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): **July 13, 2022 (July 13, 2022)**

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 Global 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 July 13, 2022, Pluristem Therapeutics Inc., or the registrant, announced topline results from its Phase III Study of muscle regeneration following hip fracture surgery. The registrant designed the study to determine the efficacy, safety, and tolerability of intramuscular administration of allogeneic PLX-PAD cells for the treatment of muscle injury following arthroplasty for hip fracture.

PLX-PAD was demonstrated to be an effective accelerator of muscle strength and regeneration. A significant increase in Hip Abduction Strength, or HAS, was observed at week 26 and week 52 for patients treated with PLX-PAD (n=120) in the injured leg (p=0.047, p=0.0022) and uninjured leg (p=0.073, p=0.0046) compared to placebo (n=120). This new data confirms the results demonstrated in the registrant's phase I/II study. The study did not meet the primary endpoint, which was the Short Physical Performance Battery test, or SPPB, at week 26. The SPPB is a series of physical performance tests used in older persons to assess lower extremity function and mobility.

PLX-PAD was well tolerated and demonstrated a significant increase in HAS. In the injured leg (i) patients treated with PLX-PAD cells showed an increase of 3.2kg from reference (week 6) to week 26 compared to 1.3kg in the placebo group, a 2kg difference (p=0.047); and (ii) patients treated with PLX-PAD cells showed an increase of 5.01kg from reference (week 6) to week 52 compared to 0.86kg in the placebo group, a 4kg difference (p=0.0022). In the uninjured leg (i) patients treated with PLX-PAD cells showed an increase of 2.3kg from reference (week 6) to week 26 compared to 0.51kg in the placebo group, a 1.8kg difference (p=0.073); and (ii) patients treated with PLX-PAD cells showed an increase of 3.3kg from reference (week 6) to week 52 compared to a decrease of 0.7kg in the placebo group, a 4kg difference, (p=0.0046).

When comparing the absolute HAS between study groups (treated versus placebo) at week 52, patients treated with PLX-PAD showed a 2.6kg higher score than placebo treated patients in the injured leg (p=0.0511). A similar benefit was seen in the uninjured leg, with a 2.2kg difference (p=0.113).

The increase in HAS was further supported by a positive trend in a 6-minute walk test at week 52, showing an increase in walking distance. PLX-PAD treated patients (n=36) were able to walk 296 meters versus only 266 meters in placebo treated patients (n=45). The 6-minute walk test evaluates the global and integrated responses of all the systems involved in walking (pulmonary, cardiovascular, systemic and peripheral circulation, musculoskeletal function, neuromuscular units, and muscle metabolism), and is an acceptable functional endpoint.

The registrant intends to seek further regulatory advice to find a way to bridge the gap between the impact on muscle strength and the functionality score as observed in the study. In addition, the registrant intends to explore business opportunities and partnerships to advance the development of its PLX-PAD product candidate.

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 that it intends to seek further regulatory advice to find a way to bridge the gap between the impact on muscle strength and the functionality score as observed in the study and that it intends to explore business opportunities and partnerships to advance the development of its PLX-PAD product candidate. 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: July 13, 2022