

PLURISTEM THERAPEUTICS INC

Form 8-K

January 18, 2011

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): January 18, 2011 (January 18, 2011)

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 (I.R.S. Employer Identification Number)
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MATAM Advanced Technology Park Building No. 20 Haifa, Israel (Address of principal executive offices)	31905 (Zip Code)
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Registrant's telephone number, including area code: 011 972 74 710 7171

N/A
(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))
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Item 8.01 Other Events.

On January 18, 2011 the registrant announced that it successfully completed a parallel scientific advisory process with the European Medical Agencies (EMA) and the U.S. Food and Drug Administration (FDA) regarding the registrant's planned clinical development program for the registrant's product, PLX-PAD.

The registrant plans to conduct two clinical studies of PLX-PAD, and to file the necessary regulatory documentation requesting the joint approval of the FDA-EMA for a Phase II/III study of PLX-PAD for critical limb ischemia (CLI) and a joint approval of the FDA and the Paul Ehrlich Institute (PEI) in Germany to conduct Phase II study for Intermittent Caludication (IC).

Safe Harbor Statement

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, we are using forward looking statements when we say that we plan to conduct two clinical studies and file the regulatory documentation to obtain the required approvals for that. These forward-looking statements 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 PLX-PAD cells 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; we may encounter delays or obstacles in launching our clinical trials; our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we 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; our products may wind up being more expensive than we anticipate; results in the laboratory may not translate to equally good results in real surgical settings; our patents may not be sufficient; our 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 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: January 18, 2011

By: /s/ Yaky Yanay
Yaky Yanay
Chief Financial Officer