

CELL THERAPEUTICS INC
Form 8-K
September 18, 2006

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): **September 15, 2006**

CELL THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Washington
(State or other jurisdiction of
incorporation or organization)

001-12465
(Commission File Number)

91-1533912
(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)

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- “ 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))
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Item 1.01. Entry into a Material Definitive Agreement.

License Agreement

On September 15, 2006, Cell Therapeutics, Inc. (the "Corporation") entered into a License and Co-Development Agreement (the "License Agreement") by and among the Corporation, Cell Therapeutics Europe S.r.L., a corporation organized under the laws of Italy and a wholly-owned subsidiary of the Corporation, and Novartis International Pharmaceutical Ltd, a limited company organized under the laws of Bermuda ("Novartis"). Pursuant to the License Agreement, the Corporation will grant Novartis an exclusive worldwide license for the development and commercialization of Xyotax. The Corporation will continue to develop Xyotax at the Corporation's sole cost. Novartis has the right to elect to participate and control the future development and commercialization of Xyotax (the "Xyotax Election") at any time until thirty (30) days after approval of Xyotax in the U.S. or Europe which satisfies certain conditions (the "Xyotax Participation Period"). Novartis is under no obligation to make such election and there is no guarantee that the Corporation will ever receive approval of Xyotax. If the Xyotax Participation Period lapses without Novartis having made the Xyotax Election, then all rights to Xyotax would revert to the Corporation. If Novartis makes the Xyotax Election, then it would become responsible for development and commercialization of Xyotax going forward and generally be obligated to pay 100% of development and commercialization costs incurred after the election; provided that the Corporation would reimburse Novartis for 20% of development costs associated with label expansion or regulatory required post-approval trials. In addition, if Novartis makes the Xyotax Election then, subject to certain conditions, the Corporation would (i) have the right to devote up to 35 full-time employees to Xyotax commercialization efforts, (ii) receive a royalty on Xyotax worldwide net sales and (iii) be eligible to receive up to \$270 million of milestone payments if all milestones were achieved. Milestone payments are based on a mix of targets regarding sales levels and regulatory approvals for various indications.

Also pursuant to the License Agreement, the Corporation has granted Novartis an exclusive option to enter into an exclusive worldwide license to develop and commercialize pixantrone (the "Pixantrone Option"). Novartis may exercise the Pixantrone Option at any time until the later to occur of (i) three hundred sixty-five (365) days after the database on the Corporation's ongoing phase III study of pixantrone is locked or (ii) thirty (30) days after the expiration of the Xyotax Participation Period. If Novartis exercises the Pixantrone Option, then the Corporation and Novartis are obligated to use commercially reasonable efforts to negotiate in good faith the details of a definitive agreement, based on certain agreed terms. These agreed financial terms vary depending on whether Novartis has also made the Xyotax Election. In general, if Novartis has decided not to make the Xyotax Election, then the Corporation would be eligible to receive (i) a customary royalty on pixantrone worldwide sales and (ii) up to \$71 million of milestone payments (if all milestones were achieved). If Novartis decides to exercise the Pixantrone Option and at such time has exercised, or has not given up, its rights with respect to Xyotax, then the Corporation would be eligible to receive (i) up to \$104 million of milestone payments if all milestones were achieved, (ii) a \$7.5 million license fee, (iii) a customary royalty on pixantrone worldwide net sales and (iv) expense reimbursement and future expense sharing on terms similar to those related to the Xyotax Election. Milestone payments under the Pixantrone Option are also based on a mix of targets regarding sales levels and regulatory approvals.

The effectiveness of the License Agreement is subject to regulatory clearance under the Hart-Scott-Rodino Premerger Notification Act (the "HSR Act"). The description of terms and conditions of the License Agreement set forth herein does not purport to be complete and is qualified in its entirety by the full text of the License Agreement, which is attached hereto as Exhibit 10.1 and is incorporated herein by reference.

Securities Purchase Agreement

In connection with the License Agreement, the Corporation entered into a Securities Purchase Agreement dated as of September 15, 2006 (the Purchase Agreement), by and between the Corporation and Novartis Pharma AG, pursuant to which the Corporation has agreed to sell to Novartis Pharma AG, and Novartis Pharma AG has agreed to purchase, an aggregate of 8,670,520 shares of the Corporation's common stock, no par value (the Securities), for a purchase price per share of \$1.73 and a total purchase price of \$15 million.

The issuance of the Securities pursuant to the Purchase Agreement is subject to certain conditions, including regulatory clearance under the HSR Act. The description of terms and conditions of the Purchase Agreement set forth herein does not purport to be complete and is qualified in its entirety by the full text of the Purchase Agreement, which is attached hereto as Exhibit 4.1 and is incorporated herein by reference.

Registration Rights Agreement

In connection with the sale of the Securities, the Corporation entered into a registration rights agreement with the Novartis Pharma AG (the Registration Rights Agreement), under which the Corporation has agreed to prepare, file and have declared effective a shelf registration statement with the Securities and Exchange Commission (the Commission) covering the resale of the Securities sold to Novartis Pharma AG. The Corporation has agreed to have a resale registration statement declared effective no later than (i) in the event the shelf registration statement is not reviewed by the Commission, fifteen (15) days following the date the Corporation receives notice that the shelf registration statement will not be reviewed by the Commission or (ii) in the event the shelf registration statement is reviewed by the Commission, ninety (90) days following the date the shelf registration statement is first filed with the Commission. If the Corporation fails to timely have such shelf registration declared effective, the Corporation may be required to make a default payment to the Investor. The effectiveness of the Registration Rights Agreement is subject to consummation of the purchase and sale of the Securities pursuant to the Securities Purchase Agreement.

The description of terms and conditions of the Registration Rights Agreement set forth herein does not purport to be complete and is qualified in its entirety by the full text of the Registration Rights Agreement, which is attached hereto as Exhibit 4.1 and is incorporated herein by reference. The License Agreement, the Purchase Agreement and the Registration Rights Agreement are collectively referred to herein as the Transaction Agreements.

The Transaction Agreements have been included to provide investors with information regarding their respective terms and are not intended to provide any other factual information regarding the Corporation or its affiliates. The Transaction Agreements each contain representations and warranties the parties thereto made to and solely for the benefit of each other. In addition, the assertions embodied in the representations and warranties contained in the Transaction Agreements are qualified by information in a confidential disclosure schedule that the parties have exchanged. Accordingly, investors should not rely on the representations and warranties as characterizations of the actual state of facts, since (i) they were made only as of the date of such agreement or a prior, specified date, (ii) in some cases they are subject to qualifications with respect to materiality, knowledge and/or other matters, and (iii) in the case of the representations and warranties, they may be modified in important part by the underlying disclosure schedule. Moreover, information concerning the subject matter of the representations and warranties may have changed since the date of the Transaction Agreements, which subsequent information may or may not be fully reflected in the Corporation's public disclosures.

The Corporation knows of no material relationship between the Corporation or its affiliates and either of Novartis or Novartis Pharma AG other than in respect of the Transaction Agreements.

On September 18, 2006, the Company issued a press release relating to the matters described herein, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 3.02. Unregistered Sales of Equity Securities.

The information provided in Item 1.01 of this Current Report on Form 8-K is incorporated herein by reference.

The Securities are being sold in a private placement transaction in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933 and Rule 506 promulgated thereunder. Novartis Pharma AG is an accredited investor as defined in Rule 501 of Regulation D promulgated under the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are attached with this report on Form 8-K:

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|------|---|
| 4.1 | Registration Rights Agreement, dated September 15, 2006, by and between Cell Therapeutics, Inc. and Novartis Pharma AG |
| 10.1 | License and Co-Development , dated September 15, 2006, by and among Cell Therapeutics, Inc., Cell Therapeutics Europe S.r.L. and Novartis International Pharmaceutical Ltd. |
| 10.2 | Securities Purchase Agreement, dated September 15, 2006, by and between Cell Therapeutics, Inc. and Novartis Pharma AG |
| 99.1 | Press Release dated September 18, 2006 of Cell Therapeutics, Inc. |

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: September 18, 2006

By: /s/ JAMES A. BIANCO, M.D.
James A. Bianco, M.D.

President and Chief Executive Officer

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EXHIBIT INDEX

**Exhibit
Number**

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