CELL THERAPEUTICS INC
Form 8-K
November 17, 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): November 17, 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.**

On November 18, 2010, members of the management team of Cell Therapeutics, Inc. (the Company ) will host a presentation for investors and analysts in Milan, Italy at 12:00 p.m. (Milan time). A copy of the Company s slide presentation for such meeting is furnished and not filed 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, 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 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 to prove safe and effective for treatment of non-small cell lung and ovarian cancers, the potential failure of PixuvriTM (pixantrone dimaleate) to prove safe and effective (including complete and overall response rates) for treatment of non-Hodgkin s lymphoma as determined by the U.S. Food and Drug Administration (the FDA ) and/or the European Medicines Agency (the EMA ), that the Company s appeal to the FDA may not be successful, that the FDA s decision regarding the Company s appeal may not be made within 30 days of submission, that the Company may not accept the Company s Special Protocol Assessment and/or the proposed design for the protocol of the Company s clinical trial and/or may request additional clinical trials, that the FDA may revise or may not accept the proposed endpoints for the additional clinical trial, that if the Company conducts an additional clinical trial, it may not demonstrate the safety and effectiveness of PixuvriTM, 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 Company may not initiate the new PIX306 trial in 2010 or obtain data by the end of 2011, that the EMA may not approve the Company s Marketing Authorization Application, that the

Company may not obtain interim survival results for the Phase III GOG212 trial in 2011, that the Company may not achieve expected key milestones in the next twelve months or at all, that the Company may not be able to retire its 2011 debt, that the Company s expected financing of up to $75 million over the next two years may not occur or the terms of such financing may change, the Company s ability to continue to raise capital as needed to fund its operations, that the Company may not be able to reduce its burn rate as expected, 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 most recent Quarterly Report on Form 10-Q, 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 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: November 17, 2010

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

**EXHIBIT INDEX**

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