

PLURISTEM THERAPEUTICS INC

Form 8-K

June 20, 2011

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): June 20, 2011 (June 19, 2011)

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. 20
Haifa, Israel
(Address of Principal Executive Offices)

31905
(Zip Code)

011 972 74 710 7171
(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))
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Item 1.01. Entry Into a Material Definitive Agreement.

On June 19, 2011, the registrant's wholly owned Israeli subsidiary, Pluristem Ltd. ("Pluristem"), entered into an Exclusive License Agreement (the "Agreement") with United Therapeutics Corporation ("United Therapeutics"), for the use of Pluristem's PLacental eXpanded ("PLX") cells to develop and commercialize a cell-based product for the treatment of Pulmonary Hypertension (the "Field"). Under the terms of the Agreement, United Therapeutics will receive exclusive worldwide license rights for development and the commercialization of the PLX-based product in the Field. In addition, in the event that United Therapeutics and Pluristem develop a tissue-engineered product based on PLX to replace lung function, United Therapeutics shall receive a first right to negotiate the use of such product outside the Field. Pluristem will hold manufacturing rights for the developed product, except for certain events of failure to supply where United Therapeutics would then have the right to manufacture the developed product for use in the Field.

Pursuant to the terms of the Agreement, Pluristem is eligible to receive aggregate payments of up to approximately \$55 million, to be paid by United Therapeutics as follows: (i) \$7 million within 15 days following the Effective Date (as defined below); (ii) up to \$37.5 million upon reaching certain regulatory milestones with respect to the product in the Field; and (iii) in the event the parties agree to establish a manufacturing facility in North America following a successful Phase II clinical trial in the Field, the cost of such facility would be shared by the parties with United Therapeutics' commitment not to exceed \$10 million. Pluristem is also entitled to reimbursement of certain costs in connection with the development of the product. In addition, following commercialization, United Therapeutics will purchase commercial supplies of the developed product from Pluristem at a specified margin over Pluristem's cost. Finally, United Therapeutics will pay Pluristem specified royalties as a percentage of its gross profits generated from the developed product.

The Agreement contains mutual non-competition covenants during the term of the Agreement, a unilateral termination right exercisable by United Therapeutics and customary indemnification provisions.

The registrant has agreed to unconditionally guarantee the obligations and liabilities of Pluristem under the Agreement. The Agreement requires Pluristem to request, within 7 days from the date of the Agreement, the consent of the Office of Chief Scientist in Israel with respect to the subject matter of the Agreement. Upon receipt of this consent, the Agreement will automatically become effective (the "Effective Date"). If this consent is not obtained within 60 days from the date of the Agreement, then, absent a waiver by United Therapeutics, the Agreement will terminate.

Safe Harbor Statement

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, we are using forward-looking statements when we imply that we may receive future payments if our products are commercialized and generate gross profits. These forward-looking statements 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 our clinical trials; we may not obtain the required regulatory approval which is a condition to closing under the Agreement; 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; our patents may not be sufficient; our products may harm recipients; changes in legislation; inability to timely develop and introduce or commercialize 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.

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: June 20, 2011

By: /s/ Yaky Yanay
Name: Yaky Yanay
Title: Chief Financial
Officer

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