CELL THERAPEUTICS INC
Form 8-K
May 03, 2011

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 3, 2011

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.

On May 3, 2011, Cell Therapeutics, Inc. (the Company) issued a press release entitled Cell Therapeutics to Re-submit Pixantrone NDA in Consideration for Accelerated Approval in Accordance with Guidance from FDA s Office of New Drugs. A copy of the press release is furnished and not filed pursuant to Item 7.01 as Exhibit 99.1 hereto.

The information provided pursuant to this Item 7.01 shall not be deemed 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 filing or other document filed by the Company pursuant to the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof and regardless of any general incorporation language in such filings or documents, except to the extent expressly set forth by specific reference in such a filing or document. The information furnished pursuant to this Item 7.01 shall instead be deemed furnished.

Item 8.01 Other Events.

On May 3, 2011, the Company announced the decision of the Office of New Drugs (the OND) of the U.S. Food and Drug Administration (the FDA) with respect to the appeal that the Company filed in December 2010 under the FDA s formal dispute resolution process. In the appeal, the Company requested that the OND conclude that PIX301 demonstrated the efficacy of pixantrone. The OND indicated that after considering the data available in the appeal, it does not believe that accelerated approval of the Company s New Drug Application for pixantrone (the NDA) is necessarily out of reach based on a single controlled clinical trial, provided that two key matters can be resolved satisfactorily. First, the circumstances of stopping the PIX301 trial early must be resolved to assure that ongoing results assessment were not dictating the decision to stop. Second, ascertainment of the primary endpoint in the PIX301 study must be determined to have been sound and not subject to bias.

The OND also indicated that the Company s request that the OND find that the data in the NDA demonstrate efficacy and return the NDA to the Office of Oncology Drug Products for consideration of safety and other issues was denied because the OND was not able to conclude that efficacy had been demonstrated. However, the OND also did not find that it could be concluded that PIX301 was a failed study, which warranted application of interim analysis statistical thresholds. The OND further indicated that the Company could re-submit the NDA for a re-review of the safety and efficacy, provided that the two key matters can be resolved satisfactorily.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is furnished with this report on Form 8-K:

Exhibit Number	Description
99.1	Press Release, dated May 3, 2011, entitled Cell Therapeutics to Re-submit Pixantrone NDA in Consideration for Accelerated Approval in Accordance with Guidance from FDA s Office of New Drugs.

SIGNATURE

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.

CELL THERAPEUTICS, INC.

Date: May 3, 2011

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

EXHIBIT INDEX

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