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 16, 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 16, 2021, Altimmune, Inc., or the Company, issued a press release announcing positive interim data of its investigational GLP-1/glucagon dual receptor agonist, ALT-801.

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 16, 2021, the Company announced results from a prespecified 6-week interim analysis of its ongoing 12-week, Phase 1, placebo-controlled, single and multiple ascending dose trial of ALT-801, an investigational GLP-1/glucagon dual receptor agonist, in healthy overweight and obese volunteers. The study is currently being conducted in Australia under a clinical trial application.

The interim data showed a mean weight loss of 5.4% was achieved by Week 6 with a once weekly ALT-801 dose of 1.8 mg administered subcutaneously (sc) compared to a weight gain of 0.9% in the placebo group (net change from placebo of 6.3%, $p < .0001$), surpassing the pre-established treatment target of 2% weight loss. All but one subject who received the 1.8 mg sc dose achieved at least 3% weight loss by Week 6. A lower dose cohort that received a weekly 1.2 mg sc dose achieved a mean weight loss of 1.8% (net change from placebo of 2.7%, $p < .05$) at the same time point. ALT-801 was well-tolerated without dose titration, with transient nausea rates of 14.3% at the 1.2 mg dose and 22.2% at the 1.8 mg dose, and no reports of vomiting, diarrhea or constipation at either dose. All nausea events at the 1.8 mg dose were mild in severity. Gastrointestinal adverse events have required other GLP-1 based agents to dose titrate over 16 to 20 weeks to maintain adequate tolerability.

Because the recruited study population was young (mean age 29.8 years) and non-diabetic, the proportion of subjects with MRI-PDFF greater than 10% was insufficient to perform an analysis of liver fat reduction in this population. Consequently, the Company plans to expand the enrollment criteria and conduct a separate 12-week Phase 1b study of diabetic and non-diabetic subjects with non-alcoholic fatty liver disease (NAFLD) in the United States, which is anticipated to commence in Q3 2021, and to initiate a 52-week biopsy-driven NASH trial in Q1 2022. The expansion of enrollment criteria to diabetic and older subjects will accelerate the recruitment of the target NAFLD population and mirror the anticipated study population in the 52-week trial.

Forward-Looking Statement

The Company cautions you that statements included in this Current Report on Form 8-K 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 timing of the 12-week data readout from the ALT-801 Phase 1 clinical trial in Q3 2021, the timing of the filing of IND applications, the potential to initiate a 12 week NAFLD trial in Q3 2021, the timing of the filing of an additional IND applications, the potential to initiate an obesity program in 2021, the potential therapeutic effects of ALT-801, the prospects for regulatory approval, our ability to manufacture ALT-801 for our clinical trials and commercial needs, and 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 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, 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 manufacture clinical trial materials and commercial supply 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, 2020 filed with the SEC, which is 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 16, 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 16, 2021

ALTIMMUNE, INC.

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

Exhibit 99.1

Altimmune Announces Positive Interim Data from ALT-801 Phase 1 Trial in Overweight and Obese Volunteers

- *Weight loss of 5.4% achieved at 6 weeks of treatment with 1.8 mg once weekly dose, surpassing the 2% pre-established treatment target*
- *Ascending multi-dose regimen well-tolerated without necessity for dose titration*
- *Trial continuing with 12-week data expected in Q3 2021*
- *Company plans to file an additional IND and initiate an obesity program in 2021*
- *Altimmune to host a conference call today at 8:30 a.m. ET*

GAITHERSBURG, MD, June 16, 2021 -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced results from a prespecified 6-week interim analysis of its ongoing 12-week, Phase 1, placebo-controlled, single and multiple ascending dose trial of ALT-801, an investigational GLP-1/glucagon dual receptor agonist, in healthy overweight and obese volunteers. The study is currently being conducted in Australia under a clinical trial application.

The interim data showed a mean weight loss of 5.4% was achieved by Week 6 with a once weekly ALT-801 dose of 1.8 mg administered subcutaneously (sc) compared to a weight gain of 0.9% in the placebo group (net change from placebo of 6.3%, $p < .0001$), surpassing the pre-established treatment target of 2% weight loss. All but one subject who received the 1.8 mg sc dose achieved at least 3% weight loss by Week 6. A lower dose cohort that received a weekly 1.2 mg sc dose achieved a mean weight loss of 1.8% (net change from placebo of 2.7%, $p < .05$) at the same time point. ALT-801 was well-tolerated without dose titration, with transient nausea rates of 14.3% at the 1.2 mg dose and 22.2% at the 1.8 mg dose, and no reports of vomiting, diarrhea or constipation at either dose. All nausea events at the 1.8 mg dose were mild in severity. Gastrointestinal adverse events have required other GLP-1 based agents to dose titrate over 16 to 20 weeks to maintain adequate tolerability.

“These data are encouraging considering that only a 2% weight loss was targeted at 6 weeks of treatment and that nausea rates were low, without emesis, which is particularly notable in the absence of dose titration,” commented Stephen Harrison, MD, Visiting Professor of Hepatology, University of Oxford, and Medical Director, Pinnacle Research. “The high degree of weight loss, the very good safety and tolerability profile, and the absence of dose titration with short treatment duration is very favorable for ALT-801 and makes it an attractive candidate among the GLP-1 class of drugs. Based on the relationship between weight loss and liver fat reduction, and NASH resolution observed in other studies, ALT-801 appears to be a promising therapeutic candidate for both obesity and NASH.”

Because the recruited study population was young (mean age 29.8 years) and non-diabetic, the proportion of subjects with MRI-PDFF greater than 10% was insufficient to perform an analysis of liver fat reduction in this population. Consequently, the Company plans to expand the enrollment criteria and conduct a separate 12-week Phase 1b study of diabetic and non-diabetic subjects with non-alcoholic fatty liver disease (NAFLD) in the United States, which is anticipated to commence in Q3 2021, and to initiate a 52-week biopsy-driven NASH trial in Q1 2022. The expansion of enrollment criteria to diabetic and older subjects will accelerate the recruitment of the target NAFLD population and mirror the anticipated study population in the 52-week trial.

The ALT-801 Phase 1 trial is currently progressing through higher dose cohorts, and the Company plans to report the results following 12-weeks of dosing in Q3 2021. Based on these latest results, Altimmune now plans to file a second IND in obesity in Q3 2021 to supplement its ongoing NASH program.

“We are very excited about the potential for ALT-801 in the expanding GLP-1 therapeutics marketplace,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. “We know that weight loss is strongly correlated with NASH resolution and that the obesity epidemic in developed nations has led to an unacceptable increase in chronic illnesses. Assuming ALT-801 is shown to improve upon the metabolic control and side effect profile of existing GLP-1 therapies, we believe that ALT-801 could enable more patients to benefit from this type of treatment.”

About the ALT-801 Phase 1 Trial

The ALT-801 Phase 1 clinical trial is a placebo-controlled, first-in-human, single ascending dose (SAD) and multiple ascending dose (MAD) study in overweight and obese volunteers being conducted in Australia under a clinical trial application. Study subjects did not participate in behavioral weight loss programs or undergo caloric restriction. The primary objectives of the trial are to assess the safety and tolerability, pharmacokinetics, and weight loss in ALT-801 recipients compared to placebo over 12 weeks of weekly dosing. Reduction in liver fat content will be assessed in a separate 12-week Phase 1b trial of diabetic and non-diabetic subjects with NAFLD anticipated to commence in Q3 2021. Dosing in the MAD phase commenced with a cohort receiving ALT-801 1.2 mg sc or placebo once weekly and is progressing through higher dose cohorts. Subjects in the 1.2 mg and 1.8 mg cohorts currently have completed 6 weeks of treatment. Interim analyses at 6 weeks of dosing have been performed for the first two study cohorts, and the results of 12 weeks of dosing in these and additional cohorts are expected to be announced in Q3 2021.

Conference Call Information

Date:	Wednesday, June 16, 2021
Time:	8:30 am Eastern Time
Domestic Dial-in	877-423-9813
International Dial-in:	201-689-8573
Conference ID:	13720570
Webcast:	http://public.viavid.com/index.php?id=145274

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 ALT-801

ALT-801 is a novel, investigational, peptide-based dual GLP-1/glucagon receptor agonist that is designed to treat the obesity and metabolic dysfunction that causes NASH. As the most severe form of non-alcoholic fatty liver disease, or NAFLD, NASH involves multiple metabolic pathways leading to the abnormal accumulation of liver fat, toxic lipid metabolites, and inflammation, resulting ultimately in fibrosis (cirrhosis) or liver cancer. Altimmune believes the treatment of obesity is the cornerstone of treating NASH and the principal morbidities of NASH. Glucagon increases energy expenditure and adipose tissue browning and works synergistically with GLP-1 to facilitate greater degrees of weight loss than GLP-1 alone. As observed in a well-established preclinical model of the disease, ALT-801 induced significantly greater weight loss compared to semaglutide, a GLP-1 receptor agonist, along with significantly greater decreases in liver fat, plasma ALT, and other markers of NASH. The pharmacokinetic profile of ALT-801 may provide for once weekly administration without dose-titration and may have a low incidence of GI side effects, attributes that we believe could improve patient compliance and reduce treatment discontinuation.

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.

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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 key milestones for our clinical assets, the timing of the 12-week data readout from the ALT-801 Phase 1 clinical trial in Q3 2021, the timing of the filing of IND applications, the potential to initiate a 12 week NAFLD trial in Q3 2021, the timing of the filing of an additional IND and initiate an obesity program in 2021, the potential therapeutic effects of ALT-801, the prospects for regulatory approval, our ability to manufacture ALT-801 for our clinical trials and commercial needs, and 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 Company’s ability to manufacture clinical trial materials and commercial supply 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, 2020 filed with the SEC, which is available at www.sec.gov.

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