

PLURISTEM THERAPEUTICS INC
Form 8-K
January 09, 2018

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 8, 2018

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 31905
Haifa, Israel
(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 2.01. Completion of Acquisition or Disposition of Assets.

On January 8, 2018, the registrant sold its entire holdings in CHA Biotech Co. Ltd, or CHA, consisting of 400,368 shares of CHA, or the CHA Shares, on the open market for aggregate net proceeds to the registrant of approximately \$10.5 million, representing a net gain of \$6.2 million. The CHA Shares were previously presented as "Marketable Securities" and classified in the registrant's financial statement as available-for-sale in accordance with Accounting Standards Codification 320, "Investments - Debt and Equity Securities." The registrant expects to recognize net financial income of \$6.2 million from the sale of the CHA Shares in the registrant's statement of operations for the nine months that will end on March 31 2018. For additional information regarding the registrant's relationship with CHA, see Note 1.c of the notes to interim condensed consolidated financial statements contained in the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017.

Item 8.01. Other Events.

On January 9, 2018, the registrant announced that the U.S. Food & Drug Administration has cleared the registrant's Expanded Access Program, or EAP, for the use of its PLX-PAD cell treatment in patients with Critical Limb Ischemia, or CLI. EAP allows the use of an investigational medical product outside of clinical trials and is usually granted in cases where patients are unsuitable for inclusion under the study protocol and the patient's condition is life-threatening with an unmet medical need. As part of the EAP, the registrant's PLX-PAD cell therapy will be made available to a limited number of Rutherford Category 5 CLI patients in the U.S., who are unsuitable for revascularization and cannot take part in the registrant's ongoing Phase III clinical study.

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 expected recognition of financial income from its sale of the CHA Shares, as well as that its PLX-PAD cell therapy will be made available to a limited number of Rutherford Category 5 CLI patients in the U.S. 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: January 9, 2018 By: /s/ Erez Egozi
Name: Erez Egozi
Title: Chief Financial Officer
