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 29, 2021

Altimmune, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-32587**	**20-2726770**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 29, 2021, Altimmune, Inc., or the Company, issued a press release announcing the results of, and an update on, the Phase 1 trial for AdCOVID, the Company's intranasal COVID-19 vaccine candidate, as well as an update on the Phase 1/2 trial for T-COVID, the Company's investigational agent for the treatment of early COVID-19.

A copy of the press release is attached hereto as Exhibit 99.1.

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 29, 2021, the Company issued a press release announcing the results of its Phase 1 trial for AdCOVID and the discontinuation of further development of AdCOVID, based in part on the Phase 1 results. The Company also announced that it has terminated further enrollment of its Phase 1/2 trial of T-COVID because of the Company's inability to enroll subjects in the final cohort as a result of effective rollout in the United States of authorized COVID-19 vaccines and decreasing incidence of disease, which has significantly reduced the number of patients meeting these criteria. The Company is evaluating other development options for the T-COVID program.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Altimmune, Inc. dated June 29, 2021

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 29, 2021

ALTIMMUNE, INC.

By: /s/ William Brown
William Brown
Chief Financial Officer

Exhibit 99.1

Altimmune Announces Update on AdCOVID™ Phase 1 Clinical Trial

- *AdCOVID was well tolerated but did not stimulate an adequate immune response in healthy volunteers*
- *Altimmune will discontinue further development of AdCOVID and focus its resources on its ongoing obesity and liver programs*
- *Altimmune also provides an update on its T-COVID™ Phase 1/2 Clinical Trial*

GAITHERSBURG, MD – June 29, 2021 -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today provided an update on its AdCOVID investigational vaccine for the prevention of COVID-19. The Company also provided an update on its T-COVID Phase 1/2 clinical trial to evaluate the potential of T-COVID to prevent clinical worsening in patients with early COVID-19.

AdCOVID Update

The Phase 1 AdCOVID clinical trial is evaluating the safety and immunogenicity of the intranasally administered vaccine candidate in approximately 80 healthy adult volunteers between the ages of 18 and 55. Subjects received either 1 or 2 doses of AdCOVID as a nasal spray at 3 dose levels. In addition to the primary study endpoint of safety and tolerability, the immunogenicity evaluation of AdCOVID included serum binding and neutralizing antibody titers and mucosal IgA antibody from nasopharyngeal swabs post-vaccination.

AdCOVID appeared to be well tolerated with an overall adverse event profile similar to intranasal saline placebo. The immunogenicity data demonstrated lower than expected immune responses for each of the immune parameters tested. Although antibodies were detected that bound the SARS-CoV-2 Spike protein and neutralized the virus in a subset of subjects, the magnitude of the response and the percent of subjects responding to AdCOVID were substantially lower than what had been demonstrated for other vaccines already authorized for emergency use. Based on these data, and in view of the highly competitive COVID-19 vaccine landscape, Altimmune is discontinuing further development of AdCOVID beyond the completion of this Phase 1 trial.

“The immune response to AdCOVID was inferior to that seen in our NasoVAX influenza vaccine trial,” commented Scot Roberts, PhD, Chief Scientific Officer at Altimmune. “Unlike the NasoVAX study, the AdCOVID study population lacked immunity from prior infection or vaccination. We believe that prior immunity in humans may be important for a robust immune response to intranasal dosing with AdCOVID.”

“The top-line Phase 1 clinical data are disappointing given the encouraging preclinical data and our substantial efforts in advancing a differentiated, intranasal vaccine candidate in the fight against COVID-19,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer at Altimmune. “However, we are fortunate to have a strong pipeline with highly differentiated product candidates targeting indications of significant unmet need. Moving forward, Altimmune will focus its resources on the development of ALT-801 and HepTcell, its novel peptide-based therapeutics for obesity and liver diseases.

Dr. Garg continued, “Encouraging 6-week interim data were recently demonstrated in our ongoing ALT-801 12-week Phase 1 clinical trial in overweight and obese volunteers, demonstrating significant weight loss without the need for dose titration and only transient nausea with no reports of vomiting, diarrhea or constipation. With our strong balance sheet providing a cash runway into 2023, we look forward to advancing our obesity and liver disease programs in the second half of 2021 and beyond.”

T-COVID Update

The Phase 1/2 trial completed dosing in 2 of the 3 planned dose cohorts. The first 2 cohorts were designed to assess the safety of T-COVID treatment and were comprised of COVID-19 infected patients 49 years or younger with a low risk of progression to serious disease. In these cohorts, T-COVID was well tolerated without any serious adverse events observed. The 3rd cohort was intended to evaluate the efficacy of treatment and enroll patients over the age of 65 or with increased risk of serious sequelae by virtue of pre-existing comorbidities. However, the effective rollout in the United States of authorized COVID-19 vaccines and decreasing incidence of disease significantly reduced the number of patients meeting these criteria, and Altimmune has been unable to enroll subjects in the final cohort.

As a result of these enrollment challenges, the Company has decided to terminate further enrollment and evaluate options for future T-COVID development following an assessment of the available data and discussions with its partners, the U.S. Army Medical Research & Development Command (USAMRDC) and the Medical Technology Enterprise Consortium (MTEC).

About Altimmune

Altimmune is a clinical stage biopharmaceutical company focused on developing treatments for obesity and liver disease and intranasal vaccines. Our pipeline includes next generation peptide therapeutics for obesity, NASH (ALT-801), and chronic hepatitis B (HepTcell™); proprietary intranasal vaccines; and an immune modulating therapeutic for COVID-19 (T-COVID™). 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 data readouts from ALT-801 clinical trials in the second half of 2021 and beyond, sufficient cash on hand to fund the Company into 2023, the prospects for regulatory approval, our ability to manufacture material for our clinical trials and commercial needs, and commercializing or selling any product or drug candidates, including ALT-801 and HepTcell, 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 obtain potential regulatory approvals on the timelines anticipated; the success of future product advancements, including the success of future clinical trials; and funding delays, reductions in or elimination of U.S. government funding with USAMRDC. 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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