

PLURISTEM THERAPEUTICS INC
Form 8-K
May 18, 2015

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 18, 2015

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)

31905
(Zip Code)

011 972 74 710 8607
(Registrant's Telephone Number, Including Area Code)

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))
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Item 8.01. Other Events.

On May 18, 2015, the registrant announced that its PLX cell program in critical limb ischemia (CLI) has been selected for the European Medicines Agency's Adaptive Pathways pilot project, the goal of which is to improve timely access for patients to new medicines. This project allows for early marketing authorization of a therapy in a restricted patient population, followed by additional assessments and the possibility of later approval for use in broader patient populations. Acceptance of the registrant's cells for the treatment of CLI into the Adaptive Pathways project could significantly curtail the time and investment needed to bring this product to market.

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, when the registrant discusses that the acceptance of its cells for the treatment of CLI into the Adaptive Pathways project could significantly curtail the time and investment needed to bring this product to market. 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; its products may not be approved by regulatory agencies, its technology may not be validated as the registrant 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 its products; unforeseen scientific difficulties may develop with its process; its 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. 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.

Date: May 18, 2015

By: /s/ Yaky Yanay
Name: Yaky Yanay
Title: Chief Financial Officer,
Secretary, Chief
Operating Officer and
President