CELL THERAPEUTICS INC
Form 8-K
February 17, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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): February 17, 2012

CELL THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Washington	**001-12465**	**91-1533912**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

501 Elliott Avenue West, Suite 400

Seattle, Washington 98119

(Address of principal executive offices)

Registrant s telephone number, including area code: (206) 282-7100

Not applicable

(Former name or former address, if changed since last report).

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 (see General Instruction A.2. below):

¨ 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))

Item 7.01 Regulation FD Disclosure.

A copy of Cell Therapeutics, Inc. s (the Company) press release, entitled European Medicines Agency s Committee for Medicinal Products for Human Use Issues Positive Opinion for Conditional Approval on Marketing Authorization Application for Pixuvri is furnished and not filed pursuant to Item 7.01 as Exhibit 99.1 hereto. Such information shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the Exchange Act) or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any of the Company s filings under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date hereof and regardless of any general incorporation language in such filings, except to the extent expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On February 17, 2012, the Company announced that Pixuvri (pixantrone dimaleate) has been granted a positive opinion for conditional approval from the European Medicines Agency s (the EMA) Committee for Medicinal Products for Human Use (CHMP). CHMP recommended Pixuvri for conditional approval as monotherapy for the treatment of adult patients with multiple relapsed or refractory aggressive non-Hodgkin s B-cell lymphomas. A conditional marketing authorization is renewable annually. Under the provisions of the conditional marketing authorization for Pixuvri, the Company will be required to complete a post-marketing study aimed at confirming the clinical benefit previously observed.

Cautionary Statement Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995, regarding CHMP s positive opinion recommending conditional approval of the marketing authorization application for Pixuvri. Such forward-looking statements are based on current expectations, are predictive in nature, and involve known and unknown risks and uncertainties that may cause the Company s actual outcomes and results to differ materially from those projected or contemplated in the forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that that Pixuvri may not be approved as monotherapy for the treatment of adult patients with multiple relapsed or refractory aggressive non-Hodgkin s B-cell lymphomas, that the European Commission may not adopt CHMP s recommendation regarding Pixuvri, that the conditional marketing authorization may not be renewed and that the Company may not be able complete a post-marketing study aimed at confirming the clinical benefit previously observed. The Company can give no assurances that any results or events projected or contemplated by its forward-looking statements will in fact occur and the Company cautions you not to place undue reliance on these statements. The Company undertakes no duty to update these forward-looking statements to reflect any future events, developments or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release, dated February 17, 2012, entitled European Medicines Agency s Committee for Medicinal Products for Human Use Issues Positive Opinion for Conditional Approval on Marketing Authorization Application for Pixuvri.

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CELL THERAPEUTICS, INC.

Date: February 17, 2012

By: /s/ JAMES A. BIANCO, M.D.
James A. Bianco, M.D.
Chief Executive Officer

EXHIBIT INDEX

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