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)
October 5, 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 7.01. Regulation FD Disclosure.

AIM ImmunoTech Inc. (the "Company" or "AIM") is providing this update on efforts being undertaken by Shionogi & Co. Ltd. (Shionogi") and Japan's National Institute of Infectious Diseases (the "NIID") for the potential use of Ampligen as part of a COVID-19 vaccine, and the tripartite agreement between AIM, Shionogi and the NIID related to Ampligen as a potential adjuvant for an NIID COVID-19 vaccine candidate whose primary component, known as the antigen, is a protein molecule that triggers an immune response specific to the COVID-19 virus. This is created using a method known as the baculovirus-expression vector system ("BEVS").

The Japan Agency for Medical Research and Development ("AMED") has expressed support for efforts in Japan in a recent publication: "'The products of BEVS have already been used in human papillomavirus vaccine and influenza HA vaccine,' says Hideki Hasegawa, director of the NIID's Influenza Virus Research Center, and the project's principal investigator. 'Through our experience of influenza vaccine studies, we know that serum IgG antibodies are not protective against viral infection in upper respiratory epithelial cells. Secretory IgA antibodies instead play an essential role in the prevention of respiratory tract infection. So our final target is a COVID-19 mucosal vaccine which induces protective secretory IgA antibody in the respiratory tract mucosa.'" (see AMED's advertisement, which mentions AIM, "How AMED is supporting Japanese researchers tackling the novel coronavirus", *Nature Research, September 23, 2020*, a copy of which is furnished herewith as Exhibit 99.1). (See also: Ichinohe J Infect Dis. 2007, Overton Vaccine 2014 and AIM PR February 11, 2020)

Like many vaccines, the NIID candidate also contains a molecule known as an adjuvant, which aims to strengthen the immune response, and reduce the amount of antigen required. The team is planning to use a TLR9 or TLR3 (Ampligen) agonist as the adjuvant, according to Hasegawa, who is also collaborating with Kyushu University and Florida-based AIM ImmunoTech Inc. for adjuvant candidates.

AIM has made two shipments of Ampligen to Japan, first to the NIID and subsequently to Shionogi directly. Shionogi stated, "On 26th Aug., Shionogi most recently received Ampligen (80 frozen vials) provided by AIM. Shionogi has continuously conducted immunogenicity tests in mice in collaboration with the National Institute of Infectious Diseases (NIID) to examine the multiple candidate antigen proteins including candidate adjuvants."

The information in this item, including Exhibit 99.1, is "furnished" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Securities Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended, if and to the extent such subsequent filing specifically references the information herein as being incorporated by reference in such filing.

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 example, according to the advertisement, the NIID candidate contains a molecule known as an adjuvant and the team is planning to use a TLR9 or TLR3 agonist. No assurance can be given that the Company's Ampligen (a TLR3 agonist) will be chosen. In addition, 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. 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, 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 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.

We note that some of the information provided in this Report is from the AMED advertisement furnished herewith as Exhibit 99.1. According to the advertisement, AMED "was established by the Japanese government in 2015 to support medical R&D in various fields, ranging from basic research to clinical trials. AMED is funding at least five research projects related to COVID-19." The advertisement states: "As the world struggles to adjust to a new normal with the novel coronavirus, researchers around the globe are working to end the pandemic. In Japan, AMED is supporting scientists to contribute to the international effort to develop a vaccine, as well as drugs to treat COVID-19, the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)."

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 AMED's advertisement, "How AMED is supporting Japanese researchers tackling the novel coronavirus".

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.

October 5, 2020

By: */s/ Thomas K. Equels*

Thomas K. Equels, CEO

How AMED is supporting Japanese researchers tackling the novel coronavirus

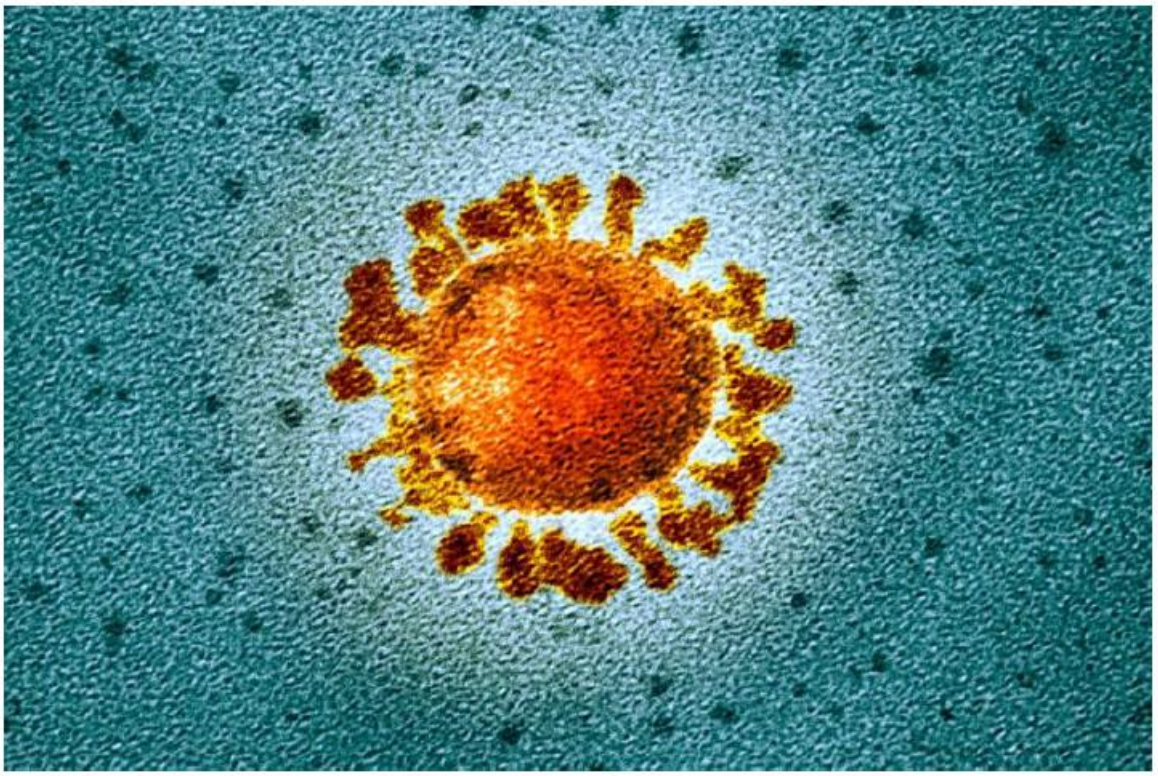
Japanese medical R&D funding body AMED has thrown its weight behind projects aiming to prevent or treat COVID-19.

Produced by

nature research custom media

Japan Agency for Medical Research and Development

As the world struggles to adjust to a new normal with the novel coronavirus, researchers around the globe are working to end the pandemic. In Japan, AMED is supporting scientists to contribute to the international effort to develop a vaccine, as well as drugs to treat COVID-19, the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).



False-color transmission electron micrograph of a SARS-CoV-2 coronavirus particle isolated from a UK COVID-19 patient.(c) NATIONAL INFECTION SERVICE/SCIENCE PHOTO LIBRARY

Quest for a vaccine

The most eagerly awaited defence against the coronavirus is a vaccine. Around the world, countries have pledged billions of dollars to support vaccine research and implementation, and there are more than 70 candidates in development. In May, Osaka-based pharmaceutical company Shionogi & Co. said it hopes to begin clinical trials this year with an eye to launching a vaccine as early as autumn 2021. It's aiming to produce enough vaccine for 10 million people, and is working with its subsidiary, Yokohama-based manufacturer, UMN Pharma, and researchers at Japan's National Institute of Infectious Diseases (NIID).

The research is supported by funds from the Japan Agency for Medical Research and Development (AMED), which was established by the Japanese government in 2015 to support medical R&D in various fields, ranging from basic research to

clinical trials. AMED is funding at least five research projects related to COVID-19. Aside from the vaccine effort, it's supporting basic science for coronavirus rapid- diagnosis kits and therapeutic drugs to treat patients with COVID-19, and exploring the use of animal models such as hamsters, mice, and ferrets.

The NIID vaccine candidate's primary component, known as the antigen, is a protein molecule that triggers an immune response specific to the COVID-19 virus. This is created using a method known as the baculovirus-expression vector system (BEVS).

"The products of BEVS have already been used in human papillomavirus vaccine and influenza HA vaccine," says Hideki Hasegawa, director of the NIID's Influenza Virus Research Center, and the project's principal investigator. "Through our experience of influenza vaccine studies, we know that serum IgG antibodies are not protective against viral infection in upper respiratory epithelial cells. Secretory IgA antibodies instead play an essential role in the prevention of respiratory tract infection. So our final target is a COVID-19 mucosal vaccine which induces
protective secretory IgA antibody in the respiratory tract mucosa."

Like many vaccines, the NIID candidate also contains a molecule known as an adjuvant, which aims to strengthen the immune response, and reduce the amount of antigen required. The team is planning to use TLR9 or TLR3 agonists as the adjuvant, according to Hasegawa, who is also collaborating with Kyushu University, as well as Florida-based AIM Immuno Tech for adjuvant candidates.

Work at the NIID is progressing despite the requirement to study the virus in biosafety level-3 facilities, which demands protective clothing and equipment such as biosafety cabinets. There are also limits on meeting colleagues physically, even though social restrictions have not been as stringent in Japan relative to some countries.

A multifront fight

AMED is supporting research efforts in drug discovery, including an open-label, randomized clinical trial to evaluate favipiravir, a drug developed by Fujifilm Holdings' unit Fujifilm Toyama Chemical Co. for influenza. There are hopes that favipiravir, marketed as Avigan, might help moderate and mild cases of COVID-19.

With AMED backing, NIID researchers have also been searching for compounds that can inhibit growth of the virus through methods such as random screening of existing approved drug libraries. They're also focused on antibodies.

"By using a high-throughput monoclonal antibody isolation technique, a human- type therapeutic monoclonal antibody against the virus is rapidly being established," says Makoto Takeda, director of the NIID's Department of Virology 3 and principal investigator of the project. "Currently, work is being done on the analysis of infection mechanisms; purification and structural analysis of high- purity proteins; screening of small-molecule compound libraries; preparation of recombinant antigens targeting therapeutic antibodies; research and development of human monoclonal antibodies using these antigens; screening of existing drugs; virus propagation development of a real-time reverse transcription polymerase chain reaction system for monitoring systems; and screening of natural compound libraries."

One of those natural compounds has shown potential. The anti-inflammatory cepharanthine, isolated from the perennial vine *Stephania cephalantha* Hayata, has been used in Japan for decades to treat disorders such as a low white blood cell count, dry mouth and alopecia. In a paper published on BioRxiv, a preprint repository for studies that have not been peer-reviewed, Takeda and colleagues describe how they developed a SARS-CoV-2 isolation and propagation system that helped them create an efficient screening system for antiviral drugs. Computer modeling showed that a drug called nelfinavir could inhibit viral replication while cepharanthine could stop the virus from latching onto and entering cells and in vitro assays highlighted their synergistic effect against the virus. "Combining nelfinavir/cepharanthine enhanced their predicted efficacy to control viral proliferation, to ameliorate both the progression of disease and risk of transmission," the authors wrote.

Defeating the coronavirus is a mammoth effort. While working to find other potential tools to help the effort, Takeda is encouraged that Japan is still able to contribute.

“Of course, Japan may also face the risk of explosion of cases like the US or Europe,” he says, “but our knowledge on COVID-19 is greater than before, and every day we learn more about what we should do to contain COVID-19.”

AMED is seeking experience international researchers to review grant proposals submitted to AMED. If you are interested in becoming a grant reviewer, find out more here.