PLURISTEM THERAPEUTICS INC
Form 8-K
May 03, 2017

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 3, 2017 (May 3, 2017)

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 7108607
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

On May 3, 2017, the registrant announced promising results of its non-human primates, or NHPs, pilot study for PLX-R18 as a treatment for Acute Radiation Syndrome. The study, conducted and funded by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, was designed to assess the safety and efficacy of PLX-R18 following intramuscular injection into irradiated and non-irradiated NHPs. While this pilot study was not powered to demonstrate statistical significance, all cohorts treated with PLX-R18 showed improved survival compared to cohorts that received placebo. In addition, No serious adverse reactions were observed in non-irradiated NHPs.

The data provided by the study will help inform a pivotal study designed to meet the requirements for a Biologics License Application, or BLA, submission under the Food and Drug Administration's, or FDA's, Animal Rule regulatory pathway.

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, forward-looking statements are being used when the registrant discusses its belief that the data from the NHP pilot study of PLX-R18 will help inform a pivotal study designed to meet the requirements for a BLA submission under the FDA's Animal Rule regulatory pathway. 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; the registrant's products may not be approved by regulatory agencies, the registrant's technology may not be validated as it 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 our products; unforeseen scientific difficulties may develop with our process; the registrant's 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. In addition, historic results of scientific research do not guarantee that the conclusions of future research would not suggest different conclusions or that historic results would not be interpreted differently in light of additional research or otherwise. 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 3, 2017 By: /s/ Yaky Yanay
Name: Yaky Yanay
Title: Co-Chief Executive Officer and President