CELL THERAPEUTICS INC
Form 8-K
April 09, 2010

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): April 9, 2010

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 the Cell Therapeutics, Inc. s (the Company) press release, entitled CTI Receives Complete Response Letter from the FDA for Pixantrone NDA; CTI to File for Expanded Access for Patients with Relapsed or Refractory Aggressive Non-Hodgkin s Lymphoma 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. The information furnished pursuant to this Item 7.01 shall instead be deemed furnished.

Item 8.01 Other Events.

On April 9, 2010, the Company announced that it had received a Complete Response Letter from the U.S. Food and Drug Administration (the FDA) regarding its New Drug Application for Pixuvri™ (pixantrone dimaleate) for relapsed or refractory aggressive non-Hodgkin s lymphoma (NHL). The FDA cited as its primary reason for the action its concerns previously raised at the Oncologic Drugs Advisory Committee (ODAC) meeting on March 22, 2010 and recommended the Company conduct an additional trial to demonstrate the safety and effectiveness of its product. Based on the FDA s ODAC presentation, which provided the Committee and the Company with alternative options to consider to make investigational drugs available to patients if drugs need to be studied further prior to approval, the Company has decided to pursue expanded access program for pixantrone while it conducts an additional study in aggressive NHL.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated April 9, 2010, entitled CTI Receives Complete Response Letter from the FDA for Pixantrone NDA; CTI to File for Expanded Access for Patients with Relapsed or Refractory Aggressive Non-Hodgkin s Lymphoma.

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: April 9, 2010

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

EXHIBIT INDEX

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