CELL THERAPEUTICS INC
Form 8-K
June 24, 2013

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): June 23, 2013 (June 17, 2013)

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)**

3101 Western Avenue, Suite 600

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 8.01. Other Events.

On June 17, 2013, the U.S. Food and Drug Administration (the FDA) notified Cell Therapeutics, Inc. (the Company) that a partial clinical hold has been placed on Tosedostat (IND 075503), the Company s aminopeptidase inhibitor under development for the treatment of blood-related cancers. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the investigational new drug (IND) application (e.g., a specific protocol or part of a protocol is not allowed to proceed; however, other protocols or parts of the protocol are allowed to proceed under the IND). Under the partial clinical hold, the Company may not enter new patients onto any of the ongoing Tosedostat protocols until agreement is reached with the FDA.

Recently, a patient, who was in their seventies and was being treated with Tosedostat in combination with 5-azacitine or cytarabine on an investigator sponsored trial in patients with relapsed or refractory acute myeloid leukemia or high risk myelodysplastic syndrome (MDS), died of myocarditis. The FDA has requested additional data on patients treated with Tosedostat, including additional information about the patient that died, a detailed review of all grades of cardiac adverse events or cardiac-related investigations in patients treated with Tosedostat, as well as benefit-risk analysis based on the data presented. The Company has begun work to comply with the FDA request and expects to be able to submit these data to the FDA in the coming weeks.

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, 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 our ability to address FDA requests or the development of Tosedostat more generally 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; the risk that we may not be able to submit data to the FDA in the coming weeks or that the FDA may expand its information request or initiate a complete clinical hold or take other actions; 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 and 10-Q. 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.

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: June 23, 2013

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