CELL THERAPEUTICS INC
Form 8-K
November 07, 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): November 7, 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 November 7 and 8, 2011, members of the management team of Cell Therapeutics, Inc. (the Company) will meet with analysts from brokers and with investors in Milan, Italy. A copy of the Company s slide presentation for such meetings is furnished and not filed as Exhibit 99.1 hereto.

The information provided pursuant to this Item 7.01 (including the information in the document filed as Exhibit 99.1) 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 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 (including the information in the document filed as Exhibit 99.1) shall instead be deemed furnished.

Certain Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report on Form 8-K include statements about future financial and operating results, and risks and uncertainties that could affect the Company s products under development. These statements are based on management s current expectations and beliefs and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These statements are not guarantees of future performance, involve certain risks, uncertainties and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. Therefore, actual outcomes and results may differ materially from what is expressed herein. In any forward-looking statement in which the Company expresses an expectation or belief as to future results, such expectation or belief is expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will result or be achieved or accomplished.

The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: risks associated with preclinical, clinical and sales and marketing developments in the biopharmaceutical industry in general and in particular, including, without limitation: the potential failure of Opaxio (Opaxio) to prove safe and effective for treatment of non-small cell lung and ovarian cancers; that the interim survival results for the phase III clinical trial for Opaxio may not be ready in 2012; the potential failure of PixuvriTM (pixantrone dimaleate) (pixantrone) to prove safe and effective (including complete and overall response rates) for treatment of relapsed or refractory, aggressive non-Hodgkin s lymphoma (NHL) as determined by the U.S. Food and Drug Administration (the FDA) and/or the European Medicines Agency (the EMA); that accelerated approval by the FDA of pixantrone may not be possible or occur; that the Company may not be able to address satisfactorily the two key matters raised by the FDA s Office of New Drugs (the OND) or other matters raised by the OND and/or the FDA; that the Company s interpretation of the guidance provided by the OND may be different than the intent of the OND; that the OND may change its guidance; that the PIX301 study may not be deemed successful; that a re-review of the pixantrone NDA may not be warranted and, if warranted, that the FDA may find pixantrone to not be safe

and/or effective; that the PIX301 study may still be deemed to be a failed study; that the FDA may require an additional clinical trial of pixantrone; that if the Company conducts an additional clinical trial, it may not demonstrate the safety and effectiveness of pixantrone; that the Company may not be able to provide satisfactory information in response to the FDA s Complete Response Letter; that the FDA may not approve the NDA in the first half of 2012 or at all; that the Company may not obtain a PDUFA date of April 2012; that the Company cannot predict or guarantee the pace or geography of enrollment of its clinical trials, including whether or not the majority of the patients will be enrolled in the U.S.; that the commercial launch of pixantrone may not commence in the first half of 2012; that the EMA may not approve the MAA; that the Company cannot guarantee the timing of the approval and launch of its products; that the Company cannot predict the results of the EMA s Committee for Medicinal Products for Human Use (CHMP) opinion or guarantee that the CHMP will provide its recommendation regarding the MAA during the first half of 2012; that the Company cannot guarantee exclusivity in the market for its products; that the Company cannot predict or guarantee that Novartis will exercise its option to negotiate a license for pixantrone or what the actual milestone amounts will be; that the Company cannot guarantee that the Gynecologic Oncology Group will conduct an interim survival analysis in 2012 or what the market size or outcome of such analysis will be; the potential failure of tosedostat to prove safe and effective for the treatment of Acute Myeloid Leukemia (AML); that the FDA may not accept the proposed clinical trial design of tosedostat and/or may request additional clinical trials; that clinical trials may not demonstrate the safety and effectiveness of tosedostat; that the phase III pivotal trial for tosedostat for AML and/or myelodysplastic syndromes may not start during the second quarter of 2012; that the Company may not be able to retire its outstanding convertible senior notes due in December 2011; that the Company may not consummate additional financings; that the Company may not be able to maintain its expected burn rate; that the Company s ability to continue to raise capital as needed to fund its operations; that the Company may not be able to maintain its burn rate as expected; that the Company may be unable to comply with NASDAQ listing standards; determinations by regulatory, patent and administrative governmental authorities; competitive factors; technological developments; costs of developing, producing and selling the Company s products under development; and other economic, business, competitive, and/or regulatory factors affecting the Company s business generally, including those set forth in the Company s filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for its most recent fiscal year and its Quarterly Reports on Form 10-Q since its most recent Annual Report on Form 10-K, especially in the Factors Affecting Our Operating Results and Management s Discussion and Analysis of Financial Condition and Results of Operations sections, and its Current Reports on Form 8-K. Except as may be required by law, the Company does not intend to update or alter its forward-looking statements whether as a result of new information, future events, or otherwise.

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	Cell Therapeutics, Inc. Presentation Slides.

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: November 7, 2011

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

EXHIBIT INDEX

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