# 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 4, 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)

 $(336)\ 480\text{--}2100$  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 2.02 Results of Operations and Financial Condition.

On November 4, 2010, Targacept, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2010. 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 4, 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: November 4, 2010

/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 4, 2010

#### **Targacept Reports Third Quarter 2010 Financial Results**

Winston-Salem, North Carolina – November 4, 2010 – Targacept, Inc. (NASDAQ: <u>TRGT</u>), a clinical-stage biopharmaceutical company developing novel NNR Therapeutics<sup>TM</sup>, today reported its financial results for the third quarter ended September 30, 2010.

Targacept reported net income of \$2.5 million for the third quarter of 2010, compared to \$1.3 million for the third quarter of 2009. For the nine months ended September 30, 2010, Targacept reported net income of \$13.1 million, compared to a net loss of \$13.0 million for the corresponding period of 2009. The net income position for the 2010 periods was primarily due to the recognition into revenue of \$18.3 million and \$54.3 million, respectively, of the \$200.0 million upfront payment received in January 2010 from AstraZeneca under a collaboration agreement for TC-5214. As of September 30, 2010, Targacept's cash, cash equivalents and investments totaled \$268.0 million.

"The third quarter saw continued execution of the clinical programs for our product candidates," said J. Donald deBethizy, Ph.D., Targacept's President and Chief Executive Officer. "The Renaissance Program for TC-5214 as an adjunct to antidepressant therapy for major depressive disorder is now well underway, and we continue to expect AstraZeneca to file an NDA in the second half of 2012. Clinical trial results for our first-in-class product candidates for cognitive disorders have yielded mixed efficacy results, but have validated our unique ability to design and develop selective, well tolerated nicotinic compounds. We continue to believe in the promise of NNR Therapeutics for treating cognitive disorders and also look forward to expanding our clinical focus with the expected initiation of a learning trial of TC-6987 in patients with asthma before year end."

#### **Recent Highlights and Program Updates:**

TC-5214 (co-development with AstraZeneca)

- Enrollment ongoing for the five Phase 3 clinical studies that comprise the Renaissance Program, which is designed to support the planned filing of a New Drug Application with the FDA in the second half of 2012 as an adjunct (add-on) therapy for patients with major depressive disorder who do not respond adequately to first-line treatment with an SSRI or SNRI;
- Initiation of a Phase 2 clinical trial as a second-line "switch" monotherapy expected in the first quarter of 2011;

#### TC-5619

- Enrollment completed in two ongoing Phase 2 clinical proof of concept studies, one in cognitive dysfunction in schizophrenia and one in adults with attention deficit/hyperactivity disorder (ADHD), which represent Targacept's first evaluation of an alpha7-selective NNR Therapeutic in patients with cognitive impairment; results from each of these trials expected in the first quarter of 2011;
- · Studies progressing to support potential advancement into Phase 2 clinical development for Alzheimer's disease;

#### AZD3480

- Discussions with AstraZeneca regarding potential future development for ADHD remain ongoing; whether AstraZeneca will decide to conduct any additional development in ADHD is uncertain in light of reservations about the adequacy of the therapeutic margin to support development across the broad ADHD patient population;
- Decision by AstraZeneca whether to advance as a treatment for ADHD expected by the end of 2010; additionally, Targacept exploring the practicability of further development in Alzheimer's disease;

#### AZD1446

- AstraZeneca concluded three of four Phase 1/2a clinical studies expected to inform an advancement decision, with results from the fourth study
  expected in the first half of 2011:
- AstraZeneca expected to determine whether to conduct future development for Alzheimer's disease in the coming months;
- No further development planned in ADHD based on unfavorable outcome on the Conners' Adult ADHD Rating Scale-Investigator Rated Total ADHD Symptoms score (CAARS-INV) in recently completed study in adults with ADHD;

#### TC-6987

- Alpha7 NNR modulator generally well tolerated in both Phase 1 single rising dose and Phase 1 multiple rising dose clinical trials at doses well in excess of the doses expected to be evaluated in Phase 2;
- Preclinical studies indicate promise across a variety of inflammatory disorders; multiple Phase 2 learning trials planned to identify optimal
  indication, with an asthma study expected to initiate in the fourth quarter of 2010;

#### Company Developments

- Received notice of approval from the Internal Revenue Service for all six of Targacept's grant applications under the Qualifying Therapeutic
  Discovery Project tax credit program, representing an aggregate amount to Targacept of \$1,466,875; this program, enacted as part of the Patient
  Protection and Affordable Care Act of 2010, was targeted to benefit therapeutic projects that show potential to result in new therapies to treat areas of
  unmet medical need, taking into consideration the potential to advance U.S. competitiveness and create and sustain high quality, high paying jobs;
- Named by Deloitte for 2010 to its Technology Fast 500<sup>™</sup>, 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 2,024% from 2005 to 2009; and

#### NNR Research & Development Day

• Targacept to host an NNR Research & Development Day in New York on December 2, 2010 with presenters that include Targacept scientists and other leaders in the NNR field; this event will be webcast via Targacept's website at www.targacept.com. For additional information about the event, please contact Jo Peay at Targacept at 336-480-2102 or jo.peay@targacept.com.

#### **Financial Results**

Targacept reported net income of \$2.5 million for the third quarter of 2010, compared to \$1.3 million for the third quarter of 2009. For the nine months ended September 30, 2010, Targacept reported net income of \$13.1 million, compared to a net loss of \$13.0 million for the corresponding period in 2009. The net income position for the 2010 periods was primarily due to the recognition into revenue of \$18.3 million and \$54.3 million, respectively, of the \$200.0 million upfront payment received in January 2010 from AstraZeneca. The results included non-cash, stock-based compensation charges of \$1.2 million and \$553,000 for the third quarter of 2010 and 2009, respectively, and \$3.7 million and \$1.7 million for the nine months ended September 30, 2010 and 2009, respectively.

Net operating revenues totaled \$21.8 million for the third quarter of 2010, compared to \$12.7 million for the third quarter of 2009. The higher net operating revenues for the 2010 period were principally attributable to the recognition of \$18.3 million of license fee revenue described above and \$2.4 million of the \$11.0 million payment received from AstraZeneca in connection with an April 2010 expansion of the development program for TC-5619, partially offset by the achievement of a \$10.0 million milestone event under Targacept's 2005 collaboration agreement with AstraZeneca focused in cognitive disorders during the three months ended September 30, 2009 and decreases for the 2010 period of \$1.1 million in collaboration research and development revenue and \$313,000 of license fee revenue resulting from the January 2010 completion of the term of the preclinical research collaboration under the cognitive disorders agreement with AstraZeneca.

For the nine months ended September 30, 2010, net operating revenues totaled \$62.2 million, compared to \$21.6 million for the corresponding period in 2009. The higher net operating revenues for the 2010 period were primarily attributable to recognition of an aggregate of \$58.2 million of license fee revenue derived from the \$200.0 million and \$11.0 million payments from AstraZeneca described above, partially offset by the achievement during the 2009 period of the \$10.0 million milestone event described above, a decrease of \$2.5 million in milestone payments from GlaxoSmithKline and decreases of \$3.7 million in collaboration research and development revenue and \$833,000 of license fee revenue resulting from the January 2010 completion of the term of the preclinical research collaboration under the cognitive disorders agreement with AstraZeneca.

Research and development expenses totaled \$17.3 million for the third quarter of 2010, compared to \$9.3 million for the third quarter of 2009. The higher research and development expenses for the 2010 period were principally attributable to increases of \$5.2 million in costs incurred for third-party research and development services in connection with clinical-stage product candidates, a \$1.5 million payment made upon entering into an exclusive worldwide license agreement with Cornerstone Therapeutics, Inc., and \$1.4 million in compensation-related costs for research and development personnel and infrastructure costs. For the 2010 period, third-party research and development costs related to clinical-stage product candidates totaled \$7.0 million and were incurred principally with respect to activities for the ongoing Phase 2 clinical proof of concept trials of TC-5619 in cognitive dysfunction in schizophrenia and adults with ADHD, Phase 3 clinical development of TC-5214 and Phase 1 clinical development of TC-6987.

For the nine months ended September 30, 2010, research and development expenses totaled \$42.1 million, compared to \$29.8 million for the corresponding period in 2009. The higher research and development expenses for the 2010 period were principally attributable to increases of \$7.9 million in costs incurred for third-party research and development services in connection with clinical-stage product candidates and \$4.2 million in compensation-related costs for research and development personnel and infrastructure costs, as well as the \$1.5 million upfront payment to Cornerstone Therapeutics, Inc. These increases were partially offset by a decrease of \$1.4 million in costs incurred for third-party research and development services in connection with preclinical programs. For the 2010 period, third-party research and development costs related to clinical-stage product candidates totaled \$15.6 million and were incurred principally in connection with the activities described above for the third quarter of 2010.

General and administrative expenses totaled \$2.1 million for the third quarter of 2010, compared to \$1.6 million for the third quarter of 2009. For the nine months ended September 30, 2010, general and administrative expenses totaled \$5.7 million, compared to \$4.5 million for the corresponding period in 2009. The higher general and administrative expenses for the 2010 periods were principally attributable to increases in stock based compensation expense, salary and other compensation-related expenses for general and administrative personnel of \$407,000 and \$984,000, respectively.

Other income, net of expense, totaled \$326,000 for the third quarter of 2010, compared to \$120,000 for the third quarter of 2009. For the nine months ended September 30, 2010, other income, net of expense, totaled \$986,000, compared to \$623,000 for the corresponding period in 2009. The increase for both 2010 periods reflected significantly increased cash and investment balances, partially offset by lower interest rates.

Income tax expense totaled \$257,000 for the third quarter of 2010, compared to a \$10,000 income tax benefit for the third quarter of 2009. For the nine months ended September 30, 2010, income tax expense totaled \$2.4 million compared to an income tax benefit of \$83,000 for the corresponding period in 2009. Income tax expense for each of the 2010 periods was primarily due to the tax effect recognized for periods with net income of the difference in treatment of stock-based compensation for income tax purposes as compared to U.S. generally accepted accounting principles.

#### **Update to 2010 Financial Guidance**

Based on current operating plans, Targacept now expects to have at least \$240 million in cash, cash equivalents and investments at December 31, 2010. Targacept also now expects operating expenses for the year ending December 31, 2010 to be in the range of \$70 million to \$75 million, which includes both cash and non-cash expense items. Targacept continues to expect that its current cash resources will be sufficient to meet its operating requirements at least through the end of 2013.

#### **Conference Call**

As previously announced, Targacept will be hosting a conference call and webcast today, November 4, 2010, at 5:00 p.m. Eastern Daylight Time. The conference call may be accessed by dialing 800-291-5365 for domestic participants and 617-614-3922 for international callers (reference passcode 12434137). A replay of the conference call may be accessed from approximately 8:00 p.m. Eastern Daylight Time on November 4, 2010 through November 18, 2010 by dialing 888-286-8010 for domestic callers and 617-801-6888 for international callers (reference passcode 54926435).

A live audio webcast of the conference call will be accessible from the Investor Relations page of Targacept's website, <a href="www.targacept.com">www.targacept.com</a>. 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<sup>TM</sup> 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 in Phase 3 development as an adjunct treatment for major depressive disorder. Targacept leverages its scientific leadership and proprietary drug discovery platform Pentad<sup>TM</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 <a href="https://www.targacept.com">www.targacept.com</a>.

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 any clinical trial, for availability of results from any clinical trial, for submission or approval of any regulatory filing (including a New Drug Application for TC-5214) or where applicable for an advancement decision by AstraZeneca; the competitive position of any Targacept product candidate or the commercial opportunity in any target indication; any payments that AstraZeneca or GlaxoSmithKline 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 AZD3480 in ADHD, AZD1446 in Alzheimer's disease or ADHD or TC-5619 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; the overall impact of GlaxoSmithKline's shift in discovery research focus on Targacept's alliance with GlaxoSmithKline; 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.

NNR Therapeutics  $^{\text{TM}}$ , Pentad  $^{\text{TM}}$  and Building Health, Restoring Independence  $^{\text{TM}}$  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.

#### **Contacts:**

Alan Musso, SVP 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>

# TARGACEPT, INC

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

|  |    | Three Months Ended<br>September 30, |         |          |    | Nine Months Ended<br>September 30, |    |           |  |
|--|----|-------------------------------------|---------|----------|----|------------------------------------|----|-----------|--|
|  | _  | 2010                                |         | 2009     | _  | 2010                               |    | 2009      |  |
| Net operating revenues                               | \$ | 21,798                              | \$      | 12,663   | \$ | 62,218                             | \$ | 21,634    |  |
| Operating expenses:                                  |    |                                     |         |          |    |                                    |    |           |  |
| Research and development                             |    | 17,329                              |         | 9,275    |    | 42,058                             |    | 29,819    |  |
| General and administrative                           |    | 2,052                               |         | 1,628    |    | 5,688                              |    | 4,477     |  |
| License fees and royalties                           |    | _                                   |         | 350      |    | _                                  |    | 350       |  |
| Cost of product sales                                |    |                                     |         | 206      |    | _                                  |    | 691       |  |
| Total operating expenses                             |    | 19,381                              |         | 11,459   |    | 47,746                             |    | 35,337    |  |
| Operating income (loss)                              |    | 2,417                               |         | 1,204    |    | 14,472                             |    | (13,703)  |  |
| Other income, net                                    |    | 326                                 |         | 120      |    | 986                                |    | 623       |  |
| Income (loss) before income taxes                    | ·  | 2,743                               | <u></u> | 1,324    |    | 15,458                             |    | (13,080)  |  |
| Income tax (expense) benefit                         |    | (257)                               |         | 10       |    | (2,395)                            |    | 83        |  |
| Net income (loss)                                    | \$ | 2,486                               | \$      | 1,334    | \$ | 13,063                             | \$ | (12,997)  |  |
| Basic net income (loss) per share                    | \$ | 0.09                                | \$      | 0.05     | \$ | 0.46                               | \$ | (0.52)    |  |
| Diluted net income (loss) per share                  | \$ | 0.08                                | \$      | 0.05     | \$ | 0.43                               | \$ | (0.52)    |  |
| Weighted average common shares outstanding - basic   | 28 | ,622,187                            | 25      | ,126,823 | 28 | 3,482,224                          | 2  | 5,019,953 |  |
| Weighted average common shares outstanding - diluted | 30 | ,173,406                            | 26      | ,943,535 | 30 | ),109,023                          | 2  | 5,019,953 |  |

# TARGACEPT, INC

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

|  | September 30,<br>2010 | December 31,<br>2009 |
|--|-----------------------|----------------------|
| Cash, cash equivalents and investments             | \$ 268,020            | \$ 111,066           |
| Collaboration receivables and other current assets | 5,048                 | 203,363              |
| Property and equipment, net                        | 5,037                 | 4,783                |
| Other assets, net                                  | 154                   | 167                  |
| Total assets                                       | \$ 278,259            | \$ 319,379           |
| Current portion of deferred revenue                | \$ 84,138             | \$ 77,243            |
| Other current liabilities                          | 11,661                | 23,984               |
| Deferred revenue, net of current portion           | 90,258                | 147,195              |
| Long-term debt, net of current portion             | 1,838                 | 1,966                |
| Total stockholders' equity                         | 90,364                | 68,991               |
| Total liabilities and stockholders' equity         | \$ 278,259            | \$ 319,379           |