# 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 8, 2011**

# TARGACEPT, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **000-51173** | **56-2020050** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **200 East First Street, Suite 300**<br>**Winston-Salem, North Carolina**<br>**(Address of principal executive offices)** | **27101**<br>**(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))

**Item 8.01 Other Events.**

On November 8, 2011, Targacept, Inc. and AstraZeneca issued a joint press release reporting top-line results from RENAISSANCE 3, a Phase 3 clinical trial of TC-5214 as an adjunct to antidepressant therapy for patients with major depressive disorder who do not respond adequately to initial antidepressant treatment. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release dated November 8, 2011 |

**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: November 8, 2011

/s/ Peter A. Zorn

Peter A. Zorn

Senior Vice President, Legal Affairs, General Counsel and Secretary

**EXHIBIT INDEX**

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press release dated November 8, 2011 |

**Exhibit 99.1**

**AstraZeneca and Targacept Announce First Top-line Phase 3 Results for TC-5214 as an Adjunct Treatment in Patients with Major Depressive Disorder**

**Wilmington, DE and Winston-Salem, NC** – November 8, 2011– AstraZeneca and Targacept, Inc. today announced top-line results from the first of four RENAISSANCE Phase 3 studies investigating the efficacy and tolerability of TC-5214 as an adjunct therapy to an antidepressant in patients with major depressive disorder (MDD) who do not respond adequately to initial antidepressant treatment. The study did not meet its primary endpoint of change on the Montgomery-Asberg Depression Rating Scale (MADRS) after eight weeks of treatment with TC-5214 as compared to placebo.

TC-5214 was overall well tolerated in the study and showed an adverse event profile generally consistent with the earlier Phase 2b study. Analyses of the full data set from the RENAISSANCE 3 study remain ongoing.

The RENAISSANCE clinical trial program consists of four randomized, double blind, placebo controlled Phase 3 efficacy and tolerability studies and a fifth long-term safety study. The results announced today are from the RENAISSANCE 3 study, a flexible dose trial conducted in Europe. All RENAISSANCE Phase 3 studies have now completed enrollment, and reporting of all results is expected by the first half of 2012.

TC-5214 has the potential to be a first-in-class nicotinic channel modulator to serve as an adjunct treatment for MDD in patients with an inadequate response to initial antidepressant therapies, for example, selective serotonin reuptake inhibitors (SSRIs) or serotonin/norephinephrine reuptake inhibitors (SNRIs).

An NDA filing in the US is planned for the second half of 2012, with an MAA filing in the EU targeted for 2015.

**Targacept and AstraZeneca Collaboration**

In December 2009, AstraZeneca and Targacept signed a collaboration and license agreement for the global development and commercialization of TC-5214. The initial goal for the collaboration is to develop TC-5214 as an adjunct treatment for MDD in patients with an inadequate response to an SSRI or SNRI.

**About MDD**

MDD is characterized by one or more major depressive episodes without a history of manic, mixed or hypomanic episodes. The essential feature of a major depressive episode is a period of at least two weeks during which there is depressed mood or the loss of interest or pleasure in nearly all activities. In the large-scale STAR*D study sponsored by the US National Institute of Mental Health between 2001 and 2006, approximately 63 percent of patients with MDD did not achieve study-defined remission with first-line treatment with the SSRI citalopram hydrobromide.

**RENAISSANCE Program**

The RENAISSANCE Program consists of five studies. In this first study RENAISSANCE 3, there were 780 patients with MDD that were screened at 79 sites in Europe, of which 624 initially received one of seven SSRIs or SNRIs on an open label basis for eight weeks to determine the extent of therapeutic response. At the end of the eight weeks, 295 patients who did not respond adequately, based on predefined criteria, were randomized into the double blind phase of the study and received either a flexible dose of TC-5214 or placebo, twice daily, while continuing the SSRI or SNRI therapy for an additional eight weeks. The dosage of TC-5214 was initially 2 mg/day and could be increased at the discretion of the investigator to 4 mg/day and 8 mg/day based on tolerability and therapeutic response.

In addition to RENAISSANCE 3, there is one more flexible dose study (RENAISSANCE 2) and two fixed dose studies (RENAISSANCE 4 and RENAISSANCE 5) designed to evaluate the efficacy and tolerability of TC-5214 as an adjunct treatment to SSRI/SNRI therapy. RENAISSANCE 7 is a randomized, double blind, placebo controlled, long-term safety study in which patients receive TC-5214 or placebo, plus baseline SSRI/SNRI, for one year.

**About the Montgomery-Asberg Depression Rating Scale**

The Montgomery-Asberg Depression Rating Scale (MADRS) is a commonly used 10-item questionnaire that psychiatrists employ to measure the severity of depressive episodes in patients with mood disorders.

**About Targacept**

Targacept is developing a diverse pipeline of innovative NNR Therapeutics™ for difficult-to-treat diseases and disorders of the nervous system. NNR Therapeutics selectively modulate the

activity of specific neuronal nicotinic receptors, a unique class of proteins that regulate vital biological functions that are impaired in various disease states. Targacept's lead program, TC-5214, is being co-developed with AstraZeneca and is in Phase 3 clinical trials as an adjunct treatment for major depressive disorder. Targacept leverages its scientific leadership and proprietary drug discovery platform Pentad™ to generate novel small molecule product candidates to fuel its pipeline and attract significant collaborations with global pharmaceutical companies. For more information, please visit www.targacept.com.

**About AstraZeneca**

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

**Forward-Looking Statements**

This press release includes "forward-looking statements" made under the provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements, other than statements of historical fact, regarding, without limitation: the timing for completion of or reporting of results from any of the remaining clinical trials in the Phase 3 RENAISSANCE Program for TC-5214 or for submission or approval of an NDA for TC-5214 in the United States or an MAA for TC-5214 in the European Union; the number of successful clinical trials required to support regulatory approval for TC-5214 in the United States; the competitive position of or commercial opportunity for TC-5214; any payments that AstraZeneca may make to Targacept; or Targacept's plans, expectations or future operations, financial position, revenues, costs or expenses. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various important factors, including without limitation risks and uncertainties relating to: Targacept's dependence on the success of its collaboration for TC-5214 with AstraZeneca; the control or significant influence that AstraZeneca has over the development of TC-5214; the conduct and results of clinical trials and non-clinical studies and assessments of TC-5214, including the performance of third parties engaged to execute such trials, studies and assessments and difficulties or delays in data analysis; whether positive findings from the completed Phase 2b clinical trial of TC-5214 will be replicated in ongoing or any future clinical trials; the discretion of the FDA in determining whether to approve any NDA that may be filed for TC-5214; Targacept's ability to protect its intellectual property covering TC-5214; and the timing and success of submission, acceptance and approval of regulatory filings for TC-5214. These and other risks and uncertainties are described in greater detail under the heading "Risk Factors" in Targacept's most recent Annual Report on Form 10-K and in other filings that it makes with the Securities and Exchange Commission. As a result of the risks and uncertainties, the results or events indicated by the forward-looking statements may not occur. Targacept cautions you not to place undue reliance on any forward-looking statement.

In addition, any forward-looking statement in this press release represents Targacept's views only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. Targacept disclaims any obligation to update any forward-looking statement, except as required by applicable law.

NNR Therapeutics™ and Pentad™ are trademarks of Targacept, Inc. Any other service marks, trademarks and trade names appearing in this press release are the properties of their respective owners.

**TARGACEPT CONTACTS**

Alan Musso, SVP and CFO
**Targacept, Inc.**
Tel: (336) 480-2186
Email: alan.musso@targacept.com

Michelle Linn
**Linnden Communications**
Tel: (508) 362-3087
Email: linnmich@comcast.net

**ASTRAZENECA CONTACTS**

**Media Enquiries**

| | |
|---|---|
| Esra Erkal-Paler | +44 20 7604 8030 (24 hours) |
| Abigail Baron | +44 20 7604 8034 (24 hours) |
| Isabelle Jouin | +44 20 7604 8031 (24 hours) |

**Investor Enquiries UK**

| | |
|---|---|
| Karl Hård | +44 20 7604 8123 mob: +44 7789 654364 |
| Nicklas Westerholm | +44 20 7604 8124 mob: +44 7585 404950 |

**Investor Enquiries US**

| | |
|---|---|
| Ed Seage | +1 302 886 4065 mob: +1 302 373 1361 |
| Jorgen Winroth | +1 212 579 0506 mob: +1 917 612 4043 |