

**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 8, 2021**

**AIM IMMUNOTECH INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(state or other jurisdiction  
of incorporation)

**001 - 27072**  
(Commission  
File Number)

**52-0845822**  
(I.R.S. Employer  
Identification No.)

**2117 SW Highway 484, Ocala FL**  
(Address of principal executive offices)

**34473**  
(Zip Code)

Registrant's telephone number, including area code: **(352) 448-7797**

AIM ImmunoTech Inc.  
(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 (see General Instruction A.2. below):

- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	AIM	NYSE American

**Item 1.01 Entry into a Material Definitive Agreement.**

On July 8, 2021, we executed a Reservation and Start-Up Agreement (the "Agreement") with hVIVO Services Limited ("hVIVO"). Pursuant to the Agreement, we have reserved space in hVIVO's quarantine facility in the United Kingdom to conduct a Phase 2a Human Challenge Trial ("HCT") to test Ampligen as a potential intranasal antiviral therapy using a human Rhinovirus hRV (common cold virus) and Influenza. In an HCT, subjects are intentionally exposed to particular diseases to test how the diseases will respond to potential therapeutics. We believe that an HCT will allow us to expedite the development process for Ampligen by ensuring high infection rates for subjects who receive the drug, therefore also ensuring large data sets with potentially statistically significant results. The HCT is anticipated to commence in the beginning of November 2021.

The Agreement includes a detailed study proposal and budget. Commencement of the study is dependent upon the parties entering into a clinical trial agreement ("CTA") on or before September 1, 2021 (unless extended) finalizing the full scope and budget for the study. We have paid hVIVO approximately \$440,450, representing half of the booking fee for use of its quarantine facility. The balance of the booking fee is due upon execution of the CTA. If there are no changes to the reservation terms for the quarantine facility, the booking fee will be credited against payments due under the CTA.

**Cautionary Statement**

This Current Report on Form 8-K contains forward-looking statements that involve a number of risks and uncertainties. Among other things, for those statements, we claim the protection of safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements set forth herein speak only as of the date hereof. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. The Agreement is subject to us finalizing the CTA. The full scope and budget of the HCT are subject to change prior to execution of the CTA or thereafter as the HCT proceeds. No assurance can be given that the HCT will yield positive results and, if it does, additional testing will be required to confirm that Ampligen will be an effective intranasal antiviral

therapy. We are in various stages of seeking to determine whether Ampligen will be effective in the treatment of multiple types of viral diseases, cancers, and immune-deficiency disorders. Our planned activities are subject to change for a number of reasons. Significant additional testing and trials will be required to determine whether Ampligen will be effective in the treatment of these conditions. Results obtained in animal models do not necessarily predict results in humans. Human clinical trials will be necessary to prove whether or not Ampligen will be efficacious in humans. No assurance can be given as to whether current or planned clinical trials will be successful or yield favorable data and the trials are subject to many factors including lack of regulatory approval(s), lack of study drug, or a change in priorities at the institutions sponsoring other trials. In addition, initiation of planned clinical trials may not occur secondary to many factors including lack of regulatory approval(s) or lack of study drug. Even if these clinical trials are initiated, the Company cannot assure that the clinical studies will be successful or yield any useful data or require additional funding. Operating in foreign countries carries with it a number of risks, including potential difficulties in enforcing intellectual property rights. We cannot assure that our potential foreign operations will not be adversely affected by these risks.

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#### 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.

AIM IMMUNOTECH INC.

By: /s/ Thomas K. Equels  
Thomas K. Equels, CEO

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July 13, 2021

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