CELL THERAPEUTICS INC
Form 8-K
November 15, 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): November 15, 2013 (November 14, 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 1.01. Entry into a Material Definitive Agreement.

On November 14, 2013 (the Effective Date), Cell Therapeutics, Inc. (the Company) entered into a Development, Commercialization and License Agreement (the Agreement) with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, Baxter) for the development and commercialization of pacritinib (the Compound) for use in oncology and potentially additional therapeutic areas.

Under the terms of the Agreement, the Company has granted to Baxter an exclusive, worldwide (subject to certain co-promotion rights of the Company in the U.S.), royalty-bearing, non-transferable, and (under certain circumstances outside of the U.S.) sub-licensable license to its know-how and patents relating to the Compound. Licensed Products consist of products in which the Compound is an ingredient.

Baxter has granted to the Company a non-exclusive license in order for the Company to perform its rights and obligations under the Agreement, including its co-promotion rights and manufacturing obligations.

Baxter has agreed to pay the Company an upfront payment of $60 million, which includes an amount equal to $30 million to acquire 30,000 shares of the Company s convertible preferred stock (the Series 19 Preferred Stock), which is convertible into the Company s common stock at an initial conversion price of $1.914 per share. The information in Item 3.02 below with respect to the Series 19 Preferred Stock is incorporated into this Item 1.01 by reference.

The Company is also eligible to receive potential payments of up to $302 million upon the successful achievement of certain development and commercialization milestones, comprised of $112 million of potential clinical, regulatory and commercial launch milestone payments, and potential additional sales milestone payments of up to $190 million. The Company and Baxter will jointly commercialize and share profits and losses on sales of the Compound in the United States. Outside the United States, the Company is eligible to receive tiered high single digit to mid-teen percentage royalty payments based on net sales for myelofibrosis, and higher double digit royalties for other indications, subject to reduction by up to 50% if (i) Baxter is required to obtain additional third party licenses, on which it is obligated to pay royalties, to fulfill its obligations under the Agreement and (ii) in any jurisdiction where there is no longer either regulatory exclusivity or patent protection. The Company will be responsible for all development costs incurred prior to January 1, 2014, as well as for U.S. and E.U. development costs incurred on or after January 1, 2014 of approximately $96 million, subject to potential upward or downward adjustment in certain circumstances. All development costs exceeding such threshold will generally be shared as follows: (i) costs generally applicable worldwide will be shared 75% to Baxter and 25% to the Company, (ii) costs applicable to territories exclusive to Baxter will be 100% borne by Baxter and (iii) costs applicable exclusively to co-promotion in the U.S. will be shared equally between the parties, subject to certain exceptions. Of the above milestones, $52 million relate to activities prior to commercialization for myelofibrosis, $45 million relate to activities on or after first commercialization of myelofibrosis and $15 million relates to initiating a registration directed trial for an additional indication.

Joint commercialization, manufacturing, development and steering committees with representatives from the Company and Baxter will be established pursuant to the Agreement. The Agreement will expire when there is no longer any obligation for Baxter to pay royalties to the Company in any jurisdiction, at which time the licenses granted to Baxter will become perpetual and royalty-free. The Company or Baxter may terminate the Agreement prior to its expiration in certain circumstances. Following the one year anniversary of receipt of regulatory approval in Australia, Canada, China, France, Germany, Italy, Japan, Spain, the United Kingdom or the U.S., the Company may terminate the Agreement as to one or more particular countries if Baxter has not undertaken requisite regulatory or commercialization efforts in the applicable country and certain other conditions are met. Baxter may terminate the Agreement earlier than its expiration in certain circumstances including (i) in the event development costs for myelofibrosis for the period commencing January 1, 2014 are reasonably projected to exceed a specified threshold, (ii) as to some or all countries in the event of commercial failure of the licensed product or (iii) without cause following the one-year anniversary of the Effective Date, provided that such termination will have a lead-in period of

six months before it becomes effective. Additionally, either party may terminate the Agreement prior to its expiration in events of force majeure, or the other party s uncured material breach or insolvency. In the event of a termination prior to the expiration date, rights in the Compound will revert to the Company.

The Agreement also requires Baxter and the Company to negotiate and enter into a Manufacturing and Supply Agreement, which will provide for the manufacture of the licensed products, with an option for Baxter to finish and package encapsulated bulk product, within 180 days of the Agreement.

The foregoing is a brief description of the terms and conditions of the Agreement and is intended to summarize the terms of the Agreement that are material to the Company. The Company intends to file the Agreement with the SEC as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2013 or a future Current Report on Form 8-K, together with a request for confidential treatment of certain terms of the Agreement.

The Company obtained the right, title and interest in the Compound pursuant to an asset purchase agreement, dated April 18, 2012, with S*BIO Pte Ltd. (S*BIO), a Singapore private limited company. As part of the consideration, S*BIO retains a contingent right to certain milestone payments and royalties from the Company in connection with any pharmaceutical product containing or comprising the Compound for use for any specific disease, infection or other condition recognized by U.S. regulatory authorities. The foregoing description of the asset purchase agreement does not purport to be complete and is qualified in its entirety by reference to the description included in the Company s Annual Report on Form 10-K filed on February 28, 2013 and the form of agreement incorporated by reference to Exhibit 10.1 therein, which is incorporated herein by reference.

Item 3.02. Unregistered Sale of Equity Securities.

Each share of Series 19 Preferred Stock, no par value per share, has a stated value of $1,000 per share and is convertible, in certain circumstances, at the option of the holder at any time prior to the automatic conversion of such shares. The Series 19 Preferred Stock is convertible into a total of 15,673,981 shares of common stock at a conversion price of $1.914 per share of common stock. Shares of the Series 19 Preferred Stock will receive dividends in the same amount as any dividends declared and paid on shares of common stock, but are entitled to a liquidation preference over the common stock in certain liquidation events. The Series 19 Preferred Stock has no voting rights on general corporate matters. A copy of the form of the Series 19 Preferred Stock Certificate is attached hereto as Exhibit 4.1. The issuance of shares of Series 19 Preferred Stock on November 15, 2013 is pursuant to an exemption from registration under the Securities Act of 1933, as amended (the Securities Act) in reliance on Section 4(2) thereunder.

The Company has agreed to register the common stock issuable upon conversion of the Series 19 Preferred Stock pursuant to the terms of a registration rights agreement (the Registration Rights Agreement) with Baxter Healthcare SA, which was executed and delivered on the Effective Date. Pursuant to the Registration Rights Agreement, the Company has agreed to file a registration statement with the U.S. Securities and Exchange Commission (the SEC) within 30 days after the Effective Date to register the resale of the common stock issuable upon conversion of the Series 19 Preferred Stock. The Company has agreed to use its commercially reasonable efforts to have the registration statement declared effective by the SEC within 90 days following the Effective Date (subject to reasonable extension in certain limited circumstances). The Company has also agreed, among other things, to indemnify Baxter Healthcare SA under the registration statement from certain losses and to pay all fees and expenses (excluding legal fees of Baxter Healthcare SA) in connection with the Company s registration obligations under the Registration Rights Agreement. The description of the Registration Rights Agreement is not intended to be complete and is qualified in its entirety by reference to the Registration Rights Agreement, attached hereto as Exhibit 10.1, which is incorporated by reference herein.

The information set forth in Item 1.01 above with respect to the issuance of unregistered shares of Series 19 Preferred Stock is incorporated herein by reference.

Item 5.03. Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

The Articles of Amendment of the Company dated November 15, 2013, establish and designate the Series 19 Preferred Stock and the rights, preferences and privileges thereof. A copy of the Articles of Amendment is attached hereto as Exhibit 3.1 and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

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 incorporated by reference into any filing or other document filed by the Company pursuant to the Exchange Act or the Securities Act, except as shall be expressly set forth by specific reference in such filing or document. The information provided pursuant to this Item 7.01 shall instead be deemed furnished.

On November 14, 2013, the Company issued a press release announcing the Company s entry into the Agreement with Baxter. The full text of such press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company has also announced that a conference call discussing the Agreement will be webcast live at 8:30 a.m. ET. The Company expects its initial development obligations under the Agreement to be partially offset by the receipt of milestone payments of $40 million in 2014 and $27 million in 2015, subject to satisfaction of certain conditions.

Cautionary Statement Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements about the timing and amount of future milestones, 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. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; product quality or patient safety issues; product development risks; the impact of competitive products and pricing and reimbursement; and other risks identified in the Company s most recent filings on Form 10-K, Form 10-Q and other Securities and Exchange Commission filings. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description	Location
3.1	Articles of Amendment to Amended and Restated Articles of Incorporation of Cell Therapeutics, Inc. (Series 19 Preferred Stock).	Filed herewith.
4.1	Form of Series 19 Preferred Stock Certificate.	Filed herewith.
10.1	Registration Rights Agreement, among Cell Therapeutics, Inc. and Baxter Healthcare SA, dated November 14, 2013.	Filed herewith.
99.1	Press release, dated November 15, 2013, announcing entry into the Agreement.	Furnished herewith.

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 15, 2013

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

EXHIBIT INDEX

Exhibit

No.	Description	Location
3.1	Articles of Amendment to Amended and Restated Articles of Incorporation of Cell Therapeutics, Inc. (Series 19 Preferred Stock).	Filed herewith.
4.1	Form of Series 19 Preferred Stock Certificate.	Filed herewith.
10.1	Registration Rights Agreement, among Cell Therapeutics, Inc. and Baxter Healthcare SA, dated November 14, 2013.	Filed herewith.
99.1	Press release, dated November 15, 2013, announcing entry into the Agreement.	Furnished herewith.