Altimmune Announces First Quarter 2020 Financial Results and Provides a Business Update

May 13, 2020

GAITHERSBURG, Md., May 13, 2020 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the quarter ended March 31, 2020 and provided a business update.

“Throughout 2020 we have put significant effort into developing our pipeline; from advancing our vaccine candidates, AdCOVID and Nasoshield, to IND enabling studies and manufacturing for ALT-801 and HepTcell,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer. “Based on our progress, we are poised for a data-rich year, with the expected initiation of NasoShield, ALT-801 and AdCOVID clinical trials.”

Recent Highlights

- **Preclinical testing commences on COVID-19 vaccine candidate, AdCOVID**
  In collaboration with the University of Alabama at Birmingham (UAB), we have commenced preclinical testing of candidates for our COVID-19 vaccine, AdCOVID. AdCOVID is being developed as a single dose, intranasal vaccine that is designed to activate multiple arms of the immune system including humoral (antibodies), cellular (T-cell) and mucosal immunity.

  Our platform vaccine technology is ideally suited for pandemic use and based on Phase 2 clinical data obtained with our influenza vaccine candidate, NasoVAX, AdCOVID is expected to meet or exceed key attributes of the World Health Organization’s (WHO) preferred Target Product Profile (TPP) for a COVID-19 vaccine:

WHO Preferred Attribute (TPP)[1]	**AdCOVID Expected Attribute (based on NasoVAX data)**
Single dose	Seroprotection with single dose administration
Rapid onset of protection	Strong serological response at 2 weeks
Immunity lasting at least 1 year	Serological response unchanged at 400 days
Non-injected	Intranasal administration
Temperature stability	At least 3 months at 25^{o}C in a liquid formulation
Ability to provide at low cost	High yield, scalable manufacturing process

[1] *https://www.who.int/blueprint/priority-diseases/key-action/WHO_Target_Product_Profiles_for_COVID-19_web.pdf*

It is expected that the studies at UAB will confirm the broad and robust immune response of the vaccine technology and identify the best vaccine candidate for clinical development. The Company is finalizing manufacturing plans, and intends to conduct a Phase 1 clinical trial of AdCOVID in Q4 of this year.

- **NasoShield Phase 1b trial expected to begin in June**
  The Phase 1b clinical trial of Nasoshield, our single-dose intranasal anthrax vaccine candidate, is expected to commence in June of this year. A data readout is expected in November 2020 and will inform BARDA’s decision to exercise the remaining options on the contract. The NasoShield program is funded through a contract with BARDA (HHSO100201600008C), with a total potential value of $133.7 million if all options in the contact are exercised. NasoShield is the only single dose vaccine candidate for anthrax currently funded by BARDA. NasoShield’s intranasal route of administration allows for administration without injections and its stability at room temperature may permit distribution without cold chain.

- **ALT-801 manufacturing commences**
  We have commenced manufacturing of the clinical trial material for ALT-801, our dual GLP-1/glucagon receptor agonist for the treatment of non-alcoholic steatohepatitis (NASH). The combination of GLP-1 and glucagon agonism within the same molecule is ideal for treating obesity, the basic underlying cause of NASH. In animal studies, ALT-801 resulted in more than twice the weight loss of semaglutide and greater improvement in histologic measures of fatty liver, liver inflammation, and fibrosis. The Company is currently completing toxicology studies that will enable the commencement of clinical trials in Q4 2020.

- **HepTcell manufacturing completed, IND filing expected next week**
  We have completed manufacturing for HepTcell, our synthetic peptide immunotherapeutic candidate designed to break immune tolerance in patients with chronic hepatitis B (HBV) infection. The completion of this activity enables the filing of our IND, which is expected next week. The planned Phase 2 trial is a 6-month course of treatment in chronically infected HBV patients in both North America and Europe. Considering this is a multi-site, multi-national study with a long duration of treatment, the Company is actively monitoring the COVID-19 situation and will determine the actual start date of this trial once more information becomes available.

- **Diane Jorkosky, M.D. joins Altimmune Board of Directors**
  Former Pfizer and GSK executive, Diane Jorkasky, M.D., joined Altimmune's Board of Directors on May 11, 2020. Dr. Jorkasky's experience in the biopharmaceutical industry, academia and as a physician bring valuable experience to Altimmune.

Financial Results for the Quarter Ended March 31, 2020

- The Company had cash, cash equivalents and short-term investments of $33 million at March 31, 2020.

- The Company's income tax receivable increased $3.4 million primarily due to an expected cash tax refund claim of $2.9 million with the Internal Revenue Service reflecting a partial refund of its 2016 tax liability by carrying back its 2019 and 2018 net operating losses. Additionally, the Company estimates it will claim $0.36 million related to net operating losses arising during the three months ended March 31, 2020. The expected refund claims are due 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.

- Revenue was $2.2 million for the quarter ended March 31, 2020 compared to $3 million in the prior year period. The change was due primarily 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 $7.2 million for the quarter ended March 31, 2020 compared to $3.2 million in the prior year period. The increase was primarily attributable to development costs for IND-enabling preclinical studies for ALT-801; an increase in the contingent liability for stock-based milestone payments associated with the acquisition of ALT-801; and an increase in employee compensation and professional services. These increases were offset by decreased spend for NasoShield.

- General and administrative expenses were $2.3 million for the quarter ended March 31, 2020 compared to $2.1 million in the prior year period. The increase is attributable to higher employee compensation and legal costs.

- Other income (expense) was $0.2 million for the quarter ended March 31, 2020 compared to $0.2 million in the prior year. Income for both periods is primarily attributable to interest earned on cash and investment balances.

- Income tax benefit was $3.2 million for the three months ended March 31, 2020, as compared to zero for the same period in 2019. The increase is attributable to the income tax refund claims described above related to the "CARES Act".

- Net loss attributed to common stockholders for the quarter ended March 31, 2020 was $3.9 million, or ($0.26) per share, compared to $2.6 million in the prior year, or ($0.27) per share. The difference in net loss is primarily attributable to higher research and development expenses, lower revenue, offset by an increase to income tax benefit.

Conference Call Information

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

Date:	Thursday, May 14, 2020
Time:	8:30 am Eastern Time
Domestic:	855-327-6837
International:	631-891-4304
Conference ID:	10009533
Webcast:	http://public.viavid.com/index.php?id=139687

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 Altimmune
Altimmune is a clinical stage biopharmaceutical company focused on developing treatments for liver disease, immune modulating therapies and vaccines. Our diverse pipeline of product candidates 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™, NasoShield™ an AdCOVID™). For more information on 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, 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 filing of the IND for ALT-801 in 2020, the initiation of a

Phase 1 clinical study in Q4 2020 and receipt of data from this clinical study in 2021, the initiation of a NasoShield Phase 1b clinical study in June 2020 and receipt of data from this clinical study November 2020, the filing of the IND for HepTcell in 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 preservation of the Company's net operating loss carryforwards; 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

	March 31, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,275,214	$ 8,962,686
Restricted cash	34,174	34,174
Total cash, cash equivalents and restricted cash	11,309,388	8,996,860
Short-term investments	21,644,214	28,277,386
Accounts receivable	1,994,736	1,021,179
Tax refund receivable	3,989,728	629,096
Prepaid expenses and other current assets	698,905	470,228
Total current assets	39,636,971	39,394,749
Property and equipment, net	1,062,834	1,104,208
Right of use asset	680,826	698,321
Intangible assets, net	12,737,735	12,732,195
Other assets	114,764	128,547
Total assets	$ 54,233,130	$ 54,058,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 929,629	$ 18,232
Accrued expenses and other current liabilities	5,115,694	3,904,767
Total current liabilities	6,045,323	3,922,999
Contingent consideration	4,500,000	2,750,000
Other long-term liabilities	1,791,190	1,864,875
Total liabilities	12,336,513	8,537,874
Commitments and contingencies (Note 13)		
Stockholders' equity:		

Common stock, $0.0001 par value; 200,000,000 shares authorized; 15,359,644 and 15,312,381 shares issued; 15,359,502 and 15,312,167 shares outstanding at March 31, 2020 and December 31, 2019, respectively	1,514	1,508
Additional paid-in capital	188,209,465	187,914,916
Accumulated deficit	(141,261,771)	(137,376,122)
Accumulated other comprehensive loss, net	(5,052,591)	(5,020,156)
Total stockholders' equity	41,896,617	45,520,146
Total liabilities and stockholders' equity	$ 54,233,130	$ 54,058,020

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

	For the Three Months Ended March 31,	
	2020	**2019**
Revenue	$ 2,212,694	$ 2,955,592
Operating expenses:		
Research and development	7,187,531	3,217,671
General and administrative	2,331,917	2,066,482
Total operating expenses	9,519,448	5,284,153
Loss from operations	(7,306,754)	(2,328,561)
Other income (expense):		
Interest expense	(1,885)	(740)
Interest income	151,569	185,246
Other income, net	25,542	46,749
Total other income, net	175,226	231,255
Net loss before income tax benefit	(7,131,528)	(2,097,306)
Income tax benefit	3,245,879	—
Net loss	(3,885,649)	(2,097,306)
Other comprehensive loss – unrealized loss on investments	(32,435)	—
Comprehensive loss	$ (3,918,084)	$ (2,097,306)
Net loss	$ (3,885,649)	$ (2,097,306)
Deemed dividends	—	(452,925)
Net loss attributed to common stockholders	$ (3,885,649)	$ (2,550,231)
Weighted-average common shares outstanding, basic and diluted	15,110,585	9,489,765
Net loss per share attributed to common stockholders, basic and diluted	$ (0.26)	$ (0.27)

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Source: Altimmune, Inc.