PLURISTEM THERAPEUTICS INC
Form 8-K
May 27, 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): May 27, 2015 (May 25, 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<br>Building No. 5<br>Haifa, Israel | 31905 |
| (Address of Principal Executive Offices) | (Zip Code) |

011 972 74 7107171
(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 May 25, 2015, the registrant issued a letter to its shareholders as of that date. The letter is furnished as Exhibit 99.1 to this Current Report on Form 8-K. On May 27, 2015, the registrant posted an updated presentation to its website. A copy of the presentation is furnished with this Current Report on Form 8-K as Exhibit 99.2 and is incorporated herein by reference.

Warning Concerning Forward Looking Statements

Exhibit 99.1 and Exhibit 99.2 to this Current Report on Form 8-K contain 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 moving closer to reaching the registrant's objective to bring innovative, effective treatments to patients, when the registrant discusses its anticipation for new accomplishments in 2015, when the registrant discusses potential of approving its cells for the treatment of CLI via the Adaptive Pathway to significantly curtail the time and investment needed to bring this product to market, when the registrant discusses its anticipation that PLX-PAD cells could enter the market in 2018 to treat patients with the clearly defined subtype of CLI studied in the trial, when the registrant discusses achieving additional partnership for its CLI program over the next twelve months, when the registrant discusses its planned study of PLX-R18 in humans, the timing of its submission and related FDA and NIH approvals, when the registrant discusses the timing for completion of recruitment for its phase II IC trial, when the registrant discusses that PLX-PAD cells may potentially treat additional muscle indications, when the registrant discusses the timing for submission of Phase II study protocol to several national authorities for PLX-PAD cells in CLI and submission for Phase I/II study protocol to the PMDA, or when the registrant discusses timing for receipt of preliminary data from the Phase I trial in pulmonary arterial hypertension. 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; 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 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 referred to in this letter would not be interpreted differently in light of additional research or otherwise. Also, while the company's program was selected for the European Medicines Agency's Adaptive Pathways pilot project, as well as recognized by the PMDA, these agencies are not bound by these communications and accordingly may change their position in the future due to reasons within or outside the control of the registrant 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.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 – Letter to the shareholders of Pluristem Therapeutics Inc. dated May 25, 2015.

99.2 – Presentation of Pluristem Therapeutics Inc. dated May 27, 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: May 27, 2015

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