# 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): September 15, 2008

# 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))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 8.01 Other Events.

On September 15, 2008, Targacept, Inc. issued a joint press release with its strategic collaborator AstraZeneca announcing top-line results from the Phase 2b clinical trial of AZD3480 (TC-1734) in mild to moderate Alzheimer's disease conducted by AstraZeneca and a press release announcing a conference call to be held by Targacept to discuss the results. The full texts of the press releases are attached as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit <u>Number</u>	Description
99.1	Joint press release dated September 15, 2008 announcing top-line results
99.2	Press release dated September 15, 2008 announcing conference call

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 Vice President, Chief Financial Officer and Treasurer

Date: September 15, 2008

# EXHIBIT INDEX

Exhibit Number	Description
99.1	Joint press release dated September 15, 2008 announcing top-line results

99.2 Press release dated September 15, 2008 announcing conference call

# AstraZeneca and Targacept Announce Top-Line Results from Phase 2b Study of AZD3480 in Alzheimer's Disease

> Results inconclusive, as primary outcome measure not statistically significant for either donepezil or AZD3480; results impacted by improvement in placebo group

- > Improvements shown on secondary outcome measures ADCS-CGIC and MMSE
- > Overall safety and tolerability profile comparable to placebo, with fewer GI-related AEs than donepezil
- > Next steps include further analysis of full dataset and planned discussions with leading medical experts

Wilmington, DE and Winston-Salem, NC – September 15, 2008 – AstraZeneca (NYSE: AZN) and Targacept, Inc. (NASDAQ: TRGT) today announced that results from the Phase 2b clinical trial of AZD3480 (TC-1734) conducted by AstraZeneca in mild to moderate Alzheimer's disease were inconclusive.

In the 12-week placebo-controlled study, known as the Sirocco trial, neither the active comparator donepezil nor AZD3480 met the trial's criteria for statistical significance on the primary outcome measure, ADAS-Cog<sup>1</sup>. Both results were impacted by an improvement in the placebo group.

At two of the three doses tested, AZD3480 showed an improvement on the secondary outcome measures ADCS-CGIC<sup>2</sup>, a widely accepted measure of clinician assessment of change in patients' behavior and ability to function, and MMSE<sup>3</sup>, a quantitative cognition scale commonly used by neurologists in a clinical setting. Of the three AZD3480 doses, the middle dose performed best on both measures (0.5 point improvement, ADCS-CGIC and 0.9 point improvement, MMSE). Donepezil also showed an improvement on ADCS-CGIC (0.2 point improvement) and the MMSE (1.0 point improvement). Neither donepezil nor AZD3480 showed improvement in any domain of the Cognitive Drug Research computerized test battery in the pooled dataset of all subjects.

AZD3480 exhibited an overall safety and tolerability profile comparable to placebo in the trial, with fewer gastrointestinal-related adverse events (diarrhea, nausea and vomiting) than donepezil.

Analyses of the full dataset from the Sirocco trial are ongoing. AstraZeneca and Targacept plan to discuss the data with leading medical experts and to present and publish more detailed results over the coming months. A decision by AstraZeneca with respect to potential further development of AZD3480 is expected in December 2008.

- <sup>1</sup> Alzheimer's Disease Assessment Scale Cognition Subscale.
- <sup>2</sup> Alzheimer's Disease Cooperative Study Clinical Global Impression of Change, a 7-point scale.
- <sup>3</sup> Mini Mental State Examination, a 30-point scale.

"While we had hoped for a more conclusive overall outcome, we believe the Sirocco trial provides further support for the clinical rationale for AZD3480 by demonstrating improvement on both ADCS-CGIC, an accepted scale that reflects improvement in everyday activities, and the widely used MMSE cognitive assessment, as well as a favorable safety and tolerability profile," said J. Donald deBethizy, Ph.D., President and Chief Executive Officer of Targacept. "These findings also strengthen the scientific foundation for our pipeline of NNR Therapeutics. We thank AstraZeneca for its execution of this trial and investment in the broad development of AZD3480."

In addition to Alzheimer's disease, AZD3480 is currently being evaluated in a Phase 2b trial in cognitive dysfunction in schizophrenia (the "HALO" trial), as well as a Phase 2 exploratory study in adult attention deficit/hyperactivity disorder. Top-line results from the cognitive dysfunction in schizophrenia trial are expected by the end of 2008.

#### About the Study

The Phase 2b Sirocco trial was conducted by AstraZeneca under the terms of an exclusive global license and research collaboration agreement. The trial was a multi-center, randomized, double blind, placebo controlled, dose-finding study conducted at 84 sites in Western Europe, Eastern Europe and Canada. Subjects (n = 567) were between 60 and 85 years of age and diagnosed with probable Alzheimer's disease that was classified, based on a quantitative scale, as mild or moderate in severity. Subjects were assigned to one of three dose groups of AZD3480, to an active comparator, donepezil, or to placebo and dosed over 12 weeks. The primary outcome measure in the trial was change from baseline after 12 weeks on ADAS-Cog. A number of secondary outcome measures were also used in the trial.

#### **About Alzheimer's Disease**

Alzheimer's disease is a progressive, degenerative disorder that attacks the brain's nerve cells, or neurons, resulting in loss of memory, thinking and language skills, and behavioral changes. Approximately 26 million people worldwide suffer from Alzheimer's disease. In the United States, Alzheimer's disease is estimated to affect

more than five million people and the number of people age 65 and over afflicted with the disease is projected to increase by more than 50 percent to 7.7 million by 2030. Current treatment options have limited efficacy and significant side effects in many patients.

#### About AstraZeneca

AstraZeneca is a major international healthcare business engaged in research, development, manufacturing and marketing of prescription pharmaceuticals and supplier for healthcare services. AstraZeneca is one of the world's leading pharmaceutical companies with healthcare sales of US \$29.55 billion and is a leader in gastrointestinal, cardiovascular, neuroscience, respiratory, oncology and infection product sales. AstraZeneca is listed in the Dow Jones Sustainability Index (Global) as well as the FTSE4Good Index. For more information about AstraZeneca, please visit: <a href="https://www.astrazeneca.com">www.astrazeneca.com</a>.

#### **About Targacept**

Targacept is a clinical-stage biopharmaceutical company that discovers and develops NNR Therapeutics (TM), a new class of drugs for the treatment of central nervous system diseases and disorders. Targacept's product candidates selectively modulate neuronal nicotinic receptors that serve as key regulators of the nervous system to promote therapeutic effects and limit adverse side effects. Targacept has product candidates in development for Alzheimer's disease, cognitive dysfunction in schizophrenia, pain and major depressive disorder, as well as multiple preclinical programs. Targacept also has a cognition-focused collaboration with AstraZeneca and a strategic alliance with GlaxoSmithKline. Targacept's news releases are available on its website at www.targacept.com.

#### **Forward-Looking Statements**

Statements in this press release that are not purely historical in nature, including, without limitation, statements regarding further development of AZD3480 (TC-1734) in Alzheimer's disease, the timing for a decision by AstraZeneca as to whether to conduct further development of AZD3480 in Alzheimer's disease or for the results from the ongoing trial of AZD3480 in cognitive dysfunction in schizophrenia, or Targacept's plans, expectations, future operations, financial position, revenues, costs or expenses, constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those expressed or implied by forward-looking statements as a result of various important factors, including risks and uncertainties relating to: the significant control that AstraZeneca has over the development of AZD3480, including as to whether to conduct any further development of AZD3480 in Alzheimer's disease; the results of ongoing clinical trials of AZD3480 and the conduct of such trials, including the amount and timing of resources that AstraZeneca devotes to them, the performance of third parties engaged to execute them and difficulties or delays in the completion of subject enrollment or data analysis; and the risks that successful results in a particular clinical trial of AZD3480 may not be replicated in other clinical trials or that successful results in clinical trials of AZD3480 in a condition characterized by one degree of cognitive impairment may not be predictive of successful results in clinical trials of AZD3480 in a condition characterized by more severe cognitive impairment or in cognitive impairment resulting from a different condition. 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 e

In addition, any forward-looking statements in this release represent Targacept's views

only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Targacept anticipates that subsequent events and developments may cause its views to change. Although Targacept 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.

NNR Therapeutics  ${}^{\rm TM}$  is a trademark of Targacept, Inc.

#### Contacts

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## Targacept to Host Conference Call Today at 5:15 p.m. to Discuss Phase 2b Results for AZD3480 in Alzheimer's Disease

Winston-Salem, North Carolina – September 15, 2008 – Targacept, Inc. (NASDAQ: TRGT), a clinical-stage biopharmaceutical company developing a new class of drugs known as NNR Therapeutics(TM), announced that it will conduct a conference call and audio webcast today at 5:15 p.m. Eastern Daylight Time regarding the Phase 2b trial results for AZD3480 in Alzheimer's disease that were just announced. Participants from Targacept will include J. Donald deBethizy, Ph.D., President and Chief Executive Officer; Geoffrey C. Dunbar, M.D., Vice President, Clinical Development and Regulatory Affairs; David A. Hosford, M.D., Ph.D., Senior Medical Director; and Alan A. Musso, Vice President and Chief Financial Officer.

The conference call may be accessed by dialing (888) 396-2369 for domestic participants and (617) 847-8710 for international callers (reference passcode 99156824). A replay of the conference call may be accessed through September 30, 2008 by dialing (888) 286-8010 for domestic callers and (617) 801-6888 for international callers (reference passcode 89622161).

A live webcast of the conference call will be accessible from the Investor Relations page of Targacept's website, www.targacept.com. To ensure a timely connection to the webcast, it is recommended that users register at least 15 minutes prior to the scheduled start time. An archived version of the webcast will also be available on Targacept's website for at least two weeks following the call.

### About Targacept

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