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)
February 2, 2021

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

Delaware	**001 – 27072**	**52-0845822**
(state or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

2117 SW Highway 484, Ocala FL	**34473**
(Address of principal executive offices)	(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 8.01 Other Events.

On February 2, 2021, the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) recommended to the European Commission that AIM ImmunoTech Inc.'s wholly owned subsidiary's rintatolimod (Ampligen) receive designation as an orphan medicinal product for the treatment of pancreatic cancer. Please see the report of COMP's January 2021 meeting, which is available at: https://www.ema.europa.eu/en/documents/committee-report/comp-meeting-report-review-applications-orphan-designation-january-2021_en.pdf.

To qualify for orphan designation, a medicine must meet a number of criteria: (i) it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; (ii) the prevalence of the condition in the EU must not be more than 5 in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and (iii) no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

The European Union (EU) provides a range of incentives for medicines that have been granted an orphan designation including: protocol assistance; access to the centralized authorization procedure; up to ten years of market exclusivity; additional incentives for micro, small and medium-sized enterprises (MSMEs); fee reductions; grants; and other incentives in member states.

While AIM ImmunoTech is encouraged by the outcome of the meeting, the EMA must first send the COMP opinion to the European Commission, which is responsible for granting the orphan designation and there can be no assurance that the European Commission will ultimately approve Ampligen for orphan designation.

Cautionary Statement

This report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). Words such as "may," "will," "expect," "plan," "anticipate" and similar expressions (as well as other words or expressions referencing future events or circumstances) are intended to identify forward-looking statements. Many of these forward-looking statements 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 PSLRA. The EMA must first send the COMP opinion to the European Commission, which is responsible for granting the orphan designation and there can be no assurance that the European Commission will ultimately approve Ampligen (rintatolimod) for orphan designation. Orphan Designation, while beneficial, does not assure commercial approval. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

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.

February 5, 2021

By: */s/ Thomas K. Equels*