

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): **August 10, 2020 (August 10, 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 August 10, 2020, Pluristem Therapeutics Inc., or the registrant, announced that Germany’s health regulatory agency, the Paul Ehrlich Institute, has cleared the registrant’s Phase II clinical protocol for its study titled, “A Randomized, Controlled, Multicenter, Parallel-Group Phase II Study to Evaluate the Efficacy and Safety of Intramuscular Injections of PLX PAD for the Treatment of severe COVID-19.” Forty patients hospitalized with severe cases of COVID-19 complicated by Acute Respiratory Distress Syndrome will be enrolled in the study. 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. Safety and survival follow-up will be conducted at day 60, week 26 and week 52.

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: August 10, 2020