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): **May 14, 2020 (May 14, 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 May 14, 2020, Pluristem Therapeutics Inc., or the registrant, provided an update on the status of COVID-19 infected patients treated with PLX cells under a compassionate use program in Israel and the FDA single patient Expanded Access Program in the U.S. All treated patients were in Intensive Care Units (ICU), on invasive mechanical ventilation and suffered from Acute Respiratory Distress Syndrome (ARDS) at the time of treatment. As of May 14, 2020, a total of 18 patients were treated in Israel and in the U.S., of which 8 (1 in the U.S and 7 in Israel) so far have completed a 28 day follow up period. Of the 8 patients, the registrant reported that the survival rate of patients treated with PLX cells was 87.5% at 28 day follow up, 75% of patients were off any mechanical ventilation at 28 day follow up, and 62.5% of patients were discharged alive from the hospital by 28 day follow up compared to 3.3% (38 out of 1,151 patients) in data published in the NY area during March-April 2020 for patients requiring mechanical ventilation and discharged alive. The registrant reported that it continues to treat patients through its compassionate use and Single Patient Expanded Access Programs in Israel and the U.S., and intends to provide a final update regarding such programs once it has completed them and its Phase II study with respect to the use of its PLX cells for the treatment of severe COVID-19 cases complicated by ARDS. Additionally, the registrant reported that it expects to treat its first patient with respect to its Phase II clinical study in the U.S. for the use of PLX cells in the treatment of severe COVID-19 cases complicated by ARDS in the coming days.

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 intention to provide updates on the remaining patients treated under the compassionate use program in Israel and an Expanded Access program in the U.S. once available and after the conclusion of its Phase II study, its intention to continue to enroll patients in its Expanded Access Program and the timing of the enrollment of its first patient in its Phase II study in the U.S. 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: May 14, 2020