

**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): March 9, 2021

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 1.01. Entry into a Material Definitive Agreement.

On March 9, 2021, Altimmune, Inc. (the “Company”) and Lonza Houston Inc. (“Lonza”) entered into a Statement of Work (the “SOW”), effective March 8, 2021, pursuant to which the parties expanded their current manufacturing collaboration. The SOW provides that Lonza will engineer, construct and qualify a dedicated manufacturing suite for the clinical and commercial supply of the Company’s AdCOVID product candidate. Pursuant to the SOW, the Company will pay Lonza an aggregate of \$19.0 million at set milestones during the build-out and qualification of the manufacturing suite.

If the Company terminates the services provided by Lonza pursuant to the SOW due to its discontinuation of the AdCOVID program, it will be required to reimburse Lonza a cancellation fee equal to the total fees set forth in the SOW and specified out-of-pocket expense of Lonza (the “Cancellation Fee”), subject to certain off-sets. Either party may terminate the SOW upon a material breach of the terms of the other party that remains uncured for thirty days after notice. If the SOW is terminated as a result of an uncured breach by the Company, the Company will be required to pay Lonza the Cancellation Fee.

The foregoing is only a brief description of the material terms of the SOW and, therefore, does not purport to be complete and is qualified in its entirety by reference to the SOW which the Company expects to file as an exhibit to its Quarterly Report on Form 10-Q for the fiscal quarter ending March 31, 2021.

Item 7.01. Regulation FD Disclosure.

On March 12, 2021, the Company issued a joint press release announcing the SOW. The press release is attached to this Current Report as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Altimmune, Inc. dated March 12, 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: March 12, 2021

ALTIMMUNE, INC.

By: /s/ William Brown

William Brown

Chief Financial Officer

Altimune Expands AdCOVID™ Manufacturing Collaboration with Lonza

Lonza to Commission a Dedicated Suite for Clinical and Commercial Supply of Altimune's COVID-19 Vaccine Candidate at its Houston Facility

GAITHERSBURG, Maryland (USA) and Basel, Switzerland, March 12, 2021 — Altimune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that it has expanded its previously-announced AdCOVID manufacturing collaboration with Lonza. Under the expanded agreement, Lonza will commission a dedicated manufacturing suite for clinical and commercial production of AdCOVID, Altimune's single-dose intranasal vaccine candidate for COVID-19, at its facility near Houston, Texas.

"Manufacturing capacity for COVID-19 vaccines has been severely constrained, and this limitation has presented considerable challenges for vaccine developers," said Dr. Vyjayanthi Krishnan, Ph.D., Vice President of Product Development for Altimune. "By expanding our Lonza collaboration and commissioning our own dedicated manufacturing suite, we are building extra capacity and redundancy into our manufacturing to support potential late-stage clinical trials with AdCOVID and potential future commercial supply. Lonza continues to be an outstanding partner in this mission, and we are pleased to have the opportunity to further our relationship with this world class team."

Alberto Santagostino, SVP, Head of Cell and Gene Technologies for Lonza, commented, "Altimune's COVID-19 vaccine candidate could be a complete game-changer in the fight against COVID-19. Our reinforced commitment is to enable the team at Altimune to scale-up production as needed and deliver vaccines at a global scale when ready."

AdCOVID is a COVID-19 vaccine candidate that is administered via nasal spray. In preclinical studies, AdCOVID was shown to activate systemic immunity (neutralizing antibodies and T cell responses) and mucosal immunity in the respiratory tract. Activation of mucosal immunity may prevent both SARS-CoV-2 virus infection and transmission. In preclinical studies, AdCOVID stimulated a 29-fold increase in mucosal IgA, well above the level associated with protection in clinical studies of influenza.

"We recently commenced our AdCOVID Phase 1 clinical trial and anticipate having a data readout in the second quarter of 2021," said Vipin K. Garg, Ph.D., President and Chief Executive Officer at Altimune. "If the clinical data from our Phase 1 trial and subsequent clinical trials validate our preclinical observations, and AdCOVID is successfully commercialized, we believe that it could become an important new option for vaccination against COVID-19, offering the simplicity of nasal administration, potential ease of deployment and storage, and the potential to block viral transmission."

Based on clinical experience with Altimune's vaccine platform technology, Altimune anticipates that AdCOVID could provide immunity of up to a year or more following a single dose with the potential for a favorable tolerability profile. Vaccine stability is critical for efficient vaccine deployment and based on data from Altimune's other intranasal vaccine candidates, AdCOVID is expected to be shipped without cold chain logistics, permitting common refrigerated storage at community-based vaccination centers without the need for specialized freezer storage.

About AdCOVID

AdCOVID is a single-dose intranasal vaccine candidate for COVID-19. It is designed to stimulate a broad immune response including both systemic immunity (neutralizing antibody) and local immunity (mucosal IgA, resident memory T cells) in the nasal cavity and respiratory tract.

In published preclinical studies (www.biorxiv.org/content/10.1101/2020.10.10.331348v1) conducted in collaboration with the University of Alabama at Birmingham, potent serum neutralizing antibody responses, T cell responses, and a robust induction in mucosal immunity were observed in mice following a single intranasal dose of AdCOVID. 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 importantly, transmission.

Based on data from Altimmune's other intranasal platform vaccine candidates, AdCOVID is expected to have extended stability at room temperature that would allow for cold chain-free shipment of the vaccine. If demonstrated, AdCOVID could be stored in the common refrigerators found in community-based doctors' offices and pharmacies for two years or more. The Company believes that these simple and convenient handling requirements, together with the potential ability to block SARS-CoV-2 transmission, could position AdCOVID as a leading intranasal COVID-19 vaccine.

About Lonza

Lonza is the preferred global partner to the pharmaceutical, biotech and nutrition markets. We work to prevent illness and enable a healthier world by supporting our customers to deliver new and innovative medicines that help treat a wide range of diseases. We achieve this by combining technological insight with world-class manufacturing, scientific expertise and process excellence. These enable our customers to commercialize their discoveries and innovations in the healthcare sector.

Founded in 1897 in the Swiss Alps, today Lonza operates across three continents. With approximately 14,000 full-time employees, we are built from high-performing teams and of individual talent who make a meaningful difference to our own business, as well as to the communities in which we operate. The company generated sales of CHF 4.5 billion in 2020 with a CORE EBITDA of CHF 1.4 billion. Find out more at www.lonza.com.

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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 for Altimune

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 data readout from the AdCOVID Phase 1 clinical trial in Q2 2021, the potential immunization effects of AdCOVID, the potential of AdCOVID to block SARS-CoV-2 transmission, the shipping and storage requirements for AdCOVID, and the prospects for regulatory approval, our ability to manufacture AdCOVID for our clinical trials and commercial needs, 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 Altimune, 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; 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, 2020 filed with the SEC, which is available at www.sec.gov.

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Additional Information and Disclaimer for Lonza

Lonza Group Ltd has its headquarters in Basel, Switzerland, and is listed on the SIX Swiss Exchange. It has a secondary listing on the Singapore Exchange Securities Trading Limited (“SGX-ST”). Lonza Group Ltd is not subject to the SGX-ST’s continuing listing requirements but remains subject to Rules 217 and 751 of the SGX-ST Listing Manual.

Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.

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