# 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): November 1, 2011**

# TARGACEPT, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **000-51173** | **56-2020050** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **200 East First Street, Suite 300**<br>**Winston-Salem, North Carolina**<br>**(Address of principal executive offices)** | **27101**<br>**(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 2.02 Results of Operations and Financial Condition.**

On November 1, 2011, Targacept, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2011. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

The following exhibit is furnished with this report:

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release dated November 1, 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: November 1, 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 November 1, 2011 |

**Exhibit 99.1**

**Targacept Reports Third Quarter 2011 Financial Results**

Winston-Salem, North Carolina, November 1, 2011 – Targacept, Inc. (NASDAQ: TRGT), a clinical-stage biopharmaceutical company developing novel NNR Therapeutics™, today reported its financial results for the third quarter and nine months ended September 30, 2011.

Targacept reported net loss of $9.1 million for the third quarter of 2011, compared to net income of $2.5 million for the corresponding 2010 period, and net income of $1.3 million for the nine months ended September 30, 2011, compared to net income of $13.1 million for the corresponding 2010 period. As of September 30, 2011, cash and investments in marketable securities totaled $270.9 million.

“We look forward to top-line results becoming available soon from the first of five studies in the Phase 3 RENAISSANCE Program for TC-5214, a drug candidate under investigation as an adjunct to antidepressant treatment for patients with major depressive disorder who do not respond adequately to initial therapy,” said J. Donald deBethizy, Ph.D., President and Chief Executive Officer of Targacept. “Our recent initiation of the Phase 2b trial of AZD3480 in Alzheimer’s disease reflects our commitment to advancing a deep pipeline of innovative NNR Therapeutics, with the goal of delivering new medicines to build health and restore independence for patients in multiple areas where large unmet medical needs continue to exist.”

**Recent Highlights and Program Updates:**

TC-5214 (co-development with AstraZeneca)

- Enrollment completed in each of the five clinical trials – two fixed dose studies, two flexible dose studies and one long-term safety study – that comprise the Phase 3 RENAISSANCE Program designed to support a planned second half of 2012 filing of a new drug application with the FDA as an adjunct to antidepressant therapy for major depressive disorder (MDD);
- Expect to report top-line results this month from a flexible dose clinical trial conducted in Europe (RENAISSANCE 3), the first study in the RENAISSANCE Program to complete; results from the remaining RENAISSANCE Program studies expected to be reported through the first half of 2012;
- Recruitment continuing for a Phase 2b “switch” monotherapy trial, known as the EXPLORER study, for patients with MDD who do not respond adequately to initial treatment with an SSRI or SNRI;

TC-5619

- Planned Phase 2b clinical trial for further evaluation as a treatment for negative symptoms and cognitive dysfunction in schizophrenia expected to initiate by the end of 2011 or in early 2012;
- Further analysis of the full dataset from the completed Phase 2 ADHD clinical trial revealed encouraging efficacy signals on the Conners’ Adult ADHD Rating Scale-Investigator Rated Total ADHD Symptoms score (the primary outcome variable) in patients with inattentive predominant ADHD; expect to initiate a Phase 2 study to further assess potential of this product candidate to benefit these patients by the end of 2011 or in early 2012;

- Completed enabling activities for a potential Phase 2 clinical trial of TC-5619 in Alzheimer's disease; evaluation of additional Alzheimer's disease development remains ongoing;

AZD3480 and AZD1446

- Initiated a Phase 2b potential registration study of AZD3480 in mild to moderate Alzheimer's disease and received $2.0 million in payments from AstraZeneca in the third quarter;
- Based on feedback received from AstraZeneca, further development of AZD3480 in ADHD is not currently expected and AstraZeneca's decision surrounding any future development of AZD1446 in Alzheimer's disease is anticipated by the end of the year;

TC-6987

- Executed contingency plans to address slower than expected enrollment in ongoing Phase 2 clinical studies in asthma and type 2 diabetes; expect to complete both studies in the first half of 2012;

Scientific Leadership

- Remained at the forefront of NNR research, with the following publications authored or co-authored by Targacept scientists:
  - Kucinski AJ, Stachowiak MK, Wersinger SR, Lippiello PM, Bencherif M. Alpha7 neuronal nicotinic receptors as targets for novel therapies to treat multiple domains of schizophrenia. *Curr Pharm Biotechnol* 12: 437-48 (2011);
  - Lippiello PM, Mazurov A, Bencherif M. The a7 nicotinic acetylcholine receptor in health and disease. *In Pharmacology of Nicotinic Acetylcholine Receptors from the Basic and Therapeutic Perspectives*, Ed. Hugo R. Arias. pp. 101-150 (2011); and
  - Letchworth, SR, Whiteaker, P. Progress and challenges in the study of a6-containing nicotinic acetylcholine receptors. *Biochem Pharmacol* 82: 862-72 (2011);
- Contributing to the burgeoning field of NNR research with planned participation at "Nicotinic Acetylcholine Receptor-Based Therapeutics: Emerging Frontiers in Basic Research & Clinical Science," a satellite meeting to the Society for Neuroscience taking place in Washington, D.C. on November 9-11, 2011; and

Company Developments

- Named by Deloitte for 2011 to its Technology Fast 500(TM), a ranking of 500 of the fastest growing technology, media, telecommunications, life sciences and clean technology companies in North America; recognition based on Targacept's revenue growth of 211% from 2006 to 2010.

**Financial Results**

Targacept reported net loss of $9.1 million for the third quarter of 2011, compared to net income of $2.5 million for the third quarter of 2010. The net loss position for the 2011 period as compared to net income for the 2010 period was primarily due to an increase in research and development expenses and a decrease in amounts recognized into revenue from payments previously received from AstraZeneca and GlaxoSmithKline. For the nine months ended September 30, 2011, Targacept reported net income of $1.3 million, compared to net income of $13.1 million for the corresponding period of 2010. The decrease in net income for the 2011 period was primarily due to an increase in research and development expenses, partially offset by an increase in amounts recognized into revenue from payments previously received from AstraZeneca and GlaxoSmithKline. Non-cash, stock-based compensation charges of $2.1 million and $1.2 million were recorded for the third quarter of 2011 and 2010, respectively, and $6.5 million and $3.7 million for the nine months ended September 30, 2011 and 2010, respectively.

Net operating revenues totaled $19.0 million for the third quarter of 2011, compared to $21.8 million for the third quarter of 2010. The lower net operating revenues for the 2011 period were principally attributable to decreases of $2.4 million in recognition of deferred revenues associated with TC-5619 and $826,000 in recognition of deferred revenues associated with a now concluded alliance with GlaxoSmithKline.

For the nine months ended September 30, 2011, net operating revenues totaled $78.7 million, compared to $62.2 million for the corresponding 2010 period. The higher net operating revenues for the 2011 period were principally attributable to increases of $15.9 million in recognition of deferred revenues associated with the concluded GlaxoSmithKline alliance and $638,000 in recognition of deferred revenues associated with TC-5619.

Research and development expenses totaled $25.4 million for the third quarter of 2011, compared to $17.3 million for the third quarter of 2010. The higher research and development expenses were principally attributable to increases of $7.4 million in costs incurred for third-party research and development services in connection with clinical-stage product candidates, $1.4 million in costs incurred for third-party research and development services in connection with preclinical programs and $793,000 in other research and development-related operating costs, including compensation-related expenses for research and development personnel and infrastructure costs. These increases were partially offset by the inclusion for the 2010 period of a $1.5 million upfront payment made to Cornerstone Therapeutics Inc. in August 2010. The higher costs incurred for third-party research and development services in connection with clinical-stage product candidates for the 2011 period were principally due to: a greater level of development activities for TC-5214 as the Phase 3 program progressed; the conduct of activities in preparation for a Phase 2b clinical trial of AZD3480 in Alzheimer’s disease; and the conduct of two Phase 2 clinical trials of TC-6987; partially offset by lower clinical trial costs for TC-5619 as a result of the completion of two Phase 2 studies.

For the nine months ended September 30, 2011, research and development expenses totaled $69.1 million, compared to $42.1 million for the corresponding 2010 period. The higher research and development expenses were principally attributable to increases of $22.0 million in costs incurred for third-party research and development services in connection with clinical-stage product candidates, $3.6 million in costs incurred for third-party research and development services in connection with preclinical programs and $3.0 million in other research and development-related operating costs, including compensation-related expenses for research and development personnel and infrastructure costs. These increases were partially offset by the inclusion for the 2010 period of the upfront payment to Cornerstone Therapeutics Inc. The higher costs incurred for third-party research and development services in connection with clinical-stage product candidates for the 2011 period were principally due to the activities described above for the third quarter, further offset by a decrease in costs for TC-6499 as a result of the completion of an exploratory Phase 2 clinical study in the third quarter of 2010.

General and administrative expenses totaled $2.8 million for the third quarter of 2011, compared to $2.1 million for the third quarter of 2010. The higher general and administrative expenses were primarily attributable to an increase of $718,000 in compensation-related expenses for general and administrative personnel. For the nine months ended September 30, 2011, general and administrative expenses totaled $9.1 million, compared to $5.7 million for the corresponding 2010 period. The higher general and administrative expenses were principally attributable to increases of $2.2 million in compensation-related expenses for general and administrative personnel and $1.3 million in infrastructure costs associated with growth.

There was no income tax expense for the third quarter or nine months ended September 30, 2011, compared to income tax expense of $257,000 and $2.4 million for the third quarter and nine months ended September 30, 2010, respectively. Income tax expense for the 2010 periods was primarily due to the income tax effect of stock option exercises that is recognized only in certain circumstances.

**Updated Financial Guidance**

Targacept now expects its cash, cash equivalents and investments balance to be at least $240 million at December 31, 2011. Targacept continues to expect its cash resources to be sufficient to meet its operating requirements at least through the end of 2014. This guidance does not include amounts that Targacept could receive if any milestone events are achieved under its collaboration agreements with AstraZeneca. Targacept is not making any adjustment to its previously announced guidance for expected net operating revenues or expected operating expenses for the year ended December 31, 2011.

**Conference Call**

As previously announced, Targacept will be hosting a conference call and webcast today, November 1, 2011, at 5:00 p.m. Eastern Time. The conference call may be accessed by dialing (866) 730-5764 for domestic participants and (857) 350-1588 for international callers (reference passcode 91779970). A replay of the conference call may be accessed from approximately 8:00 p.m. Eastern Time on November 1, 2011 through November 15, 2011 by dialing (888) 286-8010 for domestic callers and (617) 801-6888 for international callers (reference passcode 49874736).

A live audio 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 the Investor Calendar section of the Investor Relations page of Targacept's website for at least two weeks following the call.

**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 being co-developed with AstraZeneca and is in Phase 3 clinical trials 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.

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: the progress or scope of development of TC-5214, TC-5619, AZD3480, AZD1446, TC-6987 or any other Targacept product candidate or program, such as the target indication(s) for development, the size, design, population, conduct, duration or objective of any clinical trial or the timing for initiation or completion of or reporting of results from any clinical trial or for submission or approval of any regulatory filing (such as a new drug application with the FDA); the timing for a decision by AstraZeneca whether to conduct further development of AZD1446 in Alzheimer’s disease; any further development of AZD3480 in ADHD; the competitive position of any Targacept product candidate or the commercial opportunity in any target 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 Targacept’s critical accounting policies and risks and uncertainties relating to: Targacept’s dependence on the success of its collaborations with AstraZeneca; the control or significant influence that AstraZeneca has over the development of TC-5214, AZD3480 and AZD1446, including as to the timing, scope and design of any future clinical trials and as to the conduct at all of further development of AZD1446 in Alzheimer’s disease; the conduct and results of clinical trials and non-clinical studies and assessments of TC-5214, TC-5619, AZD3480, AZD1446, TC-6987 and any other Targacept product candidate, 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; whether positive findings from completed clinical trials of TC-5214 or TC-5619 will be replicated in ongoing or any future clinical trials of that product candidate; Targacept’s ability to protect its intellectual property; 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.



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**TARGACEPT, INC**

**Unaudited Condensed Statements of Operations**
**(in thousands, except share and per share amounts)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| Net operating revenues | $ 18,955 | $ 21,798 | $ 78,692 | $ 62,218 |
| Operating expenses: | | | | |
| Research and development | 25,444 | 17,329 | 69,146 | 42,058 |
| General and administrative | 2,842 | 2,052 | 9,146 | 5,688 |
| Total operating expenses | 28,286 | 19,381 | 78,292 | 47,746 |
| Operating (loss) income | (9,331) | 2,417 | 400 | 14,472 |
| Interest income, net of interest expense | 277 | 326 | 876 | 986 |
| (Loss) income before income taxes | (9,054) | 2,743 | 1,276 | 15,458 |
| Income tax (expense) benefit | — | (257) | — | (2,395) |
| Net (loss) income | $ (9,054) | $ 2,486 | $ 1,276 | $ 13,063 |
| Basic net (loss) income per share | $ (0.27) | $ 0.09 | $ 0.04 | $ 0.46 |
| Diluted net (loss) income per share | $ (0.27) | $ 0.08 | $ 0.04 | $ 0.43 |
| Weighted average common shares outstanding - basic | 33,377,874 | 28,622,187 | 31,049,104 | 28,482,224 |
| Weighted average common shares outstanding - diluted | 33,377,874 | 30,173,406 | 32,361,508 | 30,109,023 |

**TARGACEPT, INC**

**Unaudited Condensed Balance Sheets**
**(in thousands)**

| | September 30, 2011 | December 31, 2010 |
|---|---|---|
| Cash, cash equivalents and investments | $ 270,860 | $ 252,509 |
| Collaboration receivables and other current assets | 3,334 | 4,057 |
| Property and equipment, net | 5,409 | 6,072 |
| Other assets, net | 136 | 149 |
| Total assets | $ 279,739 | $ 262,787 |
| Current portion of deferred revenue | $ 74,449 | $ 81,710 |
| Other current liabilities | 19,132 | 16,947 |
| Deferred revenue, net of current portion | 1,951 | 70,934 |
| Long-term debt, net of current portion | 2,195 | 1,349 |
| Total stockholders’ equity | 182,012 | 91,847 |
| Total liabilities and stockholders’ equity | $ 279,739 | $ 262,787 |