

TERCICA INC
Form 8-K
May 17, 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): May 17, 2007 (November 10, 2006)

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

Edgar Filing: TERCICA INC - Form 8-K

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:

- 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.

Amendments to Manufacturing Services Agreement

In December 2002, Tercica, Inc. (Tercica) entered into a Manufacturing Services Agreement (the Cambrex Manufacturing Agreement) with Cambrex Bio Science Baltimore, Inc. (Cambrex Baltimore) for the manufacture and supply of bulk recombinant human insulin-like growth factor-1 (IGF-1) used in the manufacture of Increlex®, which is marketed by Tercica as a long-term replacement therapy for the treatment of children with severe primary insulin-like growth factor deficiency or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. Under the Cambrex Manufacturing Agreement, Cambrex Baltimore is obligated to provide Tercica with up to 24 kilograms of bulk IGF-1 per year, and Tercica is obligated to purchase from Cambrex Baltimore such bulk IGF-1 on a per-batch basis plus the acquisition cost paid by Cambrex Baltimore for any materials used in the manufacture of bulk IGF-1. The Cambrex Manufacturing Agreement carried an initial term continuing until December 31, 2008 and contained customary termination rights, including termination for material breach or upon various insolvency events. On November 10, 2006, Tercica and Cambrex Baltimore entered into Amendment No. 1 to Manufacturing Services Agreement (the First Amendment) pursuant to which the initial term of the Cambrex Manufacturing Agreement was extended until December 31, 2012. The First Amendment also effected certain other modifications to the Cambrex Manufacturing Agreement related to the pricing structure for bulk IGF-1 and that Cambrex Baltimore would manufacture, and Tercica would purchase from Cambrex Baltimore, certain batches of bulk IGF-1. The foregoing description of the First Amendment does not purport to be complete and is qualified in its entirety by the First Amendment, a copy of which is filed as Exhibit 10.8B to this current report on Form 8-K.

In February 2007, Cambrex Corporation completed the sale of the businesses that comprise its Bioproducts and Biopharma segments, which included its Baltimore manufacturing operations, to Lonza Group AG (Lonza). On May 14, 2007, Tercica and Lonza Baltimore, Inc., a subsidiary of Lonza (Lonza Baltimore), as successor in interest to Cambrex Baltimore, entered into an Addendum (the Addendum) to the Cambrex Manufacturing Agreement. Under the Addendum, Tercica and Lonza Baltimore agreed that Lonza Baltimore would manufacture, and Tercica would purchase from Lonza Baltimore, certain batches of bulk IGF-1 (the 2007 Additional Batches) in addition to an existing order for bulk IGF-1 for delivery in 2007. Also, the parties agreed that prior to September 30, 2007, Tercica may place an order for certain batches of bulk IGF-1 in addition to the 2007 Additional Batches (the 2007 Extended Batches). Under the Addendum, Tercica agreed to purchase the 2007 Additional Batches and the 2007 Extended Batches on a per-batch basis plus the acquisition cost paid by Lonza Baltimore for any materials used in manufacture of such batches. Tercica also agreed to partially defray Lonza Baltimore's costs for certain key employees retained by Lonza Baltimore to manufacture certain of the batches. Upon the delivery of and payment for all of the 2007 Additional Batches and the 2007 Extended Batches, if any, the Cambrex Manufacturing Agreement will terminate. The foregoing description of the Addendum does not purport to be complete and is qualified in its entirety by the Addendum, a copy of which Tercica will file as an exhibit to its next quarterly report on Form 10-Q.

Lonza Manufacturing Agreement

On May 14, 2007, Tercica and Lonza Hopkinton, Inc., a subsidiary of Lonza (Lonza Hopkinton) entered into an Agreement (the Lonza Agreement) pursuant to which Lonza Hopkinton was retained as Tercica's contract manufacturer for bulk IGF-1. Under the Lonza Agreement, the parties agreed to effect a technology transfer of Tercica's manufacturing process for bulk IGF-1 to Lonza Hopkinton's facility in Hopkinton, Massachusetts (the Hopkinton Site). In addition, Lonza Hopkinton will provide Tercica with process development and manufacturing services for the production of bulk IGF-1 at the Hopkinton Site. Under the Lonza Agreement, Tercica is obligated to make certain up-front, non-refundable payments to Lonza Hopkinton, as well as to pay Lonza Hopkinton for certain costs and other work performed. Tercica also agreed to purchase bulk IGF-1 batches from Lonza Hopkinton on a per-batch basis (subject

to the parties' agreement to switch to per-gram pricing under certain circumstances) plus the acquisition cost paid by Lonza Hopkinton for any materials used in the manufacture of such batches. Tercica also agreed to certain minimum purchase requirements and that it would not manufacture, or seek alternative manufacturers for, bulk IGF-1 during the term of the Lonza Agreement, subject to certain exceptions.

The Lonza Agreement contemplates that the parties will enter into a more detailed agreement incorporating and consistent with the terms and conditions of the Lonza Agreement that includes additional terms and conditions (the "Detailed Agreement"). The Lonza Agreement provides that if the parties are unable to enter into the Detailed Agreement by July 31, 2007, the Lonza Agreement would control and any omitted terms and conditions would be supplied by applicable provisions of the Uniform Commercial Code (as in effect in the State of New York) in a manner consistent with the terms and conditions of the Lonza Agreement. The Detailed Agreement will carry an initial term of eight years, subject to renewal for one or more additional terms of five years each, provided the parties agree to any such renewal no later than two years prior to the expiration of the initial term or any renewal term. Lonza Hopkinton and Tercica would each be able to terminate the Detailed Agreement for convenience upon three years' prior written notice or the fourth anniversary of the Lonza Agreement, whichever is later, as well as for cause. The Lonza Agreement will terminate at such time as the Detailed Agreement is entered into.

The FDA has not approved the Lonza Hopkinton facilities or its operations for the manufacture of bulk IGF-1 for use in the manufacture of Increlex® for commercial sale or clinical use, and Tercica cannot assure you that the Lonza Hopkinton facilities or their operations will be approved by the FDA to manufacture bulk IGF-1 on a timely basis, or at all. In the event that the FDA does not approve the Lonza Hopkinton facilities or its operations for the manufacture of bulk IGF-1, or if Lonza Hopkinton fails or refuses to supply Tercica for any reason, it would take a significant amount of time and expense to qualify a new manufacturer, which could delay or prevent the supply of commercial and clinical quantities of Increlex®, delay or otherwise adversely affect Tercica's revenues, delay or prevent Tercica from meeting its obligations to supply Increlex® to Ipsen, or hinder or prevent Tercica from continuing its business.

The foregoing description of the Lonza Agreement does not purport to be complete and is qualified in its entirety by the Lonza Agreement, a copy of which Tercica will file as an exhibit to its next quarterly report on Form 10-Q.

Item 1.02. Termination of a Material Definitive Agreement.

Reference is made to the disclosures under Item 1.01 above with respect to the Cambrex Manufacturing Agreement and the Addendum. The description of the Cambrex Manufacturing Agreement under Item 1.01 above does not purport to be complete and is qualified in its entirety by the Cambrex Manufacturing Agreement, a copy of which was filed as Exhibit 10.8 to Tercica's Registration Statement on Form S-1 (File No. 333-108729) and amendments thereto, declared effective on March 16, 2004.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Exhibit Title
10.8B	Amendment No. 1 to Manufacturing Services Agreement, dated as of November 10, 2006, by and between Cambrex Bio Science Baltimore, Inc. and Tercica.

Confidential treatment has been requested with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.

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.

TERCICA, INC.

Dated: May 17, 2007

By:

/s/ Stephen N. Rosenfield
Stephen N. Rosenfield

Executive Vice President of Legal Affairs

EXHIBIT INDEX

Exhibit	Exhibit Title
10.8B	Amendment No. 1 to Manufacturing Services Agreement, dated as of November 10, 2006, by and between Cambrex Bio Science Baltimore, Inc. and Tercica.

Confidential treatment has been requested with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.