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**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): **September 18, 2017**

**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 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. ☐

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**Item 8.01. Other Events.**

On September 18, 2017, the registrant announced that the U.S. Food and Drug Administration, or the FDA, has granted Fast Track Designation to the registrant's ongoing Phase III study of PLX-PAD cells for the treatment of Critical Limb Ischemia, or CLI, in patients ineligible for revascularization. With Fast Track Designation, there is an increased possibility for a priority review by the FDA of PLX-PAD cells for the treatment of CLI.

**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 states that the Fast Track Designation of its Phase III study of PLX-PAD cells for the treatment of CLI may increase the possibility of a priority review by the FDA. 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.

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**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: September 18, 2017

By: /s/ Yaky Yanay  
Name: Yaky Yanay  
Title: Co-Chief Executive Officer and  
President

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