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): **April 24, 2020 (April 24, 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 April 24, 2020, Pluristem Therapeutics Inc., or the registrant, announced that the European Investment Bank, or the EIB, approved a €50 million non-dilutive financing, or the Approved Financing, to the registrant's subsidiary, or the Subsidiary, to support the Subsidiary's research and development in the EU to further advance its regenerative cell therapy platform, and to assist moving the products the products in its pipeline to market, with a special focus on clinical development of PLX cells as a treatment for complications associated with COVID-19. The registrant expects the signing of the definitive agreement relating to the Approved Financing to take place on April 30, 2020. The Approved Financing is expected to be deployed in three tranches, subject to the achievement of certain clinical, regulatory and scaling up milestones with the first tranche consisting of €20 million. The Approved Financing, if granted, will not be secured and will be payable to the EIB in lump sums following 5 years from the disbursement of the first and second tranches and, for the third tranche, in two annual payments following 4 years from its disbursement, with each tranche having an interest rate of between 3% to 4%.The Approved Financing will support up to 50% of the registrant's research and development project costs. In addition, the EIB would be entitled to receive royalties from future revenues for a period of seven years starting 2024, at a rate of 0.2% to 2.3%, pro-rated to the amounts that the registrant disbursed from the Approved Financing. The registrant believes that the Approved Financing will allow it to significantly advance the clinical development of its lead product candidates and further believes that the Approved Financing will accelerate its path to the approval of its multinational clinical trial for PLX cells to treat patients suffering from complications associated with COVID-19 and to make a potentially effective COVID-19 treatment available worldwide. While the EIB has approved the Approved Financing, there is no guarantee that the registrant and the EIB will execute the definitive agreement on April 30, 2020, if at all, or that it will achieve the milestones necessary to receive any or all of the three tranches.

The Company is also supplementing the risk factors previously disclosed in the Company's Annual Report on Form 10-K for the year ended June 30, 2019 and its subsequent Quarterly Reports on Form 10-Q with the following risk factor:

The COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease, may materially and adversely affect our business and operations.

The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries, including the United States, Israel and many European countries in which we operate. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. While COVID-19 is still spreading and the final implications of the pandemic are difficult to estimate at this stage, it is clear that it has affected the lives of a large portion of the global population. At this time, the pandemic has caused states of emergency to be declared in various countries, travel restrictions imposed globally, quarantines established in certain jurisdictions and various institutions and companies being closed. We are actively monitoring the pandemic and we are taking any necessary measures to respond to the situation in cooperation with the various stakeholders.

Based on guidelines provided by the Israeli Government, employers (including us) are also required to prepare and increase as much as possible the capacity and arrangement for employees to work remotely. Nevertheless, in compliance with applicable rules, our offices remain open during the pandemic, though some of our workforce works remotely. In addition, COVID-19 infection of our workforce could result in a temporary disruption in our business activities, including manufacturing, and other functions.

The COVID-19 pandemic is also affecting the United States, Israel and global economies and has affected, and may continue to affect, the conduct of our clinical trials and may in the future affect our operations and those of third parties on which we rely, including by causing disruptions in our raw material supply, though to date we have not experienced any such disruptions.

In addition, the COVID-19 pandemic may affect the operations of the U.S. Food and Drug Administration, or the FDA, and other health authorities, which could result in delays of reviews and approvals, including with respect to our Phase III clinical trials relating to critical limb ischemia and muscle recovery following surgery for hip fracture. The evolving COVID-19 pandemic has already impacted, and may continue to, directly or indirectly impact the pace of enrollment in our clinical trials as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff can no longer get to the clinic. Additionally, such facilities and offices have been and may continue to be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, thereby decreasing availability, in whole or in part, for clinical trial services.

On April 7, 2020, we announced reporting preliminary data from our COVID-19 compassionate use program in Israel after treating seven patients suffering from acute respiratory failure and also announced our intention to apply for the initiation of a multinational regulated clinical trial program for the potential use of PLX cells in the treatment of patients suffering from complications associated with COVID-19. Further, on April 13, 2020, we announced that we treated our first patient suffering from COVID-19 complications in the United States under the FDA's Single Patient Expanded Access Program, also called a compassionate use program, which is part of the U.S. Coronavirus Treatment Acceleration Program, an emergency program for possible therapies that uses every available method to move new treatments to patients as quickly as possible. On April 13, 2020, we further announced that in parallel with our planned clinical trial, we expect to continue treating patients under compassionate use through the appropriate regulatory clearances in the United States and Israel, as well as expanding treatment under compassionate use in other countries. The impact of the use of our PLX cells in these compassionate use programs, as well as our expected clinical trial, if any, on our business and our results of operations cannot be predicted with certainty, as factors including, but not limited to, the ultimate duration and scope of the compassionate use authorization, as well as the availability of our product internationally, are not determinable at this time. Our PLX cells may not be successful in treating complications associated with COVID-19. Additionally, the stock market has been unusually volatile during the COVID-19 outbreak and such volatility may continue. To date, during certain periods of the COVID-19 pandemic, our stock price fluctuated significantly, and such fluctuation may continue to occur. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities, or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

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 timing of the execution of a definitive agreement for the Approved Financing and the proposed terms of such financing, that the Approved Financing will support the research and development in the EU to further advance its regenerative cell therapy platform, and to assist moving the products in its pipeline to market, with a special focus on clinical development of PLX cells as a treatment for complications associated with COVID-19, the belief that the Approved Financing will allow it to significantly advance the clinical development of its lead product candidates and the expectation that the Approved Financing will accelerate its path to approval of its COVID-19 multinational clinical trial and to making a potentially effective COVID-19 treatment available worldwide as well as statements concerning the implications of the COVID-19 pandemic on our clinical trials and operations. 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: April 24, 2020