

**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): December 23, 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 8.01. Other Events.

On December 23, 2020, Altimmune, Inc. (the “Company”) issued a press release announcing an update on the Company’s Investigational New Drug application for a Phase 1 clinical trial of AdCOVID. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Altimmune, Inc. dated December 23, 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: December 23, 2020

ALTIMMUNE, INC.

By: /s/ William Brown

William Brown

Chief Financial Officer



Altimune Provides an Update on its Investigational New Drug Application for a Phase 1 AdCOVID™ Clinical Trial

GAITHERSBURG, MD, December 23, 2020 — Altimune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has issued a clinical hold on the Company's Investigational New Drug (IND) application for AdCOVID, a single-dose intranasal COVID-19 vaccine candidate. The Agency requested certain protocol modifications and the submission of additional Chemistry, Manufacturing and Controls (CMC) data. Altimune has responded to the Agency's clinical hold letter received on December 22, 2020 and, at this time, does not anticipate a significant impact on the overall clinical development timeline as the Company has agreed to each of the FDA's requests.

"We appreciate the FDA's support and guidance as we seek to bring a novel, single-dose intranasal COVID-19 vaccine candidate into the clinic," said Vipin K. Garg, President and Chief Executive Officer of Altimune. "We look forward to working with the FDA and will continue preparing to commence our planned Phase 1 clinical trial of AdCOVID."

About AdCOVID

AdCOVID is a single-dose intranasal COVID-19 vaccine candidate developed by Altimune based on the Company's significant experience in the development of intranasal vaccines for respiratory pathogens. In recently published preclinical studies (www.biorxiv.org/content/10.1101/2020.10.10.331348v1) conducted in collaboration with the University of Alabama at Birmingham, AdCOVID induced potent serum neutralizing antibody and T cell responses in mice as well as a robust induction in mucosal immunity against the spike protein of the virus that causes COVID-19. Importantly, the mucosal immunity was characterized by IgA antibody and resident memory T cell responses in the respiratory tract, both of which are believed to be important in fighting infection and transmission.

Data from Altimune's other intranasal platform vaccines (NasoVAX™ and NasoShield™) suggest that AdCOVID likely will have extended stability at room temperature, which would allow for cold chain-free shipment of the vaccine. If such stability is demonstrated, AdCOVID could be stored in the common refrigerators found in community-based doctors' offices and pharmacies for two years or more. The simple and convenient handling requirements may greatly increase the accessibility of the vaccine, if approved for use.

About Altimune

Altimune 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 Altimune, 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 initiation and timing of the AdCOVID Phase 1 clinical trial and data readout, the potential immunization effects or safety of AdCOVID, the shipping and storage requirements for AdCOVID, our ability to manufacture AdCOVID, our ability to achieve commercial-readiness for AdCOVID in 2021 and the prospects for regulatory emergency use authorization or 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, 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 likelihood or timing of the U.S. Food and Drug Administration allowing the Company’s AdCOVID investigational new drug application to go into effect; the Company’s ability to manufacture clinical trial materials 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, 2019 and quarterly report on Form 10-Q for the quarter ended September 30, 2020 filed with the SEC, which are available at www.sec.gov.

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