
**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 4, 2011

TARGACEPT, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-51173
(Commission
File Number)

56-2020050
(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))
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Item 8.01 Other Events.

On April 4, 2011, David A. Hosford, M.D., Ph.D., Vice President, Clinical Development of Targacept, Inc. ("Targacept"), presented data from Targacept's completed Phase 2 clinical trial of TC-5619 in patients with schizophrenia at the 13th International Congress on Schizophrenia Research. The slide presentation made by Dr. Hosford is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Slide presentation made at the 13th International Congress on Schizophrenia Research on April 4, 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: April 4, 2011

/s/ Peter A. Zorn

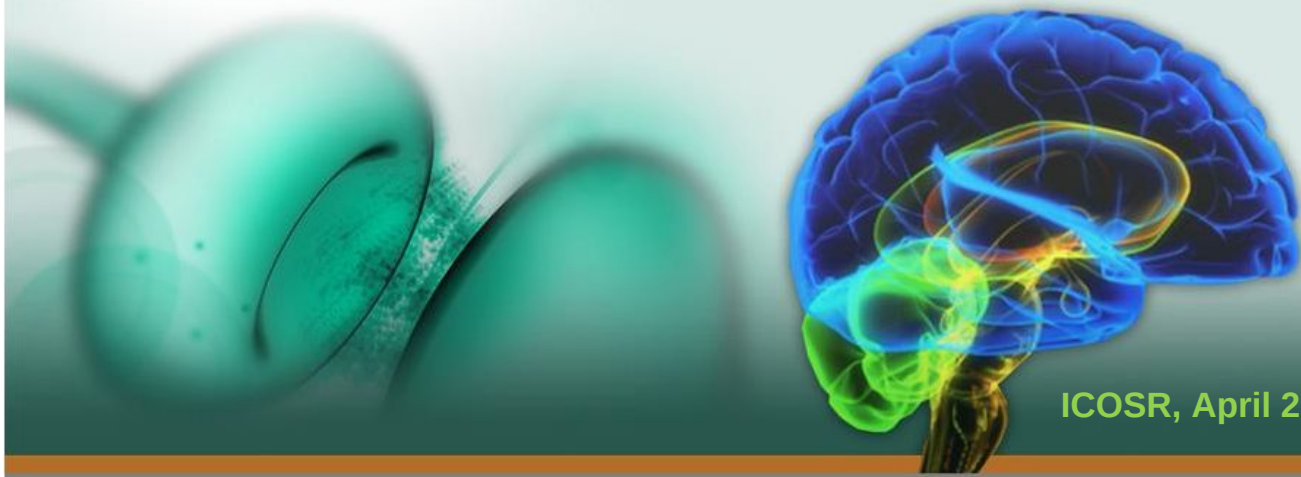
Peter A. Zorn

Senior Vice President, Legal Affairs, General Counsel and Secretary

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
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TARGACEPT

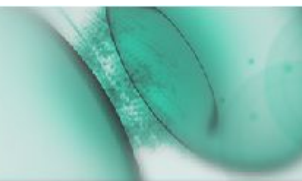


ICOSR, April 2011

The Alpha7 Nicotinic Receptor Agonist TC-5619 had Beneficial Effects with Favorable Tolerability in a Phase 2 Trial in Cognitive Dysfunction in Schizophrenia

G Dunbar, D Hosford, JA Lieberman, A Segreti

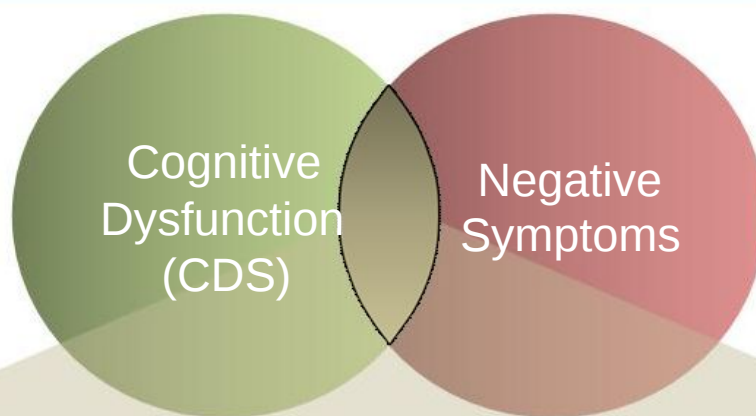
Cautionary Note re: Forward-Looking Statements



This presentation includes “forward-looking statements” made under the provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements that are not purely historical in nature regarding, without limitation: any future development of TC-5619, including the indication(s) for which TC-5619 may be developed; the commercial opportunity in any particular indication; the benefits that may be derived from TC-5619; the competitive position of TC-5619; the timing for a decision by AstraZeneca as to whether to license TC-5619; or Targacept’s plans, expectations, objectives, prospects or future operations, financial position, revenues, costs or expenses. The words “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “forecast,” “potential,” “continue,” “ongoing,” “scheduled” and similar expressions are intended to identify forward-looking statements. 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: whether any future clinical trials of TC-5619 that may be conducted will be sufficient to obtain approval for cognitive dysfunction in schizophrenia, residual phase schizophrenia or any other indication; the timing and success of submission, acceptance and approval of regulatory filings; AstraZeneca’s discretion in determining whether to license TC-5619; whether a filing under the Hart-Scott-Rodino Antitrust Improvements Act will be required in connection with any license of TC-5619 by AstraZeneca and, if so, whether all required clearances will be obtained; and the risks and uncertainties 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 Targacept 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. In addition, any market or industry statistics contained in this presentation are based on information available to Targacept that it believes to be reliable but has not independently verified.

All forward-looking statements included in this presentation speak only as of the date the presentation is made and should not be relied upon as representing Targacept’s views as of any date after the presentation is made. Targacept specifically disclaims any obligation to update any forward-looking statement, except as required by applicable law.

Significant Unmet Medical Need: “Residual Phase Schizophrenia”



- Dr. Tom Laughren has suggested the term “residual phase schizophrenia” to encompass both CDS and negative symptoms¹.
- Current antipsychotics have little effect against cognitive dysfunction or negative symptoms.
- These residual symptoms are a large unmet medical need.

¹ Laughren and Levin 2011. Schiz Bull. doi:10.1093/schbul/sbq162

TC-5619: A Selective Alpha7 NNR Modulator



- Promising preclinical results
 - Complete profile with repeat tox, genotox, reprotox, safety pharmacology
 - Beneficial effects in preclinical models of memory and of sensory gating (schizophrenia)
- Completed single and multiple ascending dose studies
 - Maximum tolerated dose between 406mg and 609mg (free base)
 - No clustering of AE signals through 406mg
 - Positive signal in Power of Attention measured at 6.8mg
 - Half-life 20-24 hrs
- Phase 2 study objectives to assess the efficacy, safety and tolerability of TC-5619 as augmentation therapy to quetiapine or risperidone to improve cognition in stable outpatients with schizophrenia

Key Inclusion/Exclusion Criteria

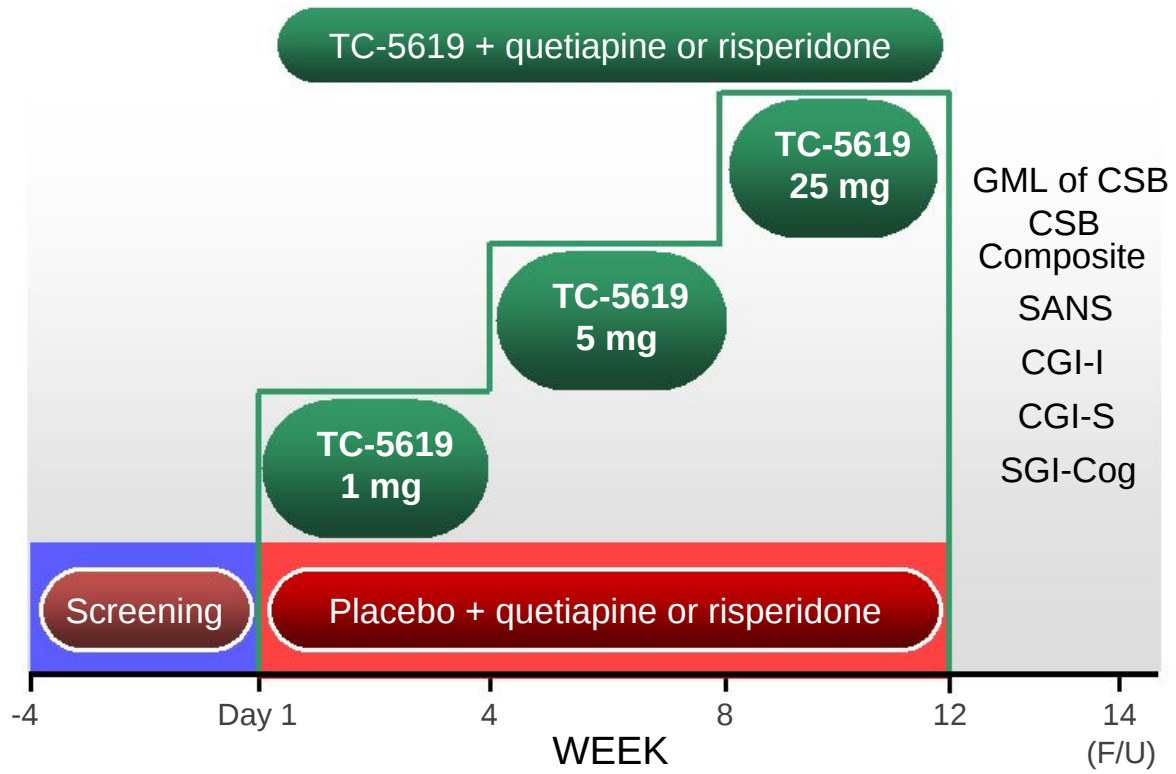


- Male or female subjects ages 18-60 years
- Stable outpatients with DSM-IV criteria for schizophrenia
 - Lack of psychiatric hospitalization for 2 months before Screening
 - On unchanged dose of quetiapine or risperidone for 2 months before Screening
 - Score ≤ 4 on PANSS items of delusions, hallucinations, conceptual disorganization, unusual thought content at Screening and at Baseline
- No other co-morbid Axis 1 or Axis 2 psychiatric disorder
- No unstable medical disorder

Clinical Trial Design

- Subjects enrolled at sites in India (12) and US (7)
 - Goal to enroll approximately 200 subjects with 120 to complete
 - 2 treatment cohorts
 - TC-5619 (1mg, 5mg, 25mg each for 4 weeks)
 - Placebo
- Target for each cohort:
50% tobacco-users &
50% non-users
- Primary Outcome Measure: Change from Baseline (Day 1) in **GrotonMazeLearning(GML)** test score as a function of treatment over 3 time points (Weeks 4, 8 and 12)
 - Pre-defined success: $p < 0.10$ (one-tailed) against the 3 time points (Weeks 4, 8 and 12) using the Hochberg adjustment for multiplicity

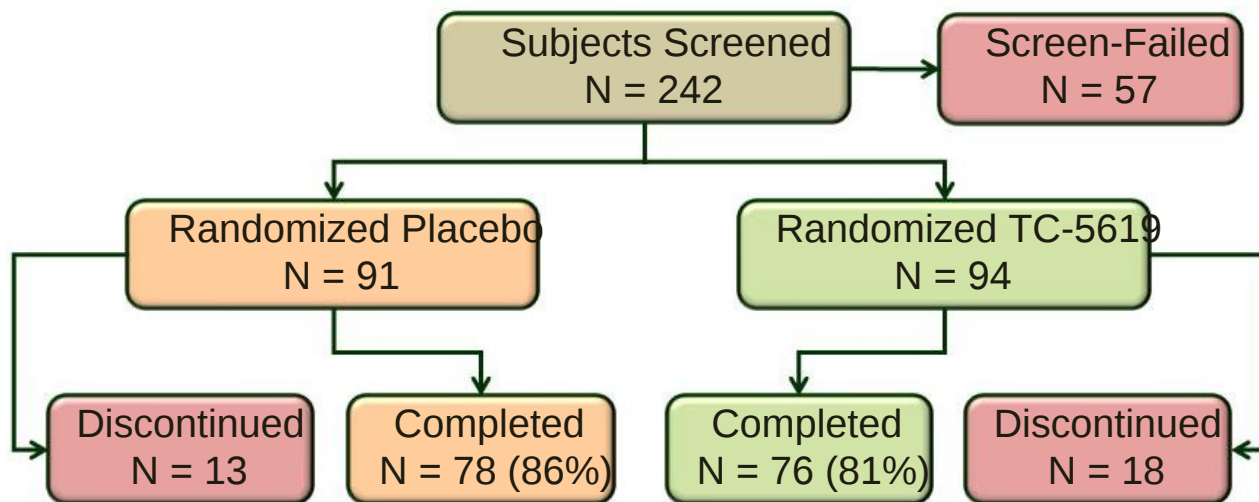
Clinical Trial Schematic



Demographics of Randomized Subjects (N=185)

		Placebo: n (%)	TC-5619: n (%)
Variable		91 (49%)	94 (51%)
Age		36.3 yrs	36.3 yrs
Gender	Male	63 (69%)	65 (69%)
	Female	28 (31%)	29 (31%)
Race	Asian	60 (66%)	61 (65%)
	African-American	25 (28%)	26 (28%)
	Hispanic / Latino	2 (2%)	1 (1%)
	Caucasian	4 (4%)	6 (6%)
Tobacco status	User	41 (45%)	45 (48%)
	Non-user	50 (55%)	49 (52%)
BMI		24.9	25.0
Completed HS or above		60 (66%)	62 (66%)

Disposition of Subjects



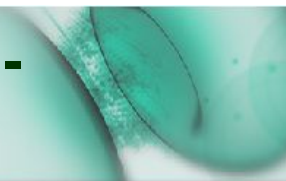
Reasons for placebo discontinuation

- Adverse event: n = 3
- Consent withdrawn: n = 2
- Positive illicit drug screen: n = 1
- Non-compliance: n = 3
- Lost to follow-up: n = 2
- Other: n = 2

Reasons for TC-5619 discontinuation

- Adverse event: n = 4
- Consent withdrawn: n = 7
- Positive illicit drug screen: n = 3
- Non-compliance: n = 0
- Lost to follow-up: n = 3
- Other: n = 1

TC-5619: Generally Well Tolerated - Most Common Adverse Events



Adverse Event (preferred term)	Placebo: Subject N (%)	TC-5619: Subject N (%)
Constipation	2 (2%)	4 (4%)
Nausea	0	5 (5%) (4 mild, 1 moderate)
Body temperature increased	2 (2%)	3 (3%)
Decreased appetite	5 (5%)	4 (4%)
Somnolence	2 (2%)	3 (3%)
Schizophrenia	0	3 (3%)
Headache	2 (2%)	3 (3%)
Insomnia	0	3 (3%)

No Clinically Meaningful Changes or Cohort Differences in Other Safety Measures

- Both SAEs were deemed by the investigator to be unrelated to study drug: gastritis (placebo); and acute exacerbation of schizophrenia (TC-5619) several weeks after a subject stopped taking quetiapine
- 7 AEs leading to discontinuation (all deemed by the investigator to be unrelated to study drug): 3 in placebo cohort and 4 in TC-5619 cohort
- Physical exam, vital signs, clinical chemistry, hematology or urinalysis assessments unchanged from baseline
 - There were no abnormal involuntary movements as a function of treatment, assessed by AIMS
- QTcF unchanged within and between cohorts after dosing began
- No evidence of suicidality after treatment began as assessed by the Columbia Suicide Severity Rating Scale
- No signs of depression after treatment began as assessed by the Calgary Depression Scale for Schizophrenia

Primary Outcome Measure: Groton Maze Learning (GML)

CDS

All Patients				GML (Total Error) LOG			Tobacco users
Visit	Treatment	Adjusted Mean	Standard Error of Adjusted Mean	Mean Difference ± SE between TC-5619 and Placebo (Placebo-TC5619)	One-sided 90% Confidence Interval for Mean Difference	One-sided P-Value	
Week 1	Placebo	-0.02	0.01				
	TC-5619	-0.01	0.01				
				-0.01 ± 0.02	(-0.03, ∞)	0.6709	0.8523
Week 4	Placebo	0.02	0.02				
	TC-5619	-0.03	0.02				
				0.05 ± 0.02	(0.02, ∞)	0.0180	0.0143
Week 8	Placebo	-0.02	0.02				
	TC-5619	-0.05	0.02				
				0.02 ± 0.02	(-0.00, ∞)	0.1308	0.0858
Week 12	Placebo	-0.02	0.02				
	TC-5619	-0.06	0.02				
				0.04 ± 0.02	(0.01, ∞)	0.0405	0.0016

Primary outcome measure, log (10) transformed due to skew, is statistically significant based on Hochberg adjustment for 3 comparisons (at Weeks 4, 8 and 12; one-sided **p = 0.054**)

Secondary Outcome Measure: Negative Symptoms

Negative
Symptoms

TEST	WEEK 4	WEEK 8	WEEK 12
SANS:			
ALL SUBJECTS	0.255	0.118	0.015
SANS:			
TOBACCO USERS	0.098	0.054	0.033

One-tailed p-values

This effect on the SANS was driven by statistically significant scores on 3 of 5 items:

- Anhedonia
- Avolition / Apathy
- Affect

Secondary Outcome Measures: Clinical and Subject Global Impressions

TEST	WEEK 4	WEEK 8	WEEK 12
CGI-I			
ALL SUBJECTS	0.049	0.253	0.150
TOBACCO USERS	0.047	0.075	0.189
SGI-COG			
ALL SUBJECTS	0.428	0.491	0.046
TOBACCO USERS	0.607	0.313	0.109
CGI-S			
ALL SUBJECTS	0.674	0.544	0.450
TOBACCO USERS	0.434	0.224	0.307

One-tailed p-values

CogState Item Scores

TEST	WEEK 4	WEEK 8	WEEK 12
Composite score *	0.838	0.821	0.326 [0.098, tobacco users]
Detection * (psychomotor processing)	0.693	0.650	0.567 [0.265, tobacco users]
Identification * (attention)	0.311	0.111	0.063 [0.057, tobacco users]
1-Card Learning * (visual learning)	0.660	0.899	0.841 [0.338, tobacco users]
1-Back * (working memory)	0.691	0.647	0.042 [0.020, tobacco users]
Int'l Shopping List (verbal memory)	0.970	0.813	0.177 [0.027, tobacco users]
Social-Emotional Cognition *	0.259	0.217	0.546 [0.752, tobacco users]

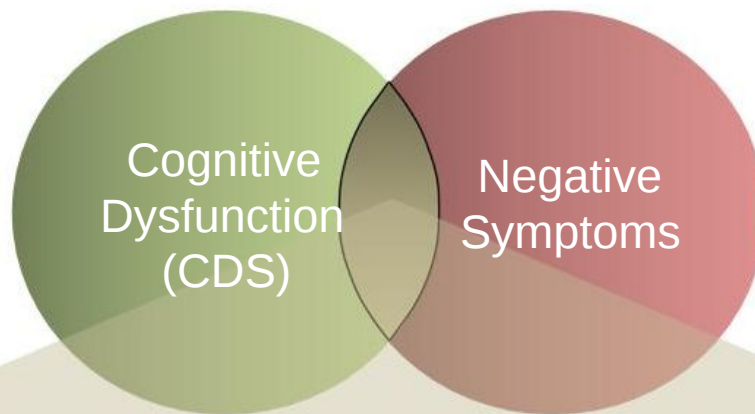
One-tailed p-values

*Analyzed in dataset meeting integrity criteria predefined by CogState

Summary of Results

- Statistically significant results favoring TC-5619 on:
 - **GML** primary outcome measure
 - executive function (objective measure)
 - **SANS, CGI-I and SGI-Cog** secondary outcome measures
 - negative symptoms- Week 12, and global improvement- Week 4 (clinician measures)
 - global cognitive improvement Week 12 (subject measure)
 - **Other CogState outcome measures**
 - attention and working memory - Week 12 (objective measures)
- These results were driven by tobacco users and often better in the US
- TC-5619 was generally well tolerated, without any clinically noteworthy changes in physical examination, vital signs, ECG, laboratory findings, or suicidality

Conclusion and Opportunity



TC-5619 represents a novel mechanism with unique potential to treat “residual phase schizophrenia”:

- Cognitive dysfunction
- Negative symptoms

TARGACEPT



**The Alpha7 Nicotinic Receptor Agonist TC-5619
had Beneficial Effects with Favorable
Tolerability in a Phase 2 Trial in Cognitive
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