CELL THERAPEUTICS INC Form 8-K January 02, 2014

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): January 2, 2014 (December 26, 2013)

CELL THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Washington (State or other jurisdiction of 001-12465 (Commission 91-1533912 (I.R.S. Employer

incorporation or organization)

File Number) 3101 Western Avenue, Suite 600 **Identification Number**)

Edgar Filing: CELL THERAPEUTICS INC - Form 8-K

Seattle, Washington 98121

(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 January 2, 2014, Cell Therapeutics, Inc. (the Company) issued a press release announcing the removal of the partial clinical hold on tosedostat. The full text of such press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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, as amended (the Exchange Act) or otherwise subject to the liabilities of that section, and shall not 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, except as shall be expressly set forth by specific reference in such filing or document. The information provided pursuant to this Item 7.01 shall instead be deemed furnished.

Item 8.01. Other Events.

On December 26, 2013, the U.S. Food and Drug Administration (the FDA) notified the Company that the partial clinical hold has been removed on tosedostat (IND 075503), the Company s aminopeptidase inhibitor under development for the treatment of blood-related cancers. Under the prior partial clinical hold, the Company was not able to enter new patients onto any of the ongoing tosedostat protocols.

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, including, but not limited to, the potential benefits of tosedostat. Such statements are subject to risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results and the trading price of the Company s securities. Specifically, the risks and uncertainties that could affect the development of tosedostat include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general and with tosedostat in particular including, without limitation, the potential failure of tosedostat to prove safe and effective as determined by the FDA and/or the European Medicines Agency; determinations by regulatory, patent, and administrative governmental authorities; competitive factors; technological developments; costs of developing and producing tosedostat; and the risk factors listed or described from time to time in the Company s filings with the Securities and Exchange Commission, including, without limitation, the Company s most recent filings on Forms 10-K, 10-Q and 8-K. 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

No.

Description

Location

99.1 Press Release, dated January 2, 2014, announcing removal of the partial clinical hold.

Furnished herewith.

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: January 2, 2014

By:

/s/ Louis A. Bianco Louis A. Bianco Executive Vice President, Finance and Administration

EXHIBIT INDEX

Exhibit

No.	Description	Location
99.1	Press Release, dated January 2, 2014, announcing removal of the partial clinical hold.	Furnished herewith.