loss per share, compared to \$10.6 million in the same period in 2020, or \$0.29 net loss per share, due to the factors noted above.

Conference Call Information

Date:	Tuesday, March 15
Time:	8:30 am Eastern Time
Domestic Dial-in:	(844) 615-6509
International Dial-in:	(918) 922-3148
Conference ID:	4557398
Webcast:	https://edge.media-server.com/mmc/p/5www3cgz

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 comparable to bariatric surgery. 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 initiation and timing of the Phase 2 clinical trial of pemvidutide, the timing of the data readouts for the Phase 2 clinical trial of pemvidutide, and the prospects for 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. (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 due to crises, including conflicts and wars (like the ongoing conflict in Ukraine) and pandemics (like 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 filed with the SEC, which is available at www.sec.gov.

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**ALTIMMUNE, INC.
 CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 190,300,776	\$ 115,917,807
Restricted cash	34,174	34,174
Total cash, cash equivalents and restricted cash	190,334,950	115,951,981
Short-term investments	—	100,005,558
Accounts receivable	428,836	4,610,202
Income tax and R&D incentive receivables	5,409,639	7,762,793
Prepaid expenses and other current assets	7,952,690	1,926,675
Total current assets	204,126,115	230,257,209
Property and equipment, net	1,447,786	1,056,920
Intangible assets, net	12,418,967	12,823,846
Other assets	871,976	977,238
Total assets	\$ 218,864,844	\$ 245,115,213
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,034,493	\$ 612,293
Contingent consideration	6,090,000	—
Accrued expenses and other current liabilities	10,151,437	11,408,154
Total current liabilities	18,275,930	12,020,447
Contingent consideration	—	5,390,000
Other long-term liabilities	1,454,203	1,828,443
Total liabilities	19,730,133	19,238,890
Commitments and contingencies (Note 17)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 40,993,768 and 37,142,946 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	4,090	3,697
Additional paid-in capital	497,342,207	417,337,742
Accumulated deficit	(293,171,423)	(186,420,599)
Accumulated other comprehensive loss, net	(5,040,163)	(5,044,517)
Total stockholders' equity	199,134,711	225,876,323
Total liabilities and stockholders' equity	\$ 218,864,844	\$ 245,115,213

**ALTIMMUNE, INC.
 CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

Three Months Ended December 31,		Year Ended December 31,	
2021	2020	2021	2020

Revenues	\$ 3,277,658	\$ 2,312,706	\$ 4,410,356	\$ 8,185,027
Operating expenses:				
Research and development	20,185,064	8,950,572	74,541,115	49,774,328
General and administrative	3,777,281	4,111,929	15,413,282	13,209,440
Impairment loss on construction-in-progress	3,300,000	—	11,370,000	—
Total operating expenses	<u>27,262,345</u>	<u>13,062,501</u>	<u>101,324,397</u>	<u>62,983,768</u>
Loss from operations	(23,984,687)	(10,749,795)	(96,914,041)	(54,798,741)
Other income (expense):				
Interest expense	61,107	(1,953)	(5,656)	(9,421)
Interest income	114,894	44,360	202,741	322,514
Other (expense) income, net	<u>(80,635)</u>	<u>(24,735)</u>	<u>(373,868)</u>	<u>24,147</u>
Total other (expense) income, net	<u>95,366</u>	<u>17,672</u>	<u>(176,783)</u>	<u>337,240</u>
Net loss before income tax benefit	(23,889,321)	(10,732,123)	(97,090,824)	(54,461,501)
Income tax benefit	—	110,346	—	5,417,024
Net loss	\$ (23,889,321)	\$ (10,621,777)	\$ (97,090,824)	\$ (49,044,477)
Other comprehensive income (loss) — unrealized gain (loss) on short-term investments	—	(2,245)	4,354	(24,361)
Comprehensive loss	\$ (23,889,321)	\$ (10,624,022)	\$ (97,086,470)	\$ (48,017,632)
Net loss per share, basic and diluted	\$ (0.57)	\$ (0.29)	\$ (2.35)	\$ (1.91)
Weighted-average common shares outstanding, basic and diluted	41,705,563	36,295,023	41,283,498	25,637,023



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Source: Altimune, Inc