CELL THERAPEUTICS INC
Form 8-K
May 14, 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): May 14, 2012 (May 10, 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 Cell Therapeutics Pixuvri® Approved in European Union as Monotherapy to Treat Adult Patients with Multiply Relapsed or Refractory Aggressive Non-Hodgkin B-Cell Lymphomas 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, as amended (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 May 10, 2012, the Company announced that it has received conditional marketing authorization from the European Commission (EC) for Pixuvri as monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive non-Hodgkin B-cell lymphomas (NHL). Pixuvri is the first approved treatment in the European Union (EU) in this patient setting. The decision allows the Company to market Pixuvri in the 27 Member States of the EU as well as in Iceland, Liechtenstein and Norway. The Company expects to make Pixuvri immediately available in the EU, initially through a named patient program. The Company plans to market and commercialize Pixuvri with its own sales force in the EU starting in the second half of 2012.

Similar to accelerated approval regulations in the United States, conditional marketing authorizations are granted in the EU to medicinal products with a positive benefit/risk assessment that address unmet medical needs and whose availability would result in a significant public health benefit. 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. The European Medicine Agency s (the EMA) Committee for Medicinal Products for Human Use (the CHMP) has accepted PIX306, the Company s ongoing randomized controlled phase 3 clinical trial, which compares Pixuvri-rituximab to gemcitabine-rituximab in patients who have relapsed after one to three prior regimens for aggressive B-cell NHL and who are not eligible for autologous stem cell transplant (ASCT). As a condition of approval, the Company has agreed to have available the PIX306 clinical trial results by June 2015.

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, and include risks and uncertainties that could affect the development of Pixuvri and include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general, and with Pixuvri in particular, including, without limitation, that Pixuvri may not be immediately available to patients in the EU, that the Company may not market and commercialize Pixuvri with its own sales force in the EU starting in the second half of 2012, that the Company may not be able to complete the PIX306 clinical trial of Pixuvri-rituximab compared to gemcitabine-rituximab in patients who have relapsed after one to three prior regimens for aggressive B-cell NHL and who are not eligible for ASCT by June 2015 or at all as required by the EMA or have the results of such trial available by June 2015 or at all, that the Company may not be able complete a post-marketing study aimed at confirming the clinical benefit observed in the PIX 301 trial and that the conditional marketing authorization for Pixuvri may not be renewed. 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 May 10, 2012, entitled Cell Therapeutics Pixuvri® Approved in European Union as Monotherapy to Treat Adult Patients with Multiply Relapsed or Refractory Aggressive Non-Hodgkin B-Cell Lymphomas.

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: May 14, 2012

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

EXHIBIT INDEX

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