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)
November 17, 2020

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.

Given the tremendous and important advances toward rapid commercialization of effective COVID-19 vaccine candidates with highly successful Phase 3 results in humans, such as Moderna and Pfizer, AIM has shifted its strategic focus in COVID-19 toward commencing authorized clinical trials for Ampligen as an early onset therapy for COVID-19 in cancer patients and Ampligen as a therapy for COVID-19 induced chronic fatigue a/k/a COVID Long Haulers. The Company plans to provide a further update in the weeks ahead on the status of commencing its first Long Haulers trial and enrolling the first patients. Ampligen is uniquely positioned as the only drug approved for severe chronic fatigue syndrome (in Argentina, as of 2016) and the only late-stage chronic fatigue drug candidate in the U.S. pipeline. The Company believes its planned trial for COVID-19 induced chronic fatigue is the only such trial underway in the world.

Many survivors of the first SARS-CoV-1 epidemic in 2003 continued to report classic chronic fatigue-like symptoms after recovering from the acute illness. In fact, approximately 27% of survivors met the CDC criteria for chronic fatigue syndrome (See: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/415378). There is now increasing evidence that patients with COVID-19 – the disease caused by SARS-CoV-2 – can develop a similar, ME/CFS-like illness (See: https://jamanetwork.com/journals/jama/fullarticle/2768351).

Given the fact that more than 57 million individuals worldwide have contracted COVID-19, the Company believes there is a substantial unmet need for an effective COVID-19 induced chronic fatigue therapy.

As further support for the Company's decision to shift its strategic focus, AIM was notified by Shionogi & Co., Ltd. ("Shionogi") of Japan on November 17, 2020 that Shionogi intends to utilize a TLR agonist other than AIM's Ampligen as Shionogi's designated adjuvant in its ongoing efforts to develop a potential Shionogi vaccine for COVID-19. Ampligen had been under consideration and preclinical evaluation as a potential adjuvant.

Shionogi's pre-clinical work determined that Ampligen used as a vaccine adjuvant provided 100% survival in a pre-clinical rodent model of SARS-CoV as a surrogate model of SARS-CoV-2, in contrast to the control group, which demonstrated 100% mortality. In addition, the Ampligen-treated animals survived through to term by experimental protocol sacrifice (Day 10) with not only no overall net weight loss, but rather a modest weight gain. Weight loss was a primary indicator, along with mortality, measuring adverse reaction to the combination of vaccine and Ampligen. A potential VDE risk (vaccine-induced disease enhancement) was observed. The other TLR agonist at an unspecified dose lowered the eosinophilic score with their vaccine antigen more than Ampligen and their vaccine antigen (no data for other TLR agonist was provided). Importantly, Shionogi presented no evidence that Ampligen had any potential VDE risk by itself. In fact, the preclinical findings of 100% survival and no loss of weight suggests Ampligen was generally well-tolerated by the experimental cohort. We note that Shionogi's report indicated that an assessment of eosinophilic infiltration in the lungs of the Ampligen + vaccine antigen treated animals was significantly lower than that seen of the rodents treated with the Shionogi vaccine antigen alone. This indicates that the use of Ampligen lowered the potential for any vaccine-induced disease enhancement.

Effective November 19, 2020, by mutual agreement, AIM and Shionogi have terminated their Material Transfer Agreement.

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 in this Report speak only as of the date of this Report. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. For instance, no assurance can be given as to whether or when we will commence trials on Long Haulers or, if commenced, whether such trials will prove successful. 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 immuno-oncology 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, we cannot assure that the clinical studies will be successful or yield any useful data or require additional funding. Some of the world's largest pharmaceutical companies and medical institutions are racing to find a treatment for COVID-19. Even if Ampligen proves effective in combating the virus, no assurance can be given that our actions toward proving this will be given first priority or that another treatment that eventually proves capable will not make our efforts ultimately unproductive. 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.

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.

November 20, 2020

By: */s/ Thomas K. Equels*