

PLURISTEM THERAPEUTICS INC
Form 8-K
January 21, 2014

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 21, 2014

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 7171
(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 January 21, 2014, the registrant issued a press release announcing initial results from its Phase I/II clinical trial testing the safety and efficacy of PLacental eXpanded (PLX-PAD) cells in the treatment of muscle injury. The trial was conducted at the Orthopedic Clinic of the Charité University Medical School under the auspices of the Paul-Ehrlich-Institute (PEI), Germany's health authority. The 20 patients in the study were randomized into three treatment groups. Each patient received an injection in the gluteal muscle that had been traumatized during surgery. One group was treated with 150 million PLX-PAD cells per dose (n=7), the second was administered 300 million PLX-PAD cells per dose (n=6), and the third received placebo (n=7). The registrant announced that the trial indicated PLX-PAD cells were safe and well tolerated. Statistical significance was reached ($p=0.0067$) for the primary efficacy endpoint of the study, the change in maximal voluntary isometric contraction force of the gluteal muscle at six months after total hip replacement with the group receiving the 150 million cell dose. The registrant reported that patients treated with PLX-PAD had a greater improved change of maximal voluntary muscle contraction force than the placebo group. The registrant expects complete dataset that includes biopsy results and functional assessments to be presented at a medical conference once the final analyses are completed.

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, when we discuss that PLX cells may be efficacious in the treatment of orthopedic injuries including muscles and tendons, we are using forward-looking statements. 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. In addition, historic results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions or that historic results referred to in this press release would be interpreted differently in light of additional research and clinical and preclinical trials results. 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 and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, 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; results of preclinical studies may not correlate with the results of human clinical trials; 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 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: January 21, 2014

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