

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 8, 2020 (May 8, 2020)**

PLURISTEM THERAPEUTICS INC.
(Exact Name of Registrant as Specified in Its Charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-31392
(Commission File Number)

98-0351734
(IRS Employer
Identification No.)

**MATAM Advanced Technology Park
Building No. 5
Haifa, Israel**

(Address of Principal Executive Offices)

3508409
(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 8, 2020, Pluristem Therapeutics Inc., or the registrant, announced that the U.S. Food and Drug Administration has cleared the registrant's investigational new drug (IND) application for a Phase II study of its PLX cells in the treatment of severe COVID-19 cases complicated by Acute Respiratory Distress Syndrome, or ARDS. The Phase II study will treat 140 adult patients that are intubated and mechanically ventilated and are suffering from respiratory failure and ARDS due to COVID-19. The primary efficacy endpoint of the study is the number of ventilator free days during the 28 days from day 1 through day 28 of the study. The objective of the study is to evaluate the efficacy and safety of one or two intramuscular injections, in three different dosages, of PLX-PAD for the treatment of ARDS resulting from COVID-19. The primary endpoint determination will be performed at the end of the 28 day main study period. Safety and survival follow-up will be conducted at week 8, 26 and 52. In addition, the registrant reported that a clinical trial authorization (CTA) has also been filed in Europe for a Phase II COVID-19 trial, with the first European clinical sites planned in Germany and Italy. The registrant further announced that it believes it can complete enrollment quickly and further expects to provide guidelines on the expected study duration a few weeks following the commencement of the study.

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 the scope, endpoints, and enrollment of patients in the Phase II COVID-19 study, its expectation that it will complete a quick enrollment of its study, and that it will be able to provide guidelines on the expected study duration in the coming weeks. 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 8, 2020