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 21, 2020 (July 21, 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. Entry into a Material Definitive Agreement.

On July 21, 2020, Pluristem Therapeutics Inc. issued a press release which includes a letter from its Chief Executive Officer, Mr. Yaky Yanay. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated July 21, 2020

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 21, 2020

Pluristem CEO Issues Shareholder Update on Clinical Programs

HAIFA, Israel, July 21, 2020 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing a platform of novel biological products, today issued an update to its shareholders from its Chief Executive Officer and President, Yaky Yanay.

Dear Fellow Shareholders,

During this challenging period marked by the ongoing global COVID-19 pandemic, we are continuing to advance our regenerative medicine product candidates with the aim of improving the lives and health of people around the world. In addition to our clinical programs, we are also taking an active role in finding an effective treatment solution to COVID-19 complications. We hope and believe that PLX-PAD may play an instrumental role in overcoming the devastating impact of the coronavirus.

Today I would like to provide an update on the key clinical milestones and corporate developments for the year to come. We are heading towards a pivotal year with four clinical readouts, on multiple opportunities for success in advancing PLX product candidates towards registration with applicable regulatory agencies. The entire Pluristem team is dedicated to success, and I would like to make sure all of you are aware of important milestones ahead of us.

Phase III Critical Limb Ischemia (CLI) Study

Over the last few months, we held discussions with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to reaffirm understandings related to the interim readout of our global pivotal Phase III study of PLX-PAD in CLI. We expect to announce top line interim data analysis results during the fourth quarter of calendar 2020.

***The interim process and possible outcomes*:**

An analysis of the interim data will have three possible outcomes: a) an earlier than planned end-of-study may be achieved if the top line interim data analysis achieves overwhelming efficacy ($p \leq 0.01$), b) the study may be declared futile if there is no probability of successfully achieving the primary endpoint on the full data set after enrolling all patients, or c) the study is in line with the protocol assumptions and considered to be in a promising zone for success. If the third possible outcome results, Pluristem will continue to enroll patients, and will analyze the data again on the full data set.

Following the FDA's and EMA's advice and recommendations, the following are the main items implemented in the study design and the interim readout:

1. The primary endpoint for the interim analysis will be identical to the full study endpoint, a comparison between the PLX-PAD treated group and the placebo treated group of the number of days from randomization to occurrence of major amputation of the index leg or death. We believe that meeting this endpoint in the interim readout will potentially enable us to start a discussion with the FDA and EMA regarding filing of a Biologics License Application (BLA) and Marketing Authorisation Application (MAA), respectively.

2. The original protocol design was to enroll 246 patients, with the protocol assumptions expecting 82 amputation or death events upon completion of one-year follow-up. Based on the regulators' recommendations, and in order to secure the statistical power for success, the full study analysis will be based on 82 events, rather than enrollment of 246 patients. We do not expect a significant change in the number of enrolled patients required to complete the 82 events. The interim readout will be conducted based on a minimum of 45 events, which have already occurred.

After a slowdown in enrollment due to COVID-19, we currently expect the pace of enrollment to accelerate and forecast to complete enrollment of the study population in the U.S., Europe and Israel by the fourth quarter of calendar 2020. This expectation takes into consideration the impact of COVID-19 on the access to treatment and follow up sites while maintaining the safety of the patients, as we continue to follow FDA and EMA guidelines for conducting clinical studies during COVID-19.

Phase III Muscle Regeneration Study following Hip Fracture

For our Phase III trial of PLX-PAD in muscle regeneration following hip fracture in the U.S., Europe and Israel, we have enrolled more than 60% of the 240 patients planned for the study and we expect to complete enrollment by the end of calendar 2020. Top line results are expected in the third quarter of calendar 2021.

Phase II COVID-19 Study

The Phase II U.S. study evaluating PLX-PAD in patients suffering from severe COVID-19 complicated by Acute Respiratory Distress Syndrome (ARDS) is planned to enroll 140 subjects. We continue to open sites in accordance with the changing dynamics of the spread of COVID-19 in the U.S. In addition, we are finalizing our discussions with Germany's health regulatory agency, the Paul Ehrlich Institute, in order to launch a study in Europe. Our target is to complete enrollment and to provide top line 28-days follow-up data on our U.S. study during the fourth quarter of calendar 2020.

Phase I Hematopoietic Cell Transplantation (HCT) Study

Our Phase I study of PLX-R18 in hematology, specifically for incomplete hematopoietic recovery following HCT, is enrolling patients in the U.S. and in Israel. Following discussions with our advisory board, we intend to complete enrollment with 20 patients. We expect to meet this milestone by the end of the third quarter of calendar 2020, and subsequently provide top line results in the first quarter of calendar 2021.

Financial Update

Pluristem had approximately $59 million in cash and cash equivalents as of June 30, 2020. We expect that our current resources, together with the funds expected from the European Investment Bank (EIB), assuming all agreed milestones are achieved, will support our operations for over three years. We believe this will enable us to complete the development of our current pipeline, with the goal to bring multiple product registrations both in the U.S. and Europe.

In these times of global challenges, we continue advancing our ongoing clinical trials, while keeping our commitment to the health and wellbeing of all of our stakeholders. We wish all our shareholders, clinical and business partners, employees and patients good health and resilience at this time.

Sincerely,
Yaky Yanay
Chief Executive Officer

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy product candidates. The Company has reported robust clinical trial data in multiple indications for its patented PLX cell product candidates and is currently conducting late stage clinical trials in several indications. PLX cell product candidates are believed to release a range of therapeutic proteins in response to inflammation, ischemia, muscle trauma, hematological disorders and radiation damage. The cells are grown using the Company's proprietary three-dimensional expansion technology and can be administered to patients off-the-shelf, without tissue matching. Pluristem has a strong intellectual property position; a Company-owned and operated GMP-certified manufacturing and research facility; strategic relationships with major research institutions; and a seasoned management team.

Safe Harbor Statement

This press release contains express or implied forward-looking statements within the Private/ Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, Pluristem is using forward-looking statements when it discusses its hope and belief that PLX-PAD will play an instrumental role in overcoming the impact of the coronavirus, the expected timing of the completion of enrollment and release of top line readouts from its various clinical studies, the potential outcomes from the top line interim data analysis results relating to its Phase III CLI study, the belief that the changes in the primary endpoint for the interim analysis from the Phase III CLI study will enable its study to meet the required endpoints for both the FDA and EMA and to start discussions regarding filing of a BLA, that it expects to receive the funds from the EIB and, such funds together with its existing cash and equivalents, will fund and support its operations for over three years and will enable it to execute its goals. These forward-looking statements and their implications are based on the current expectations of the management of Pluristem 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; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Pluristem's products may not be approved by regulatory agencies, Pluristem's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Pluristem may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Pluristem's process; Pluristem's products may wind up being more expensive than it anticipates; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; Pluristem's patents may not be sufficient; Pluristem's products may harm recipients; changes in legislation may adversely impact Pluristem; 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 Pluristem to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Pluristem 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 Pluristem, reference is made to Pluristem's reports filed from time to time with the Securities and Exchange Commission.

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