



Altimune Announces Second Quarter 2020 Financial Results and Provides a Business Update

August 11, 2020 at 4:05 PM EDT

GAITHERSBURG, Md., Aug. 11, 2020 (GLOBE NEWSWIRE) -- Altimune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three and six months ended June 30, 2020 and provided a business update.

"We are pleased with Altimune's progress during 2020 as we have launched two new product candidates for COVID-19, progressed our NASH candidate toward clinical testing and forged strategic alliances with Vigene Biosciences and DynPort Vaccine Company" said Vipin K. Garg, Ph.D., President and Chief Executive Officer. "With the support of our shareholders, we now have more than \$200 million of cash and investments on hand to drive continued development of our product pipeline."

Recent Highlights

- **Received gross proceeds of \$199.4 million from a public offering, warrant exercises and ATM sales since Q1 2020**
Since the first quarter, the Company has received \$132.2 million in gross proceeds from a public offering of common stock and pre-funded warrants, \$40.9 million from warrant exercises and \$26.3 million in gross proceeds from ATM sales. The cash received will be used primarily for the development of AdCOVID and T-COVID, including scale up of manufacturing and advanced clinical trials; the continued development of ALT-801, a dual GLP-1/glucagon receptor agonist for the treatment of non-alcoholic steatohepatitis (NASH), including the first-in-human trial later this year; and for capital expenditures and general working capital purposes.
- **Announced positive preclinical results for AdCOVID**
The Company announced positive results from the preclinical studies of its single-dose intranasal COVID-19 vaccine candidate, AdCOVID. The studies, which were conducted in collaboration with the University of Alabama at Birmingham (UAB), showed strong serum neutralizing activity and potent mucosal immunity in the respiratory tract. The induction of mucosal IgA antibody in the respiratory tract may be necessary to block both infection and transmission of the virus to prevent further spread of COVID-19. Based on these findings, the Company has initiated manufacturing of AdCOVID and plans to advance the vaccine candidate to a Phase 1 safety and immunogenicity study in Q4 of this year.
- **Announced manufacturing agreement with Vigene Biosciences for AdCOVID**
The Company announced that it has entered into an agreement with Vigene Biosciences to manufacture AdCOVID, the Company's single-dose intranasal vaccine candidate for COVID-19. Vigene, a Rockville, Maryland-based award-winning Contract Development and Manufacturing Organization, specializes in viral vectors and will deploy its capabilities to manufacture AdCOVID. Following recent positive pre-clinical data, the Company plans to start a Phase 1 clinical trial of AdCOVID in Q4 2020.
- **Formed teaming agreement with DynPort Vaccine Company for AdCOVID**
The Company announced that it has entered into a teaming agreement with DynPort Vaccine Company (DVC), a General Dynamics Information Technology (GDIT) company, to coordinate U.S. Government funding efforts and, if successful, to provide program management, drug development activity integration, and regulatory support for AdCOVID.
- **Initiated T-COVID program and received \$4.7 million award from the DoD to fund Phase 1/2 clinical trial**
The U.S. Food and Drug Administration (FDA) authorized the Company to proceed with a Phase 1/2 clinical trial of T-COVID, an investigational therapeutic agent for the treatment of early COVID-19. The EPIC Trial (Efficacy and Safety of T-COVID in the Prevention of Clinical Worsening in COVID-19) is being funded through a \$4.7 million competitive award from the U.S. Army Medical Research & Development Command (USAMRDC) and Department of Defense (DoD) working in collaboration with the Medical Technology Enterprise Consortium (MTEC), a 501(c)(3) biomedical technology consortium. Altimune recently initiated multiple clinical sites across the United States and expects that enrollment will commence imminently.
- **Completed enrollment in Phase 1b clinical trial of NasoShield**
The Company completed enrollment in its Phase 1b clinical trial of NasoShield, a single dose intranasal anthrax vaccine candidate. The NasoShield program is being developed under a contract with the Biomedical Advanced Research and Development Authority (BARDA), with a total potential value of \$133.7 million if all options in the contract (HHSO100201600008C) are exercised. At the conclusion of the Phase 1b NasoShield trial, BARDA will have the option of exercising the remaining contract options valued at approximately \$105 million to enable Phase 2 development.
- **Advanced IND-enabling activities for ALT-801 GLP-1/glucagon dual receptor agonist for NASH**

The Company has successfully completed the in-life portion of the safety and toxicological assessment of ALT-801 and is manufacturing the clinical trial material for the first-in-human trial, expected to start in Q4 2020. The single and multiple ascending dose trial will be conducted in Australia and will evaluate the safety and activity of ALT-801 in overweight and obese volunteers. Data from that study, including validation of the compound's weight loss and liver fat-reducing effects, is expected to read out in the spring of 2021.

- **Received HepTcell IND clearance for Phase 2 trial**

The FDA cleared the Company's Investigational New Drug (IND) application to conduct a Phase 2 trial of HepTcell, a peptide-based immunotherapeutic for the treatment of chronic hepatitis B (HBV). The Company is also filing CTAs in Canada and three European countries. Altimune plans to initiate the multinational trial in Q4 of this year, subject to an ongoing assessment of the impact of COVID-19 on study conduct.

Financial Results for the Second Quarter Ended June 30, 2020

- The Company had cash, cash equivalents and short-term investments of \$80.3 million at June 30, 2020. Subsequent to the quarter ended June 30, 2020, the Company received approximately \$136.2 million in net proceeds from the public offering of its common stock, warrant exercises, and ATM sales.
- Revenue was \$0.7 million for the quarter ended June 30, 2020 compared to \$1.6 million in the prior year period. The change was primarily due to a decrease in billings under the Company's U.S. government contracts due to timing of manufacturing and clinical trials for the NasoShield program.
- Research and development expenses were \$16.5 million for the quarter ended June 30, 2020 compared to \$2.9 million in the prior year period. The increase was primarily attributable to an increase in the contingent liability for stock-based milestone payments associated with the acquisition of ALT-801; development costs for IND-enabling preclinical studies for ALT-801; and development costs for the COVID-19 programs. These increases were partially offset by decreased spend on the NasoShield program.
- General and administrative expenses were \$2.5 million for the quarter ended June 30, 2020 compared to \$2.2 million in the prior year period. The increase is attributable to higher employee compensation and legal costs.
- Income tax benefit was \$1.6 million for the three months ended June 30, 2020, as compared to zero for the same period in 2019. The increase is attributable to the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") passed on March 27, 2020 which made temporary changes regarding the utilization and carry back of net operating losses. The Company intends to file a tax refund claim with the Internal Revenue Service reflecting a partial refund of its 2016 tax liability by carrying back net operating losses arising during the three and six months ended June 30, 2020.
- Net loss attributed to common stockholders for the quarter ended June 30, 2020 was \$16.8 million, or \$0.94 net loss per share, compared to \$3.4 million in the prior year, or \$0.26 net loss per share. The difference in net loss is primarily attributable to higher research and development expenses, lower revenue, offset by an increase in income tax benefit.

Conference Call Information

Altimune will host a conference call to discuss the company's second quarter results and other business information.

Date: Wednesday, August 12, 2020
Time: 8:30 am Eastern Time
Domestic: 877-423-9813
International: 201-689-8573
Conference ID: 13706947
Webcast: <http://public.viavid.com/index.php?id=140748>

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 investor relations portion of its website as a means of disclosing material non-public information and for complying with disclosure obligations under Regulation FD.

About Altimune

Altimune is a clinical stage biopharmaceutical company focused on developing intranasal vaccines, immune modulating therapies and treatments for liver disease. Our diverse pipeline includes proprietary intranasal vaccines for COVID-19 (AdCOVID™), anthrax (NasoShield™) and influenza (NasoVAX™); an intranasal immune modulating therapeutic for COVID-19 (T-COVID™); and next generation peptide therapeutics for NASH (ALT-801) and chronic hepatitis B (HepTcell™). For more information on Altimune, please visit www.altimmune.com.

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, statements regarding the impact of COVID-19 on our business operations, clinical trials and results of operations, the timing of key milestones for our clinical assets, the development of our AdCOVID vaccine product candidate and initiation of animal testing in Q2 2020 and a Phase 1 clinical study in Q4 2020 for AdCOVID, the initiation of a Phase 1 clinical study in Q4 2020 for ALT-801 and receipt of data from this clinical study in 2021, the initiation of a Phase 2 clinical trial for HepTcell in Q4 2020, 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 the COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, the reliability of the results of the studies relating to human safety and possible adverse effects resulting from the administration of the Company’s product candidates; funding delays, reductions in or elimination of U.S. government funding and/or non-renewal of expiring funding under the Company’s agreement with Biomedical Advanced Research and Development Authority (“BARDA”), or the Company’s contract with the National Institutes of Allergy and Infectious Diseases (“NIAID”); the Company’s ability to satisfy certain technical milestones under the Company’s contracts with BARDA and NIAID that would entitle the Company to receive additional funding over the period of the agreement; the receipt of future potential payments under government contracts or grants; the Company’s ability to obtain potential regulatory approvals on the timelines anticipated, or at all; the Company’s ability to obtain additional patents or extend existing patents on the timelines anticipated, or at all; the Company’s ability to identify and consummate potential future strategic partnerships; and the Company’s ability to expand its pipeline of products and the success of future product advancements, including the success of future clinical trials, and the Company’s ability to commercialize its products. 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 reports on Form 10-K and quarterly reports on Form 10-Q filed with the SEC, which are available at www.sec.gov.

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ALTIMMUNE, INC.

CONSOLIDATED BALANCE SHEETS

	June 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 64,741,921	\$ 8,962,686
Restricted cash	34,174	34,174
Total cash, cash equivalents and restricted cash	64,776,095	8,996,860
Short-term investments	15,484,402	28,277,386
Accounts receivable	1,182,099	1,021,179
Tax refund receivable	5,506,946	629,096
Prepaid expenses and other current assets	1,020,876	470,228
Total current assets	87,970,418	39,394,749
Property and equipment, net	1,024,640	1,104,208
Right of use asset	662,074	698,321
Intangible assets, net	12,785,655	12,732,195
Other assets	100,980	128,547
Total assets	\$ 102,543,767	\$ 54,058,020
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	\$ 195,217	\$ 18,232
Accrued expenses and other current liabilities	4,089,749	3,904,767
Notes payable	632,000	—
Total current liabilities	4,916,966	3,922,999
Contingent consideration	16,390,000	2,750,000
Other long-term liabilities	1,715,024	1,864,875
Total liabilities	23,021,990	8,537,874
Commitments and contingencies (Note 14)		
Stockholders’ equity:		

Common stock, \$0.0001 par value; 200,000,000 shares authorized; 26,553,957 and 15,312,381 shares issued; 26,553,886 and 15,312,167 shares outstanding at June 30, 2020 and December 31, 2019, respectively	2,635	1,508
Additional paid-in capital	242,579,532	187,914,916
Accumulated deficit	(158,028,687)	(137,376,122)
Accumulated other comprehensive loss, net	(5,031,703)	(5,020,156)
Total stockholders' equity	79,521,777	45,520,146
Total liabilities and stockholders' equity	\$ 102,543,767	\$ 54,058,020

ALTIMMUNE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2020	2019	June 30, 2020	2019
Revenues	\$ 721,636	\$ 1,626,029	\$ 2,934,330	\$ 4,581,622
Operating expenses:				
Research and development	16,594,250	2,945,096	23,781,781	6,162,768
General and administrative	2,545,356	2,231,817	4,877,273	4,298,299
Total operating expenses	19,139,606	5,176,913	28,659,054	10,461,067
Loss from operations	(18,417,970)	(3,550,884)	(25,724,724)	(5,879,445)
Other (expense) income:				
Changes in fair value of warrant liability	—	(46,000)	—	(46,000)
Interest expense	(3,308)	(748)	(5,193)	(1,488)
Interest income	81,458	239,964	233,027	425,211
Other (expense) income, net	(5,878)	(29,220)	19,664	17,528
Total other (expense) income, net	72,272	163,996	247,498	395,251
Net loss before income tax benefit	(18,345,698)	(3,386,888)	(25,477,226)	(5,484,194)
Income tax benefit	1,578,782	—	4,824,661	—
Net loss	(16,766,916)	(3,386,888)	(20,652,565)	(5,484,194)
Other comprehensive loss – unrealized gain (loss) on investments	20,888	—	(11,547)	—
Comprehensive loss	\$ (16,746,028)	\$ (3,386,888)	\$ (20,664,112)	\$ (5,484,194)
Net loss	\$ (16,766,916)	\$ (3,386,888)	\$ (20,652,565)	\$ (5,484,194)
Deemed dividends	—	—	—	(452,925)
Net loss attributed to common stockholders	\$ (16,766,916)	\$ (3,386,888)	\$ (20,652,565)	\$ (5,937,119)
Net loss per share attributed to common stockholders, basic and diluted	\$ (0.94)	\$ (0.26)	\$ (1.25)	\$ (0.52)
Weighted-average common shares outstanding, basic and diluted	17,886,853	13,127,773	16,498,719	11,318,819



Source: Altimune, Inc.