PLURISTEM THERAPEUTICS INC
Form 8-K
November 03, 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): November 3, 2011

PLURISTEM THERAPEUTICS INC.
(Exact Name of Registrant as Specified in Its Charter)

Nevada
(State or Other Jurisdiction of Incorporation)

001-31392	98-0351734
(Commission File Number)	(IRS Employer Identification No.)
MATAM Advanced Technology Park Building No. 20 Haifa, Israel	31905
(Address of Principal Executive Offices)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On November 3, 2011, Pluristem Therapeutics Inc., or we or our, issued a press release announcing data from the completion of our twelve month clinical follow-up with respect to our placenta-derived cell therapy, PLX-PAD. The data from our two open-label, dose-escalation, Phase I clinical trials conducted in the US and Germany demonstrated a safe immunologic profile at all dosage levels and found PLX-PAD to be potentially effective in treating patients suffering from Critical Limb Ischemia (CLI), the end-stage of Peripheral Artery Disease (PAD). During the Phase I clinical trials we have collected information regarding the Amputation Free Survival (AFS) rate and compared with another published CLI trial's data. The data showed that from a total of twenty-seven patients, four treatment failures (Event) occurred during the observation period of twelve months, which resulted in an AFS rate of 85.2%, as opposed to historical control data of 66.8% for the same time period. This corresponded to an Event rate of 14.8%, as opposed to historical control data showing a 33.2% Event rate.

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 other federal securities laws. For example, we are using forward looking statements when we discuss the potential effectiveness of PLX-PAD in treating CLI, potentially reduced amputation rates from the use of PLX-PAD and the potential safety of PLX-PAD. These forward-looking statements are based on our current expectations 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: results in the clinical trials regarding safety and effectiveness may not translate to equally good results in real surgical settings or on a more widespread basis; technology and market requirements may change; 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; our patents may not be sufficient to protect our proprietary information; our products may harm recipients; legislation may change making it difficult for us to proceed with clinical trials or product sales; we may be unable to timely develop and introduce new technologies, products and applications; competition could cause us to lose market share and put pressure on pricing, all of which could cause our actual results or performance to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, we undertake 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 us, reference is made to our 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: November 3, 2011

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