TERCICA INC
Form 8-K
March 12, 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): March 6, 2007

TERCICA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-50461	**26-0042539**
(Commission File Number)	**(IRS Employer Identification No.)**

651 Gateway Boulevard, Suite 950

South San Francisco, CA 94080-7111

(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:

¨ 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 March 6, 2007, Tercica, Inc. (Tercica), Genentech, Inc. (Genentech), Insmed Incorporated and Insmed Therapeutic Proteins, Inc. (collectively, Insmed) entered a Settlement, License and Development Agreement (the Settlement Agreement) in which Tercica, Genentech and Insmed have settled all outstanding litigation amongst the parties, including the patent infringement suits brought by Tercica and Genentech against Insmed in the United States (N.D. Cal.) and United Kingdom, and the unfair business practices suit (E.D. Virginia). In exchange for the settlement and release of all claims, including a waiver by Tercica and Genentech of all damages award by the jury in the U.S. patent infringement litigation, the parties have granted licenses to each other with respect to the development, manufacture and commercialization of products to treat certain indications.

Tercica/Genentech Indications and Non-Tercica/Genentech Indications.

Under the terms of the Settlement Agreement, Insmed may no longer supply IPLEX in connection with the treatment of certain indications, including severe Primary IGF-1 Deficiency, Noonan s Syndrome, Laron Syndrome, growth hormone deficiencies, idopathic short stature, other short stature indications and growth hormone insensitivity (the Tercica/Genentech Indications) and has agreed to withdraw its IPLEX marketing authorization application for the treatment of primary IGF-1 deficiency and patients with growth hormone gene deletion in the European Union. In exchange, Tercica and Genentech have each granted Insmed a non-exclusive, freedom to operate, license with respect to the manufacture, development and commercialization of IPLEX for most non-short stature indications including severe insulin resistance, myotonic muscular dystrophy, retinopathy of prematurity, recovery from burns and trauma, recovery from hip fracture and HIV associated adipose redistribution syndrome (the Non-Tercica/Genentech Indications), subject to opt-in rights of Tercica and Genentech and certain royalty provisions, as more fully described below. Insmed is permitted to continue to provide IPLEX on a named patient basis for certain of the Non-Tercica/Genentech Indications in the European Union, and for ALS in Italy. Any cost reimbursement obtained from such program would be subject to a tiered royalty of 4% to 15% shared between Tercica, Genentech and Ipsen, S.A.

Tercica and Genentech s Opt-In Rights.

Pursuant to the Settlement Agreement, Tercica and Genentech have the right to opt in to participate in Insmed s development and commercialization of IPLEX for each of Non-Tercica/Genentech Indications up to 90 days after Insmed provides Phase III-enabling clinical data. Tercica has the first right to opt in to orphan indications (the Tercica Opt-In Right), and Genentech has the first right to opt in to non-orphan indications (the Genentech Opt-In Right). If the Tercica Opt-In Right is not exercised, Genentech has the right to exercise the opt-in right in its stead. Similarly, if Genentech does not exercise the Genentech Opt-In Right, Tercica will have the right to exercise the opt-in right in its stead.Insmed retains development control prior to approval of the product for the treatment of any Non-Tercica/Genentech Indication and Tercica or Genentech, as applicable, has the right to control the development of such product following exercise of its opt-in rights. In addition, once such opt in right is exercised, and upon product approval, Genentech or Tercica, as the case may be, can elect to enter into a co-promotion relationship with Insmed for IPLEX with respect to such indication, and such activities will be conducted under a commercialization plan and overseen by a joint commercialization committee. Alternatively, such opt-in party may elect to obtain the sole right to promote IPLEX for such indication and Insmed has agreed to supply IPLEX to such party under a separate supply agreement.

If the Tercica Opt-In Right is exercised, Insmed will be reimbursed at the time of exercise for 50% of any expenses then-incurred in connection with the development of such indication and any further development costs will be shared equally between Insmed and Tercica. Upon commercialization, Insmed and Tercica have agreed to divide profits equally after accounting for relevant expenses, including sales-based tiered royalties of 6%-15% to Genentech. If the Genentech Opt-In Right is exercised, Insmed will be reimbursed at the time of exercise for 50% of any expenses incurred in connection with the

development of such indication and further development costs and profits will be divided equally between Insmed and Genentech; provided, however, that no royalty will be paid to Tercica. If neither the Tercica Opt-In Right nor the Genentech Opt-In Right is exercised, Insmed will pay a 4% royalty on all commercial sales of the approved drug to Genentech.

Tercica, Genentech and Insmed have also agreed to form a joint development and a joint commercialization committee to guide the development and commercialization of the Non-Tercica/Genentech Indications and to oversee the tracking of sales of the product for use in the treatment of specific indications.

Indemnification.

Each of Tercica, Genentech and Insmed has the obligation to indemnify the other party for losses resulting from third party claims arising out of the first party s manufacture, use or sale of IPLEX, its breach of its representations, warranties or obligations under the Settlement Agreement, or its willful misconduct or negligent acts, except to the extent such claims are subject to the indemnification obligations of any other party.

Termination.

The Settlement Agreement is in effect until the expiration of all payment obligations or the expiration of all Tercica Opt-In Rights and Genentech Opt-In Rights, whichever is later. In addition, each of Tercica and Genentech has the right to terminate the Settlement Agreement in its entirety or on an indication by indication basis for any uncured material breach by Insmed of its obligations. Further, Insmed has the right to terminate the Settlement Agreement in its entirety or on an indication by indication basis in the case of an uncured material breach by Tercica or Genentech. If the Settlement Agreement is terminated in its entirety, Insmed s license to make, use and sell IPLEX will terminate in its entirety as of the effective date of such termination. If either the Tercica Opt-In Right or Genentech Opt-In Right has been exercised for an indication prior to such termination and the Settlement Agreement is terminated for such indication, then Insmed s license to sell IPLEX with respect to such indication will terminate, but Tercica or Genentech has the right to continue selling IPLEX after such termination. Further, Insmed will be reimbursed for development costs then-incurred for IPLEX for such indication and thereafter receive a royalty at the rate of 4% for the sales of IPLEX, on a country-by-country basis, so long as Insmed s patents cover the making, using or selling of IPLEX in such country.

If Insmed terminates the Settlement Agreement with respect to an indication for which the Tercica Opt-In Right or Genentech Opt-In Right has been exercised, then Insmed will have the sole and exclusive right to commercialize IPLEX for such indication and either Tercica or Genentech, as the case may be, will be reimbursed for its development costs then-incurred for IPLEX for such indication and thereafter receive a royalty at the rate of 4% for the sales of IPLEX, on a country-by-country basis, so long as the licensed patents cover the making, using or selling of IPLEX in such country.

The foregoing description is a summary of the material terms and is qualified in its entirety by the Settlement Agreement, a copy of which will be filed as an exhibit to Tercica s next quarterly report on Form 10-Q.

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: March 12, 2007

By: /s/ Stephen N. Rosenfield
Stephen N. Rosenfield

Executive Vice President of Legal Affairs