PLURISTEM THERAPEUTICS INC
Form 8-K
March 24, 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): March 24, 2015

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. 5 Haifa, Israel	31905
(Address of Principal Executive Offices)	(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:

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 7.01. Regulation FD Disclosure.

On March 24, 2015, the registrant issued a press release describing key strategic objectives for development of PLX-R18 in hematopoietic indications. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Warning Concerning Forward Looking Statements

Exhibit 99.1 to 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 used in this press release when we discuss that PLX-R18 is safe and may significantly improve outcomes after bone marrow failure or hematopoietic cell transplantation, PLX-R18's potential to treat a broad range of indications, related to bone marrow function which, taken together, constitute a substantial global market, when we discuss our strategy, plans and clinical trials for the development of PLX-R18 in the upcoming year, when we discuss submitting an application to advance into an FDA-approved clinical trial this year in order to determine if the product can treat insufficient engraftment of transplanted hematopoietic cells, when we discuss our plans to continue working in partnership with the NIH in developing PLX-R18 as a potential treatment for acute radiation syndrome, when we discuss our expectation to receive in the upcoming months FDA guidance on the additional animal studies that would be required to approve PLX-R18, when we discuss our belief that an agreement with the FDA on the next steps needed for development of PLX-R18 in ARS couldwill encourage the NIH to support the required trials, when we discuss our plans to potentially contract with the U.S. government to stockpile the treatment for use in case of a nuclear disaster if the Company attains FDA approval of PLX-R18 for treatment of ARS, when we discuss continuous support, clinical trials and data generated by the NIH with respect to for PLX-R18, when we discuss our primary strategic focus in the upcoming year to initiate advanced trial in critical limb ischemia (CLI) via the rapid regulatory pathways now available in Japan and Europe, or when we discuss our belief that PLX-R18 may become a transformative treatment option for patients with insufficient engraftment of hematopoietic stem cells. These forward-looking statements and their implications are based on the current expectations of the management of Pluristem 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; 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 Pluristem to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Pluristem 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 Pluristem, reference is made to Pluristem's reports filed from time to time with the Securities and Exchange Commission.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 – Press release of Pluristem Therapeutics Inc. dated March 24, 2015.

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: March 24, 2015

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