

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): June 1, 2020

Altimune, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-32587
(Commission
File Number)

20-2726770
(I.R.S. Employer
Identification No.)

910 Clopper Road Suite 201S
Gaithersburg, Maryland
(Address of principal executive offices)

20878
(Zip Code)

Registrant's telephone number, including area code: (240) 654-1450

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	ALT	The NASDAQ Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

On June 1, 2020, Altimmune, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration (the “FDA”) had cleared the Company’s Investigational New Drug application (“IND”) to proceed with a Phase 1/2 clinical trial of T-COVID, the Company’s investigational agent for the treatment of early COVID-19 (“T-COVID”).

The information in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On June 1, 2020, the Company announced FDA clearance of the IND for T-COVID. The Company expects to initiate a placebo-controlled Phase 1/2 double-blind clinical trial to evaluate the potential of T-COVID to prevent clinical worsening in patients with early COVID-19 in June 2020 and expects a data read out in the fourth quarter of 2020.

Forward-Looking Statement

The Company cautions you that statements included in this Current Report on Form 8-K that are not a description of historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including without limitation, the timing of key milestones for our clinical assets, the development of our T-COVID product candidate, initiation of a Phase 1/2 clinical trial for T-COVID and corresponding data read out in the fourth quarter of 2020. In some cases, forward-looking statements can be identified by terminology such as “may,” “could,” “should,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict” and similar expressions and their variants or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. 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; 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 report on Form 10-K for the fiscal year ended December 31, 2019 and our quarterly report on Form 10-Q for the quarter ended March 31, 2020, which are available at www.sec.gov. Except as required by law, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this Current Report on Form 8-K in the event of new information, future developments or otherwise. These forward-looking statements speak only as of the date hereof.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Altimmune, Inc. dated June 1, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 1, 2020

ALTIMMUNE, INC.

By: /s/ William Brown

William Brown

Chief Financial Officer



Altimune Launches Clinical Trial of T-COVID™, an Investigational Intranasal Immune Modulator for the Treatment of Patients with Early COVID-19

- *Clearance of IND application received from the U.S. FDA*
- *Planned Phase 1/2 outpatient clinical trial will focus on patients with early SARS-CoV-2 infection*
- *Placebo-controlled trial expected to commence in June with data readout expected in Q4 2020*
- *Therapeutic development program will complement Company's single-dose intranasal COVID-19 vaccine candidate, AdCOVID*
- *Company to host conference call on Monday, June 1, 2020 at 8:30 a.m.*

GAITHERSBURG, MD, June 1, 2020 (GLOBE NEWSWIRE) — Altimune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced the U.S. Food and Drug Administration (FDA) has authorized the Company to proceed with a clinical trial of T-COVID, an investigational agent for the treatment of early COVID-19. Patient enrollment in the Phase 1/2 clinical trial is expected to commence in June, with data readout anticipated in Q4 2020.

T-COVID is based on the same replication-deficient adenovirus 5 (RD-Ad5) vector technology behind Altimune's intranasal vaccine candidates, which include NasoVAX for influenza, NasoShield for anthrax, and AdCOVID for COVID-19, but it acts through a different mechanism. In preclinical studies sponsored by the National Institute of Allergy and Infectious Diseases, intranasal administration of RD-Ad5 vectors modulated the innate immune response to lethal challenge with a respiratory virus in mice and protected them from death. The immunomodulatory effects resulted in significantly decreased cellular inflammation and lower concentrations of IL-6 and other inflammatory cytokines in the lungs of treated animals compared to controls. Excessive production of inflammatory cytokines like IL-6 has been associated with the lung pathology and death in COVID-19. The protective effects were independent of any specific immunity or vaccine effects against the challenge virus. These protective effects were only observed with intranasal administration of RD-Ad5, and intramuscular administration provided no survival benefit.

The Company believes that treatment with T-COVID administered as a single intranasal dose to patients with an early onset of symptoms and recent diagnosis of COVID-19 may prevent the progression to severe lung inflammation and thereby decrease the development of severe COVID-19 and the need for hospitalization. The FDA has agreed that the Company may use its existing lot of RD-Ad5-based NasoVAX influenza vaccine for the planned T-COVID clinical trial allowing the Company to immediately initiate the study.

The planned clinical trial will evaluate the potential of T-COVID to prevent clinical worsening in patients with early COVID-19. The double-blind trial is expected to enroll approximately 100 patients who are 35 years and older randomized 1:1 to receive either intranasal T-COVID or placebo administered in an outpatient (non-hospitalized) setting within 48 hours of onset of symptoms and 24 hours of diagnosis. The study will be enrolled in 3 cohorts of increasing risk factors for severe COVID-19, with the final cohort enrolling patients of all ages and risk factors. The primary efficacy endpoint is the proportion of patients with clinical worsening, defined as a 4% decrease in pulse oxygen saturation (SpO₂), or need for hospitalization.



The Company believes this approach is differentiated from other COVID-19 therapeutics currently in development as it is focused on non-hospitalized patients prior to the development of pulmonary dysfunction or the need for hospitalization. T-COVID is being studied as a single intranasal dose, not requiring the use of needles or infusions, and has the potential to be self-administered. Additionally, based on the current stability profile at ambient (room) temperatures, T-COVID has the potential to be widely distributed without the need for refrigeration.

“The preclinical data on RD-AD5 and the potential applicability of our vector technology as a therapeutic approach to COVID-19 suggests that we may be able to protect patients with COVID-19 from the need for hospitalization”, said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimune. “With the addition of T-COVID, we now have both a vaccine candidate and a therapeutic candidate in development as our team is working rapidly and diligently to fight this pandemic”.

The Company’s intranasal RD-Ad5 vectors have been studied in five clinical studies in healthy subjects and appeared to be safe and well-tolerated. Pending a successful trial readout, Altimune anticipates future discussions with FDA about additional clinical trials and Emergency Use Authorization. The Company believes the mechanism of action underlying T-COVID has the potential to be studied for both pre- and post-exposure prophylaxis for higher-risk individuals, such as frontline healthcare workers, making it attractive as a potential first-line defense for other viral pathogens for which vaccines are not yet available, such as in an influenza pandemic or new strains of coronavirus.

“I am encouraged by the potential use of T-COVID in the treatment of respiratory viral illnesses like COVID-19” added Dr. Michael Yin, Associate Professor of Infectious Diseases at Columbia Presbyterian Hospital and Lead Investigator of the T-COVID trial. “There is a serious unmet need for therapeutics for this condition, and while multiple investigative efforts are underway, they are mainly focused on the hospitalized patients with established pulmonary deterioration. T-COVID focuses on the prevention of worsening in patients not yet hospitalized and has the potential of being broadly applied to other respiratory illnesses and future pandemics.”

This therapeutic intervention complements the Company’s development of AdCOVID, a single-dose, prophylactic intranasal vaccine candidate designed to specifically protect against COVID-19, which is also based on the RD-Ad5 vector. It is expected that AdCOVID, which expresses the spike antigen of SARS-CoV-2 virus, will promote mucosal and systemic immunity including IgA in the nasal cavity, neutralizing antibodies and T cell responses as previously demonstrated in a clinical study with the Company’s intranasal adenoviral vector technology. Stimulation of nasal mucosal immunity may be especially important in the prevention and control of COVID-19 as the nasal cavity is a key site for SARS-CoV-2 replication.



Conference call and Webcast Information

Altimmune will host a conference call and webcast to discuss T-COVID on Monday, June 1, 2020 at 8:30 a.m. Eastern Time. The conference call will be accessible by dialing (877) 423-9813 (US/Canada) or (201) 689-8573 (International) and providing conference ID: 13704790. The call will also be webcast and will be accessible at <http://public.viavid.com/index.php?id=140145>.

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 includes next generation peptide therapeutics for NASH (ALT-801) and chronic hepatitis B (HepTcell™), an intranasal immune modulator for COVID-19 (T-COVID™) and intranasal vaccines (NasoVAX™, NasoShield™ and 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, the timing of key milestones for our clinical assets, the development of our T-COVID product candidate, initiation of a Phase 1/2 clinical trial for T-COVID in June 2020, corresponding data readout in Q4 2020, the development of our AdCOVID vaccine product candidate, 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; 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



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