

TERCICA INC
Form 8-K
July 10, 2007

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): July 6, 2007

TERCICA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-50461
(Commission File Number)

26-0042539
(IRS Employer Identification No.)

2000 Sierra Point Parkway, Suite 400

Brisbane, CA 94005

(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 624-4900

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:

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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))
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Item 1.01. Entry into a Material Definitive Agreement.
Combination Product Development and Commercialization Agreement

Effective as of July 6, 2007, Tercica, Inc. (Tercica) and Genentech, Inc. (Genentech) entered into a Combination Product Development and Commercialization Agreement (the Combination Product Agreement), which Combination Product Agreement governs the worldwide development and commercialization of combination products containing IGF-1 and human growth hormone for the treatment of all indications except those of the central nervous system. The Combination Product Agreement became effective on July 9, 2007 (the Effective Date), the date of the satisfaction of all conditions to the effectiveness of the Combination Product Agreement.

Opt-In Rights

Under the terms of the Combination Product Agreement, the parties contemplate the development of two combination products for the following indications: one product formulation for certain defined short stature indications (Short Stature Indications) and another separately formulated combination product for adult growth hormone deficiency (AGHD) and any potential other indications (the Other Indications). Initially, Tercica will be responsible for the development and commercialization of all combination products under the Combination Product Agreement and agreed to pay Genentech a royalty on net sales of combination products covered by Genentech 's (or the parties ' joint) patents, subject to Genentech 's right to opt in, as described below.

Genentech has a right to opt into Tercica 's development and commercialization of such combination products for the Short Stature Indications, AGHD and the Other Indications, exercisable within 60 days after notice, subject to certain extensions, following the FDA 's acceptance of Tercica 's investigational new drug application for the first Phase II clinical trial for such indication(s) (the First Option). If Genentech does not exercise the First Option, it would then have the right to acquire a second right to opt in (a Second Option), exercisable for 90 days, subject to certain extensions, after Tercica obtains Phase II clinical trial data that is pivotal study-enabling for the Short Stature Indication at issue, or for AGHD or the Other Indications.

If Genentech opts in, it would then become the lead party with respect to the development and commercialization of combination products for the Other Indications, and it may also choose to become the lead party for AGHD, and Tercica would remain the lead development party for the development and commercialization of combination products for the Short Stature Indications. The lead commercialization party would determine the commercialization plan for such combination products for such indications, and the non-lead party would have the right to co-promote such combination products.

Upon opting in, Genentech would become obligated to reimburse Tercica for a portion of the development costs incurred since the Effective Date, and thereafter the parties would share future costs and all operating profits and losses. Genentech would receive such profit share in lieu of its royalty payment. Upon opting in, Genentech would also be entitled to acquire, upon payment of a cash fee to Tercica, the right to have the deciding vote on commercialization matters as between the parties (a Commercial Deciding Vote Election). If Genentech opts in, it would have the right to subsequently elect to opt out of such development and commercialization of combination products, but only for all indications. In addition, following an opt in by Genentech, Tercica would have the right to subsequently elect to opt out of the joint development and commercialization of the combination products for AGHD and the Other Indications only, but not for the Short Stature Indications. If a party elects to opt out, the other party would have a limited period of time in which it could also elect to opt out, in which case the parties would wind down development and commercialization of the applicable products. After opting out, a party would remain responsible for its share of operating profits and losses for a transition period only, after which time such party would be entitled to a royalty payment from the continuing party on net sales of such combination product.

If Genentech opts in and neither party elects to opt out before a combination product receives regulatory approval for any Other Indication (such receipt of regulatory approval, the Milestone), Genentech would owe Tercica a cash Milestone payment.

Development and Commercialization Governance

The Joint Steering Committee formed under the parties' License and Collaboration Agreement, effective as of April 15, 2002, as amended (U.S. IGF-1 Agreement), will govern the joint development and commercialization of combination products under the Combination Product Agreement. Subject to certain limitations, any matters that the Joint Steering Committee cannot decide by consensus will be decided by the lead development or lead commercialization party for the applicable indication.

Under the Combination Product Agreement, the parties have granted each other sublicenseable licenses under their respective technology. The parties will share manufacturing responsibilities and costs depending on which opt-in or opt-out rights have been exercised, but in general the parties contemplate that Tercica will supply IGF-1 needed for the combination products, and Genentech will supply human growth hormone for such products.

Termination

The Combination Product Agreement will remain in effect until all payment obligations have expired and two years have elapsed since the parties developed or commercialized combination products for indications for which the parties will be sharing operating profits and losses under the Combination Product Agreement. In addition, either party has the right to terminate the Combination Product Agreement in its entirety or on a per-product basis depending on the circumstances, in the event of an uncured material breach by the other party.

If Genentech terminates the Combination Product Agreement as to a given product for Tercica's material breach, Genentech's rights would revert to it and it would also receive licenses from Tercica to exclusively develop and commercialize the terminated product, subject to payment to Tercica of a royalty on Genentech's net sales of the terminated product. Similarly, if Tercica terminates the Combination Product Agreement for Genentech's material breach, Tercica would retain or be granted all needed license rights from Genentech to exclusively develop and commercialize the terminated product, subject to payment to Genentech of a royalty on Tercica's net sales of the terminated product.

Amendment to Existing IGF-1 Agreements

Effective as of July 6, 2007, Tercica and Genentech entered into a letter agreement (the Letter Agreement) amending the terms of the U.S. IGF-1 Agreement. The Letter Agreement, which became effective on the Effective Date, amends the U.S. IGF-1 Agreement to provide that a failure by Tercica to fulfill certain diligence obligations with respect to the development of IGF-1 for the treatment of diabetes will not be a material breach of either the U.S. IGF-1 Agreement or the parties' International License and Collaboration Agreement, effective as of July 25, 2003, as amended (the International IGF 1 Agreement and together with the U.S. IGF-1 Agreement, the IGF-1 Agreements). The Letter Agreement also provides that subject to milestone and/or royalty payments to Tercica, Genentech has the right to elect to initiate and continue development of IGF-1 for the treatment of diabetes and upon written mutual agreement between the parties, Genentech would have the right to substitute a new indication for diabetes, subject to certain minimum market size requirements. In the event that Tercica initiates development of IGF-1 for the treatment of diabetes before Genentech elects (if ever) to initiate such development pursuant to the Letter Agreement, the provisions of the Letter Agreement would have no further force or effect.

Genentech Purchase Agreement

Effective as of July 6, 2007, Tercica and Genentech entered into a Common Stock Purchase Agreement (the Genentech Purchase Agreement), pursuant to which Tercica agreed to sell, and Genentech agreed to purchase, up to a maximum of 2,603,328 shares of Tercica's common stock (the Genentech Shares) in three separate closings. At the first closing (the First Closing), which would, subject to customary closing conditions, occur within 30 days of the Effective Date, Genentech would purchase 708,591 shares of common stock (the First Closing Shares) at price per share of \$5.645. In connection with the First Closing, Tercica, Genentech and certain other holders of Tercica's common stock would enter into a Second Amended and Restated Investors' Rights Agreement, which would amend and restate Tercica's current Amended and Restated Investors' Rights Agreement to, among other things, grant registration rights to Genentech with respect to the shares of Tercica's common stock issued under the Genentech Purchase Agreement.

In the event that Genentech acquires a Second Option, Genentech would, subject to customary closing conditions, purchase up to 842,105 shares of Tercica's common stock (the Second Option Shares) in a subsequent closing (the Second Option Closing) at a price per share equal to the average of the closing prices of Tercica's common stock for the 20 trading days ending on the trading date immediately prior to the expiration of the First Option (the Second Option Price), provided that Genentech may purchase no more than \$4,000,000 of Tercica's common stock in the Second Option Closing. If the Second Option Price is below \$4.75, however, the purchase of the Second Option Shares in the Second Option Closing would be at Tercica's option, exercisable in its sole discretion, by making an affirmative request to Genentech to purchase the Second Option Shares. In the event that the Second Option Price is below \$4.75 and Tercica does not deliver a timely purchase request to Genentech, Genentech may acquire the Second Option without purchasing the Second Option Shares.

In the event that Genentech opts in, neither party elects to opt out and the Milestone occurs, upon Tercica's request, Genentech would, subject to customary closing conditions, purchase up to 1,052,632 shares of Tercica's common stock in a subsequent closing (the Milestone Closing) at a price per share equal to the average of the closing prices of Tercica's common stock for the 20 trading days ending on the trading date immediately prior to the effective date of regulatory approval of a combination product for any Other Indication (the Milestone Price), provided that Genentech may purchase no more than \$5,000,000 of Tercica's common stock in such closing.

In the event that the Combination Product Agreement is terminated, the Genentech Purchase Agreement would terminate in its entirety.

Ipsen Purchase Agreement

On July 9, 2007, Tercica, Ipsen, S.A. (Ipsen) and Suraypharm (an affiliate of Ipsen) entered into a Common Stock Purchase Agreement (the Ipsen Purchase Agreement) pursuant to which Tercica agreed to sell, and Ipsen agreed to purchase, 519,101 shares of Tercica's common stock (the Ipsen Shares). Under the terms of the Affiliation Agreement Tercica entered into with Ipsen and Suraypharm, Suraypharm has a right of first offer to purchase up to its pro rata portion of new equity securities offered by Tercica (subject to certain exceptions). Ipsen, as Suraypharm's designated affiliate, would acquire the Ipsen Shares in exercise of Suraypharm's pro rata right under the Affiliation Agreement with respect to the sale and issuance of the First Closing Shares to Genentech.

The Ipsen Shares would, subject to customary closing conditions, be issued and sold to Ipsen on the date of the First Closing under the Genentech Purchase Agreement. In the event that the First Closing under the Genentech Purchase Agreement is not consummated and/or the Genentech Purchase Agreement is terminated, the Ipsen Purchase Agreement would terminate and no shares would be issued and sold to Ipsen thereunder. The Ipsen Shares would be issued and sold to Ipsen at a price per share of \$5.63, which equals the closing bid price of Tercica's common stock on July 6, 2007, unless Tercica obtains a written interpretation by NASDAQ that would permit Ipsen and/or Suraypharm to purchase shares of Tercica's common stock in exercise of Suraypharm's pro rata right at a price per share less than the closing bid price immediately preceding the entering into of a binding agreement to issue such shares without Tercica stockholder approval under applicable NASDAQ rules. If Tercica is able to obtain such a written interpretation by NASDAQ prior to the closing of the sale and purchase of the Ipsen Shares, then the price per share to Ipsen would be \$5.645, which represents the price per share applicable to the Genentech First Closing Shares. In connection with the closing under the Ipsen Purchase Agreement, Tercica, Ipsen and Suraypharm would enter into an amendment to Tercica's current Registration Rights Agreement with Ipsen and Suraypharm that would grant registration rights with respect to the shares of Tercica's common stock issued under the Ipsen Purchase Agreement.

The foregoing is a brief summary of the material terms of each of the Combination Product Agreement, the Letter Agreement, the Genentech Purchase Agreement and the Ipsen Purchase Agreement (together the Agreements). Such summary does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreements, each of which will be filed as an exhibit to Tercica's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2007.

On July 10, 2007, Tercica issued a press release announcing the above transactions. A copy of the press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

Item 3.02. Unregistered Sales of Equity Securities.

See the description set forth under Item 1.01 above with respect to the Genentech Purchase Agreement and the Ipsen Purchase Agreement, which is incorporated into this Item 3.02 by reference. The Genentech Shares and the Ipsen Shares would, if issued, be issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended (the Act), and Rule 506 promulgated thereunder, and each of Ipsen and Genentech has represented to Tercica that it is an accredited investor within the meaning of Rule 501 under the Act.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

| Number | Description |
|---------------|--|
| 99.1 | Press Release entitled Tercica Announces Agreement with Genentech for Worldwide Growth Hormone and IGF-1 Combination Product Development and Commercialization, dated July 10, 2007. |

SIGNATURES

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.

Dated: July 10, 2007

TERCICA, INC.

By: /s/ Stephen N. Rosenfield
Stephen N. Rosenfield
Executive Vice President of Legal Affairs

EXHIBIT INDEX

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