



Altimune Announces Second Quarter 2019 Financial Results and Provides a Business Update

August 13, 2019 at 4:15 PM EDT

Conference Call & Webcast Scheduled for Wednesday, August 14, at 8:30am Eastern Time

GAITHERSBURG, Md., Aug. 13, 2019 (GLOBE NEWSWIRE) -- Altimune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three and six months ended June 30, 2019 and provided a business update.

"2019 continues to be a transformative year for Altimune, as we have met important strategic milestones through the acquisition of our NASH drug candidate, ALT-801, by successfully completing a pre-IND meeting with the FDA on HepTcell, and by obtaining encouraging data on NasoShield," said Vipin K. Garg, Ph.D., President and Chief Executive Officer. "These milestones solidify our value proposition as a biotech company with a diversified product pipeline poised to address large unmet medical needs. We are keenly focused on advancing the development of our product candidates to achieve meaningful inflection points in the near future."

Recent Highlights

- **Acquisition of Spitfire Pharma, Inc. with NASH Candidate ALT-801**

The Company acquired Spitfire Pharma, Inc. including the product candidate ALT-801, a potent GLP-1/Glucagon receptor dual agonist for the treatment of non-alcoholic steatohepatitis (NASH). ALT-801 is a peptide-based therapeutic candidate with balanced agonist activity on the GLP-1 and glucagon receptors and a differentiated PK profile. ALT-801 is designed to treat the underlying metabolic dysfunction that leads to NASH, the most severe form of non-alcoholic fatty liver disease (NAFLD), by acting upstream to block disease progression. The Company is preparing for an IND submission in 2020, with data readouts from a Phase 1 clinical trial anticipated during 2021.

- **HepTcell Successful Pre-IND Meeting with FDA**

The Company successfully completed a pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA) regarding its Phase 2 trial design and manufacturing plans for HepTcell. The FDA provided no objection to the planned study design and patient populations, or plans for manufacturing and product testing, and did not recommend any additional studies for an IND submission and initiation of Phase 2 trials. A recently completed Phase 1 study in chronically infected subjects was performed in the United Kingdom and South Korea where clear evidence of anti-HBV T cell activation in the highly immune-tolerized study population was noted. Altimune intends to conduct a Phase 2 study in the United States in 2020 and the pre-IND meeting was held to obtain feedback from the FDA on the Company's intended development path.

- **NasoShield Investigation Results Point Toward Improved Clinical Performance**

An investigation into the lower than expected Phase 1 immunogenicity of NasoShield has provided compelling data that may resolve the disparate results obtained from the previous preclinical and clinical studies with the intranasal anthrax vaccine. The key finding was that induction of rapid and robust immunity was significantly impacted by the dosing position. In the investigation, nearly 80% of the vaccinated animals survived a lethal challenge when dosed in the standard supine position, compared to 0% survival following dose administration in a sitting position similar to the dosing position used in the Phase 1 study. Based on these results, the Company believes that a simple adjustment to the dosing position in humans will result in significantly higher immunogenicity similar to what was observed during the preclinical development of NasoShield. The Company is in discussions with Biomedical Advanced Research and Development Authority ("BARDA") about next steps for the program. NasoShield is funded through a contract with BARDA (HHSO100201600008C) with a total potential value of \$130 million if all options in the contract are exercised.

- **ALT-702 Preclinical Development Update**

During Q2, the Company received a Notice of Allowance from the United States Patent and Trademark Office for patent application No. 15/968,839, entitled "Immunogenic Compound" related to its immunostimulant product candidate, ALT-702, which, when granted, will be the second issued patent for this product. This candidate is based on a new synthetic peptide conjugate technology platform and represents a new approach in immuno-oncology that can act alone or improve the effectiveness of immune checkpoint inhibitors, oncolytic viruses and other approaches in immuno-oncology. The Company is currently conducting experiments on ALT-702 in murine tumor models and expects to provide an update on the results of these experiments later this year.

Financial Results for the Second Quarter Ended June 30, 2019

- The Company had cash, restricted cash and cash equivalents of \$41.7 million at June 30, 2019. Subsequent to quarter end, the Company collected \$1.5 million in accounts receivable from U.S. government contracts representing payment on outstanding invoices from Q2.

- Revenue in the second quarter was \$1.6 million compared to \$2.4 million in the prior year period. The change was due to a decrease in billings under the Company's U.S. government contracts due to timing of manufacturing and clinical trials.
- Research and development expenses in the second quarter were \$2.9 million compared to \$4.9 million in the prior year period. The decrease was attributable to lower manufacturing and clinical trial costs on its programs offset by transaction costs recognized related to the acquisition of Spitfire Pharma, Inc.
- General and administrative expenses in the second quarter were \$2.2 million compared to \$2.9 million in the prior year period. The decrease was due primarily to a reduction in labor, legal and professional costs.
- Net loss attributed to common stockholders for the second quarter was \$3.4 million, or (\$0.26) per share, compared to \$9.8 million, or (\$10.29) per share in the same period of 2018. The lower net loss is attributable to a \$5.2 million charge related to the warrant liability in 2018, in addition to the changes in revenue, research and development expense, and general and administrative expense described above.

Conference Call Details

Date: Wednesday, August 14, 2019
 Time: 8:30am Eastern Time
 Domestic: 877-423-9813
 International: 201-689-8573
 Conference ID: 13692577
 Webcast: <http://public.viavid.com/index.php?id=135358>

Following the conclusion of the call, the webcast will be available for replay for 30 days on the Investor Relations page of the Company's website at www.altimmune.com.

About Altimmune

Altimmune is a clinical stage biopharmaceutical company focused on developing treatments for liver disease and immune modulating therapies. Our diverse pipeline includes next generation peptide therapeutics for NASH (ALT-801) and chronic hepatitis B (HepTcell™), conjugated immunostimulants for the treatment of cancer (ALT-702) and intranasal vaccines (NasoVAX™ and NasoShield™). For more information or Altimmune, 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, our ability to expand our product pipeline via acquisition or licensing opportunities, the timing of key milestones for our clinical assets, the timing of key milestones for ALT-801, the filing of the IND for ALT-801 in 2020, the initiation of a Phase 1 clinical study in 2020 and receipt of data from this clinical study in 2021, and the prospects for regulatory approval or commercializing ALT-801, the initiation of a NasoShield Phase 1b clinical study, the initiation of a HepTcell Phase 2 clinical study in the U.S. in 2020, the announcement of results later this year on our ALT-702 experiments, the prospects for 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: 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 preservation of the Company's net operating loss carryforwards; the impact of the Tax Cuts and Jobs Act; delays caused by third parties challenging government contracts awarded to the Company; the receipt of future potential payments under government contracts or grants; the Company's ability to identify potential future government contracts or grant awards; 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 or business combinations; 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; the Company's anticipated financial or operational results; the Company's ability to obtain additional capital resources; unforeseen safety and efficacy issues; breaches of data privacy, or disruptions in the Company's information technology systems; and the Company's ability to continue to satisfy the listing requirements of the NASDAQ Global Market. 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
 (unaudited)

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 41,671,738	\$ 33,718,713
Restricted cash	34,174	634,416
Total cash, cash equivalents and restricted cash	41,705,912	34,353,129
Accounts receivable	2,629,840	3,461,938
Tax refund receivable	1,080,559	1,008,973
Prepaid expenses and other current assets	688,862	548,094
Total current assets	46,105,173	39,372,134
Property and equipment, net	1,222,130	1,342,802
Right of use asset	732,380	—
Intangible assets, net	13,760,216	13,851,924
Other assets	156,115	183,682
Total assets	\$ 61,976,014	\$ 54,750,542
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 163,724	\$ 71,596
Accounts payable	270,097	372,860
Accrued expenses and other current liabilities	3,046,567	4,082,949
Total current liabilities	3,480,388	4,527,405
Deferred income taxes	58,500	58,500
Other long-term liabilities	2,212,104	1,852,071
Total liabilities	5,750,992	6,437,976
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 13,451,106 and 9,078,735 shares issued; 13,450,751 and 9,078,238 shares outstanding at June 30, 2019 and December 31, 2018, respectively	1,313	876
Additional paid-in capital	183,604,057	170,207,844
Accumulated deficit	(122,340,185)	(116,855,991)
Accumulated other comprehensive loss – foreign currency translation adjustments	(5,040,163)	(5,040,163)
Total stockholders' equity	56,225,022	48,312,566
Total liabilities and stockholders' equity	\$ 61,976,014	\$ 54,750,542

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

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2019	2018	June 30, 2019	2018
Revenue	\$ 1,626,029	\$ 2,417,140	\$ 4,581,622	\$ 5,108,121
Operating expenses:				
Research and development	2,945,096	4,918,961	6,162,768	10,665,890
General and administrative	2,231,817	2,933,982	4,298,299	5,381,917
Impairment charges	—	—	—	490,676
Total operating expenses	5,176,913	7,852,943	10,461,067	16,538,483
Loss from operations	(3,550,884)	(5,435,803)	(5,879,445)	(11,430,362)
Other income (expense):				
Changes in fair value of warrant liability	(46,000)	(5,228,691)	(46,000)	(3,680,709)
Changes in fair value of embedded derivatives	—	4,912	—	(2,130)
Interest expense	(748)	(1,921)	(1,488)	(2,791)
Interest income	239,964	25,617	425,211	57,206
Other income (expense)	(29,220)	(49)	17,528	257,675

Total other income (expense)	163,996	(5,200,132)	395,251	(3,370,749)
Net loss before income tax benefit	(3,386,888)	(10,635,935)	(5,484,194)	(14,801,111)
Income tax benefit	—	1,497,093	—	2,488,731
Net loss	(3,386,888)	(9,138,842)	(5,484,194)	(12,312,380)
Other comprehensive income (loss) – foreign currency translation adjustments	—	(1,078,648)	—	(463,177)
Comprehensive loss	\$ (3,386,888)	\$ (10,217,490)	\$ (5,484,194)	\$ (12,775,557)
Net loss	\$ (3,386,888)	\$ (9,138,842)	\$ (5,484,194)	\$ (12,312,380)
Preferred stock accretion and other deemed dividends	—	(700,093)	(452,925)	(2,591,414)
Net loss attributed to common stockholders	\$ (3,386,888)	\$ (9,838,935)	\$ (5,937,119)	\$ (14,903,794)
Weighted-average common shares outstanding, basic and diluted	13,127,773	956,057	11,318,819	817,077
Net loss per share attributed to common stockholders, basic and diluted	\$ (0.26)	\$ (10.29)	\$ (0.52)	\$ (18.24)



Source: Altimune, Inc.