

CELL THERAPEUTICS INC
Form 8-K
January 29, 2009

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 23, 2009

CELL THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Washington
(State or other jurisdiction of
incorporation or organization)

001-12465
(Commission

91-1533912
(I.R.S. Employer

File Number)
501 Elliott Avenue West, Suite 400

Identification Number)

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):

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- .. 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 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On January 23, 2009, Cell Therapeutics, Inc. (the Company) received an Additional Staff Determination (the Determination Letter) from The NASDAQ Stock Market (NASDAQ) stating that the staff had concluded that the Company's recent issuance of 38,185,911 shares of common stock (the Shares) in connection with an amendment to the earn-out provision (the Amendment) of the Acquisition Agreement, dated as of July 27, 2007, by and among the Corporation, Cactus Acquisition Corp., Saguaro Acquisition Corporation LLC, Systems Medicine, Inc. (SMI) and Tom Hornaday and Lon Smith, in their capacities as representatives of the SMI stockholders (the Stockholder Representatives), whereby the Company acquired Systems Medicine, Inc. in a stock-for-stock merger, did not comply with the shareholder approval requirements set forth in NASDAQ Marketplace Rule 4350(i)(1)(C). Marketplace Rule 4350(i)(1)(C) requires shareholder approval in connection with an acquisition if the issuance or potential issuance is greater than 20% of the pre-acquisition shares outstanding.

In response to the concerns raised by the NASDAQ staff, the Company entered into a Cancellation Agreement dated January 23, 2009 with the Stockholder Representatives to cancel the Amendment and rescind the issuance of the 38,185,911 shares and to reinstate the original terms of the earn-out provision without modification.

The Determination Letter also indicated that the Company has at times not complied with Marketplace Rule 4310(c)(17), which requires companies to submit a Listing of Additional Shares form to NASDAQ no later than 15 days prior to entering into a transaction that involves the issuance of additional securities, including the form that was submitted in connection with the Amendment, and based upon the Company's history of non-compliance with certain of NASDAQ's corporate governance criteria, indicated that the Staff had raised public interest concerns under Marketplace Rule 4300.

As previously disclosed in the Company's Current Report on Form 8-K filed on January 8, 2009, the NASDAQ Listing Qualifications Panel (the Panel) recently granted the Company's request to transfer the listing of its common stock from The NASDAQ Global Market to The NASDAQ Capital Market, subject to the Company evidencing compliance with all applicable requirements for continued listing on The NASDAQ Capital Market, including the \$35 million market value of listed securities requirement or its alternatives, by February 12, 2009. The Determination Letter provided formal notice that the Panel will consider the additional matters raised by the Staff in rendering a determination regarding the Company's continued listing on The NASDAQ Capital Market. Pursuant to Marketplace Rule 4804(c), the Company will present its views with respect to those matters for the Panel's review no later than January 30, 2009.

On January 26, 2009, the Company issued a press release relating to the matters described herein, a copy of which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 8.01 Other Events

On January 27, 2009, the Company issued a press release announcing that after communication with the Food and Drug Administration (FDA), it expects to begin submission of a rolling New Drug Application (NDA) and request priority review for pixantrone to treat relapsed aggressive non-Hodgkin's lymphoma in the first quarter of 2009. The full text of the press release is attached hereto as Exhibit 99.2.

On January 28, 2009, the Company issued a press release announcing preliminary progression-free survival (PFS) results from its pivotal phase III EXTEND (PIX301) trial of pixantrone that show patients with advanced, relapsed aggressive non-Hodgkin's lymphoma (NHL) treated with pixantrone experienced a

statistically significant improvement in median progression-free survival, compared with other single-agent chemotherapeutic agents (4.7 months vs. 2.6 months, $p < 0.01$, pixantrone vs. standard chemotherapy) based on an intent to treat analysis. PFS was a prospectively defined secondary endpoint in the study. The full text of the press release is attached hereto as Exhibit 99.3.

By settlement agreement dated as of January 28, 2009, the Company agreed to pay within three court days a total amount of \$494,500 to settle all outstanding claims for attorneys' fees and expenses (such claims were previously disclosed to total \$1.4 million) by the *qui tam* Relator, in connection with an investigation by the United States Attorney's Office into certain of the Company's prior marketing practices relating to TRISENOX[®] (arsenic trioxide). This agreement fully and finally resolves all remaining claims in this civil action. The Company's separate action seeking indemnification for all losses incurred in the *qui tam* action is pending in the Ninth Circuit Court of Appeals.

As of January 28, 2009, the Company has 295,943,993 shares of its common stock, no par value, issued and outstanding.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Cell Therapeutics, Inc. dated January 26, 2009 regarding NASDAQ Additional Staff Determination.
99.2	Press Release of Cell Therapeutics, Inc. dated January 27, 2009 regarding Pixantrone Pre-NDA Communication.
99.3	Press Release of Cell Therapeutics, Inc. dated January 28, 2009 regarding Pixantrone Preliminary Progression-Free Survival Results.

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: January 29, 2009

By: /s/ Louis A. Bianco
Louis A. Bianco

Executive Vice President, Finance and Administration

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EXHIBIT INDEX

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