

**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 24, 2020 (June 23, 2020)

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 June 23, 2020, we entered into a Specialized Services Agreement (the “Agreement”) with Utah State University (“USU”). Pursuant to the Agreement, USU will conduct *in vitro* tests on the antiviral activity of Ampligen on SARS-CoV-2 in Diploid normal human bronchial epithelial (dNHBE) cells. Please see Item 8.01 below.

Item 8.01. Other Events.

Pursuant to the Agreement and our previously discussed Material Transfer and Research Agreement with the University of Rochester (“UR”), we are seeking to create toll-like receptor sensitive *in vitro* (in glassware, test tubes or labware) experimental models that are designed to accommodate the biological mechanism of action of Ampligen, a TLR3 agonist, as well as that of other up-and-coming TLR based antivirals. Such immune-based antivirals are potentially important tools in the future of virology, principally because, if proven effective, these types of antivirals have the potential to work on many viral types, casting a very broad spectrum. Thus, when there is a new virus that emerges, TLR based antivirals may become the first line of defense for novel viral outbreaks. The public health importance of developing broad spectrum immunological antivirals cannot be ignored. We believe *in vitro* testing is an important tool in developing these future immunological antivirals and compliments and accelerates progress in understanding a prospective therapy’s biomechanism of action. We intend to conduct such testing in parallel to *in vivo* (*in a live animal*) experiments as well as human clinical trials involving Ampligen. Similar *in vitro* protocols, complimenting planned *in vivo* animal experiments, are also expected to be adopted as part of our Japanese based programs.

We previously noted that certain initial *in vitro* tests performed at Japan’s NIID were inconclusive due to problems with AIM’s experimental model. We believe that the work being done at UR and USU will provide a usable experimental model here and in Japan.

It is important to note several factors, as we work to obtain an effective *in vitro* model for experimentation that allows examination and understanding of Ampligen’s unique Toll-like Receptor 3 mechanism of action against SARS-CoV-2.

First, Ampligen has proven efficacy in animals in SARS-Cov-1 virus animal experiments. In the SARS-CoV-1 virus, using *in vivo* mouse models, which are a far better general gauge of potential effectiveness in mammals than experiments *in vitro*. Ampligen demonstrated *in vivo* 100% protective survival benefit compared to 100% mortality in a saline control group. Ampligen also reduced SARS-CoV-1 lung titers to below the level of detection ([Day 2009](#) and [Barnard 2006](#)). However, similar animal models with mice designed to replicate the human response to SARS-CoV-2 are not yet readily available for experimentation.

Accordingly, while waiting for experimental animal models for COVID-19 research to become readily available, we initially attempted an *in vitro* experimental model using an “off the shelf,” commercially available African Green Monkey (AGM) kidney cell line, called BS-C-1. AGM kidney cell lines are often used to reproduce viruses and are a cheap and available resource. These are acceptable cells to grow both SARS-CoV-1 and -2. However, we knew that there could be a problem using AGM cells, because some have lost the genetic capacity to allow Ampligen’s biomechanics to be expressed. This general effect was first observed and reported in 2006 in Table 1 of the [Barnard, et al. publication in Antiviral Chemistry and Chemotherapy 2006, 17:275](#), where Ampligen showed no *in vitro* activity against SARS-COV-1 using an AGM Vero76 cell line. Recognizing that phenomenon, we attempted something slightly different, using off the shelf AGM kidney BS-C-1 cells instead of Vero76 cells in our experimental model. However, similar to the problem observed by Dr. Barnard with the AGM Vero76 cells, this AGM kidney BS-C-1 cell line did not prove a workable experimental model either. This may be due to the very same feature which impaired the AGM Vero76 cell *in vitro* experimentation with Ampligen in 2006. Unfortunately, over the last 17 years, it appears that some AGM cell lines may have lost through the cloning selection process the genetic information needed for Ampligen to express and exert its antiviral activity.

Recognizing this defect in the *in vitro* model, Barnard, et al. then used an *in vivo* mouse model, Ampligen showed high antiviral activity with reduction in lung titers of SARS-CoV-1 to below the level of detection. Then, in a 2009 follow-up animal experiment, Ampligen demonstrated 100% protective survival as compared to 100% mortality in the control group of rodents. For these reasons, while awaiting the availability of an *in vivo* animal experimental model, we are pursuing a potentially more relevant *in vitro* model, which allows for analysis of TLR3 activity using primary human lung epithelial cells to study Ampligen’s antiviral activity against SARS-CoV-2. Diploid normal human bronchial epithelial (dNHBE) cells, taken from human lungs, or similar primary cells, will be the experimental cells for future *in vitro* testing. These primary cells have TLR3 receptors and the ability to produce and be influenced by type 1 interferon, all of which are central to Ampligen’s mechanism of action. Accordingly, we are currently working on such a modified *in vitro* model with the above referenced institutions while preparing for animal and clinical data because we believe that such experiments can provide important information regarding Ampligen’s mechanism of action, both corroborating and possibly explaining future *in vivo* animal pre-clinical and human clinical data.

Cautionary Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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. These statements involve a number of risks and uncertainties. While finding an appropriate *in vitro* experimental model for testing TLR based anti-viral drugs is not essential to Ampligen’s future development, having such a functional experimental model in place will be beneficial to future anti-viral research involving TLR drugs. No assurance can be given that an effective *in vitro* experimental model for TLR applications will be developed or, if developed, that Ampligen will prove effective in such a model against any particular virus. With regard to the Company’s activities related to COVID-19, significant additional testing and trials will be required to determine whether Ampligen will be effective in the treatment of COVID-19 in humans and no assurance can be given that it will be the case. With regard to the Company’s activities with Ampligen generally, no assurance can be given as to whether current or planned 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. Some of the world’s largest pharmaceutical companies 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, even if Ampligen proves effective, another treatment that eventually proves effective will not make our efforts ultimately unproductive. No assurance can be given that future studies will not result in findings that are different from those reported in studies we are relying on. 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. Commercialization in Argentina still requires, among other things, an appropriate reimbursement level, appropriate marketing strategies, completion of manufacturing preparations for launch. Approval of rintatolimod for severe CFS in Argentina does not in any way suggest that the Ampligen NDA in the United States or any comparable application filed in the European Union or elsewhere will obtain commercial approval. Any forward-looking statements set forth herein speak only as of the date of this press release. The Company does not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. The information found on our website is not incorporated by reference herein and is included for reference purposes only.

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.

June 24, 2020

By: /s/ Thomas K. Equels

Thomas K. Equels, CEO
