
**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): December 3, 2009

TARGACEPT, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-51173
(Commission
File Number)

56-2020050
(IRS Employer
Identification No.)

200 East First Street, Suite 300
Winston-Salem, North Carolina
(Address of principal executive offices)

27101
(Zip Code)

(336) 480-2100

Registrant's telephone number, including area code

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

Collaboration and License Agreement

On December 3, 2009, Targacept, Inc. (the “**Company**”) entered into a collaboration and license agreement (the “**Collaboration Agreement**”) with AstraZeneca AB (“**AstraZeneca**”) for the global development and commercialization of TC-5214, the Company’s product candidate for major depressive disorder. Effectiveness of the Collaboration Agreement is contingent on expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act (the “**HSR Act**”).

Pursuant to the Collaboration Agreement, the Company has granted to AstraZeneca an exclusive global license under patents and other technology owned or licensed by the Company to develop and commercialize TC-5214, as well as any other compounds of the Company that meet specified structural and pharmacological criteria designed to reflect substantial similarity to TC-5214, for all fields of use except hypertension. The Collaboration Agreement provides for AstraZeneca to make a non-refundable upfront payment of \$200,000,000 to the Company triggered upon effectiveness of the Collaboration Agreement and for the Company to be eligible to receive up to an additional \$540,000,000 if specified development, regulatory and first commercial sale milestones are achieved, up to an additional \$500,000,000 if specified sales-related milestones are achieved, and significant stepped double digit royalties on any net sales following regulatory approval. Under the terms of an existing license agreement, the Company would be required to pay a percentage of the upfront payment and each of the milestone payments that may be received from AstraZeneca, as well as royalties on net sales following regulatory approval, to the University of South Florida Research Foundation. Based on the terms of the license agreement with the University of South Florida Research Foundation and the terms of another existing license agreement with Yale University, the Company expects to pay royalties at an effective worldwide rate in the low single digits and such effective royalty rate could in some circumstances reach the mid single digits.

AstraZeneca’s obligation to pay royalties to the Company for TC-5214 expires on a country-by-country basis on the later of expiration of the patent rights in each country licensed by the Company to AstraZeneca that have a specified scope or 12 years after the first commercial sale of TC-5214 in that country. The U.S. patent rights to TC-5214 licensed by the Company to AstraZeneca expire between 2017 and 2020 and the corresponding licensed foreign patent rights licensed by the Company to AstraZeneca expire between 2017 and 2019. The Company has also licensed to AstraZeneca pending U.S. and foreign patent applications that, if issued as patents, would expire between 2019 and 2030. None of the foregoing years of expiration reflect any patent term extension that may be available in a particular country. It is uncertain whether any of the pending U.S. and foreign patent applications, even if issued as a patent, would be sufficient to extend the Company’s royalty term under the Collaboration Agreement in any particular country. Royalty rates are subject to reduction under the Collaboration Agreement in specified circumstances, including in any country if TC-5214 is not subject to patent protection with a specified scope in that country or if AstraZeneca licenses patent rights from any third party under circumstances in which it is more likely than not that TC-5214 would infringe the third party’s patent rights.

The Collaboration Agreement provides for the Company and AstraZeneca to co-develop TC-5214 under the oversight of a committee comprised of representatives of each company. The initial global clinical program is planned to include development of TC-5214 as an adjunct (or add-on) to antidepressant therapy and as a second-line “switch” monotherapy, in each case in adults with major depressive disorder who do not respond adequately to first-line antidepressant treatment. AstraZeneca is responsible for 80% of the costs of the initial program, except that AstraZeneca is responsible for 100% of development costs that are required only to obtain or maintain regulatory approval in countries outside the United States and the European Union. The Company is responsible for 20%

of the costs of the initial program and has the right to defer its share of development costs that exceed a specified threshold. Any development costs deferred by the Company would be recoverable by AstraZeneca out of any future milestones and royalties payable under the Collaboration Agreement. In addition, if the Company and AstraZeneca mutually agree to develop TC-5214 for any indication other than major depressive disorder or in any formulation other than those contemplated by the initial program, the same cost sharing arrangement would apply, except that the Company would have the right to defer 100% of its share of development costs for the additional indication or formulation and the deferred development costs would be recoverable by AstraZeneca out of future milestones and royalties payable under the Collaboration Agreement only from and after the occurrence of a specified event to be agreed upon by the parties (e.g., receipt of regulatory approval of the applicable indication or formulation).

AstraZeneca is responsible under the Collaboration Agreement for executing and funding the costs of global commercialization of TC-5214, with the Company retaining an option to co-promote TC-5214 to a specified target physician audience in the United States. If the Company exercises its co-promotion option, AstraZeneca would compensate the Company on a per detail basis. AstraZeneca is also responsible under the Collaboration Agreement for the manufacture and supply of TC-5214 and has agreed to assume the Company's rights and obligations under its applicable third party agreements, including the Amended and Restated Supply Agreement with Poli Industria Chimica, S.P.A. and Interchem Corporation described below in this Current Report on Form 8-K, following effectiveness of the Collaboration Agreement.

In addition to TC-5214, the Collaboration Agreement provides for a specified period for the Company and AstraZeneca to negotiate a potential multi-year research program that the Company would conduct to identify and develop additional product candidates that interact with neuronal nicotinic receptors for major depressive disorder and possibly other indications.

For a three-year period beginning upon effectiveness of the Collaboration Agreement, neither the Company nor AstraZeneca is permitted to conduct, or to grant a license to any third party to conduct, a Phase 2 or later clinical trial, or to commercialize, a compound as an adjunct (or add-on) treatment for major depressive disorder, subject to certain exceptions that include, among others, AstraZeneca's right to develop and commercialize atypical antipsychotic products that meet a specified condition, including quetiapine (marketed by AstraZeneca as Seroquel®).

AstraZeneca has agreed under the Collaboration Agreement not to take specified actions with respect to acquiring control of the Company without the consent of the Company for a specified period beginning upon effectiveness of the Collaboration Agreement. These restrictions, which cease to apply in various circumstances, do not preclude AstraZeneca from making confidential proposals that do not require the Company to make a public disclosure.

AstraZeneca can terminate the Collaboration Agreement in its entirety: within a specified period following completion of the Phase 3 development program for TC-5214 as an adjunct therapy; or if AstraZeneca determines there to be a serious safety issue regarding the continued development or commercialization of TC-5214; or if, having obtained the advice of independent patent counsel, AstraZeneca believes that the commercialization of TC-5214 is more likely than not to infringe or misappropriate intellectual property rights of third parties in the United States or any two specified major pharmaceutical markets and is unable to obtain a license on commercially reasonable terms. In addition,

AstraZeneca can terminate the Collaboration Agreement on a major pharmaceutical market by major pharmaceutical market basis at any time beginning four years after effectiveness of the Collaboration Agreement, except that, if AstraZeneca terminates the Collaboration Agreement with respect to the United States, the Collaboration Agreement will terminate in its entirety. The Company can terminate the Collaboration Agreement if AstraZeneca or any of its affiliates or sublicensees challenges the validity or enforceability of any of the patent rights licensed to AstraZeneca. Either party can terminate the Collaboration Agreement if the required clearances under the HSR Act are not obtained by March 1, 2010 or in the event of the insolvency or uncured material breach of the other party. However, if an uncured material breach by AstraZeneca is limited to a specified major pharmaceutical market, the Company can terminate the Collaboration Agreement only with respect to that market. The rights and obligations of the parties that survive termination of the Collaboration Agreement, including license grants and payment obligations, vary depending on the basis for the termination.

In addition, in the event of a “change of control” of the Company, AstraZeneca can terminate specified provisions of the Collaboration Agreement, including the Company’s right to participate on the committee overseeing development under the Collaboration Agreement and the Company’s co-promotion rights.

The Federal Food, Drug, and Cosmetic Act, as amended (the “**FFDCA**”) provides a five-year period of marketing exclusivity in the United States to the first applicant to obtain approval of a new drug application (“**NDA**”) for a drug that meets specified criteria to qualify as a new chemical entity. During this period, the U.S. Food and Drug Administration (“**FDA**”) may not accept for review an abbreviated new drug application or an NDA where the applicant does not own or have a legal right of reference to all the data required for approval (except that either of these applications may be submitted after four years with a certification that applicable patents are invalid or not infringed, in which case a timely challenge to the certification would trigger a stay of FDA’s approval of the application for a defined term). The five-year period of marketing exclusivity runs concurrently with any patents that may claim or cover the new chemical entity, but provides exclusivity for such period independent from and irrespective of the patents.

TC-5214 is one of two enantiomers of a previously approved racemate. Enantiomers are mirror images of each other that have the same chemical but potentially different biological properties, and a racemate is a chemical mixture comprised of two corresponding enantiomers. Under Section 505(u) of the FFDCA, as added by the FDA Amendments Act of 2007, an NDA applicant may, if certain conditions are met, elect that a single enantiomer of a previously approved racemate not be considered the same active ingredient as the racemate and thereby preserve potential eligibility for the single enantiomer as a new chemical entity. The election may only be made for an NDA submitted prior to October 1, 2012, when the statutory provision that permits the election is scheduled to expire unless re-authorized by the U.S. Congress. It is uncertain whether the statutory provision will be re-authorized. The Company and AstraZeneca anticipate beginning a Phase 3 clinical development program for TC-5214 in mid 2010 with the goal of submitting an NDA in 2012. If the Company and AstraZeneca are unable to submit an NDA for TC-5214 prior to October 1, 2012 and the statutory provision is not reauthorized, or if other statutory conditions are not met, TC-5214 will not receive the five years of regulatory marketing exclusivity, will be limited to three years of regulatory marketing exclusivity provided by the FFDCA for applications for which new clinical investigations, other than bioavailability studies, conducted or sponsored by the applicant are deemed essential to approval, and the Company and AstraZeneca will otherwise be substantially reliant on patent protection to provide exclusivity in the United States.

Amended and Restated Supply Agreement

Effective December 3, 2009, the Company entered into an Amended and Restated Supply Agreement (the “**Restated Supply Agreement**”) with Poli Industria Chimica, S.P.A. (“**Poli**”) and Interchem Corporation (“**Interchem**”), Poli’s U.S. agent, with respect to the manufacturing by Poli and supply to the Company of the active pharmaceutical ingredient TC-5214 (“**TC-5214 API**”). The Restated Supply Agreement amends and restates in its entirety the Supply Agreement dated as of July 23, 2001 among the Company, as assignee of Layton Bioscience Inc., Poli and Interchem, as amended, except that specified sections of the 2001 supply agreement continue in effect as applied to mecamlamine hydrochloride (in racemic form) manufactured or delivered, and related activities performed, under the 2001 supply agreement prior to the Restated Supply Agreement. Pursuant to the Collaboration Agreement described above in this Current Report on Form 8-K, the Company has agreed to assign the Restated Supply Agreement to AstraZeneca and AstraZeneca has agreed to accept the assignment and to assume all of the Company’s rights and obligations under the Restated Supply Agreement from and after effectiveness of the Collaboration Agreement.

The Restated Supply Agreement provides for the Company to purchase its requirements for TC-5214 API exclusively from Poli through Interchem, and for Poli to fulfill the Company’s orders for TC-5214 API and to produce TC-5214 API for use as a pharmaceutical exclusively for the Company, during the term of the Restated Supply Agreement. In addition, beginning with the Company’s submission of the first NDA or foreign counterpart of a product that contains TC-5214 API (a “**TC-5214 Product**”), Poli is required to maintain an inventory of TC-5214 API at levels determined in accordance with the Restated Supply Agreement and at a location separate from its facility in Milan, Italy and approved by the Company.

The Company’s obligation to purchase its requirements for TC-5214 API exclusively from Poli through Interchem terminates at the end of the term of the Restated Supply Agreement or during the term of the Restated Supply Agreement in the event of specified performance failures by Poli or the insolvency of Poli or Interchem. In addition, if the Company’s forecasted requirements for TC-5214 API exceed the maximum quantity that the Company believes in good faith that Poli is capable of supplying, the Company has the right to purchase its requirements in excess of such maximum quantity from a third party.

The Restated Supply Agreement has an initial term that extends for a period of years after the first occurrence of a commercial sale of a TC-5214 Product in any country or region in the world following receipt of the regulatory approval required in such country or region. A fixed pricing schedule for TC-5214 API applies during the initial term.

After the initial term, the Restated Supply Agreement is subject to automatic renewal terms, unless either the Company or Poli gives notice of non-renewal at least a specified time before the end of the initial term or the then-current renewal term. If the Company gives a notice of non-renewal, Poli is entitled to receive a fee from the Company in an amount determined in accordance with the Restated Supply Agreement. Alternatively, the Company has the right to continue the Restated Supply Agreement on a non-exclusive basis after the initial term or the then-current renewal term by notice to Poli in which the Company commits to purchase a portion of its requirements for TC-5214 API from Poli through Interchem. In that event, Poli is entitled to receive from the Company a reduced fee compared to the fee that it would have been entitled to receive had the Restated Supply Agreement not been renewed. However, if the Company’s purchase commitment is not above a specified threshold, Poli has the right to reject it and treat the Company’s notice as a notice of non-renewal.

The Restated Supply Agreement can be terminated by the Company or Poli in the case of an uncured material breach by the Company, in the case of Poli, or by Poli or Interchem, in the case of the Company, or by the Company upon written notice to Poli in the case of specified performance failures by Poli, upon certain changes in control of Poli or Interchem, if regulatory approval in the United States or any country in Europe has not occurred within seven years or if Poli or Interchem challenges the scope, validity or enforceability of any patent rights owned or licensed by the Company with respect to TC-5214.

The Restated Supply Agreement specifies various events that trigger an obligation of Poli to transfer its manufacturing process and related technology with respect to TC-5214 API to a third party designated by the Company. In some cases, the Company's obligation to purchase its requirements for TC-5214 API exclusively from Poli through Interchem would remain in effect after the technology transfer. The compensation payable to Poli for such technology transfer varies depending on the triggering time or event.

As permitted by applicable regulation, Poli has filed a drug master file with FDA that describes aspects of the process that it uses to manufacture TC-5214 API. Poli has authorized the Company to reference the drug master file in its regulatory submissions, but the Company does not have access to portions of the drug master file maintained confidentially by Poli. Under the terms of the Restated Supply Agreement, the Company is permitted to engage an independent third party to audit the drug master file (and any analogous regulatory submissions made outside the United States) on an annual basis to confirm its adequacy and completeness and Poli's compliance with it.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For this purpose, any statements contained in this Current Report, other than statements of historical fact, regarding, without limitation: the upfront or other payments that the Company may receive from AstraZeneca; the progress, scope or duration of the development of TC-5214, such as the size, design, conduct or objective of any clinical trial and the timing for initiation or completion of or availability of results from any clinical trial; the timing for filing of an NDA for TC-5214; the benefits that may be derived from TC-5214; the indication(s) for which TC-5214 may be developed; and the royalties that the Company may pay to the University of South Florida Research Foundation or Yale University. In some cases, words such as "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "scheduled" or other comparable words identify forward-looking statements. Actual results may differ materially from those expressed or implied by forward-looking statements as a result of various important factors, including, without limitation, risks and uncertainties relating to: AstraZeneca's right to terminate the Collaboration Agreement prior to effectiveness if expiration or termination of the waiting period under the HSR Act does not occur by March 1, 2010, whether exercised due to the deadline for NDA submission under the FDCA to

preserve the potential right to elect TC-5214 as a new chemical entity entitled to five years of marketing exclusivity or for any other reason; the risk of any delay of the initiation of further clinical development of TC-5214 arising from discussions with regulatory authorities; the Company's dependence on the success of its collaboration with AstraZeneca for TC-5214; the conduct and results of clinical trials and non-clinical studies and assessments of TC-5214, including the performance of AstraZeneca or third parties engaged to execute such trials, studies and assessments, delays resulting from any changes to the applicable protocols and difficulties or delays in the completion of subject enrollment or data analysis; reliance on third party contract manufacturers for the manufacture and supply of TC-5214 and clinical trial material for development of TC-5214; the outcomes of the prosecution of pending patent applications with respect to TC-5214; the timing of discussions with regulatory authorities; and the timing and success of submission, acceptance and approval of regulatory filings. These and other risks and uncertainties are described in greater detail under the caption "Risk Factors" in Item 1A of Part I of the Company's Annual Report on Form 10-K for the year ended December 31, 2008, in subsequently filed Quarterly Reports on Form 10-Q and in other filings that the Company makes with the Securities and Exchange Commission, or SEC. As a result of the risks and uncertainties, the results or events indicated by the forward-looking statements may not occur. The Company cautions you not to place undue reliance on any forward-looking statement.

In addition, any forward-looking statement in this Current Report represents the Company's views only as of the date of this Current Report and should not be relied upon as representing the Company's views as of any subsequent date. The Company anticipates that subsequent events and developments may cause the Company's views to change. Although the Company may elect to update these forward-looking statements publicly at some point in the future, it specifically disclaims any obligation to do so, except as required by applicable law. The Company's forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments it may make.

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.

TARGACEPT, INC.

Date: December 9, 2009

/s/ ALAN A. MUSSO

Alan A. Musso
Vice President, Chief Financial Officer and Treasurer