Altimmune Announces First Quarter 2021 Financial Results and Provides a Corporate Update

May 17, 2021

Data Readouts from Phase 1 AdCOVID™ and ALT-801 Clinical Trials Expected in June

Approximately $227 Million in Cash and Short-Term Investments to Advance Pipeline

GAITHERSBURG, Md., May 17, 2021 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three months ending March 31, 2021 and provided a corporate update.

"With AdCOVID™, our single-dose intranasal vaccine candidate for COVID-19 and ALT-801, our GLP-1/glucagon dual agonist candidate for non-alcoholic steatohepatitis (NASH) now advancing in the clinic, 2021 has the potential to be a data-rich period for the Company," remarked Vipin K. Garg, Ph.D., President and Chief Executive Officer at Altimmune. "We anticipate data readouts from both of these clinical trials in June. If the data from the AdCOVID Phase 1 trial are positive, we plan to quickly transition into a comprehensive global Phase 2 clinical development program. We strongly believe that a vaccine candidate like AdCOVID, which can be administered via a simple nasal spray along with what we hope will be an excellent safety and tolerability profile, could become an important tool for the global COVID-19 vaccination effort."

Dr. Garg continued, "ALT-801 is also progressing as planned through its first-in-human clinical trial in Australia and we anticipate 6-week data to be available later this quarter. We are excited about the potential of ALT-801, and hope that clinical studies will show ALT-801 can deliver similar therapeutic benefits to current GLP-1 based treatment options in development but without the GI intolerability that leads to treatment discontinuation. The NASH opportunity, together with a potential indication in obesity, could be very large for ALT-801 and early clinical success could have a dramatic effect on Altimmune's growth."

Recent Highlights:

AdCOVID, a novel, needle-free, intranasal vaccine candidate for COVID-19

- *Enrollment target met in amended AdCOVID Phase 1 clinical trial evaluating the safety and immunogenicity of AdCOVID in healthy volunteers*
    - The Phase 1 trial will measure systemic antibody responses including serum neutralizing antibody, T cell responses and mucosal IgA, a measure of mucosal immunity in the nasopharyngeal cavity
    - The study protocol was amended to reduce the number of adult subjects to approximately 80. The amendment was necessary due to the widespread availability of authorized vaccines. The final sample size of the study is comparable to the number of participants in Phase 1 studies of the U.S. authorized vaccines
    - A topline data readout is anticipated in June 2021
- *Progressed development of adapted AdCOVID vaccine candidates targeting emerging SARS-CoV-2 variants*
    - Initiated preclinical evaluation of AdCOVID vaccine candidates targeting E484K variants, including P.1, B.1.351 and B.1.617
    - Initiation of a Phase 2 trial with a variant AdCOVID vaccine candidate expected in Q4 2021
- *Expanded manufacturing capabilities through an agreement with Lonza to commission a dedicated manufacturing suite for clinical and potential future commercial supply*
    - Complements and extends existing network of strategic manufacturing partners, building extra capacity and redundancy into the AdCOVID manufacturing effort
    - Supports manufacturing of clinical supply material for potential late-stage clinical trials and commercial scale
- *Announced new data from preclinical studies conducted in collaboration with the University of Alabama at Birmingham (UAB)*

In these preclinical studies, a single intranasal dose of AdCOVID provided:

- 100% protection against a lethal challenge from the SARS-CoV-2 virus, with 1000-fold reduction of replicating virus in the nasal cavity and respiratory tract following infection with SARS-CoV-2
- Sterilizing immunity, i.e., undetectable levels of infectious virus in the lungs, believed to be essential to fully block viral transmission
- Long-lived systemic and mucosal immune responses, which were essentially unchanged over 6 months

- *Established plans for a robust Phase 2 clinical development program, which is anticipated to include:*
    - A multi-national study in adults 18 years of age and older in regions where vaccine access has been limited
    - An evaluation of AdCOVID as a potential booster for previously-infected and vaccinated individuals using a parental and P.1 variant AdCOVID vaccine
    - An age-based de-escalation study in children and adolescents
    - A study evaluating safety and immunogenicity in mother-infant pairs

ALT-801, a novel GLP-1/glucagon dual agonist candidate for NASH

- *Progressed ongoing Phase 1 clinical trial of ALT-801 in Australia*
    - Completed enrollment in the single ascending dose (SAD) phase and 3 planned cohorts of multiple ascending dose (MAD) phase of the trial, with 6-week data anticipated in June 2021, and 12-week data anticipated in Q3 2021
    - Plans to commence a 52-week, Phase 2, biopsy-trial based on NASH endpoints in early 2022
    - Anticipated mid-year IND filing to initiate U.S. NASH studies
- *Potential filing of a second IND for an obesity indication in 2H 2021*
    - The filing of a second IND in obesity in 2H 2021 is being evaluated, with the final decision based on the weight loss data from the upcoming Phase 1 trial readout

Other programs

- Continued progress in Phase 1/2 clinical trial of T-COVID, a therapeutic candidate for the treatment of SARS-CoV-2 and other respiratory infections, and a Phase 2 clinical trial of HepTcell, an immunotherapeutic candidate for the treatment of chronic hepatitis B

Financial Results for the Three Months Ended March 31, 2021

- Altimmune had cash, cash equivalents and short-term investments totaling $226.5 million at March 31, 2021 compared to $216.0 million at December 31, 2020. The increase is primarily attributable to $34.2 million of net receipts during the quarter due to its utilization of the at-the-market offering program, partially offset by $19.6 million of cash used for operating activities.
- Revenue was $0.8 million for the three months ended March 31, 2021 compared to $2.2 million in the prior period, a decrease of $1.4 million. The change in revenue quarter over quarter was primarily due to a decrease of $2.0 million in BARDA revenue during the current period due to the timing of clinical trials and development activities for NasoShield, partially offset by $0.5 million in revenue attributable to T-COVID.
- Research and development expenses were $11.9 million for the three months ended March 31, 2021, compared to $7.2 million in the prior period, representing an increase of $4.7 million. The change was primarily the result of increased expenses of $5.4 million related to development activities for the Company's COVID-19 programs, partially offset by a decrease of $1.5 million resulting from a decrease in the fair value of contingent consideration liability connected with the acquisition and development of ALT-801.
- General and administrative expenses were $3.8 million for the three months ended March 31, 2021 compared to $2.3 million in the prior period, an increase of $1.5 million. The increase during the quarter is primarily due to increased stock compensation expense and additional labor related costs.
- Net loss for the three months ended March 31, 2021 was $14.9 million, or $0.38 net loss per share, compared to $3.9 million in the prior period, or $0.26 net loss per share. The difference in net loss is primarily attributable to higher research and development expenses and general and administrative expenses.

Conference Call Information

Date:	Monday, May 17, 2021
Time:	8:30 am Eastern Time
Domestic Dial-in	877-423-9813
International Dial-in:	201-689-8573
Conference ID:	13719206
Webcast:	http://public.viavid.com/index.php?id=144634

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.

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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 AdCOVID Phase 1 clinical trial in June 2021, the potential start of the AdCOVID Phase 2 clinical program in Q2 2021, the potential immunization effects of AdCOVID, the potential of AdCOVID to block SARS-CoV-2 transmission, the shipping and storage requirements for AdCOVID, our ability to manufacture AdCOVID for our clinical trials and commercial needs, the expected completion of the single ascending dose (SAD) and multiple ascending dose (MAD) phases of the ALT-801 study, with 6-week data expected in June 2021 and 12-week data in Q3 2021, the anticipated mid-year IND filing for ALT-801, the commencement of a 52-week, Phase 2, biopsy-trial based on NASH endpoints in early 2022, the HepTcell Phase 2 clinical efficacy trial data readout anticipated in 1H 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; the Company's ability to secure manufacturing approval from its SARS-CoV-2 cell licensor 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

	March 31, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 149,932,387	$ 115,917,807
Restricted cash	34,174	34,174
Total cash, cash equivalents and restricted cash	149,966,561	115,951,981
Short-term investments	76,574,768	100,005,558
Accounts receivable	4,801,428	4,610,202
Tax refund receivable	7,898,067	7,762,793
Prepaid expenses and other current assets	5,950,999	1,926,675
Total current assets	245,191,823	230,257,209
Property and equipment, net	5,198,052	1,056,920
Right of use asset	866,336	903,825
Intangible assets, net	12,879,247	12,823,846
Other assets	115,300	73,413

Total assets	$ 264,250,758	$ 245,115,213
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 418,243	$ 612,293
Accrued expenses and other current liabilities	9,405,649	11,408,154
Total current liabilities	9,823,892	12,020,447
Contingent consideration	6,270,000	5,390,000
Other long-term liabilities	1,719,438	1,828,443
Total liabilities	17,813,330	19,238,890
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 38,257,180 and 37,142,946 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	3,810	3,697
Additional paid-in capital	462,417,706	417,337,742
Accumulated deficit	(210,944,707)	(186,420,599)
Accumulated other comprehensive loss, net	(5,039,381)	(5,044,517)
Total stockholders' equity	246,437,428	225,876,323
Total liabilities and stockholders' equity	$ 264,250,758	$ 245,115,213

ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Three Months Ended March 31,	
	2021	**2020**
Revenues	$ 837,516	$ 2,212,694
Operating expenses:		
Research and development	11,877,900	7,187,531
General and administrative	3,821,420	2,331,917
Total operating expenses	15,699,320	9,519,448
Loss from operations	(14,861,804)	(7,306,754)
Other income (expense):		
Interest expense	(11,671)	(1,885)
Interest income	42,499	151,569
Other (expense) income, net	(33,132)	25,542
Total other (expense) income, net	(2,304)	175,226
Net loss before income tax benefit	(14,864,108)	(7,131,528)
Income tax benefit	—	3,245,879
Net loss	(14,864,108)	(3,885,649)
Other comprehensive income (loss) – unrealized gain (loss) on investments	5,136	(32,435)
Comprehensive loss	$ (14,858,972)	$ (3,918,084)
Net loss per share, basic and diluted	$ (0.38)	$ (0.26)
Weighted-average common shares outstanding, basic and diluted	38,914,990	15,110,585

Source: Altimmune, Inc.