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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 19, 2011

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**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

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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 January 19, 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 cognitive dysfunction in schizophrenia. 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 January 19, 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: January 19, 2011

/s/ Alan A. Musso

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

**EXHIBIT INDEX**

Exhibit Number

Description

99.1

Press release dated January 19, 2011

## Targacept Announces Positive Top-Line Results from Phase 2 Trial of TC-5619 in Cognitive Dysfunction in Schizophrenia

**Winston-Salem, NC** – January 19, 2011 – Targacept, Inc. (NASDAQ: TRGT) today announced positive top-line results from a Phase 2 clinical proof of concept trial to assess TC-5619 as an augmentation therapy to improve cognition in patients with schizophrenia. In the trial, TC-5619 met the protocol criteria for a positive result on the primary efficacy outcome measure, the Groton Maze Learning Task (GMLT) of the CogState Schizophrenia Battery, and was well tolerated. TC-5619 is a novel small molecule discovered by Targacept scientists using the company's proprietary drug discovery platform known as Pentad™. The highly selective alpha7 neuronal nicotinic receptor modulator is subject to license by Targacept's strategic collaborator AstraZeneca.

The GMLT is a computerized test designed to assess executive function (the ability to organize cognitive processes, including the ability to plan, prioritize, stop and start activities, shift from one activity to another activity and monitor one's own behavior). Impaired executive function is thought to be an important aspect of cognitive dysfunction in schizophrenia. The trial protocol defined a positive outcome on GMLT as superiority (one-sided p-value < 0.10) for the TC-5619 dose group as compared to the placebo dose group after adjusting statistically to account for multiple comparisons.

In the trial, the results on GMLT:

- met the pre-defined success criteria (adjusted p-value = 0.054), as well as at two of the trial's three measurement dates (at 4 weeks, unadjusted p-value = 0.018; and at 12 weeks, unadjusted p-value = 0.041); and
- were favorable for tobacco users as compared to non-tobacco users and for patients at study sites in the United States as compared to patients at study sites in India; there was no activity in non-tobacco users. Estimates of the prevalence of smoking amongst schizophrenia patients vary, with one study indicating as high as 80%[1].

Each of the p-values reported above was derived after data log transformation, a commonly utilized technique where the data does not follow a normal distribution.

In addition, positive signals were observed in the trial on several secondary efficacy outcome measures, including Scale for Assessment of Negative Symptoms, an investigator assessment of improvement on the negative symptoms of schizophrenia, Clinical Global Impression – Global Improvement, an investigator assessment of overall response, and Subject Global Impression – Cognition scale, a patient self-assessment of cognitive change. Other secondary outcome measures of the trial, including a composite measure of the CogState Schizophrenia Test Battery, did not demonstrate a drug effect.

“Developing treatments for the cognitive dysfunction prevalent in schizophrenic patients is critically important to treating the disease and meeting an unmet clinical need. Currently there are no

effective treatments,” 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 preliminary results with this new agent are encouraging and offer hope that nicotinic agonists may prove to be effective treatments for cognitive dysfunction in schizophrenia.”

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.

“Companies have historically found it very difficult to achieve signals of cognitive improvement in clinical trials in this patient population, so we are very pleased that our enthusiasm for TC-5619 and the therapeutic application of alpha7 was validated in this study,” said J. Donald deBethizy, Ph.D., President and Chief Executive Officer of Targacept.

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

Based on the outcome of the trial, AstraZeneca has the right to license TC-5619 on terms specified in the parties’ December 2005 collaboration agreement focused in cognitive disorders including schizophrenia. If AstraZeneca exercises its right to license TC-5619, the agreement provides for AstraZeneca to make a \$30 million payment to Targacept and to assume responsibility for and fund all future development and commercialization. In that event, Targacept would be eligible to receive additional payments of up to \$212 million, contingent upon the achievement of development, regulatory, first commercial sale and first detail milestone events for three indications, as well as stepped double-digit royalties on any future TC-5619 product sales. AstraZeneca is expected to determine whether to exercise its license right in the first half of 2011.

### **About the Phase 2 Trial in Cognitive Dysfunction in Schizophrenia**

The double blind, placebo controlled Phase 2 trial was conducted at 7 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 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 and has shown positive effects in several preclinical models of schizophrenia[3]. 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 most often as a target of interest in the development of treatments for cognitive dysfunction in schizophrenia. The product candidate is also in development for both attention deficit/hyperactivity disorder (ADHD) and Alzheimer's disease. Results from a separate Phase 2 clinical trial of TC-5619 in adults with ADHD are expected to be available later in the first quarter of 2011.

#### **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 in Phase 3 co-development with AstraZeneca 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](http://www.targacept.com).

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 or for the availability of results from the clinical trial of TC-5619 in attention deficit/hyperactivity disorder (ADHD); 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; the conduct and results of the ongoing clinical trial of TC-5619 in adults with ADHD, including the performance of third parties engaged to execute such trial, delays resulting from any changes to the protocol and difficulties or delays in the completion of subject enrollment or data analysis; and whether the FDA or foreign regulatory authorities will determine cognitive dysfunction in schizophrenia 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 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] Swan & Lessoc-Schlaggar, *Neuropsychological Review*, 17:259-273, 2007.

[2] Derived based on 1) a reported prevalence of schizophrenia of 4.6 million in the world's seven major pharmaceutical markets in 2009 (*Patient Base*, a database of epidemiology available through Decision Resources, Inc., May 2010; and 2) an estimate of 75% of schizophrenics that have cognitive dysfunction (O'Carroll, R., *Cognitive impairment in schizophrenia. Advances in Psychiatric Treatment*, 2000).

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

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