UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): **April 13, 2020 (April 13, 2020)**

PLURISTEM THERAPEUTICS INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	**001-31392**	**98-0351734**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

MATAM Advanced Technology Park **Building No. 5** **Haifa, Israel**	**3508409**
(Address of Principal Executive Offices)	(Zip Code)

011 972 74 710 7171
(Registrant's telephone number, including area code)

Not applicable
(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:

☐ 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))

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.00001 per share	PSTI	The Nasdaq Capital Market

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. ☐

Item 8.01. Other Events.

On April 13, 2020, Pluristem Therapeutics Inc., or the registrant, announced that it treated its first patient suffering from COVID-19 complications in the United States under the U.S. Food and Drug Administration's Single Patient Expanded Access Program, also called a compassionate use program, which is part of the U.S. Coronavirus Treatment Acceleration Program, an emergency program for possible therapies that uses every available method to move new treatments to patients as quickly as possible. The patient was treated with the registrant's PLX cells at Holy Name Medical Center in New Jersey, an acute care facility that is currently an active site for the registrant's Phase III critical limb ischemia study. Prior to treatment with PLX, the patient was critically ill with respiratory failure due to acute respiratory distress syndrome and was under mechanical ventilation in an intensive care unit for three weeks. The registrant further announced that in parallel with its planned clinical trial, it expects to continue treating patients under compassionate use through the appropriate regulatory clearances in the United States and Israel, as well as expanding treatment under compassionate use in other countries. However, the registrant's main focus remains the initiation of a multinational clinical study on the effects of its PLX cells on patients suffering from COVID-19 complications.

Warning Concerning Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and federal securities laws. For example, forward-looking statements are being used when the registrant discusses its expectation that it will continue treating patients under compassionate use given continued regulatory clearance in the United States and Israel, that it expects to expand such compassionate use through the appropriate regulatory clearances in the United States and Israel, as well as expanding treatment under compassionate use in other countries and that Pluristem's main target is to initiate a multinational clinical trial as soon as possible for PLX cells in the treatment of patients suffering from complications associated with COVID-19. These forward-looking statements and their implications are based on the current expectations of the management of the registrant only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; the registrant may encounter delays or obstacles in launching and/or successfully completing its clinical trials; the registrant's products may not be approved by regulatory agencies, the registrant's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; the registrant may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; the registrant's products may wind up being more expensive than the registrant anticipates; results in the laboratory may not translate to equally good results in real surgical settings; results of preclinical studies may not correlate with the results of human clinical trials; the registrant's patents may not be sufficient; the registrant's products may harm recipients; changes in legislation; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause the actual results or performance of the registrant to differ materially from those contemplated in such forward-looking statements. In addition, historic results of scientific research do not guarantee that the conclusions of future research would not suggest different conclusions or that historic results would not be interpreted differently in light of additional research or otherwise. Except as otherwise required by law, the registrant undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting the registrant, reference is made to the registrant's reports filed from time to time with the Securities and Exchange Commission.

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.

PLURISTEM THERAPEUTICS INC.

By: */s/ Chen Franco-Yehuda*
Name: Chen Franco-Yehuda
Title: Chief Financial Officer

Date: April 13, 2020