Altimmune Announces Financial Results for the Year Ended December 31, 2020 and Provides a Corporate Update

February 25, 2021

Enrollment in the Phase 1 AdCOVID™ Clinical Trial has Commenced

Development of AdCOVID Vectors Targeting Emerging Variants of the SARS-CoV-2 Virus has Begun

ALT-801 is Progressing Through the Phase 1 Clinical Trial

Solidly Capitalized to Advance Pipeline Candidates with $216 Million in Cash and Short-Term Investments at Year-End

GAITHERSBURG, Md., Feb. 25, 2021 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the year ended December 31, 2020 and provided a corporate update.

“The past year has been a transformative time for our Company as we made substantial progress in each of our five portfolio programs,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer. “During the year we initiated multiple clinical trials for several of our product candidates (T-COVID™, ALT-801 and HepTcell™) and completed preparations to begin a Phase 1 clinical trial of AdCOVID, which has begun enrolling volunteers. These achievements have set the stage for a busy and exciting year ahead, as we anticipate multiple data readouts from these programs over the coming months. With two promising technology platforms and five novel product candidates now advancing in clinical development, we believe 2021 has the potential to be a momentous year for Altimmune.”

Program Highlights

AdCOVID:

- **Commenced enrollment in AdCOVID Phase 1 clinical trial evaluating a novel, needle-free intranasal delivery approach for COVID-19 vaccination**

Altimmune has commenced enrollment in its Phase 1 clinical trial of AdCOVID, which is designed to evaluate a needle-free intranasal delivery approach for vaccination against COVID-19. Altimmune believes AdCOVID has the potential to become a leading candidate for COVID-19 vaccination based on its ease of administration, and the potential for reduced disease transmission, and cold chain-free vaccine distribution, if the product is demonstrated to have extended stability at room temperature. As demonstrated in the NasoShield and NasoVax clinical trials, the Company believes the expected attributes of AdCOVID make it ideally suited for use in a pediatric setting as the intranasal administration and expected tolerability profile are well suited to meet the needs of children.

The Phase 1 clinical trial will evaluate the safety and immunogenicity of AdCOVID in up to 180 healthy adult volunteers between the ages of 18 and 55. Subjects will receive AdCOVID at one of three dose levels administered as a nasal spray. In addition to the primary study endpoint of safety and tolerability, the immunogenicity of AdCOVID will be evaluated by serum IgG binding and neutralizing antibody titers, mucosal IgA antibody from nasal samples, and T cell responses. Altimmune anticipates having a full data readout from this Phase 1 study in Q2 2021.

- **Initiated development of additional AdCOVID vectors targeting emerging SARS-CoV-2 variants**

The emergence of SARS-CoV-2 variants is raising concerns about the effectiveness of currently authorized vaccines and prompting vaccine developers to engineer new vaccine candidates to combat these viral mutations. Altimmune has initiated the development of vaccine candidates against several variants as one is likely to become dominant in the population in the coming months. Altimmune plans to have these new vaccine candidates ready for use in upcoming later-stage clinical trials.

- **Established a consortium of manufacturing partners for potential commercial supply of AdCOVID**

Altimmune has executed agreements with three commercial manufacturing partners with significant experience in adenoviral vector production. The Company has also established relationships with leading drug product fill/finish partners with sufficient capacity to meet potential commercial demand. Together, the Company believes that this network of strategic manufacturing partners will ensure Altimmune’s commercial readiness to supply vaccine, assuming the clinical data support this advancement.

- **Furthered AdCOVID preclinical studies in collaboration with the University of Alabama at Birmingham (UAB) and Saint Louis University**

Based on the promising preclinical data for AdCOVID published on the BioRxiv server, Altimmune continues preclinical studies of AdCOVID in collaboration with UAB and Saint Louis University to evaluate AdCOVID in additional animal models and to further evaluate heterologous prime boost regimens of AdCOVID in support of future clinical development activities. Data from these ongoing preclinical studies are expected in Q1 and Q2 2021.

ALT-801:

- **Commenced dosing in a Phase 1 clinical trial of ALT-801, a novel GLP-1/glucagon dual-agonist being evaluated for the treatment of NASH**

Altimmune commenced dosing in a Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) clinical trial of ALT-801, a GLP-1/glucagon dual-agonist being developed for the treatment of NASH. This trial is being conducted in Australia and is expected to enroll approximately 100 volunteers. The primary pharmacodynamic endpoints in the trial are weight loss and reduction in liver fat, outcomes that have been associated with NASH resolution and fibrosis improvement in advanced clinical studies of other NASH therapeutics. The Company has successfully completed the initial phases of the study and anticipates a data read-out from the 6-week MAD study in Q2 2021, followed by 12-week data in Q3 2021.

- **Amended clinical trial protocol to extend MAD cohorts to incorporate 12-week Phase 1b study in Australia**

Altimmune amended the clinical trial protocol for the ALT-801 Phase 1 clinical development program to incorporate its planned 12-week extension trial in patients with non-alcoholic fatty liver disease or NAFLD within the ongoing Phase 1 SAD/MAD trial in Australia. The Company believes that by incorporating the 12-week extension into this trial, it can avoid any potential impact of COVID-19 and maintain study timelines. Pending the results of this trial, Altimmune plans to transition rapidly to a 52-week, Phase 2, biopsy-trial based on NASH endpoints in early 2022. In parallel with these efforts, Altimmune continues to plan to file an Investigational New Drug (IND) application for ALT-801 in the United States in mid-2021.

- **Initiated chronic toxicology studies of ALT-801 to enable 52-week Phase 2 clinical study**

Altimmune completed 6-week and 13-week GLP toxicology studies of ALT-801 with no significant toxicity or GI adverse events. The Company has initiated 6-month and 9-month GLP toxicology studies to support the planned 52-week biopsy-driven Phase 2 trial planned for early 2022.

T-COVID:

- **Completed Cohorts 1 and 2 in the Phase 1/2 trial of T-COVID in patients with early COVID-19**

Altimmune, working with the Department of Defense, has completed the two safety cohorts in the EPIC (***E**fficacy and Safety of T-COVID in the **P**revention of Clinical Worsening **i**n **C**OVID-19*) study, a Phase 1/2 clinical trial of T-COVID, an investigational intranasally-administered therapeutic for the treatment of early COVID-19 infection. The trial is being overseen by an independent Data Safety Monitoring Committee, and no significant safety findings have been observed to date.

Cohort 3 is an efficacy and safety cohort that will include patients at higher-risk for severe COVID-19 infection, such as those 65 years or older, or those with one or more risk factors for severe COVID-19 complications. To ensure that a sufficient number of higher risk patients are enrolled, the study protocol was recently modified to require that a minimum number of patients meet one or more of these criteria in this final cohort. Additional enrichments of the study population are currently being evaluated to increase the event rates in the trial. While these modifications could extend the study timeline, the Company believes they could significantly enhance the probability of a meaningful trial outcome. Based on these changes, data from this trial is now expected in Q2 2021.

HepTcell:

- **Commenced dosing in a multinational Phase 2 clinical trial of HepTcell**

In December, Altimmune began a multinational Phase 2 clinical trial of HepTcell, which is being conducted in the United States, Canada and Europe. The trial is a double-blind, randomized, placebo-controlled trial of 80 adult patients with HBeAg-negative inactive CHB and HBsAg ≤ 100 IU/mL.

HepTcell will be administered in 6 doses at 4-week intervals for 24 weeks, and patients will be followed for one year to evaluate safety and durability of response. The primary efficacy endpoint is virological response, defined as a 1-log reduction in HBsAg levels from baseline. Secondary efficacy endpoints include reactivation of anti-HBV T cell responses, HBsAg clearance, and other assessments of virologic response. Altimmune anticipates a data read-out from this trial in 1H 2022.

Financial Results for the Year Ended December 31, 2020

- Altimmune had cash, cash equivalents and short-term investments of $216.0 million at December 31, 2020 compared to $37.3 million at December 31, 2019. The increase of $178.7 million is attributable to $213.5 million of net receipts during the year due primarily to its 2020 public offering, full utilization of the at-the-market offering program, and receipts from warrant exercises, offset by $34.4 million of cash used for operating activities.
- Revenue was $8.2 million for the year ended December 31, 2020 compared to $5.8 million in the prior year period, an increase of $2.4 million. The change was primarily due to an increase in revenue under the Company's U.S. government contracts due to timing of manufacturing and clinical trials for the NasoShield and T-COVID programs.
- Research and development expenses were $49.8 million for the year ended December 31, 2020, compared to $17.8 million in the prior year period, representing an increase of $32.0 million. The increase was primarily attributable to increased costs related to development of AdCOVID, T-COVID and ALT-801 and an increase in the contingent liability for stock-based milestone payments associated with the acquisition of ALT-801.
- General and administrative expenses were $13.2 million for the year ended December 31, 2020 compared to $8.5 million in the prior year period, an increase of $4.7 million. The increase is attributable to additional employee compensation as Altimmune's workforce grew in 2020 along with an increase in professional costs.
- Income tax benefit was $5.4 million for the year ended December 31, 2020, as compared to $59,000 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.

- Net loss attributed to common stockholders for the year ended December 31, 2020 was $49.0 million, or $1.91 net loss per share, compared to $21.0 million in the prior year, or $1.60 net loss per share. The difference in net loss is primarily attributable to higher research and development expenses and general and administrative expenses, offset by higher revenue and an increase in income tax benefit.

Conference Call Information

Date:	Thursday, February 25, 2021
Time:	8:30 am Eastern Time
Domestic Dial-in:	877-423-9813
International Dial-in:	201-689-8573
Conference ID:	13716171
Webcast:	http://public.viavid.com/index.php?id=143423

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 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 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 and efficacy of vaccine candidates for SARS-CoV-2 variants, the data read-out for our Phase 1 clinical trial of AdCOVID in Q2 2021, the data readout from our T-COVID trial in Q2 2021, the data read-out from our Phase 1 clinical study for ALT-801 in Q1 2021, the plan to file an IND application for ALT-801 in mid-2021, the data read-out from our Phase 2 clinical trial of HepTcell in 1H 2022, 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 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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 115,917,807	$ 8,962,686

Restricted cash	34,174	34,174
Total cash, cash equivalents and restricted cash	115,951,981	8,996,860
Short-term investments	100,005,558	28,277,386
Accounts receivable	4,610,202	1,021,179
Tax refund receivable	7,762,793	629,096
Prepaid expenses and other current assets	1,926,675	470,228
Total current assets	230,257,209	39,394,749
Property and equipment, net	1,056,920	1,104,208
Right of use asset	903,825	698,321
Intangible assets, net	12,823,846	12,732,195
Other assets	73,413	128,547
Total assets	$ 245,115,213	$ 54,058,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 612,293	$ 18,232
Accrued expenses and other current liabilities	11,408,154	3,904,767
Total current liabilities	12,020,447	3,922,999
Contingent consideration	5,390,000	2,750,000
Other long-term liabilities	1,828,443	1,864,875
Total liabilities	19,238,890	8,537,874
Commitments and contingencies (Note 17)		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 37,142,946 and 15,312,381 shares issued; 37,142,946 and 15,312,167 shares outstanding at December 31, 2020 and 2019, respectively	3,697	1,508
Additional paid-in capital	417,337,742	187,914,916
Accumulated deficit	(186,420,599)	(137,376,122)
Accumulated other comprehensive loss, net	(5,044,517)	(5,020,156)
Total stockholders' equity	225,876,323	45,520,146
Total liabilities and stockholders' equity	$ 245,115,213	$ 54,058,020

ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,	
	2020	**2019**
Revenues	$ 8,185,027	$ 5,801,401
Operating expenses:		
Research and development	49,774,328	17,765,553
General and administrative	13,209,440	8,500,783
Impairment charge	—	1,000,000
Total operating expenses	62,983,768	27,266,336
Loss from operations	(54,798,741)	(21,464,935)
Other income (expense):		
Changes in fair value of warrant liability	—	30,000
Interest expense	(9,421)	(2,244)
Interest income	322,514	843,409
Other income, net	24,147	15,139
Total other income, net	337,240	886,304
Net loss before income tax benefit	(54,461,501)	(20,578,631)
Income tax benefit	5,417,024	58,500
Net loss	(49,044,477)	(20,520,131)
Other comprehensive (loss) income — unrealized (loss) gain on investments	(24,361)	20,007
Comprehensive loss	$ (49,068,838)	$ (20,500,124)
Net loss	$ (49,044,477)	$ (20,520,131)
Deemed dividends	—	(452,925)
Net loss attributable to common stockholders	$ (49,044,477)	$ (20,973,056)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.91)	$ (1.60)
Weighted-average common shares outstanding, basic and diluted	25,637,023	13,124,951

Source: Altimmune, Inc.