



Altimune Announces Second Quarter 2021 Financial Results and Provides a Corporate Update

August 10, 2021 at 4:01 PM EDT

12-week Data Readout from ALT-801 Phase 1 Clinical Trial Expected in September

Approximately \$218 Million in Cash and Short-Term Investments to Advance Obesity and Liver Disease Pipeline

GAITHERSBURG, Md., Aug. 10, 2021 (GLOBE NEWSWIRE) -- Altimune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three- and six-months ending June 30, 2021 and provided a corporate update.

"Following data readouts in Q2, Altimune has focused its efforts on our NASH and emerging obesity pipeline with the encouraging interim data from the ALT-801 Phase 1 trial reinforcing the potential of these programs," remarked Vipin K. Garg, Ph.D., President and Chief Executive Officer at Altimune. "Our strong financial position enables us to proceed with a robust ALT-801 development program in the second half of 2021 with the goal of initiating Phase 2 trials in early 2022 for both obesity and NASH indications."

Recent Highlights:

- *Reported encouraging 6-week interim data from the ongoing Phase 1 clinical trial of ALT-801 in Australia*
 - In the study of overweight and obese subjects, a placebo-adjusted weight loss of 6.3% was achieved at 6 weeks of treatment with 1.8 mg once weekly dose, surpassing the 2% pre-established treatment target
 - The multi-dose regimen was well-tolerated without the need for dose titration
 - No subject dropouts related to drug administration reported within the first 6 weeks of treatment
- *Advancing to ALT-801 12-week data readout on three cohorts, expected in September 2021*
 - 12-week data on three dose cohorts at the 1.2mg, 1.8mg and 2.4mg dose levels are expected to be reported. The final 12-week dose for all cohorts has been administered
 - Data readouts are expected to include update on weight loss and adverse events, in addition to the following measures:
 - Pharmacokinetics (PK)
 - Lean body mass, calorie intake, resting energy expenditure (REE)
 - Glucose homeostasis
 - Insulin resistance—HOMA-IR2, adiponectin
 - Lipids (HDL, LDL, TG, & lipoprotein (a))
 - Markers of inflammation
- *Filing of ALT-801 investigational new drug (IND) application for non-alcoholic steatohepatitis (NASH) on track for Q3 2021, which will be followed by the initiation of a clinical trial in non-alcoholic fatty liver disease (NAFLD)*
 - The Phase 1b, 12-week NAFLD study will include diabetic and non-diabetic subjects and is expected to be conducted at approximately 10 US sites
 - Primary efficacy end point will be reduction in liver fat by MRI-PDFF
 - Study expected to enable a 52-week biopsy driven NASH study in Q1 2022
- *IND in obesity expected to be filed in Q4 2021*
 - Phase 2 obesity trial is expected to initiate in Q1 2022
 - Development program expected to include diabetic and non-diabetic subjects
- *Additional clinical development to support NASH and obesity programs during 2021*
 - Phase 1 drug-drug interaction study to initiate in Q4 2021 to evaluate ALT-801 interaction with commonly used drugs
 - 12-week Phase 1 study to initiate in Q4 2021 to evaluate ALT-801 effects on glucose control, hemoglobin A1C and insulin resistance in subjects with type 2 diabetes
- *Initiated development of an oral formulation for ALT-801*
 - Molecular weight and potency of ALT-801 are well-suited for oral administration

Financial Results for the Three and Six Months Ended June 30, 2021

- Altimmune had cash, cash equivalents, short-term investments and restricted cash totaling \$217.9 million at June 30, 2021 compared to \$216.0 million at December 31, 2020. Through utilization of at-the-market (ATM) offerings during the second quarter of 2021, Altimmune raised net proceeds of \$18.2 million and a total of \$52.4 million since the beginning of the year.
- Revenue was \$0.1 million for the three months ended June 30, 2021 compared to \$0.7 million in the same period in 2020. The change in revenue quarter over quarter was primarily due to a decrease in BARDA revenue during the current period due to the timing of clinical trials and development activities for NasoShield.
- Research and development expenses were \$13.3 million for the three months ended June 30, 2021, compared to \$16.6 million in the same period in 2020. The change was primarily the result of increased expenses of \$9.7 million primarily related to development activities for the Company's COVID-19 programs, offset by a decrease of \$13.0 million resulting from changes in the fair value of contingent consideration liability connected with the acquisition and development of ALT-801.
- General and administrative expenses were \$3.7 million for the three months ended June 30, 2021 compared to \$2.5 million in the same period in 2020. The increase during the quarter is primarily due to increased stock compensation expense and additional labor related costs.
- An impairment on construction-in-progress of \$8.1 million was recognized for the three months ended June 30, 2021 related to the build out of a commercial scale manufacturing suite for the Company's recently terminated COVID-19 vaccine program. No impairment was recognized in the prior year.
- Net loss for the three months ended June 30, 2021 was \$24.8 million, or \$0.60 net loss per share, compared to \$16.8 million in the same period in 2020, or \$0.94 net loss per share. Net loss for the six months ended June 30, 2021 was \$39.7 million, or \$0.99 net loss per share, compared to \$20.7 million in the same period in 2020, or \$1.25 net loss per share.

Conference Call Information

Date: Wednesday, August 11, 2021
Time: 8:30 am Eastern Time
Domestic Dial-in: (844) 615-6509
International Dial-in: (918) 922-3148
Conference ID: 9484516
Webcast: <https://edge.media-server.com/mmc/p/nc5cqqtf>

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 Altimmune

Altimmune is a clinical stage biopharmaceutical company focused on developing treatments for obesity and liver diseases. Our pipeline includes next generation peptide therapeutics for obesity, NASH (ALT-801), and chronic hepatitis B (HepTcell™). For more information on Altimmune, 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 readout from the ALT-801 Phase 1 clinical trial in September 2021, the potential start of the ALT-801 12-week NAFLD trial in September 2021, the potential start of the ALT-801 drug/drug interaction trial and Type 2 diabetes trial by year end 2021, the potential filing of a NASH IND in Q3 2021, the potential filing of an obesity IND in Q4 2021, the commencement of a 52-week, Phase 2, biopsy-trial based on NASH endpoints in Q1 2022, the commencement of a 24-week, Phase 2, obesity trial in Q1 2022, the prospects for regulatory approval of our product candidates and 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 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 and commercial supply 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, 2020 filed with the SEC, which is available at www.sec.gov.

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**ALTIMMUNE, INC.
CONSOLIDATED BALANCE SHEETS**

	June 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 174,102,382	\$ 115,917,807
Restricted cash	34,174	34,174
Total cash, cash equivalents and restricted cash	174,136,556	115,951,981
Short-term investments	43,723,840	100,005,558
Accounts receivable	4,463,442	4,610,202
Tax refund receivable	6,887,981	7,762,793
Prepaid expenses and other current assets	9,413,070	1,926,675
Total current assets	238,624,889	230,257,209
Property and equipment, net	4,751,010	1,056,920
Intangible assets, net	12,956,112	12,823,846
Other assets	928,839	977,238
Total assets	\$ 257,260,850	\$ 245,115,213
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,421,192	\$ 612,293
Accrued expenses and other current liabilities	7,674,536	11,408,154
Total current liabilities	9,095,728	12,020,447
Contingent consideration	5,270,000	5,390,000
Other long-term liabilities	1,617,150	1,828,443
Total liabilities	15,982,878	19,238,890
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 39,693,524 and 37,142,946 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	3,956	3,697
Additional paid-in capital	482,083,670	417,337,742
Accumulated deficit	(235,771,414)	(186,420,599)
Accumulated other comprehensive loss, net	(5,038,240)	(5,044,517)
Total stockholders' equity	241,277,972	225,876,323
Total liabilities and stockholders' equity	\$ 257,260,850	\$ 245,115,213

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues	\$ 137,623	\$ 721,636	\$ 975,139	\$ 2,934,330
Operating expenses:				
Research and development	13,272,412	16,594,250	25,150,312	23,781,781

General and administrative	3,658,653	2,545,356	7,480,073	4,877,273
Impairment loss on construction-in-progress	8,070,000	—	8,070,000	—
Total operating expenses	25,001,065	19,139,606	40,700,385	28,659,054
Loss from operations	(24,863,442)	(18,417,970)	(39,725,246)	(25,724,724)
Other income (expense):				
Interest expense	(22,226)	(3,308)	(33,897)	(5,193)
Interest income	32,863	81,458	75,362	233,027
Other income (expense), net	26,098	(5,878)	(7,034)	19,664
Total other income, net	36,735	72,272	34,431	247,498
Net loss before income tax benefit	(24,826,707)	(18,345,698)	(39,690,815)	(25,477,226)
Income tax benefit	—	1,578,782	—	4,824,661
Net loss	(24,826,707)	(16,766,916)	(39,690,815)	(20,652,565)
Other comprehensive income (loss) — unrealized gain (loss) on short-term investments	1,141	20,888	6,277	(11,547)
Comprehensive loss	\$ (24,825,566)	\$ (16,746,028)	\$ (39,684,538)	\$ (20,664,112)
Net loss per share, basic and diluted	\$ (0.60)	\$ (0.94)	\$ (0.99)	\$ (1.25)
Weighted-average common shares outstanding, basic and diluted	41,356,643	17,886,853	40,142,561	16,498,719



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Source: Altimune, Inc.