# 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 27, 2012

# 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)

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 March 27, 2012, Targacept, Inc. issued a press release reporting top-line results from two exploratory Phase 2 clinical trials of TC-6987, one in asthma and one in type 2 diabetes. 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<br/>NumberDescription99.1Press release dated March 27, 2012

### 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/ Peter A. Zorn

Peter A. Zorn Senior Vice President, Legal Affairs, General Counsel and Secretary

Date: March 27, 2012

# EXHIBIT INDEX

Exhibit<br/>NumberDescription99.1Press release dated March 27, 2012

#### Targacept Announces Top-Line Results from Two Exploratory Phase 2 Studies of TC-6987

- Co-Primary Endpoints in Asthma Study Achieved -

**Winston-Salem, NC – March 27, 2012**—Targacept, Inc. (NASDAQ: TRGT), a clinical-stage biopharmaceutical company developing novel NNR Therapeutics<sup>TM</sup>, today announced top-line results from two separate exploratory Phase 2 studies of its product candidate TC-6987 conducted in the United States, one in asthma and one in type 2 diabetes. In the asthma study, oral TC-6987 met protocol-defined success criteria (one-sided p < 0.1) on both co-primary outcome measures, change from baseline in forced expiratory volume for adjunct TC-6987 compared to adjunct placebo measured at two time points on day 28 (51ml and 58ml). In the type 2 diabetes study, the primary outcome measure, change in fasting plasma glucose, was not met, and Targacept will not pursue further development of TC-6987 as a treatment for diabetes. TC-6987 is a modulator of the alpha7 neuronal nicotinic receptor (NNR) discovered by Targacept scientists using Pentad<sup>TM</sup>, the company's proprietary drug discovery platform.

"The exploratory asthma trial of TC-6987 as an adjunct to a low-dose inhaled corticosteroid showed a drug effect that was seen at the first assessment point, 30 minutes after initial dosing, and was sustained throughout the duration of the study, suggesting that TC-6987 has promise and may also have benefit in a monotherapy setting," said James F. Donohue, M.D., Professor of Medicine at the University of North Carolina, School of Medicine, Department of Medicine in Chapel Hill.

"With the positive outcome in our TC-6987 asthma study, we have accomplished our goal of detecting in patients a signal of the potential of NNR Therapeutics in the treatment of disorders outside of the CNS, while at the same time further establishing a favorable safety and tolerability profile for this alpha7-selective NNR Therapeutic," said J. Donald deBethizy, Ph.D., Targacept's President and Chief Executive Officer.

TC-6987 was generally well tolerated in both studies reported today. There were no clinically meaningful changes in cardiovascular parameters in either study, an important finding that differentiates TC-6987 from many other alpha7 modulators. There were no treatment-emergent adverse events that led to discontinuation in the TC-6987 dose group in the asthma study and no clinically significant difference in the number of treatment-emergent adverse events that led to discontinuation between the TC-6987 and placebo dose groups in the type 2 diabetes study. Adverse events reported in at least five percent of patients in the TC-6987 dose group and at least twice as often as in the placebo dose group occurred only in the type 2 diabetes study and were hyperglycemia (5%) and dizziness (5%). There was one serious adverse event in each dose group in the asthma study, and one serious adverse event in the TC-6987 dose group in the type 2 diabetes study. All were deemed by the investigator to be not related to study drug.

There were multiple secondary outcome measures in the asthma study, with no consistent trends between TC-6987 and placebo observed. Analyses of the full datasets from both studies are ongoing.

#### About the Phase 2 Trial in Asthma

The asthma study was a double blind, placebo controlled, parallel group Phase 2 trial conducted at 23 sites in the United States. The study enrolled 93 adult patients with persistent mild to moderate asthma that were being treated with inhaled corticosteroids, and 90 patients completed the study. The study design provided for a four-week wash-out period during which patients received a low-dose inhaled corticosteroid while discontinuing their current asthma medication (other than permitted rescue mediation). Patients were then randomized into one of two cohorts and received either placebo or oral TC-6987 once daily, together with the low-dose inhaled corticosteroid, for four weeks. Patients in the TC-6987 cohort received a 100mg dose the first day of dosing and then a 50mg dose for the remainder of the dosing period. The study concluded with a two-week follow-up period. The study included a number of different efficacy measures, with change in forced expiratory volume (FEV<sub>1</sub>) from baseline to pre-dosing and two-hours post-dosing on the last day of the dosing period designated as the coprimary outcome measures. Adjunct TC-6987 outperformed adjunct placebo in the study from baseline to pre-dosing on day 28 (one-sided p = 0.07). FEV<sub>1</sub> is the most frequently used index for assessing airway obstruction. The study also included assessments of safety, tolerability and pharmacokinetics of TC-6987.

#### About the Phase 2 Trial in Type 2 Diabetes

The type 2 diabetes study was a double blind, placebo controlled, parallel group Phase 2 trial conducted at 24 sites in the United States. The study enrolled 112 adult patients, with 87 patients completing. The study design provided for a one-week screening period followed by a four-week washout period during which patients ceased taking their Type 2 diabetes medication. Patients were then randomized into one of two cohorts and received either TC-6987 or placebo once daily for four weeks. Patients in the TC-6987 cohort received a 20mg dose on the first day of dosing and then a 10mg dose for the remainder of the dosing period. The study concluded with a two-week follow-up period. Change in fasting plasma glucose from baseline to the last day of the dosing period for subjects receiving TC-6987 as compared to placebo was the study's primary outcome measure. Fasting plasma glucose is a metabolic measurement used to expose problems with insulin function. The study also included assessments of safety, tolerability and pharmacokinetics of TC-6987.

#### About TC-6987 and Inflammation

A large body of scientific evidence highlights the key role that the alpha7 NNR plays in pathways mediated by pro-inflammatory molecules known as cytokines, and published studies suggest that alpha7 modulation modifies the inflammatory response by inhibiting cytokine production and release. TC-6987 is a modulator of the alpha7 NNR that demonstrated a potent anti-inflammatory response in a variety of preclinical studies and was generally well tolerated in Phase 1 clinical trials.

#### **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, unique proteins that regulate vital biological functions that are impaired in various disease states. Targacept's clinical pipeline includes multiple mid-stage product candidates, all representing first-in-class opportunities. 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 www.targacept.com.

#### TARGACEPT

Building Health, Restoring Independence®

#### **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: further development of TC-6987 beyond the two completed Phase 2 clinical trials; the medical benefits that may be derived from TC-6987; the competitive position of TC-6987; the use of NNR Therapeutics to treat non-central nervous system disorders; 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: the conduct and results of any future clinical trials; Targacept's ability to protect its intellectual property related to TC-6987; and the timing and success of submission, acceptance and approval of any regulatory filings for TC-6987. Risks and uncertainties that Targacept faces 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>TM</sup>, Pentad<sup>TM</sup> and Building Health, Restoring Independence<sup>®</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.

#### 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