# 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): May 3, 2010

# 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

follo	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 wing 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 May 3, 2010, Targacept, Inc. issued a press release regarding (1) the expansion of the development program for its product candidate TC-5619 and (2) an amendment to its Collaborative Research and License Agreement dated December 27, 2005, as amended, with AstraZeneca AB to modify the terms of the agreement as applied to 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

Exhibit Number Description

99.1 Press release dated May 3, 2010

# **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: May 3, 2010 /S/ Peter A. Zorn

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

# EXHIBIT INDEX

Exhibit Number

Description

99.1

Press release dated May 3, 2010

#### Targacept and AstraZeneca Agree to Expanded TC-5619 Development Program

- Phase 2 study initiating in ADHD; potential future development in Alzheimer's disease -

- Targacept to receive \$11 million payment -

Winston-Salem, North Carolina – May 3, 2010 – Targacept, Inc. (NASDAQ: TRGT), a clinical-stage biopharmaceutical company developing novel NNR Therapeutics (TM), today announced an amendment to its 2005 collaboration agreement with AstraZeneca expanding the TC-5619 development program. In addition to the current development of TC-5619 in cognitive dysfunction in schizophrenia (CDS), the amended terms provide for parallel development in attention deficit/hyperactivity disorder (ADHD) and potentially Alzheimer's disease. AstraZeneca will make an \$11.0 million payment to Targacept and maintain its future option to license TC-5619.

Targacept is currently conducting a Phase 2 clinical proof of concept trial of TC-5619 in CDS. As part of the expanded TC-5619 program, Targacept expects to initiate a Phase 2 clinical proof of concept trial in adults with ADHD this month. In addition, Targacept has agreed to conduct specified clinical and non-clinical studies, and AstraZeneca has agreed to conduct other specified non-clinical studies, to support the potential advancement of TC-5619 into Phase 2 clinical development for Alzheimer's disease in the first half of 2011. A decision as to whether to conduct Phase 2 clinical development of TC-5619 for Alzheimer's disease would be made in the future. If TC-5619 has been licensed by AstraZeneca or remains subject to AstraZeneca's license option, any such development for Alzheimer's disease would be funded by AstraZeneca.

"Neuronal nicotinic receptor targeted therapeutics show great promise for addressing unmet medical need in these key disease areas," said Bob Holland, Vice President and Head of the Neuroscience Therapy Area, AstraZeneca. "Our continued collaboration with Targacept in cognitive disorders allows us to strengthen our clinical pipeline in therapeutic areas with inadequate treatment options where we remain committed to developing novel approaches."

"We expect that parallel development of TC-5619 will accelerate our ability to potentially improve the lives of countless patients," said J. Donald deBethizy, Ph.D., President and Chief Executive Officer of Targacept. "This expanded development program is a testament to the progress made to date with our longtime strategic collaborator AstraZeneca."

Under the amended terms of the agreement, AstraZeneca has an option for an exclusive license to TC-5619 for various cognitive disorders the first time that TC-5619 achieves clinical proof of concept, whether in CDS, ADHD or Alzheimer's disease. AstraZeneca may also exercise its option to license TC-5619 upon completion of the other clinical and non-clinical studies related to Alzheimer's disease if TC-5619 does not achieve clinical proof of concept in CDS or ADHD. If TC-5619 achieves clinical proof of concept and AstraZeneca does not exercise its resulting option, Targacept would retain all of its rights in the compound.

In connection with the expanded TC-5619 development program, the amendment restructures the financial terms for TC-5619 under the agreement. As restructured, AstraZeneca has agreed to make the \$11.0 million current payment to Targacept described above and, if AstraZeneca exercises its license option, AstraZeneca would pay Targacept \$30.0 million and assume responsibility for and fund all development and commercialization for TC-5619 beyond the currently agreed upon development program. In that event, Targacept would now be eligible to receive additional payments of up to \$212.0 million, contingent upon the achievement of development, regulatory, first commercial sale and first detail milestones for TC-5619 in three indications, and would remain eligible for stepped double-digit royalties on any future TC-5619 product sales.

Targacept and AstraZeneca entered into their global collaboration agreement focused on cognitive disorders in December 2005. In addition to TC-5619, there are two other product candidates in clinical development under the agreement, AZD3480 and AZD1446, both of which target the alpha4beta2 NNR subtype. Targacept expects AstraZeneca to initiate a Phase 2b trial of AZD3480 in adults with ADHD in the second half of 2010. AstraZeneca is currently conducting a number of clinical trials of AZD1446, including, among others, a safety and tolerability study as an add-on treatment to donepezil in subjects with Alzheimer's disease and a Phase 2 study in adults with ADHD that are expected to be completed in the second half of 2010.

#### About TC-5619

TC-5619 is a novel small molecule that is highly selective for the alpha7 NNR. The alpha7 NNR subtype has been shown to be a key regulator of cognitive function, including attention, memory and learning [1]. Preclinical studies of alpha7 modulators suggest cognition-enhancement in the central nervous system (CNS) [2]. As a result, alpha7 NNR-targeted therapies, used alone or in combination with other drugs, offer a potential new approach to treating the constellation of symptoms associated with CNS diseases and disorders. TC-5619 has little or no interaction with 5HT3 receptors or hERG channels, properties that distinguish it from other alpha7 NNR-targeted compounds and could facilitate a more favorable tolerability profile. TC-5619 was discovered by Targacept using its proprietary drug discovery platform known as Pentad<sup>TM</sup>.

#### **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 7.9 million people with schizophrenia in the world's seven major pharmaceutical markets (United States, France, Germany, Italy, Spain, United Kingdom and Japan) in 2008. It has been estimated that up to 75% of persons with schizophrenia are cognitively impaired. There is currently no drug approved in the United States or Europe specifically for cognitive dysfunction in schizophrenia.

#### **About ADHD**

Attention deficit/hyperactivity disorder (ADHD) is one of the most common neurobehavioral disorders. The principal characteristics of ADHD are inattention, hyperactivity and impulsivity. ADHD is a chronic disorder that develops during childhood, often persists into adulthood and can negatively impair many aspects of daily life, including home, school, work and interpersonal relationships. The market research firm Business Insights estimated that there were approximately 23.3 million adults and 21.6 million children with ADHD in 2009 in the world's seven major pharmaceutical markets.

#### **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. The market research firm Business Insights estimated that there were approximately 6.6 million people with Alzheimer's disease in the world's seven major pharmaceutical markets. The Alzheimer's Association has estimated

that Alzheimer's disease affects more than five million people in the United States and has projected the number of afflicted Americans age 65 and over 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 Targacept**

Targacept is a clinical-stage biopharmaceutical company with a vision of building health and restoring independence for patients. Targacept has leveraged its leadership position in NNR research to build a diverse pipeline of NNR Therapeutics (TM) in development to treat an array of central nervous system diseases and disorders, including major depressive disorder, attention deficit/hyperactivity disorder, Alzheimer's disease and cognitive dysfunction in schizophrenia. In addition, Targacept has alliances with the global pharmaceutical companies AstraZeneca and GlaxoSmithKline. Targacept's news releases are available on its website at <a href="https://www.targacept.com">www.targacept.com</a>.

#### About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines. As a leader in gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease medicines, AstraZeneca generated global revenues of US \$32.8 billion in 2009. For more information please visit: <a href="https://www.astrazeneca.com">www.astrazeneca.com</a>

#### **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 progress or scope of development of TC-5619, AZD3480 or AZD1446, such as the size, design, subject population, conduct, duration or objective of any clinical trial, the timing for initiation or completion of any clinical trial or for availability of results from any clinical trial, or the indication(s) for which TC-5619, AZD3480 or AZD1446 may be developed; the benefits or competitive position of TC-5619, AZD3480 or AZD1446 or the commercial opportunity in any particular indication; any payments that AstraZeneca may make to Targacept; 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 clinical trials and non-clinical studies and assessments of TC-5619, AZD3480 or AZD1446, including the performance of third parties engaged to execute such trials, studies and assessments, delays resulting from any changes to the applicable protocols and difficulties or delays in the completion of subject enrollment or data analysis; a decision by AstraZeneca whether to conduct Phase 2 clinical development of TC-5619 for Alzheimer's disease; a decision by AstraZeneca whether to exercise its option to license TC-5619 when exercisable; the significant control that AstraZeneca has over the development of AZD3480 and AZD1446, including as to the timing and conduct of any further development of AZD3480 in ADHD or AZD1446 in Alzheimer's disease or ADHD and the scope and design of any future clinical trial of AZD3480 or AZD1446; and the timing and success of submission, acceptance and approval of regulatory filings. 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 (TM) and Pentad (TM) are trademarks of Targacept, Inc. Any other service marks, trademarks and trade names appearing in this press release are the properties of their respective owners.

- [1] Leiser, S.C., et al., A cog in cognition: How the alpha7 nicotinic acetylcholine receptor is geared towards improving cognitive deficits, *Pharmacol Ther*, (2009), doi: 10.1016/jpharmthera.2009.03.009.
- [2] Bencherif, M., Neuronal nicotinic receptors as novel targets for inflammation and neuroprotection: mechanistic considerations and clinical relevance. *Acta Pharmacol Sin* 2009 Jun; 30 (6): 702–714.

#### **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: <a href="mailto:linnmich@comcast.net">linnmich@comcast.net</a>