



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

November 9, 2020

GAITHERSBURG, Md., Nov. 09, 2020 (GLOBE NEWSWIRE) -- Altimune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three and nine months ended September 30, 2020 and provided a business update.

"2020 has been a transformational year for Altimune as our pipeline continues to mature and we progress five novel investigational candidates into clinical development," said Vipin K. Garg, Ph.D., President and Chief Executive Officer. "The third quarter has been an especially productive time as we completed preparations to advance AdCOVID™, ALT-801 and HepTcell™ into the clinic this year, and we executed on our ongoing T-COVID and NasoShield trials. With this roster of intranasal vaccine candidates and peptide therapeutics, we are well positioned to achieve meaningful inflection points during 2021."

Recent Highlights

- **Announced positive preclinical results for AdCOVID**

Altimune shared the details of its preclinical immunogenicity studies on the BioRxiv server (www.biorxiv.org/content/10.1101/2020.10.10.331348v1). The report shows intranasal administration of AdCOVID stimulated a strong induction of neutralizing antibodies in serum and a CD8+ killer T cell response focused in the lungs of vaccinated mice. Unique among the leading COVID-19 vaccine candidates, AdCOVID also stimulated a robust mucosal IgA antibody response in the respiratory tract. This additional type of immunity can only be achieved following intranasal dosing and has the potential to block infection at its source while also blocking transmission of the virus to others. Altimune anticipates commencing a Phase 1 safety and immunogenicity trial of AdCOVID in Q4 2020 with a data read-out in Q1 2021.

- **Expanded preclinical collaboration with the University of Alabama at Birmingham (UAB) for AdCOVID**

Based on the promising preclinical data for AdCOVID that has been generated so far, Altimune and UAB have expanded their collaboration to include additional preclinical studies of AdCOVID in support of further development for AdCOVID. UAB is a premier site for the study of preclinical and clinical aspects of viral immunology and vaccine development, and has extensive experience in conducting clinical studies of vaccines and has participated in studies sponsored by the Vaccine Evaluation and Trial Unit, part of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health.

- **Initiated a collaboration with Saint Louis University for AdCOVID**

Altimune established a Sponsored Research Agreement with Dr. James Brien, Ph.D., Assistant Professor of Molecular Microbiology and Immunology at Saint Louis University (SLU), to conduct animal models of vaccine immunogenicity and efficacy. SLU has extensive expertise in studying the pathogenicity of viral infections and is part of a network of clinical sites evaluating the Operation Warp Speed vaccines. Dr. Brien has significant expertise in the development of animal models of viral infection and evaluation of functional tests for SARS-CoV-2 antibodies and will be an important addition to the Altimune COVID-19 effort.

- **Formed alliances with key manufacturing partners and entered into a teaming agreement with DynPort Vaccine Company to support AdCOVID**

Altimune has entered into an agreement with Vigene Biosciences to provide clinical manufacturing services for AdCOVID. Vigene is an award-winning contract development and manufacturing organization specializing in viral vectors. In addition to Vigene, the Company has executed agreements with additional manufacturing partners to ensure commercial readiness for AdCOVID. Altimune also executed a teaming agreement with DynPort Vaccine Company (DVC), a General Dynamics Information Technology (GDIT) company, to assist in coordinating U.S. Government funding efforts and, if successful, provide program management, drug development activity integration, and regulatory support for AdCOVID.

- **Initiated a Phase 1/2 clinical trial of T-COVID; program funded by \$4.7 million award from the Department of Defense**

Altimune commenced enrollment in 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). Based on the current rate of enrollment, Altimune anticipates a data read-out from this study in Q1 2021. For further information about the study, visit www.epicclinicalstudy.com.

- **Received regulatory clearance to commence a Phase 1 clinical trial of ALT-801 in Australia; Phase 1 trial expected to begin Q4 2020**

Altimmune received clearance from HREC (Human Research and Ethics Committee) and filed a Clinical Trial Notification (CTN) with the Australian regulatory authority. Altimmune expects to commence dosing in a Phase I clinical study of ALT-801 before the end of the year. The clinical trial will enroll approximately 100 subjects in a 6-week single ascending dose and a 6-week multiple ascending dose study. The primary pharmacodynamic endpoints in this trial are weight loss and reduction in liver fat. Altimmune anticipates a data read-out from this trial towards the end of the first quarter of 2021.

- **Completed enrollment in Phase 1b clinical trial of NasoShield intranasal anthrax vaccine**

Altimmune completed enrollment in a 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. The results from this Phase 1b study are expected to read-out near the end of Q4 2020. Based on these results, BARDA will have the option of exercising the remaining contract options valued at approximately \$105 million to enable Phase 2 development.

- **Secured approximately \$200 million in gross proceeds to advance pipeline candidates**

During 2020, Altimmune has received \$132.2 million in gross proceeds from a public offering of common stock and pre-funded warrants, \$41 million from warrant exercises and \$26.6 million in gross proceeds from ATM sales. Altimmune anticipates that the proceeds 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 and HepTcell, and for capital expenditures and general working capital purposes.

Financial Results for the Third Quarter Ended September 30, 2020

- Altimmune had cash, cash equivalents and short-term investments of \$206.8 million at September 30, 2020.
- Revenue was \$2.9 million for the quarter ended September 30, 2020 compared to \$0.6 million in the prior year period. 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 program.
- Research and development expenses were \$17.0 million for the quarter ended September 30, 2020 compared to \$8.7 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; costs for IND-enabling preclinical studies and manufacturing for ALT-801; and development costs for the COVID-19 programs.
- General and administrative expenses were \$4.2 million for the quarter ended September 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 \$0.5 million for the three months ended September 30, 2020, as compared to \$0.1 million 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 quarter ended September 30, 2020 was \$17.8 million, or \$0.54 net loss per share, compared to \$10.9 million in the prior year, or \$0.74 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

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

Date: Tuesday, November 10, 2020
Time: 8:30 am Eastern Time
Domestic: 877-300-8521
International: 412-317-6026
Conference ID: 10149733
Webcast: <http://public.viavid.com/index.php?id=142319>

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 commencement of a Phase 1 safety and immunogenicity trial of AdCOVID in Q4 2020 with a data read-out in Q1 2021, data read-out from our T-COVID trial towards the end of Q1 2021, the initiation of a Phase 1 clinical study for ALT-801 in Q4 2020 and data read-out towards the end of Q1 2021, data read-out from our Phase 1b clinical trial of NasoShield 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

	September 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 143,495,266	\$ 8,962,686
Restricted cash	34,174	34,174
Total cash, cash equivalents and restricted cash	143,529,440	8,996,860
Short-term investments	63,282,716	28,277,386
Accounts receivable	3,816,489	1,021,179
Tax refund receivable	6,193,855	629,096
Prepaid expenses and other current assets	1,309,044	470,228
Total current assets	218,131,544	39,394,749
Property and equipment, net	1,041,920	1,104,208
Right of use asset	939,855	698,321
Intangible assets, net	12,794,806	12,732,195
Other assets	87,195	128,547
Total assets	\$ 232,995,320	\$ 54,058,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable	\$ 874,885	\$ 18,232
Accrued expenses and other current liabilities	5,418,831	3,904,767
Total current liabilities	6,293,716	3,922,999
Contingent consideration	25,070,000	2,750,000
Other long-term liabilities	1,925,769	1,864,875
Total liabilities	33,289,485	8,537,874
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 33,073,035 and 15,312,381 shares issued; 33,073,035 and 15,312,167 shares outstanding at September 30, 2020 and December 31, 2019, respectively	3,289	1,508
Additional paid-in capital	380,543,640	187,914,916
Accumulated deficit	(175,798,822)	(137,376,122)
Accumulated other comprehensive loss, net	(5,042,272)	(5,020,156)
Total stockholders' equity	199,705,835	45,520,146
Total liabilities and stockholders' equity	\$ 232,995,320	\$ 54,058,020

ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	\$ 2,937,991	\$ 643,978	\$ 5,872,321	\$ 5,225,600
Operating expenses:				
Research and development	17,041,975	8,729,697	40,823,756	14,892,464
General and administrative	4,220,238	2,187,661	9,097,511	6,485,960
Impairment charges	—	1,000,000	—	1,000,000
Total operating expenses	21,262,213	11,917,358	49,921,267	22,378,424
Loss from operations	(18,324,222)	(11,273,380)	(44,048,946)	(17,152,824)
Other income (expense):				
Changes in fair value of warrant liability	—	76,000	—	30,000
Interest expense	(2,275)	(756)	(7,468)	(2,244)
Interest income	45,127	224,058	278,154	649,268
Other income (expense), net	29,218	(23,734)	48,882	(6,206)
Total other income, net	72,070	275,568	319,568	670,818
Net loss before income tax benefit	(18,252,152)	(10,997,812)	(43,729,378)	(16,482,006)
Income tax benefit	482,017	58,500	5,306,678	58,500
Net loss	(17,770,135)	(10,939,312)	(38,422,700)	(16,423,506)
Other comprehensive loss – unrealized (loss) gain on investments	(10,569)	18,953	(22,116)	18,953
Comprehensive loss	\$ (17,780,704)	\$ (10,920,359)	\$ (38,444,816)	\$ (16,404,553)
Net loss	\$ (17,770,135)	\$ (10,939,312)	\$ (38,422,700)	\$ (16,423,506)
Deemed dividends	—	—	—	(452,925)
Net loss attributed to common stockholders	\$ (17,770,135)	\$ (10,939,312)	\$ (38,422,700)	\$ (16,876,431)
Net loss per share attributed to common stockholders, basic and diluted	\$ (0.54)	\$ (0.74)	\$ (1.74)	\$ (1.35)
Weighted-average common shares outstanding, basic and diluted	33,056,971	14,768,931	22,058,424	12,481,494



Source: Altimune, Inc.