
**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): April 7, 2011

TARGACEPT, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-51173
(Commission
File Number)

56-202050
(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 8.01 Other Events.

On April 7, 2011, Targacept, Inc. ("Targacept") issued a press release regarding its presentation of data from a Phase 2 clinical trial of TC-5619 in patients with schizophrenia at the 13th International Congress on Schizophrenia Research. The press release included a statement as to possible plans of Targacept's strategic collaborator, AstraZeneca, with regard to its right to license TC-5619. 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated April 7, 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.

Date: April 7, 2011

TARGACEPT, INC.

/s/ Peter A. Zorn

Peter A. Zorn

Senior Vice President, Legal Affairs, General Counsel and Secretary

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated April 7, 2011

Targacept Presents Statistically Significant Results for TC-5619 on Measures of
Cognitive Dysfunction in Schizophrenia and Negative Symptoms of Schizophrenia

—Results from Phase 2 study presented at the *International Congress on Schizophrenia Research*—

Winston-Salem, NC – April 7, 2011—Targacept, Inc (NASDAQ: TRGT) today announced the presentation of data from a Phase 2 clinical proof of concept trial to assess TC-5619 as an augmentation therapy to improve cognition in patients with schizophrenia at the *International Congress on Schizophrenia Research* (ICOSR) in Colorado Springs, Colorado. Results presented at ICOSR showed statistically significant superiority of TC-5619 over placebo on secondary efficacy outcome measures assessing improvement on cognitive dysfunction in schizophrenia and negative symptoms of schizophrenia. Targacept announced that TC-5619 met protocol-defined success criteria on the study's primary efficacy outcome measure, the Groton Maze Learning Task (GMLT) of the CogState Schizophrenia Battery, and other top-line results in January 2011.

“TC-5619 appeared in this study to have a clinically meaningful effect on measures of cognitive and negative symptoms of schizophrenia, a profile that would represent a therapeutic advance for the field,” said Jeffrey A. Lieberman, M.D., the Lawrence C. Kolb Professor and Chairman of Psychiatry at the Columbia University College of Physicians, Surgeons and Director of the New York State Psychiatric Institute and a principal investigator for the TC-5619 trial. “The FDA has recently identified these domains as important clinical targets for drug development because the antipsychotic agents used to treat patients with schizophrenia largely provide benefit for positive symptoms of the disease, such as hallucination or delusions. The quality of life and level of function for most of these patients continues to be dramatically affected by cognitive impairment and by negative symptoms as patients enter what has been called the residual phase of schizophrenia.”

Based on the outcome of the trial, TC-5619 is subject to license by AstraZeneca under the terms of a 2010 amendment to the parties' collaboration agreement focused in cognitive disorders. Preliminary indications suggest that AstraZeneca may seek to negotiate different terms and whether it will license TC-5619 is uncertain. Discussions remain ongoing, and an outcome is expected in the coming weeks.

“This Phase 2 trial was designed to evaluate TC-5619 against an extensive list of endpoints to inform future development,” said J. Donald deBethizy, Ph.D., President and Chief Executive Officer of Targacept. “The results across various measures affirm for us the promise of TC-5619 to positively impact the lives of patients with schizophrenia. Currently approved treatments are not effective in treating either cognitive or negative symptoms of the disease, leaving a pressing need that is clearly evident to the FDA. We believe TC-5619 has unique potential to meet this need and are actively formulating development plans as we continue discussions with AstraZeneca.”

Statistically significant (1-sided p-value < 0.1) results from the trial favoring TC-5619 were reported at ICOSR on:

- Scale for the Assessment of Negative Symptoms (SANS), an investigator assessment of improvement on the negative symptoms of schizophrenia, at week 12 for all patients (p = 0.015) and at all three of the study's measurement dates for the tobacco user dataset (week 4, p = 0.098; week 8, p = 0.054; and week 12, p = 0.033);
- Clinical Global Impression–Global Improvement (CGI-I), an investigator assessment of overall response, at week 4 for all patients (p = 0.049) and at week 4 (p = 0.047) and week 8 (p = 0.075) for the tobacco user dataset;
- Subject Global Impression–Cognition (SGI-Cog), a patient self-assessment of cognitive change, at week 12 for all patients (p = 0.046); and
- two of the six computer-based items on the CogState Schizophrenia Battery (CSB) at week 12 for all patients (attention, p = 0.063; working memory, p = 0.042); three of the six computer-based CSB items at week 12 for the tobacco user dataset (attention, p = 0.057; working memory, p = 0.020; verbal memory, p = 0.027); and a composite measure of the CSB at week 12 for the tobacco user dataset (p = 0.098).

Results on the remaining items of the CSB, on a composite measure of the CSB (all patients) and on Clinical Global Impression-Severity (CGI-S) did not demonstrate a drug effect at any of the measurement dates, occasionally favoring placebo over TC-5619 with statistical significance (including on the verbal memory item of the CSB at week 4).

The favorable study results were driven by tobacco users and were often better for patients at study sites in United States as compared to India. Estimates of the prevalence of smoking amongst schizophrenia patients vary, with one study indicating as high as 80% [1].

TC-5619 exhibited a favorable tolerability profile in the trial, and there was no clinically significant difference between the TC-5619 and placebo dose groups in discontinuations due to adverse events. The most frequent adverse event was nausea (5%), which was mild to moderate in severity and never led to patient dropout. There were two serious adverse events in the trial, one in the placebo dose group and one in the TC-5619 dose group. Both were considered by the applicable investigator as not drug related.

About the Phase 2 Trial in Cognitive Dysfunction in Schizophrenia

The double blind, placebo controlled Phase 2 trial was conducted at seven sites in the United States and 12 sites in India. In the trial, 185 patients meeting DSM-IV criteria for schizophrenia, with stable psychotic symptoms and taking a stable dose of an approved atypical antipsychotic medication (either quetiapine, marketed as Seroquel®, or risperidone, marketed as Risperdal®) were randomized to receive either TC-5619 or placebo, together with continued treatment with the atypical antipsychotic, for 12 weeks. Of the randomized patients, approximately 69% were male and approximately 46% were

users of tobacco products. Patients who received TC-5619 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. The primary efficacy outcome measure was GMLT, and the trial included a number of other scales as secondary efficacy outcome measures.

About Cognitive Dysfunction in Schizophrenia

Schizophrenia is a chronic, severe and disabling form of psychosis. In addition to symptoms such as delusions, hallucinations, the inability to disregard familiar stimuli (sometimes referred to as sensory gating), disorganized speech, grossly disorganized or catatonic behavior and prolonged loss of emotion, feeling, volition or drive, schizophrenia is often marked by impairment in cognitive functions, such as attention, vigilance, memory and reasoning. These cognitive impairments play a primary role in the inability of schizophrenic patients to function normally. The market research firm Business Insights estimated that there were approximately 4.6 million people with schizophrenia in the world's seven major pharmaceutical markets in 2009. It has been estimated that up to 75% of persons with schizophrenia are cognitively impaired [2]. There is currently no drug approved in the United States or Europe specifically for cognitive dysfunction in schizophrenia.

About TC-5619

TC-5619, a novel small molecule developed by Targacept, is highly selective for the alpha7 neuronal nicotinic receptor. In a 2003 survey of 46 medical experts conducted in connection with a National Institute of Mental Health initiative known as Measurement and Treatment Research to Improve Cognition in Schizophrenia, or MATRICS, alpha7 was selected more often than any other target as a target of interest in the development of treatments for cognitive dysfunction in schizophrenia. In addition to the Phase 2 trial in schizophrenia, Targacept recently reported results from a Phase 2 trial in adults with attention deficit/hyperactivity disorder (ADHD) and is currently conducting clinical and non-clinical studies designed to support potential Phase 2 development of TC-5619 in Alzheimer's disease. Prior to entering the clinic, TC-5619 showed beneficial effects in several preclinical models of schizophrenia [3].

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.

TARGACEPT

Building Health, Restoring IndependenceSM

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: whether AstraZeneca will exercise its right to license TC-5619; the timing for AstraZeneca’s licensing decision; the benefits that may be derived from or 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; and whether the FDA or foreign regulatory authorities will determine residual phase schizophrenia, cognitive dysfunction in schizophrenia or any other indication to be an indication for which a drug may be approved. 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™, Pentad™ and Building Health, Restoring IndependenceSM 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] Swan & Lessov-Schlaggar, *Neuropsychological Review*, 17:259-273, 2007.

[2] O’Carroll, R., *Cognitive impairment in schizophrenia. Advances in Psychiatric Treatment*, 2000.

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

Contacts:

Alan Musso, SVP, Finance and Administration 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