# 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 24, 2011

# 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)

Dere-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 March 24, 2011, Targacept, Inc. issued a press release announcing top-line results from a Phase 2 clinical trial of its product candidate TC-5619 as a treatment for adults with attention deficit/hyperactivity disorder. 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 March 24, 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.

/s/ Alan A. Musso

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

Date: March 24, 2011

# EXHIBIT INDEX

Exhibit<br/>NumberDescription99.1Press release dated March 24, 2011

#### Targacept Announces Top-Line Results from Phase 2 Trial of TC-5619 in Adults with ADHD

**Winston-Salem, NC** – March 24, 2011 – Targacept, Inc (NASDAQ: TRGT) today announced top-line results from a Phase 2 proof of concept trial of TC-5619 as a treatment for adults with attention deficit/hyperactivity disorder (ADHD). In the trial, conducted in non-smokers, TC-5619 did not meet the primary efficacy outcome measure, change from baseline on the Conners' Adult ADHD Rating Scale-Investigator Rated Total ADHD Symptoms score (CAARS-INV) after four, eight and 12 weeks of dosing.

Targacept announced positive top-line results from a separate Phase 2 trial of TC-5619 in cognitive dysfunction in schizophrenia (CDS) in January. TC-5619, a highly selective alpha7 neuronal nicotinic receptor modulator, is subject to license by Targacept's strategic collaborator AstraZeneca, with a decision expected in the second quarter of 2011.

The ADHD trial included a number of scales and assessments as secondary efficacy outcome measures. The results across all of these assessments indicate that TC-5619 had activity in this patient population, with TC-5619 outperforming placebo with statistical significance (as defined by the protocol, one-sided p-value < 0.10) approximately seven times more often than placebo outperformed TC-5619 by the same standard. TC-5619 performed best on the Conners' Adult ADHD Rating Scale-Subject Rated (CAARS-S), a patient self-rating scale, where the results favored TC-5619 with statistical significance (one-sided p-value < 0.10) on four of five subscales at 12 weeks.

TC-5619 was generally well tolerated in the trial, with no serious adverse events reported and no clinically significant difference between the TC-5619 dose group and the placebo dose group in discontinuations due to adverse events. Adverse events reported in at least five percent of patients in the TC-5619 dose group and at least twice as often as in the placebo dose group included headache (9%), rash (6%; resolved during treatment phase) and somnolence (6%).

"We continue to pursue a strategy of using initial Phase 2 development to gain clinical insights that help identify the indications for which our compounds will be best suited for later-stage development," said J. Donald deBethizy, Ph.D., Targacept's President and Chief Executive Officer. "While we did not see stimulant-like efficacy in this learning trial, the overall findings provide additional evidence that TC-5619 is active in a cognitively-impaired patient population, with the safety results adding to an impressive profile for a compound that has now been studied in more than 200 subjects. Coupled with positive outcomes from our prior Phase 2 study in patients with schizophrenia on measures of executive function, negative symptoms of schizophrenia and global change, we now have a foundation to guide future development of TC-5619."

Analyses of the full dataset from the ADHD trial are ongoing, and Targacept plans to present more detailed results at a future scientific meeting.

In addition to its completed Phase 2 trials in CDS and ADHD, Targacept is currently conducting clinical and non-clinical studies designed to support potential Phase 2 development of TC-5619 in a third indication with high unmet medical need, Alzheimer's disease.

#### About the Phase 2 Trial in Adults with ADHD

The double blind, placebo controlled, forced titration Phase 2 trial was conducted at 17 sites in the United States. In the trial, 135 non-tobacco using patients, age 18 to 65 and meeting DSM-IV criteria for ADHD, were randomized to receive either TC-5619 or placebo for 12 weeks. Approximately 58% of randomized patients were male. Patients randomized to the TC-5619 dose group received a 1mg daily dose for the first four weeks, a 5mg daily dose for the next four weeks and a 25mg daily dose for the last four weeks. There was an approximately 38% dropout rate in the trial, resulting in 84 patients completing. The primary efficacy outcome measure was change from baseline on CAARS-INV after four, eight and 12 weeks of dosing, as compared to placebo. The trial also included a number of other scales and assessments as secondary efficacy outcome measures.

#### **About ADHD**

Attention deficit/hyperactivity disorder (ADHD) is a condition that develops during childhood and, if not adequately treated, can have long-term adverse effects into adolescence and adulthood. The principal characteristics of ADHD are inattention, hyperactivity and impulsivity. For an adult to be diagnosed with ADHD, the ADHD symptoms must have begun during childhood. The market research firm Decision Resources estimated that there were approximately 23.3 million adults and 21.6 million children and adolescents with ADHD in 2009 in the world's seven major pharmaceutical markets (United States, France, Germany, Italy, Spain, United Kingdom and Japan).

#### About TC-5619

TC-5619, a novel small molecule discovered by Targacept scientists, is highly selective for the alpha7 NNR. In January 2011, Targacept announced positive topline results from a Phase 2 clinical trial of TC-5619 in cognitive dysfunction in schizophrenia (CDS). The results from this trial are scheduled to be presented April 4, 2011 at the 13<sup>th</sup> International Congress on Schizophrenia Research in Colorado Springs, Colorado. The CDS trial followed several preclinical models of schizophrenia conducted by Targacept in which TC-5619 showed positive effects[1]. In addition to the completed Phase 2 trials in CDS and adults with ADHD, Targacept is currently conducting clinical and non-clinical studies designed to support potential Phase 2 development of TC-5619 in Alzheimer's disease.

#### **About Targacept**

Targacept is developing a diverse pipeline of innovative NNR Therapeutics<sup>™</sup> 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<sup>™</sup> to generate novel small molecule product candidates to fuel its pipeline and attract significant collaborations with global pharmaceutical companies. For more information, please visit <u>www.targacept.com</u>.

#### TARGACEPT Building Health, Restoring Independence<sup>SM</sup>

#### **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 a decision by AstraZeneca as to whether to license TC-5619; any amounts that Targacept may receive from AstraZeneca; any future development of TC-5619; the benefits that may be derived from TC-5619 or the future commercial position of TC-5619; 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: AstraZeneca's discretion in determining whether to license TC-5619; whether a filing under the Hart-Scott-Rodino Antitrust Improvements Act will be required in connection with any license of TC-5619 by AstraZeneca and, if so, whether all required clearances will be obtained; and whether any future clinical trials of TC-5619 that may be conducted will be sufficient to obtain approval for cognitive dysfunction in schizophrenia, residual phase schizophrenia or any other indication. 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<sup>™</sup>, Pentad<sup>™</sup> and Building Health, Restoring Independence<sup>SM</sup> are trademarks or service marks of Targacept, Inc. Any other service marks, trademarks and trade names appearing in this press release are the properties of their respective owners.

[1] Hauser et al., *Biochemical Pharmacology*, 78: 803-812, 2009.

#### **Contacts:**

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