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): July 13, 2020

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 **20878**
(Address of principal executive offices) **(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 July 13, 2020, Altimmune, Inc., or the Company, issued a press release announcing positive preclinical data of its intranasal COVID-19 vaccine candidate, AdCOVID.

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 July 13, 2020, the Company announced positive results from the preclinical studies of its intranasal COVID-19 vaccine candidate, AdCOVID. The studies, which were conducted in collaboration with the University of Alabama at Birmingham, or UAB, showed strong serum neutralizing activity and potent mucosal immunity in the respiratory tract. The induction of IgA antibody in the respiratory tract may be necessary to block both infection and transmission of the virus to prevent further spread of COVID-19. Based on these findings the Company plans to begin manufacturing of AdCOVID and advance the vaccine candidate to a Phase 1 safety and immunogenicity study in the fourth quarter of 2020.

AdCOVID is designed to express the receptor binding domain, or RBD, of the SARS-CoV-2 virus spike protein, a key immune target that is essential for the virus to bind to cells and initiate infection. By focusing the immune response to this portion of the viral spike protein, AdCOVID elicited a strong systemic antibody response against RBD in mice, achieving serum IgG antibody concentrations greater than 800 micrograms per milliliter just 14 days after administration of a single intranasal dose. In addition, AdCOVID stimulated serum viral neutralization titers of 1:320 by Day 28, which was two times higher than the titer recommended by the U.S. Food and Drug Administration for investigational convalescent plasma as a treatment for severe COVID-19. In a separate study conducted by UAB, a single intranasal dose of AdCOVID stimulated a 29-fold induction of mucosal IgA in bronchoalveolar fluid of vaccinated mice. This level of IgA antibody stimulation is well above that associated with protection from disease in clinical studies of other mucosal vaccines.

In the preclinical studies, vaccination with AdCOVID caused the rapid recruitment of immune cells into the respiratory tract and draining lymph nodes consistent with induction of mucosal and systemic immunity. Increases in CD8+ and CD4+ T cells, dendritic cells and NK cells were observed in the respiratory tract, and germinal center and memory B cells as well as T follicular helper cells were observed in regional lymph nodes and the spleen. Importantly, the latter cell types have been associated in prior vaccine development research with long-lived antibody responses. Preclinical data for antigen-specific T cell response are expected in the coming weeks.

Intranasal dosing provides AdCOVID with the potential to be administered rapidly and without the need for needles, syringes or trained healthcare personnel. In addition, AdCOVID's expected room temperature stability profile may allow for broad distribution of the vaccine without the need for expensive cold-chain logistics, such as refrigeration or freezing.

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 timing and approval of the AdCOVID investigational new drug application, or IND, submission to the U.S. Food and Drug Administration, or FDA, expected to be submitted later this year, the initiation and timing of the AdCOVID Phase 1 clinical trial in Q4 2020, the potential immunization effects of AdCOVID, our ability to manufacture AdCOVID beginning this year, and the prospects for regulatory approval, commercializing or selling any of our products or drug candidates. 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, access to clinical sites, 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 secure regulatory approval of the AdCOVID IND from the FDA, 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 the Company's 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 July 13, 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: July 13, 2020

ALTIMMUNE, INC.

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

Exhibit 99.1

Altimmune and the University of Alabama at Birmingham (UAB) Announce Positive Preclinical Results for Intranasal COVID-19 Vaccine Candidate, AdCOVID™

AdCOVID stimulated both strong serum neutralizing activity and potent mucosal immunity (IgA) in the respiratory tract

GAITHERSBURG, MD, July 13, 2020 (GLOBE NEWSWIRE) — Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced positive results from the preclinical studies of its intranasal COVID-19 vaccine candidate, AdCOVID. The studies, which were conducted in collaboration with the University of Alabama at Birmingham (UAB), showed strong serum neutralizing activity and potent mucosal immunity in the respiratory tract. The induction of IgA antibody in the respiratory tract may be necessary to block both infection and transmission of the virus to prevent further spread of COVID-19. Based on these findings the Company plans to begin manufacturing of AdCOVID and advance the vaccine candidate to a Phase 1 safety and immunogenicity study in Q4 of this year.

AdCOVID is designed to express the receptor binding domain (RBD) of the SARS-CoV-2 virus spike protein, a key immune target that is essential for the virus to bind to cells and initiate infection. By focusing the immune response to this portion of the viral spike protein, AdCOVID elicited a strong systemic antibody response against RBD in mice, achieving serum IgG antibody concentrations greater than 800 micrograms per milliliter just 14 days after administration of a single intranasal dose. In addition, AdCOVID stimulated serum viral neutralization titers of 1:320 by Day 28, and two times higher than the titer recommended by the U.S. Food and Drug Administration for investigational convalescent plasma as a treatment for severe COVID-19. In a separate study conducted by UAB, a single intranasal dose of AdCOVID stimulated a 29-fold induction of mucosal IgA in bronchoalveolar fluid of vaccinated mice. This level of IgA antibody stimulation is well above that associated with protection from disease in clinical studies of other mucosal vaccines.

“Stimulation of immunity at this level just 14 days after a single dose is impressive for any vaccine, and is particularly notable for a potential coronavirus vaccine,” said Dr. Frances Lund, Charles H. McCauley Professor and Chair, Department of Microbiology at UAB, and lead investigator for preclinical testing of the AdCOVID vaccine candidates. Dr. Lund added, “The potent stimulation of mucosal IgA immunity in the respiratory tract may be crucial to effectively block infection and transmission of the SARS-CoV-2 virus given that the nasal cavity is a key point of entry and replication for the SARS-CoV-2 virus.”

In preclinical studies, vaccination with AdCOVID caused the rapid recruitment of immune cells into the respiratory tract and draining lymph nodes consistent with induction of mucosal and systemic immunity. Increases in CD8+ and CD4+ T cells, dendritic cells and NK cells were observed in the respiratory tract, and germinal center and memory B cells as well as T follicular helper cells were observed in regional lymph nodes and the spleen. Importantly, the latter cell types have been associated in prior vaccine development research with long-lived antibody responses. Preclinical data for antigen-specific T cell response are expected in the coming weeks.

Intranasal dosing provides AdCOVID with the potential to be administered rapidly and without the need for needles, syringes or trained healthcare personnel. In addition, AdCOVID’s expected room temperature stability profile may allow for broad distribution of the vaccine without the need for expensive cold-chain logistics, such as refrigeration or freezing.

About Altimmune

Altimmune is a clinical stage biopharmaceutical company focused on developing treatments for liver disease, immune modulating therapies and intranasal vaccines. Our diverse pipeline includes next generation peptide therapeutics for NASH (ALT-801) and chronic hepatitis B (HepTcell™), an intranasal immune modulating treatment for COVID-19 (T-COVID™) and intranasal vaccines (AdCOVID™, NasoShield™ and NasoVAX™). 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 initiation and timing of the AdCOVID Phase 1 clinical trial in Q4 2020, the potential immunization effects of AdCOVID, our ability to manufacture AdCOVID beginning this year, 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, access to clinical sites, 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 secure regulatory approval for its AdCOVID investigational new drug application submission to the U.S. Food and Drug Administration, 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 March 31, 2020 filed with the SEC, which are available at www.sec.gov.

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