
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For The Quarterly Period Ended September 30, 2010

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from _____ to _____

Commission File Number: 000-51173

Targacept, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

200 East First Street, Suite 300
Winston-Salem, North Carolina
(Address of Principal Executive Offices)

56-2020050
(I.R.S. Employer
Identification No.)

27101
(Zip Code)

Registrant's telephone number, including area code: (336) 480-2100

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

| | | | |
|-------------------------|--|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> (do not check if a smaller reporting company) | Smaller reporting company | <input checked="" type="checkbox"/> |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of October 31, 2010, the registrant had 28,652,507 shares of common stock, \$0.001 par value per share, outstanding.

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FORM 10-Q
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PART I. Financial Information

Cautionary Note Regarding Forward-Looking Statements

This quarterly report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, which we refer to as the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. For this purpose, any statement contained in this quarterly report, other than statements of historical fact, regarding, among other things:

- the progress, scope or duration of the development of TC-5214, AZD3480 (TC-1734), AZD1446 (TC-6683), TC-5619, TC-6987, TC-6499 or any of our other product candidates or programs, such as the target indication(s) for development, the size, design, population, conduct, objective or endpoints of any clinical trial, or the timing for initiation or completion of or availability of results from any clinical trial, for submission or approval of any regulatory filing (including a new drug application for TC-5214 with the U.S. Food and Drug Administration), for meeting with regulatory authorities or where applicable for an advancement decision by AstraZeneca;
- the benefits that may be derived from any of our product candidates;
- any payments that AstraZeneca or GlaxoSmithKline may make to us;
- the impact on our alliance of GlaxoSmithKline's shift in discovery research focus announced in February 2010;
- our operations, financial position, taxable income, revenues, costs or expenses; or
- our strategies, prospects, plans, expectations or objectives;

is a forward-looking statement made under the provisions of The Private Securities Litigation Reform Act of 1995. In some cases, words such as "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing," "scheduled" or other comparable words identify forward-looking statements. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement for many reasons, including our critical accounting policies and risks and uncertainties relating to:

- our dependence on the success of our 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 attention deficit/hyperactivity disorder, AZD1446 in Alzheimer's disease or TC-5619 in Alzheimer's disease;
- whether AstraZeneca exercises its right to license TC-5619 when exercisable;

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- the conduct and results of clinical trials and non-clinical studies and assessments of TC-5214, TC-5619, AZD1446, TC-6987, TC-6499 or any of our other product candidates, including the performance of third parties engaged to execute them and difficulties or delays in subject enrollment and data analysis;
- our ability to establish additional strategic alliances, collaborations and licensing or other arrangements on favorable terms;
- our ability to protect our intellectual property; and
- the timing and success of submission, acceptance and approval of regulatory filings.

You should also review the risks and uncertainties described in greater detail under the caption “Risk Factors” in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2009 and in other filings that we make with the Securities and Exchange Commission, or SEC. As a result of the risks and uncertainties to which our business is subject, the results or events indicated by any forward-looking statement may not occur. We caution you not to place undue reliance on any forward-looking statement.

In addition, any forward-looking statement in this quarterly report represents our views only as of the date of this quarterly report and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments may cause our views to change. Although we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, except as required by applicable law. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

Item 1. Financial Statements

TARGACEPT, INC.
BALANCE SHEETS
(in thousands, except share and par value amounts)
(unaudited)

| | <u>September 30,</u> <u>2010</u> | <u>December 31,</u> <u>2009</u> |
|---|-------------------------------------|------------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 185,799 | \$ 83,909 |
| Investments in marketable securities - short term | 42,182 | 27,157 |
| Receivables from collaborations | 1,743 | 201,801 |
| Prepaid expenses | 3,305 | 1,562 |
| Total current assets | <u>233,029</u> | <u>314,429</u> |
| Investments in marketable securities - long term | 40,039 | — |
| Property and equipment, net | 5,037 | 4,783 |
| Intangible assets, net | 154 | 167 |
| Total assets | <u>\$ 278,259</u> | <u>\$ 319,379</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 6,306 | \$ 1,275 |
| License fee payable | — | 16,000 |
| Accrued expenses | 3,632 | 5,267 |
| Current portion of long-term debt | 1,723 | 1,442 |
| Current portion of deferred revenue | 84,138 | 77,243 |
| Total current liabilities | <u>95,799</u> | <u>101,227</u> |
| Long-term debt, net of current portion | 1,838 | 1,966 |
| Deferred revenue, net of current portion | 90,258 | 147,195 |
| Total liabilities | <u>187,895</u> | <u>250,388</u> |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock, \$0.001 par value, 100,000,000 shares authorized; 28,636,029 and 28,226,829 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively | 29 | 28 |
| Preferred stock, \$0.001 par value, 5,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2010 and December 31, 2009 | — | — |
| Capital in excess of par value | 306,253 | 298,263 |
| Accumulated other comprehensive income | 319 | — |
| Accumulated deficit | <u>(216,237)</u> | <u>(229,300)</u> |
| Total stockholders' equity | <u>90,364</u> | <u>68,991</u> |
| Total liabilities and stockholders' equity | <u>\$ 278,259</u> | <u>\$ 319,379</u> |

See accompanying notes.

TARGACEPT, INC.
STATEMENTS OF OPERATIONS
(in thousands, except share and par share amounts)
(unaudited)

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|------------|-------------------|-------------|
| | September 30, | | September 30, | |
| | 2010 | 2009 | 2010 | 2009 |
| Operating revenues: | | | | |
| Milestones and license fees from collaborations | \$ 21,662 | \$ 11,405 | \$ 61,455 | \$ 17,131 |
| Collaboration research and development | — | 1,059 | — | 3,724 |
| Product sales, net | — | 118 | — | 473 |
| Grant revenue | 136 | 81 | 763 | 306 |
| Net operating revenues | 21,798 | 12,663 | 62,218 | 21,634 |
| Operating expenses: | | | | |
| Research and development (including stock-based compensation of \$624 and \$320 for the three months ended September 30, 2010 and 2009, respectively, and \$2,138 and \$900 for the nine months ended September 30, 2010 and 2009, respectively) | 17,329 | 9,275 | 42,058 | 29,819 |
| General and administrative (including stock-based compensation of \$601 and \$233 for the three months ended September 30, 2010 and 2009, respectively, and \$1,565 and \$799 for the nine months ended September 30, 2010 and 2009, respectively) | 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 |
| Income (loss) from operations | 2,417 | 1,204 | 14,472 | (13,703) |
| Other income (expense): | | | | |
| Interest income, net | 360 | 173 | 1,100 | 793 |
| Interest expense | (34) | (53) | (114) | (170) |
| Total other income (expense) | 326 | 120 | 986 | 623 |
| Income (loss) before income taxes | 2,743 | 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 | 28,482,224 | 25,019,953 |
| Weighted average common shares outstanding - diluted | 30,173,406 | 26,943,535 | 30,109,023 | 25,019,953 |

See accompanying notes.

TARGACEPT, INC.
STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

| | Nine Months Ended | |
|--|--------------------------|-------------|
| | September 30, | |
| | 2010 | 2009 |
| Operating activities | | |
| Net income (loss) | \$ 13,063 | \$(12,997) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | |
| Recognition of deferred revenue | (61,939) | (4,487) |
| Amortization of premium on marketable securities, net | 296 | — |
| Depreciation and amortization | 1,459 | 1,391 |
| Stock-based compensation expense | 3,703 | 1,699 |
| Excess tax benefits from stock-based compensation | (2,278) | — |
| Changes in operating assets and liabilities: | | |
| Receivables from collaborations | 200,058 | 312 |
| Prepaid expenses, inventories and accrued interest receivable | (1,921) | 107 |
| Accounts payable, license fees payable and accrued expenses | (10,326) | 1,110 |
| Deferred revenue | 11,897 | 321 |
| Net cash provided by (used in) operating activities | 154,012 | (12,544) |
| Investing activities | | |
| Purchase of investments | (128,703) | (31,000) |
| Proceeds from sale of investments | 73,840 | 41,000 |
| Purchase of property and equipment | (1,700) | (152) |
| Net cash (used in) provided by investing activities | (56,563) | 9,848 |
| Financing activities | | |
| Proceeds from issuance of notes payable | 1,228 | — |
| Principal payments on long-term debt | (1,075) | (1,042) |
| Proceeds from issuance of common stock, net | 2,010 | 765 |
| Excess tax benefits from stock-based compensation | 2,278 | — |
| Net cash provided by (used in) financing activities | 4,441 | (277) |
| Net increase (decrease) in cash and cash equivalents | 101,890 | (2,973) |
| Cash and cash equivalents at beginning of period | 83,909 | 51,202 |
| Cash and cash equivalents at end of period | \$ 185,799 | \$ 48,229 |

See accompanying notes.

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS
September 30, 2010

1. The Company and Nature of Operations

Targacept, Inc., or the Company, is a Delaware corporation formed on March 7, 1997. The Company is a biopharmaceutical company engaged in the design, discovery and development of NNR Therapeutics™ for the treatment of diseases and disorders of the nervous system. The Company's NNR Therapeutics selectively target neuronal nicotinic receptors, which it refers to as NNRs. Its facilities are located in Winston-Salem, North Carolina.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information, the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's audited financial statements and notes thereto included in its Annual Report on Form 10-K for the year ended December 31, 2009. In the opinion of the Company's management, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of its financial position, operating results and cash flows for the periods presented have been included. Operating results for the three and nine months ended September 30, 2010 and 2009 are not necessarily indicative of the results that may be expected for the full year, for any other interim period or for any future year.

Use of Estimates and Reclassifications

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts of assets, liabilities, revenues and expenses reported in the financial statements and accompanying notes. Actual results could differ from these estimates.

Certain reclassifications have been made to the financial statements for the nine months ended September 30, 2009 to conform to the presentation in the financial statements for the nine months ended September 30, 2010. These reclassifications had no impact on previously reported net loss for any period.

Fair Value Measurement

The Company follows Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 820, *Fair Value Measurements and Disclosures*, or ASC 820, for application to financial assets. ASC 820 defines fair value, provides a consistent framework for measuring fair value under GAAP and requires fair value financial statement disclosures. ASC 820 applies only to the measurement and disclosure of financial assets that are required or permitted to be measured and reported at fair value under other ASC topics (except for ASC Topic 718, *Compensation – Stock Compensation*).

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

2. Summary of Significant Accounting Policies (continued)

The valuation techniques of ASC 820 are based on both observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, and unobservable inputs reflect the Company's market assumptions. ASC 820 classifies these inputs into the following hierarchy:

Level 1 Inputs— quoted prices (unadjusted) in active markets for identical assets that the reporting entity has the ability to access at the measurement date.

Level 2 Inputs— inputs other than quoted prices included within Level 1 that are observable for the asset, either directly or indirectly.

Level 3 Inputs— unobservable inputs for the asset.

The following tables present the Company's investments in marketable securities that are measured at fair value on a recurring basis as of September 30, 2010 and December 31, 2009, respectively:

| <u>September 30, 2010</u> | <u>Quoted Prices in Active Markets (Level 1)</u> | <u>Significant Other Observable Inputs (Level 2)</u> (in thousands) | <u>Significant Unobservable Inputs (Level 3)</u> |
|--|--|--|--|
| U.S. Federal Treasury and U.S. government and state government agency securities | \$46,243 | \$ — | \$ — |
| Corporate debt securities | 38,640 | — | — |
| Certificates of deposit | 13,000 | — | — |
| Accrued interest | 335 | — | — |
| Total cash equivalents and marketable securities | <u>\$98,218</u> | <u>\$ —</u> | <u>\$ —</u> |

| <u>December 31, 2009</u> | <u>Quoted Prices in Active Markets (Level 1)</u> | <u>Significant Other Observable Inputs (Level 2)</u> (in thousands) | <u>Significant Unobservable Inputs (Level 3)</u> |
|--|--|--|--|
| Certificates of deposit | \$27,000 | \$ — | \$ — |
| Accrued interest | 157 | — | — |
| Total cash equivalents and marketable securities | <u>\$27,157</u> | <u>\$ —</u> | <u>\$ —</u> |

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

2. Summary of Significant Accounting Policies (continued)

Investments in Marketable Securities

Consistent with the Company's investment policy, the Company's cash expected to be used to fund short-term liquidity requirements is invested with prominent financial institutions in bank depository accounts, certificates of deposit and institutional money market funds and cash that the Company does not expect to need to fund its short-term liquidity requirements is invested in U.S. Treasury notes and bonds, U.S. federal and state agency-backed certificates and corporate debt securities that are rated at least A quality or equivalent.

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates its designation as of each balance sheet date. All marketable securities owned during the three and nine months ended September 30, 2010 and 2009 were classified as available for sale. Interest and dividend income on investments in marketable securities are included in "Interest income." The cost of securities sold is based on the specific identification method. Investments in marketable securities are recorded as of each balance sheet date at fair value, with unrealized gains and, to the extent deemed temporary, unrealized losses in stockholders' equity. Accretion of discounts and amortization of premiums and realized gains and losses are included in interest income in the statement of operations.

An investment in marketable securities is considered to be impaired when a decline in fair value below its cost basis is determined to be other-than-temporary. The Company evaluates whether a decline in fair value below cost basis is other-than-temporary using available evidence regarding the Company's investments in marketable securities. In the event that the cost basis of a security exceeds its fair value, the Company evaluates, among other factors, the amount and duration of the period that the fair value is less than the cost basis, the financial health of and business outlook for the issuer, including industry and sector performance, and operational and financing cash flow factors, overall market conditions and trends, the Company's intent to sell the investment and whether it is more likely than not the Company would be required to sell the investment before its anticipated recovery. If a decline in fair value is determined to be other-than-temporary, the Company records an impairment charge in the statement of operations and establishes a new cost basis in the security.

Revenue Recognition

The Company uses the revenue recognition guidance established by ASC Topic 605, *Revenue Recognition*, or ASC 605. In determining the accounting for collaboration and alliance agreements, the Company follows the provisions of Subtopic 25, *Multiple Element Arrangements*, of ASC 605, or ASC 605-25. ASC 605-25 provides guidance on whether an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes and, if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. If the arrangement constitutes separate units of accounting according to the separation criteria of ASC 605-25, a revenue recognition policy must be determined for each unit. If the arrangement constitutes a single unit of accounting, the revenue recognition policy must be determined for the entire arrangement.

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

2. Summary of Significant Accounting Policies (continued)

Collaboration research and development revenue is earned and recognized as research is performed and related expenses are incurred. Non-refundable upfront fees, which may include, for example, an initial payment upon commencement of the contractual relationship, payment representing a common stock purchase premium or payment to secure a right for a future license, are recorded as deferred revenue and recognized into revenue as milestones and license fees from collaborations on a straight-line basis over (1) the estimated development period, to the extent the fees are attributable to a specific licensed product candidate, or otherwise (2) the estimated period of the Company's substantive performance obligations or, where the Company's collaborator has substantially all research and development responsibility, over the estimated research and development period.

Revenue for non-refundable payments based on the achievement of collaboration milestones is recognized as revenue when the milestones are achieved if all of the following conditions are met: (1) achievement of the milestone event was not reasonably assured at the inception of the arrangement; (2) substantive effort is involved to achieve the milestone event; and (3) the amount of the milestone payment appears reasonable in relation to the effort expended, the other milestone payments in the arrangement and the related risk associated with achievement of the milestone event. If any of these conditions is not met, the milestone payment is deferred and recognized on a straight-line basis over a period determined as discussed above.

Research and development costs that are reimbursable under collaboration agreements are recorded in accordance with ASC 605, Subtopic 45, *Principal Agent Considerations*. Reimbursable amounts received under a cost-sharing arrangement are reflected as a reduction of research and development expense.

Product sales revenue is recognized when goods are shipped, at which point title has passed, net of allowances for returns and discounts. Revenue from a grant is recognized as the Company performs the work and incurs reimbursable costs in accordance with the objectives of the award. Grant payments received prior to the Company's performance of work required by the terms of the award are recorded as deferred revenue and recognized as grant revenue as the Company performs the work and incurs qualifying costs.

Income Taxes

The Company uses the liability method in accounting for income taxes as required by ASC Topic 740, *Income Taxes*, or ASC 740. Under ASC 740, deferred tax assets and liabilities are recorded for operating loss and tax credit carryforwards and for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is recorded to reduce the carrying amounts of deferred tax assets unless it is more likely

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

2. Summary of Significant Accounting Policies (continued)

than not that the assets will be realized. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC 740 requires interim income tax expense or benefit to be calculated using an estimated annual effective tax rate, unless the taxpayer's best estimate of the annual effective tax rate is the actual year-to-date tax rate. The Company's effective income tax rates for each of the three and nine months ended September 30, 2010 was the Company's actual year-to-date effective tax rate. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosures and transition. The Company's policy is to classify any interest recognized in accordance with ASC 740 as interest expense and to classify any penalties recognized in accordance with ASC 740 as an expense other than income tax expense.

Net Income (Loss) Per Share

The Company computes net income (loss) per share in accordance with ASC Topic 260, *Earnings Per Share*, or ASC 260. Under the provisions of ASC 260, basic net income (loss) per share, or Basic EPS, is computed by dividing the net income (loss) by the weighted average number of common shares outstanding. Diluted net income (loss) per share, or Diluted EPS, is computed by dividing the net income (loss) by the weighted average number of common shares and dilutive common share equivalents outstanding. The calculations of Basic EPS and Diluted EPS are set forth in the table below (in thousands, except share and per share amounts):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|------------|------------------------------------|-------------|
| | 2010 | 2009 | 2010 | 2009 |
| Basic: | | | | |
| Net income (loss) | \$ 2,486 | \$ 1,334 | \$ 13,063 | \$ (12,997) |
| Weighted average common shares - basic | 28,622,187 | 25,126,823 | 28,482,224 | 25,019,953 |
| Basic EPS | \$ 0.09 | \$ 0.05 | \$ 0.46 | \$ (0.52) |
| Diluted: | | | | |
| Net income (loss) | \$ 2,486 | \$ 1,334 | \$ 13,063 | \$ (12,997) |
| Weighted average common shares - basic | 28,622,187 | 25,126,823 | 28,482,224 | 25,019,953 |
| Common share equivalents | 1,551,219 | 1,816,712 | 1,626,799 | — |
| Weighted average common shares - diluted | 30,173,406 | 26,943,535 | 30,109,023 | 25,019,953 |
| Diluted EPS | \$ 0.08 | \$ 0.05 | \$ 0.43 | \$ (0.52) |

Common share equivalents consist of the incremental common shares issuable upon the exercise of stock options. For the nine months ended September 30, 2009, the Company excluded all common share equivalents from the calculation of Diluted EPS because their effect is anti-dilutive. As a result, Diluted EPS is identical to Basic EPS for the nine months ended September 30, 2009.

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

2. Summary of Significant Accounting Policies (continued)

For the nine months ended September 30, 2009, shares subject to dilutive outstanding stock options may have been included in the calculation of common share equivalents using the treasury stock method if the Company had been in a net income position. Shares subject to outstanding stock options that were anti-dilutive and consequently not included in the calculation of common share equivalents totaled 923,313 and 17,380 for the three months ended September 30, 2010 and 2009, respectively, and 824,259 and 3,768,462 for the nine months ended September 30, 2010 and 2009, respectively, calculated on a weighted-average basis.

Common Stock and Stock-Based Compensation

The Company issued 35,523 and 409,200 shares of common stock upon the exercise of stock options during the three and nine months ended September 30, 2010, respectively. The Company issued 1,062,456 shares of common stock upon the exercise of stock options during the year ended December 31, 2009.

On January 19, 2010, the Company granted to employees options to purchase 841,072 shares of common stock with an estimated aggregate fair value using the Black-Scholes-Merton formula of \$11,230,000. The Company is recording this amount, as adjusted for forfeitures, as stock-based compensation on a straight line basis over a period of 16 quarters.

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income. Other comprehensive income includes unrealized gains and losses on the Company's available-for-sale securities, which are excluded from net income (loss). The following is a reconciliation of net income (loss) to comprehensive income (loss) for the periods presented.

| | Three Months Ended | | Nine Months Ended | |
|---|---------------------------|----------------|--------------------------|-------------------|
| | September 30, | | September 30, | |
| | 2010 | 2009 | 2010 | 2009 |
| | (in thousands) | | | |
| Net income (loss) | \$2,486 | \$1,334 | \$13,063 | \$(12,997) |
| Unrealized gain on marketable securities, net | 288 | — | 319 | — |
| Comprehensive income (loss) | <u>\$2,774</u> | <u>\$1,334</u> | <u>\$13,382</u> | <u>\$(12,997)</u> |

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

2. Summary of Significant Accounting Policies (continued)***Intellectual Property***

The Company capitalizes the costs of intellectual property acquired or licensed from external sources as intangible assets if, at the time of acquisition, the intellectual property has reached technological feasibility. Intellectual property acquired or licensed from external sources that has not reached technological feasibility at the time of acquisition or that has no expected future use is charged to research and development expense as incurred. The Company records all other charges related to the filing, prosecution and maintenance of patents to research and development expense as incurred.

Recent Accounting Pronouncements

In April 2010, the FASB issued Accounting Standards Update No. 2010-17, *Milestone Method of Revenue Recognition*, or ASU 2010-17. ASU 2010-17 defines a milestone event and permits an entity to make an accounting policy election to recognize a payment that is contingent upon achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. ASU 2010-17 is effective for fiscal years beginning on or after June 15, 2010, and for interim periods within those years, and may be applied prospectively to milestones achieved after the adoption date or retrospectively for all periods presented. Early adoption is permitted. The Company does not expect ASU 2010-17 to have a material impact on its financial results.

3. Investments in Marketable Securities

The following is a reconciliation of amortized cost to fair value of available-for-sale marketable securities held at September 30, 2010:

| <u>September 30, 2010</u> <i>Security type</i> | <u>Amortized Cost</u> | <u>Gross Unrealized Gains</u> | <u>Gross Unrealized Losses</u> | <u>Fair Value</u> |
|--|---------------------------|---------------------------------------|--|------------------------|
| | (in thousands) | | | |
| <u><i>Cash Equivalents</i></u> | | | | |
| U.S. Federal Treasury and U.S. government and state government agency securities | \$ 15,995 | \$ 2 | \$ — | \$15,997 |
| <u><i>Marketable Securities - Short term</i></u> | | | | |
| U.S. Federal Treasury and U.S. government and state government agency securities | 9,697 | 1 | (2) | 9,696 |
| Corporate debt securities | 19,143 | 14 | (6) | 19,151 |
| Certificates of deposit | 13,000 | — | — | 13,000 |
| Accrued interest | 335 | — | — | 335 |
| <u><i>Marketable Securities - Long term</i></u> | | | | |
| U.S. Federal Treasury and U.S. government and state government agency securities | 20,445 | 108 | (3) | 20,550 |
| Corporate debt securities - long term | 19,284 | 205 | — | 19,489 |
| Total available-for-sale marketable securities | <u>\$ 97,899</u> | <u>\$ 330</u> | <u>\$ (11)</u> | <u>\$98,218</u> |

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

3. Investments in Marketable Securities (continued)

As of September 30, 2010, several of the Company's investments in marketable securities were in an unrealized loss position for a duration of less than 12 months.

As of December 31, 2009, the Company's investments in marketable securities consisted of certificates of deposit of \$27,000,000 and accrued interest of \$157,000 for which amortized cost approximated fair value. The Company's investments in marketable securities, including those classified on its balance sheet as cash equivalents, reach maturity between October 21, 2010 and May 20, 2013, with a weighted average maturity date of approximately September 30, 2011.

4. Income Taxes

For the three and nine months ended September 30, 2010, the Company recognized \$257,000 and \$2,395,000, respectively, of income tax expense primarily as a result of the application of ASC 740 to stock-based compensation. Exercises of stock options during the three and nine months ended September 30, 2010 resulted in tax deductions for stock-based compensation in excess of expense recorded for the stock options under GAAP, resulting in income tax benefits of \$160,000 and \$2,278,000, respectively. The Company recognized the income tax benefit related to the excess tax deductions as an increase to capital in excess of par value, which based on ASC 740 resulted in an offsetting charge in the same amount to income tax expense. Exercises of stock options in prior periods resulted in \$5,716,000 in tax deductions in excess of expense recorded for the stock options under GAAP. Because these excess deductions occurred in periods for which there were no income taxes payable, the tax benefit will not be recognized as an increase to capital in excess of par value unless and until the excess deductions are used to reduce income taxes payable.

For the three and nine months ended September 30, 2010, gross unrecognized tax benefits decreased by \$278,000 and \$411,000, respectively, as a result of settlements with taxing authorities. Because the Company has incurred cumulative net operating losses since inception, all tax years remain open to examination by major jurisdictions. An examination of the Company's 2006 federal income tax return was completed in 2009 with no adjustments. An examination of the Company's 2007, 2006 and 2005 North Carolina income tax returns was completed in March 2010 and did not result in any adjustments that had a material impact on the Company's financial statements for any period.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

September 30, 2010

5. Strategic Alliance and Collaboration Agreements

AstraZeneca AB

Cognitive Disorders

In December 2005, the Company entered into a collaborative research and license agreement with AstraZeneca AB under which the Company granted AstraZeneca exclusive development and worldwide commercialization rights to the Company's product candidate known as AZD3480 (TC-1734) as a treatment for specified conditions characterized by cognitive impairment, including attention deficit/hyperactivity disorder, or ADHD. The Company is eligible to receive license fees and milestone payments under the agreement. The amount of license fees and milestone payments depends on the timing and achievement of development, regulatory, first commercial sale and first detail milestone events.

AstraZeneca paid the Company an initial fee of \$10,000,000 in February 2006. Based on the agreement terms, the Company allocated \$5,000,000 of the initial fee to the research collaboration, which the Company recognized as revenue on a straight-line basis over the four-year term of the research collaboration. The Company deferred recognition of the remaining \$5,000,000 of the initial fee, which was allocated to the AZD3480 license grants, until December 2006, when AstraZeneca made a determination to proceed with further development of AZD3480 following the completion of additional clinical and non-clinical studies that AstraZeneca conducted during 2006. On December 27, 2006, AstraZeneca communicated its decision to proceed with further development of AZD3480 to the Company. As a result, in the first quarter of 2007, the Company began recognizing the \$5,000,000 of the initial fee that it had previously deferred as revenue on a straight-line basis over the estimated five-year development period for AZD3480. In July 2009, the Company announced that it had been informed by AstraZeneca of AstraZeneca's plans to conduct further development of AZD3480 for ADHD. The Company extended its estimate of the development period for AZD3480 to continue through 2013 and began recognizing the part of the \$5,000,000 portion of the initial fee not yet recognized as of April 1, 2009 as revenue on a straight-line basis over the remaining estimated development period. The Company recognized \$145,000 and \$457,000 of the initial fee as revenue for three months ended September 30, 2010 and 2009, respectively, and \$538,000 and \$1,477,000 of the initial fee as revenue for the nine months ended September 30, 2010 and 2009, respectively.

Under the agreement, the Company is also eligible to receive (1) additional payments of up to \$103,000,000 if development, regulatory and first commercial sale milestone events for AZD3480 are achieved only for ADHD, (2) other payments if development, regulatory, first commercial sale and first detail milestone events for AZD3480 are achieved for any other target indication under the agreement and (3) if regulatory approval is achieved for AZD3480 for any particular indication, stepped double-digit royalties on any sales of AZD3480 for that indication or any other indication. Under the terms of a sponsored research agreement and a subsequent license agreement between the Company and University of Kentucky Research Foundation, or UKRF, if the Company receives any of these payments from AstraZeneca related to AZD3480, including royalties, the Company is required to pay a low single digit percentage of each such payment to UKRF.

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

5. Strategic Alliance and Collaboration Agreements (continued)

The Company is exploring the practicability of conducting an additional clinical trial of AZD3480 in Alzheimer's disease. In September 2010, the Company and AstraZeneca amended the agreement to enable the Company potentially to conduct such a trial and to provide for respective roles and responsibilities and associated financial terms. Under the amendment, AstraZeneca paid the Company \$500,000 in October 2010.

With respect to AZD1446, the most advanced product candidate that arose out of the parties' preclinical research collaboration described below, the Company is also eligible to receive payments of up to \$73,000,000, if development, regulatory, first commercial sale and first detail milestone events for AZD1446 are achieved for a single indication under the agreement, and, if regulatory approval is achieved for AZD1446 for any particular indication, stepped royalties on any sales of AZD1446 for that indication or any other indication.

The Company would recognize any revenue based on the achievement of any milestone event under the agreement upon achievement of the milestone event if the Company determines that the revenue satisfies the requirements for immediate recognition under its revenue recognition policy (see Note 2). The Company and AstraZeneca also conducted a multi-year preclinical research collaboration under the agreement. The term of the research collaboration expired in January 2010. While the research collaboration was ongoing, the Company was eligible to receive payments from AstraZeneca for research services performed. The Company recognized collaboration research and development revenue as the research was performed and related expenses were incurred. As a result of the expiration of the research collaboration in January 2010, the Company did not recognize any collaboration research and development revenue for the three or nine months ended September 30, 2010. The Company recognized collaboration research and development revenue of \$1,059,000 and \$3,724,000 for the three and nine months ended September 30, 2009, respectively.

In October 2007, the Company provided notice under the agreement offering AstraZeneca the right to license its product candidate TC-5619 for specified conditions characterized by cognitive impairment. Based on a subsequent election by AstraZeneca made under the terms of the agreement, AstraZeneca paid the Company \$2,000,000 and the Company agreed to develop TC-5619 independently through completion of Phase 1 clinical development and a Phase 2 clinical proof of concept clinical trial in accordance with a mutually acceptable development plan, following which AstraZeneca would have the right to license TC-5619 on terms specified in the agreement. The Company is recognizing the \$2,000,000 payment as revenue on a straight-line basis over the estimated period of the Company's research and development obligations for TC-5619. Accordingly, the Company recognized \$43,000 and \$122,000 of the payment as revenue for the three months ended September 30, 2010 and 2009, respectively, and \$235,000 and \$474,000 of the payment as revenue for the nine months ended September 30, 2010 and 2009, respectively.

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

5. Strategic Alliance and Collaboration Agreements (continued)

In April 2010, the Company and AstraZeneca amended the agreement to modify the terms applicable to TC-5619. In conjunction with the amendment, the Company and AstraZeneca agreed to an expanded development program for TC-5619 and the Company received a payment of \$11,000,000 to maintain AstraZeneca's future option to license TC-5619. The Company recorded the \$11,000,000 payment as deferred revenue and is recognizing it as revenue on a straight-line basis over the estimated period of the Company's research and development obligations for TC-5619. The Company recognized \$2,357,000 and \$3,929,000 of the payment as revenue for the three and nine months ended September 30, 2010, respectively.

As part of the expanded TC-5619 development program, the Company has two Phase 2 clinical proof of concept trials ongoing, one in cognitive dysfunction in schizophrenia, or CDS, and one in ADHD. The Company also agreed to conduct specified clinical and non-clinical studies, and AstraZeneca 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. 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 Phase 2 clinical development for Alzheimer's disease would be funded by AstraZeneca.

Under 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. The amended terms also allow AstraZeneca to 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 AstraZeneca exercises its option, it would pay the Company an exercise fee of \$30,000,000 and assume responsibility for and fund all future development and commercialization for TC-5619 beyond the currently agreed upon development program. In that event, the Company would be eligible to receive additional payments of up to \$212,000,000, if development, regulatory, first commercial sale and first detail milestone events for TC-5619 are achieved in three indications, and stepped double-digit royalties on any future TC-5619 product sales for any indication. If AstraZeneca does not exercise its option the first time that TC-5619 achieves clinical proof of concept, whether in CDS, ADHD or Alzheimer's disease, or if TC-5619 achieves clinical proof of concept in neither CDS nor ADHD and AstraZeneca disclaims any further interest, the Company would retain all of its rights in TC-5619.

The Company has also received payments under the agreement that it recognized in full as revenue upon achievement of the corresponding milestone event because the event met each of the conditions required for immediate recognition under its revenue recognition policy (see Note 2). In particular, the Company received a \$10,000,000 payment from AstraZeneca in July 2009 based on achievement of the objective in a completed Phase 2 clinical trial of AZD3480 in adults with ADHD, a milestone event under an amendment to the agreement. The Company made a payment of \$350,000 to UKRF in December 2009 as a result of the \$10,000,000 payment received from AstraZeneca. The Company has also received cumulative payments from AstraZeneca of \$2,400,000 based on the achievement of milestone events related to the development of product candidates arising under the parties' completed preclinical research collaboration, including AZD1446.

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

5. Strategic Alliance and Collaboration Agreements (continued)

TC-5214

In December 2009, the Company entered into a collaboration and license agreement with AstraZeneca AB for the global development and commercialization of TC-5214. Under the agreement, AstraZeneca made an upfront payment to the Company of \$200,000,000 and the Company is eligible to receive cumulative payments of up to an additional \$540,000,000 if specified development, regulatory and first commercial sale milestone events for TC-5214 are achieved, cumulative payments of up to an additional \$500,000,000 if specified sales related milestone events for TC-5214 are achieved and significant stepped double-digit royalties on net sales of TC-5214 worldwide. The Company recorded the upfront payment made by AstraZeneca as deferred revenue and is recognizing the payment as revenue on a straight-line basis over the estimated period of the Company's substantive performance obligations under the agreement, or approximately 33 months. The Company recognized \$18,290,000 and \$54,274,000 of the upfront payment as revenue for the three and nine months ended September 30, 2010, respectively. The Company would recognize as revenue the full amount of each payment received based on the achievement of milestone events under the agreement upon its achievement if the Company determines that the revenue satisfies the requirements for immediate recognition under its revenue recognition policy (see Note 2).

The Company and AstraZeneca have jointly designed a program for the global development of TC-5214. The initial program is planned to include development of TC-5214 as an adjunct therapy and as a second-line "switch" monotherapy, in each case in patients with major depressive disorder who do not respond adequately to first-line antidepressant treatment. AstraZeneca is responsible for 80% and the Company is responsible for 20% of the costs of the initial program, except that AstraZeneca is responsible for 100% of development costs that are required only to obtain or maintain regulatory approval in countries outside the United States and the European Union. The Company has the right to terminate its obligation to fund its share of the costs of the initial program once it has funded a specified amount. In addition, for each of the Company and AstraZeneca, costs that were not contemplated at execution to be part of the initial program may in some cases be excluded from the cost-sharing arrangement. If the Company funds the specified amount and terminates its obligation to fund its share of further costs of the initial program, any future milestones and royalties payable to the Company under this agreement would be reduced by the amount of the Company's unfunded share plus interest at a specified rate, subject to a maximum reduction that may be applied to any one payment. In addition, if the Company and AstraZeneca mutually agree to develop TC-5214 for any indication other than major depressive disorder or in any formulation other than those contemplated by the initial program, the same cost-sharing arrangement would apply, except that the Company would have the immediate right to terminate its obligation to fund its share of development costs for the other indication or formulation. If the Company terminates its obligation to fund its share of these other development costs, any future milestones and royalties payable to the Company under this agreement would be reduced by the amount of the Company's unfunded share plus interest at a specified rate, subject to a maximum reduction that may be applied to any one payment, but only from and after the occurrence of a specified event to be agreed upon by the parties.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

September 30, 2010

5. Strategic Alliance and Collaboration Agreements (continued)

The Company's portion of the costs of the initial program for the three and nine months ended September 30, 2010 was \$2,888,000 and \$4,915,000, respectively. AstraZeneca's allocable portion of the initial program costs paid by the Company for the three and nine months ended September 30, 2010 was \$929,000 and \$1,812,000, respectively, which is reflected in the Company's financial statements as a reduction to research and development expense.

AstraZeneca is responsible under the agreement for executing and funding the costs of global commercialization of TC-5214. The Company has retained an option to co-promote TC-5214 to a specified target physician audience in the United States. If the Company exercises its co-promotion option, AstraZeneca would compensate the Company on a per detail basis. AstraZeneca is also responsible under the agreement for the manufacture and supply of TC-5214.

Under the terms of an existing license agreement, the Company paid \$16,000,000 to University of South Florida Research Foundation, or USFRF, in February 2010 based on the Company's receipt of the upfront payment from AstraZeneca and would be required to pay to USFRF a percentage of each milestone payment that may be received from AstraZeneca, after deducting from the milestone payment the remaining portion of the Company's projected share of the costs of the initial development program for TC-5214, as well as royalties on any future product sales. The percentage of each milestone payment, net of any deduction, that the Company would be required to pay would be at least 10% and could be greater in specified circumstances. Based on the terms of the license agreement with USFRF and the terms of another existing license agreement with Yale University, the Company expects to pay royalties at an effective worldwide rate in the low single digits and that the effective royalty rate could in some circumstances reach the mid single digits.

GlaxoSmithKline

On July 27, 2007, the Company entered into a product development and commercialization agreement with SmithKline Beecham Corporation, doing business as GlaxoSmithKline, and Glaxo Group Limited, which are referred to together as GlaxoSmithKline, that sets forth the terms of an alliance designed to discover, develop and market product candidates that selectively target specified NNR subtypes in five therapeutic focus areas: pain, smoking cessation, addiction, obesity and Parkinson's disease. In February 2010, GlaxoSmithKline announced plans to cease discovery research in selected neuroscience areas, specifically including pain. Discussions between the Company and GlaxoSmithKline regarding the effects of its strategic change on the alliance remain ongoing. Until these discussions are completed, the overall impact is uncertain, but the Company anticipates that at least several of the therapeutic focus areas in the alliance will be discontinued. Because the overall impact has not yet been determined, the remainder of this discussion describes the current terms of the alliance.

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

5. Strategic Alliance and Collaboration Agreements (continued)

With respect to each therapeutic focus area in the alliance, if the Company achieves clinical proof of concept with respect to a lead product candidate, GlaxoSmithKline would have an exclusive option for an exclusive license to that lead product candidate and up to two other product candidates in development in the alliance for the same therapeutic focus area on a worldwide basis. If GlaxoSmithKline exercises its option and pays the applicable exercise fee, GlaxoSmithKline would become responsible for using diligent efforts to conduct later-stage development and commercialization of the lead product candidate at its sole expense. GlaxoSmithKline's exclusive license would include all fields of use other than those indications for which the Company has granted development and commercialization rights for product candidates under its collaboration agreement with AstraZeneca focused in cognitive disorders.

Under the agreement and a related stock purchase agreement, GlaxoSmithKline made an initial payment to the Company of \$20,000,000 and purchased 1,275,502 shares of the Company's common stock for an aggregate purchase price of \$15,000,000 on July 27, 2007. The purchase price paid by GlaxoSmithKline reflected an aggregate deemed premium of \$3,521,000, based on the closing price of the Company's common stock on the trading day immediately preceding the date that agreements were signed and announced. The Company deferred recognition of both the initial payment made by GlaxoSmithKline and the deemed premium paid for the shares of the Company's common stock purchased by GlaxoSmithKline and is recognizing both amounts into revenue on a straight-line basis over the estimated nine-year period of the Company's research and early development obligations under the agreement. The Company recognized \$653,000 of the initial payment and deemed premium as revenue for each of the three-month periods ended September 30, 2010 and 2009 and \$1,960,000 of the initial payment and deemed premium as revenue for each of the nine-month periods ended September 30, 2010 and 2009.

The terms of the alliance provide for the Company to conduct its research and development activities under the agreement at its sole expense. The Company is, however, eligible to receive additional payments from GlaxoSmithKline, contingent upon the achievement of specified discovery, development, regulatory and commercial milestones as well as stepped double-digit royalties dependent on any future sales for any product licensed by GlaxoSmithKline. The Company would recognize any revenue based on the achievement of milestones under the agreement upon achievement of the milestone event if the Company determines that the revenue satisfies the requirements for immediate recognition under its revenue recognition policy (see Note 2). The amounts that the Company may receive depend on the success of the Company's research and development activities, the timing and achievement of the discovery, development, regulatory and commercial milestone events, the extent to which the specified therapeutic focus areas remain subject to the alliance and whether GlaxoSmithKline exercises any options that are triggered under the agreement.

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2010

5. Strategic Alliance and Collaboration Agreements (continued)

In December 2007, the Company received a \$6,000,000 payment from GlaxoSmithKline upon the achievement of a specified milestone event under the agreement. The Company determined the payment did not meet each of the conditions of its revenue recognition policy (see Note 2) required for recognition of the full amount into revenue upon achievement of the milestone. Specifically, based on the progress of this product candidate as of inception of the agreement, achievement of this milestone was reasonably assured within the meaning of the Company's revenue recognition policy. Accordingly, the Company recorded the payment as deferred revenue and is recognizing it into revenue on a straight-line basis over the estimated period of the Company's research and early development obligations under the agreement. The Company recognized \$173,000 of the payment as revenue for each of the three-month periods ended September 30, 2010 and 2009 and \$519,000 of the payment as revenue for each of the nine-month periods ended September 30, 2010 and 2009.

Beyond the \$6,000,000 payment discussed above, the Company has received an aggregate of \$4,000,000 in payments from GlaxoSmithKline for achievement of various milestone events under the agreement related to progress in the Company's preclinical programs, including \$2,500,000 for the nine months ended September 30, 2009. The Company immediately recognized the full amount of each payment as revenue upon achievement of the corresponding milestone event because each event met each of the conditions required for immediate recognition under its revenue recognition policy (see Note 2).

6. Subsequent Events

In November 2010, the Internal Revenue Service notified the Company that it had approved cumulative grants of \$1,467,000 to the Company under the Qualifying Therapeutic Discovery Project tax credit program enacted as part of the Patient Protection and Affordable Care Act of 2010. Approximately \$1,431,000 of the grants reflects qualifying investments made by the Company during 2009 and are to be paid to the Company in November 2010. The remaining \$36,000 of the grants reflects qualifying investments made by the Company during 2010 and is to be paid to the Company in 2011.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes included in this quarterly report and our audited financial statements and Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2009, which is on file with the SEC. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results, performance or experience could differ materially from what is indicated by any forward-looking statement due to various important factors, risks and uncertainties, including, but not limited to, those set forth under “Cautionary Note Regarding Forward-Looking Statements” in Part I of this quarterly report and under “Risk Factors” in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2009 and other filings that we make with the SEC.

Overview

Background

We are a biopharmaceutical company engaged in the design, discovery and development of novel NNR Therapeutics for the treatment of diseases and disorders of the nervous system. Our NNR Therapeutics selectively target a class of receptors known as neuronal nicotinic receptors, which we refer to as NNRs. NNRs are found on nerve cells throughout the nervous system and serve as key regulators of nervous system activity.

We have multiple clinical-stage product candidates and preclinical programs in areas where we believe there are significant medical need and commercial potential, as well as proprietary drug discovery technologies. We have two collaboration agreements with AstraZeneca, one that we entered into in December 2009 for the global development and commercialization of TC-5214 as a treatment for major depressive disorder, or MDD, and refer to in this quarterly report as our “TC-5214 agreement with AstraZeneca” and the other focused in cognitive disorders that we entered into in December 2005 and refer to in this quarterly report as our “cognitive disorders agreement with AstraZeneca.” We also have an alliance agreement with GlaxoSmithKline. Our most advanced product candidates are described below:

- *TC-5214.* TC-5214 is a nicotinic channel blocker that is thought to derive antidepressant activity by modulating the activity of various NNR subtypes. We are co-developing TC-5214 with AstraZeneca under our TC-5214 agreement with AstraZeneca as an adjunct (or add-on) therapy for patients with MDD who do not respond adequately to first-line antidepressant treatment. Phase 3 clinical trials of TC-5214 are ongoing. In addition, we expect a Phase 2 clinical trial of TC-5214 as a second-line “switch” monotherapy to initiate in the first quarter of 2011.
- *TC-5619.* TC-5619 is a novel small molecule that modulates the activity of the $\alpha 7$ NNR. We have two Phase 2 clinical trials of TC-5619 ongoing, one in cognitive dysfunction in schizophrenia, or CDS, and one in adults with attention deficit/hyperactivity disorder, or ADHD. We are also conducting clinical and non-clinical studies to support the potential

advancement of TC-5619 into Phase 2 clinical development in Alzheimer's disease. A decision as to whether to conduct Phase 2 clinical development of TC-5619 as a treatment for Alzheimer's disease would be made in the future. AstraZeneca has an option for an exclusive license to TC-5619 for various cognitive disorders that is exercisable the first time that TC-5619 achieves Phase 2 clinical proof of concept, whether in CDS, ADHD or Alzheimer's disease. AstraZeneca also can exercise its license option upon completion of specified clinical and non-clinical studies related to Alzheimer's disease if TC-5619 does not achieve clinical proof of concept in CDS or ADHD.

- *AZD3480 (TC-1734)*. AZD3480 is a novel small molecule that modulates the activity of the $\alpha 4\beta 2$ NNR and is subject to our cognitive disorders agreement with AstraZeneca. We or AstraZeneca have conducted several clinical studies of AZD3480 in various cognitive disorders and we are in discussions with AstraZeneca regarding potential additional development as a treatment for ADHD. Whether AstraZeneca will decide to conduct any additional development of AZD3480 in ADHD is uncertain in light of reservations about the adequacy of the therapeutic margin to support development across the broad ADHD patient population. We expect AstraZeneca to make its decision by the end of 2010.
- *AZD1446 (TC-6683)*. AZD1446 is a novel small molecule that modulates the activity of the $\alpha 4\beta 2$ NNR and is under consideration for further development as a treatment for Alzheimer's disease under our cognitive disorders agreement with AstraZeneca. We discovered AZD1446 as part of a multi-year preclinical research collaboration conducted under the agreement. AstraZeneca has completed three of four Phase 1/2a clinical studies expected to inform its decision whether to advance AZD1446, and we expect AstraZeneca's decision in the coming months.
- *TC-6987*. TC-6987 is a novel small molecule that modulates the activity of the $\alpha 7$ NNR and is in development as a treatment for inflammatory disorders. We have completed a Phase 1 single rising dose clinical trial and a Phase 1 multiple rising dose clinical trial of TC-6987. We plan to conduct multiple Phase 2 learning trials to identify the optimal indication for TC-6987, with the first such study to be in asthma and expected to initiate in 2010.
- *TC-6499*. TC-6499 is a product candidate that we previously evaluated and are no longer developing as a pain treatment. Based on the activity of TC-6499 at certain NNR subtypes located in the gastrointestinal tract, we believe it may have potential as a treatment for certain gastrointestinal disorders. We are conducting an ongoing exploratory Phase 2a study of TC-6499 as a treatment for constipation-predominant irritable bowel syndrome.

Under our TC-5214 agreement with AstraZeneca, we and AstraZeneca have jointly designed an initial development program that is planned to include development of TC-5214 as an adjunct therapy and as a second-line "switch" monotherapy, in each case in patients with MDD who do not respond adequately to first-line antidepressant treatment. AstraZeneca is responsible for 80% and we are responsible for 20% of the costs of the initial program, except that AstraZeneca is responsible for 100% of development costs that are required only to obtain or maintain regulatory approval in countries outside the United States and the European Union. We have the right to terminate our obligation to fund our share of the costs of the initial program once we have funded a specified amount. In addition, for each of us and AstraZeneca, costs that were not contemplated at execution to be part of the initial program may in some cases be excluded from the cost-sharing arrangement.

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If we fund the specified amount and terminate our obligation to fund our share of further costs of the initial program, any future milestones and royalties payable to us under the agreement would be reduced by the amount of our unfunded share plus interest at a specified rate, subject to a maximum reduction that may be applied to any one payment. AstraZeneca is responsible for executing and funding the costs of global commercialization of TC-5214.

Under our cognitive disorders agreement with AstraZeneca:

- we are responsible for conducting and funding the ongoing Phase 2 clinical trials of TC-5619 in CDS and in adults with ADHD, as well as specified clinical and non-clinical studies to support the potential advancement of TC-5619 into Phase 2 clinical development for Alzheimer's disease; AstraZeneca is responsible for conducting and funding other specified non-clinical studies to support the potential advancement of TC-5619 into Phase 2 clinical development for Alzheimer's disease;
- except as discussed in the next bullet, AstraZeneca is responsible for substantially all current and future development costs for AZD3480, AZD1446 and each other compound arising from the preclinical research collaboration described below that it elects to advance;
- we are exploring the practicability of conducting an additional clinical trial of AZD3480 in Alzheimer's disease and have agreed with AstraZeneca on respective roles and responsibilities for such a study; if an Alzheimer's disease study proceeds, we would be responsible for funding the study but would be entitled to receive approximately \$6.2 million from AstraZeneca, in tranches culminating with dosing; and
- from January 2006 to January 2010, we and AstraZeneca conducted a preclinical research collaboration under the agreement to discover and develop compounds that act on the a4 β 2 NNR as treatments for conditions characterized by cognitive impairment; AstraZeneca paid us research fees, based on a reimbursement rate specified under the agreement, for research services rendered in the preclinical research collaboration.

In addition to our two collaboration agreements with AstraZeneca, we have an alliance agreement with GlaxoSmithKline that is designed to discover, develop and market product candidates that selectively target specified NNR subtypes in specified therapeutic focus areas. In February 2010, GlaxoSmithKline announced plans to cease discovery research in selected neuroscience areas. Although the overall impact of GlaxoSmithKline's strategic change on our alliance has not yet been finally determined, we anticipate that at least several therapeutic focus areas in the alliance will be discontinued.

We trace our scientific lineage to a research program initiated by R.J. Reynolds Tobacco Company in 1982 to study the activity and effects of nicotine in the body. We were incorporated in 1997 as a wholly owned subsidiary of RJR. In August 2000, we became an independent company when we issued and sold stock to venture capital investors. Since our inception, we have had limited revenue from product sales and have funded our operations principally through the sale of equity securities, revenue from collaboration agreements, grants and equipment and building lease incentive financing. We have devoted substantially all of our resources to the discovery and development of our product candidates and technologies, including the design, conduct and management of preclinical and clinical studies and related manufacturing, regulatory and clinical affairs, as well as intellectual property prosecution.

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We generated net income for the three and nine months ended September 30, 2010 due primarily to recognition into revenue of a portion of the upfront payment received under our TC-5214 agreement with AstraZeneca. We have also generated net income for two other quarterly periods since our inception, in each case due primarily to the achievement in each period of a single milestone event related to AZD3480 under our cognitive disorders agreement with AstraZeneca. Except for these periods, we have not been profitable and we may incur losses in future periods as our clinical-stage and preclinical product candidates advance into later-stage development and as we progress our programs, invest in additional product opportunities and expand our research and development infrastructure. As of September 30, 2010, we had an accumulated deficit of \$216.2 million. Clinical trials and preclinical studies are time-consuming, expensive and may never yield a product that will generate revenue.

As a clinical-stage company, our revenues, expenses and results of operations are likely to fluctuate significantly from quarter to quarter and year to year. We believe that period-to-period comparisons of our results of operations should not be relied upon as indicative of our future performance.

Revenue

In January 2010, we received a \$200.0 million upfront payment under our TC-5214 agreement with AstraZeneca, which we recorded as deferred revenue and are recognizing into revenue on a straight-line basis over the estimated development period for TC-5214 to submission of a new drug application to the U.S. Food and Drug Administration, or FDA. We are eligible under our TC-5214 agreement with AstraZeneca to receive additional payments of over \$1.0 billion if development, regulatory, first commercial sale and specified sales related milestone events for TC-5214 are achieved and stepped double-digit royalties on any future TC-5214 product sales. As of September 30, 2010, we had \$145.3 million of the deferred portion of the upfront payment remaining to be recognized into revenue. Pursuant to the April 2010 amendment to our cognitive disorders agreement with AstraZeneca, we received an \$11.0 million payment in May 2010, which we recorded as deferred revenue and are recognizing into revenue on a straight-line basis over the estimated period of our research and development obligations related to TC-5619.

As of September 30, 2010 we had received \$55.4 million in aggregate upfront fees and milestone payments under our cognitive disorders agreement with AstraZeneca and recognized an additional \$26.5 million in collaboration research and development revenue for research services that we provided under the agreement. As of September 30, 2010, we had also received \$45.0 million in aggregate payments under our alliance agreement with GlaxoSmithKline. We initially deferred recognition of an aggregate of \$52.5 million received under our cognitive disorders agreement with AstraZeneca and from GlaxoSmithKline and are recognizing these deferred amounts into revenue over the periods discussed in Note 5 to our unaudited financial statements included in this quarterly report. As of September 30, 2010, we had \$28.8 million of the deferred amounts remaining to be recognized in future periods. In October 2010, we received an additional \$500,000 from AstraZeneca in connection with an amendment to our cognitive disorders agreement with AstraZeneca.

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We acquired rights to Inversine, which is our only product approved for marketing by the FDA, in August 2002. Effective September 30, 2009, we discontinued Inversine. Sales of Inversine generated net revenue of \$118,000 and \$473,000 for the three and nine months ended September 30, 2009, respectively.

From time to time we seek and are awarded grants or work to be performed under grants awarded to third-party collaborators from which we derive revenue. As of September 30, 2010, we have been awarded two grants from The Michael J. Fox Foundation for Parkinson's Research, or MJFF. One of the grants is to fund preclinical research involving the use of compounds that modulate NNRs to address Levodopa-induced abnormal involuntary movements, known as dyskinesias, and we have received aggregate payments of \$641,000 from MJFF since August 2009 in connection with this grant. The other grant is to fund research to identify NNR-related biomarkers relevant to Parkinson's disease, and we expect to receive an aggregate of \$304,000 from MJFF over a one-year period that began in December 2009 in connection with this grant. In addition, as of September 30, 2010, we are a named subcontractor under a grant awarded to The California Institute of Technology by the National Institute on Drug Abuse, or NIDA, part of the National Institutes of Health, to fund research on innovative NNR-based approaches to the development of therapies for smoking cessation. We have received approximately \$1.1 million in the aggregate over a five-year research term that began in July 2006 in connection with the NIDA grant. Funding for awards under federal grant programs is subject to the availability of funds as determined annually in the federal appropriations process.

Research and Development Expenses

Since our inception, we have focused our activities on our drug discovery and development programs. We record research and development expenses as they are incurred. Research and development expenses represented approximately 89% and 81% of our total operating expenses for the three months ended September 30, 2010 and 2009, respectively, and 88% and 84% of our total operating expenses for the nine months ended September 30, 2010 and 2009, respectively.

We utilize our research and development personnel and infrastructure resources across several programs. We currently have clinical, preclinical and early research programs, and many of our costs are not specifically attributable to a single program. Instead, these costs are directed to broadly applicable research efforts. Accordingly, we cannot state precisely our total costs incurred on a program-by-program basis.

We have not received FDA or foreign regulatory marketing approval for any of our product candidates that are in development. Our current and future expenditures on preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. In particular, our strategy includes entering into alliances and collaborations with third parties to participate in the development and commercialization of some of our product candidates. Where a third party has responsibility for or authority over any or all of the preclinical or clinical development of a particular product candidate, the estimated completion date may be largely under the control of that third party and not under our control. We cannot forecast with certainty whether AstraZeneca will exercise any options to license particular product candidates that become exercisable under the terms of our cognitive disorders agreement with AstraZeneca, whether GlaxoSmithKline will exercise any options to license particular product candidates that become exercisable under the terms of our alliance agreement with GlaxoSmithKline, whether any of our product candidates will be subject to future alliances or collaborations or how any such arrangement would affect our

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development plans or capital requirements. Because of this uncertainty, and because of the numerous uncertainties related to clinical trials and drug development generally, we are unable to determine the duration and completion costs of our research and development programs or whether or when we will generate revenue from the commercialization and sale of any of our product candidates in development.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and other related costs for personnel in executive, finance, business development, legal and human resource functions. Other general and administrative expenses include expenses associated with stock options granted to personnel in those functions, depreciation and other facility costs not otherwise included in research and development expenses, patent-related costs, insurance costs and professional fees for consulting, legal, accounting and public and investor relations services.

Income Taxes

We have incurred net operating losses through December 31, 2009 and have not paid federal, state or foreign income taxes for any period through December 31, 2009. We expect that we may incur taxable income, before giving effect to net operating loss carryforwards, for the year ending December 31, 2010. For the three and nine months ended September 30, 2010, we recognized \$257,000 and \$2.4 million, respectively, of income tax expense primarily as a result of the application of Accounting Standards Codification Topic 740, *Income Taxes*, or ASC 740, to stock-based compensation. Exercises of stock options during the three and nine months ended September 30, 2010 resulted in tax deductions for stock-based compensation in excess of expense recorded for the stock options under U.S. generally accepted accounting principles, or GAAP, resulting in income tax benefits of \$160,000 and \$2.3 million, respectively. We recognized the income tax benefit related to the excess tax deductions as an increase to capital in excess of par value, which based on ASC 740 resulted in an offsetting charge in the same amount to income tax expense. As of September 30, 2010, we had net operating loss carryforwards of \$66.0 million for federal income tax purposes and \$76.8 million for state income tax purposes. We also had research and development income tax credit carryforwards of \$7.4 million for federal income tax purposes and \$595,000 for state income tax purposes as of September 30, 2010. The federal net operating loss carryforwards begin to expire in 2020. The state net operating loss carryforwards begin to expire in 2015. The federal and state research and development tax credits begin to expire in 2021. As a result of various factors, including the subjectivity of measurements used in the calculation of particular tax positions taken or that may in the future be taken in our tax returns, it is uncertain whether or to what extent we will be eligible to use the tax credits.

Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. When an ownership change, as defined by Section 382, occurs, an annual limitation is imposed on a company's use of net operating loss and credit carryforwards attributable to periods before the change. As a result of a series of stock issuances, we had such an ownership change in November 2002. Consequently, an annual limitation is imposed on our use of net operating loss and credit carryforwards that are attributable to periods before November 2002. In addition, a portion of the net operating loss carryforwards described above may potentially not be usable by us if we experience further ownership changes in the future. For financial reporting purposes, we have recorded a valuation allowance to fully offset the deferred tax asset related to these carryforwards and the tax credits because the likelihood that we will be eligible to use or realize any benefit from them is uncertain.

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Fair Value

The carrying amounts of our cash and cash equivalents, investments in marketable securities, accounts receivable, accounts payable and accrued expenses are considered to be representative of their respective fair values due to their short-term nature and, in the case of short-term investments, their market interest rates. Likewise, the carrying amounts of our long-term debts are considered to be representative of their fair value due to their market interest rates. Cash that we do not expect to need to fund our short-term liquidity requirements is invested in U.S. Treasury notes and bonds, U.S. federal and state agency-backed certificates and corporate debt securities that are rated at least A quality or equivalent. Our investments in marketable securities of \$98.2 million at September 30, 2010, which include marketable securities classified on our balance sheet as cash equivalents, are recorded at fair value using quoted market prices.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our unaudited financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenues and expenses that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates. In addition, our reported financial condition and results of operations could vary if new accounting standards are enacted that are applicable to our business.

Our significant accounting policies are described in Note 2 to our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2009 and in the notes to our financial statements included in this quarterly report. We believe that our accounting policies relating to revenue recognition, accrued expenses and stock-based compensation are the most critical to understanding and evaluating our reported financial results. We have identified these policies as critical because they are important to the presentation of our financial condition and results of operations and require us to make judgments and estimates on matters that are inherently uncertain and may change in future periods. These policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates" in our Annual Report on Form 10-K for the year ended December 31, 2009.

[Table of Contents](#)**Results of Operations***Three Months ended September 30, 2010 and 2009***Net Operating Revenues**

| | Three Months ended September 30, | | Change |
|---|-------------------------------------|------------------------|-----------------|
| | 2010 | 2009 (in thousands) | |
| Operating revenues: | | | |
| Milestones and license fees from collaborations | \$21,662 | \$11,405 | \$10,257 |
| Collaboration research and development | — | 1,059 | (1,059) |
| Product sales, net | — | 118 | (118) |
| Grant revenue | 136 | 81 | 55 |
| Net operating revenues | <u>\$21,798</u> | <u>\$12,663</u> | <u>\$ 9,135</u> |

Net operating revenues for the three months ended September 30, 2010 increased by \$9.1 million as compared to the three months ended September 30, 2009. The higher net operating revenues were primarily attributable to an increase of \$10.3 million in milestones and license fees from collaborations revenue, partially offset by a decrease of \$1.1 million in collaboration research and development revenue. The increase in milestones and license fees from collaborations revenue reflected recognition of \$18.3 million of the \$200.0 million upfront payment received under our TC-5214 agreement with AstraZeneca, which we entered into in December 2009, and \$2.4 million of the \$11.0 million payment received under an April 2010 amendment to our cognitive disorders agreement with AstraZeneca to modify the terms applicable to TC-5619, partially offset by achievement of a milestone event under our cognitive disorders agreement with AstraZeneca during the three months ended September 30, 2009 for which we received \$10.0 million and a decrease for the 2010 period of \$313,000 of license fees derived from the cognitive disorders agreement as a result of the expiration of the term of the preclinical research collaboration in January 2010. The decrease in collaboration research and development revenue for the 2010 period resulted from the completion of the preclinical research collaboration under our cognitive disorders agreement with AstraZeneca. We plan to recognize the remaining \$145.3 million of the upfront payment received under the TC-5214 agreement with AstraZeneca on a straight-line basis over the estimated development period for TC-5214 to submission of a new drug application to the FDA and, as a result, expect to have higher net operating revenues for the year ending December 31, 2010 as compared to the year ended December 31, 2009. As of September 30, 2010, we forecast the new drug application submission date for TC-5214 to be approximately September 30, 2012. We do not expect to record any collaboration research and development revenue from the cognitive disorders agreement for the year ending December 31, 2010 or any future period.

Research and Development Expenses

| | Three Months ended September 30, | | Change |
|-----------------------------------|---|-------------|---------------|
| | 2010 | 2009 | |
| | (in thousands) | | |
| Research and development expenses | \$17,329 | \$9,275 | \$8,054 |

Research and development expenses for the three months ended September 30, 2010 increased by \$8.1 million as compared to the three months ended September 30, 2009. The higher research and development expenses were principally attributable to:

- an increase of \$5.2 million in costs incurred for third-party research and development services in connection with our clinical-stage product candidates (including costs for clinical trial activities, formulation activities, production of clinical trial materials, and pharmacology, toxicology and other non-clinical studies) to \$7.0 million for the 2010 period from \$1.8 million for the 2009 period; this increase was principally due to the conduct of Phase 2 clinical development of TC-5619 for two indications, the conduct of later-stage Phase 1 clinical development of TC-6987 and our cost-sharing obligations with respect to ongoing Phase 3 clinical trials of TC-5214;
- a \$1.5 million upfront payment that we made to Cornerstone Therapeutics Inc. upon entering into an exclusive worldwide license agreement in August 2010;
- an increase of \$814,000 in stock-based compensation, salary and other compensation-related expenses for research and development personnel to \$4.4 million for the 2010 period from \$3.6 million for the 2009 period; the largest component of this increase was stock-based compensation expense and was primarily due to a significantly higher fair value calculated for stock options granted during 2010 as compared to the fair value calculated for stock options granted during and prior to 2009; and
- an increase of \$633,000 in other research and development expenses, including infrastructure costs, to \$3.1 million for the 2010 period from \$2.5 million for the 2009 period; this increase was primarily due to increases in the number of employees and depreciable equipment utilized in our research and development functions.

These increases were partially offset by a decrease of \$141,000 in costs incurred for third-party research and development services in connection with our preclinical programs to \$1.3 million for the 2010 period from \$1.4 million for the 2009 period. The reduced spending for the 2010 period in connection with our preclinical programs primarily resulted from the uncertainty surrounding the continuation of some of the therapeutic focus areas of our alliance with GlaxoSmithKline.

The costs that we incurred for the three months ended September 30, 2010 and 2009 for third-party services in connection with research and development of clinical-stage product candidates are shown in the table below:

| | Three Months ended September 30, | | Change |
|---------|---|-------------|---------------|
| | 2010 | 2009 | |
| | (in thousands) | | |
| TC-5214 | \$ 2,888 | \$ 832 | \$2,056 |
| TC-5619 | 2,620 | 464 | 2,156 |
| TC-6987 | 1,196 | 506 | 690 |
| TC-6499 | 294 | — | 294 |

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We expect our research and development expenses to increase for the year ending December 31, 2010 as compared to the year ended December 31, 2009, principally due to our cost-sharing obligations for the ongoing Phase 3 development program for TC-5214 and development activities for TC-5619 and TC-6987.

General and Administrative Expenses

| | Three Months ended September 30, | | Change |
|-------------------------------------|-------------------------------------|------------------------|--------|
| | 2010 | 2009 (in thousands) | |
| General and administrative expenses | \$ 2,052 | \$ 1,628 | \$ 424 |

General and administrative expenses for the three months ended September 30, 2010 increased by \$424,000 as compared to the three months ended September 30, 2009. The higher general and administrative expenses were primarily attributable to an increase of \$407,000 in stock-based compensation, salary and other compensation-related expenses for general and administrative personnel to \$1.2 million for the 2010 period from \$776,000 for the 2009 period. The largest component of the increase was stock-based compensation expense and was primarily due to a significantly higher fair value calculated for stock options granted during 2010 as compared to the fair value calculated for stock options granted during and prior to the 2009 period.

Other Income and Expense

| | Three Months ended September 30, | | Change |
|------------------|-------------------------------------|------------------------|--------|
| | 2010 | 2009 (in thousands) | |
| Interest income | \$ 360 | \$ 173 | \$ 187 |
| Interest expense | 34 | 53 | (19) |

Interest income for the three months ended September 30, 2010 increased by \$187,000 as compared to the three months ended September 30, 2009. The increase reflected a significantly increased cash balance and changes in our investment portfolio to include U.S. Treasury notes and bonds, U.S. federal and state agency-backed certificates and corporate debt securities, partially offset by lower interest rates. Interest expense for the three months ended September 30, 2010 decreased by \$19,000 as compared to the three months ended September 30, 2009.

Income Tax Expense

| | Three Months ended September 30, | | Change |
|------------------------------|---|-------------|---------------|
| | 2010 | 2009 | |
| | (in thousands) | | |
| Income tax (expense) benefit | \$ (257) | \$ 10 | \$ (267) |

Income tax expense for the three months ended September 30, 2010 was \$257,000 as compared to an income tax benefit of \$10,000 for the three months ended September 30, 2009, a change of \$267,000. The change was primarily due to tax deductions for stock-based compensation for the 2010 period in excess of expense recorded under GAAP for the corresponding stock options. Tax deductions in excess of recorded expense are only recognized for periods with net income.

*Nine months ended September 30, 2010 and 2009***Net Operating Revenues**

| | Nine Months ended September 30, | | Change |
|---|--|-----------------|-----------------|
| | 2010 | 2009 | |
| | (in thousands) | | |
| Operating revenues: | | | |
| Milestones and license fees from collaborations | \$61,455 | \$17,131 | \$44,324 |
| Collaboration research and development | — | 3,724 | (3,724) |
| Product sales, net | — | 473 | (473) |
| Grant revenue | 763 | 306 | 457 |
| Net operating revenues | <u>\$62,218</u> | <u>\$21,634</u> | <u>\$40,584</u> |

Net operating revenues for the nine months ended September 30, 2010 increased by \$40.6 million as compared to the nine months ended September 30, 2009. The higher net operating revenues were primarily attributable to an increase of \$44.3 million in milestones and license fees from collaborations revenue, partially offset by a decrease of \$3.7 million in collaboration research and development revenue. The increase in milestones and license fees from collaborations revenue reflected recognition of \$54.3 million of the \$200.0 million upfront payment received under our TC-5214 agreement with AstraZeneca and \$3.9 million of the \$11.0 million payment received under the April 2010 amendment to our cognitive disorders agreement with AstraZeneca, partially offset by the achievement of a milestone event under our cognitive disorders agreement with AstraZeneca during the nine months ended September 30, 2009 for which we received \$10.0 million and decreases for the 2010 period of \$2.5 million in aggregate payments received from GlaxoSmithKline upon achievement of milestone events under our alliance agreement and \$833,000 in license fees derived from the cognitive disorders agreement as a result of the expiration of the term of the preclinical research collaboration in January 2010. The decrease in collaboration research and development revenue for the 2010 period resulted from the completion of the preclinical research collaboration under the cognitive disorders agreement with AstraZeneca.

Research and Development Expenses

| | Nine Months ended September 30, | | Change |
|-----------------------------------|--|-------------|---------------|
| | 2010 | 2009 | |
| | (in thousands) | | |
| Research and development expenses | \$42,058 | \$29,819 | 12,239 |

Research and development expenses for the nine months ended September 30, 2010 increased by \$12.2 million as compared to the nine months ended September 30, 2009. The higher research and development expenses were principally attributable to:

- an increase of \$7.9 million in costs incurred for third-party research and development services in connection with our clinical-stage product candidates to \$15.6 million for the 2010 period from \$7.7 million for the 2009 period; this increase was principally due to the conduct of Phase 2 clinical development of TC-5619 for two indications, the conduct of multiple Phase 1 clinical trials of TC-6987 and our cost-sharing obligations with respect to ongoing Phase 3 clinical trials of TC-5214;
- an increase of \$2.5 million in stock-based compensation, salary and other compensation-related expenses for research and development personnel to \$13.6 million for the 2010 period from \$11.1 million for the 2009 period; the largest component of this increase was stock-based compensation expense and was primarily due to a significantly higher fair value calculated for stock options granted during 2010 as compared to the fair value calculated for stock options granted during and prior to 2009;
- an increase of \$1.7 million in other research and development expenses, including infrastructure costs, to \$9.1 million for the 2010 period from \$7.4 million for the 2009 period; this increase was primarily due to increases in the number of employees and depreciable equipment utilized in our research and development functions; and
- the \$1.5 million upfront payment that we made 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 our preclinical programs to \$2.2 million for the 2010 period from \$3.6 million for the 2009 period. The reduced spending for the 2010 period in connection with our preclinical programs primarily resulted from the uncertainty surrounding the continuation of some of the therapeutic focus areas of our alliance with GlaxoSmithKline.

The costs that we incurred for the nine months ended September 30, 2010 and 2009 for third-party research and development services in connection with clinical-stage product candidates are shown in the table below:

| | Nine Months ended September 30, | | Change |
|---------|--|-------------|---------------|
| | 2010 | 2009 | |
| | (in thousands) | | |
| TC-5619 | \$6,595 | \$2,030 | \$4,565 |
| TC-5214 | 4,915 | 4,200 | 715 |
| TC-6987 | 3,433 | 1,119 | 2,314 |
| TC-6499 | 633 | 182 | 451 |

General and Administrative Expenses

| | Nine Months ended September 30, | | Change |
|-------------------------------------|------------------------------------|------------------------|---------|
| | 2010 | 2009 (in thousands) | |
| General and administrative expenses | \$5,688 | \$4,477 | \$1,211 |

General and administrative expenses for the nine months ended September 30, 2010 increased by \$1.2 million as compared to the nine months ended September 30, 2009. The higher general and administrative expenses were primarily attributable to an increase of \$984,000 in stock-based compensation, salary and other compensation-related expenses for general and administrative personnel to \$3.4 million for the 2010 period from \$2.5 million for the 2009 period. The largest component of the increase was stock-based compensation expense and was primarily due to a significantly higher fair value calculated for stock options granted during 2010 as compared to the fair value calculated for stock options granted during and prior to 2009.

Other Income and Expense

| | Nine Months ended September 30, | | Change |
|------------------|------------------------------------|------------------------|--------|
| | 2010 | 2009 (in thousands) | |
| Interest income | \$ 1,100 | \$ 793 | \$ 307 |
| Interest expense | 114 | 170 | (56) |

Interest income for the nine months ended September 30, 2010 increased by \$307,000 as compared to the nine months ended September 30, 2009. The increase reflected a significantly increased cash balance and changes in our investment portfolio to include U.S. Treasury notes and bonds, U.S. federal and state agency-backed certificates and corporate debt securities, partially offset by lower interest rates. Interest expense for the nine months ended September 30, 2010 decreased by \$56,000 as compared to the nine months ended September 30, 2009.

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Income Tax Expense

| | Nine Months ended September 30, | | Change |
|------------------------------|------------------------------------|-------|-----------|
| | 2010 | 2009 | |
| Income tax (expense) benefit | \$ (2,395) | \$ 83 | \$(2,478) |

Income tax expense for the nine months ended September 30, 2010 was \$2.4 million as compared to an income tax benefit of \$83,000 for the nine months ended September 30, 2009, a change of \$2.5 million. The change was primarily due to tax deductions for stock-based compensation for the 2010 period in excess of expense recorded under GAAP for the corresponding stock options. Tax deductions in excess of recorded expense are only recognized for periods with net income.

Liquidity and Capital Resources

Sources of Liquidity

We have historically financed our operations and internal growth primarily through public and private offerings of our securities, payments under collaborations and alliances, including upfront fees, payments for research and development services and payments upon achievement of milestone events, equipment and building lease incentive financing, government grants and interest income. We discontinued our only approved product, Inversine, effective as of September 30, 2009. The net contribution from Inversine sales was not historically a significant source of cash.

In December 2009, we entered into a collaboration and license agreement with AstraZeneca for the global development and commercialization of TC-5214. We received a \$200.0 million upfront payment from AstraZeneca in January 2010. Under the terms of an existing license agreement, we paid \$16.0 million to University of South Florida Research Foundation, or USFRE, in January 2010 based on our receipt of the upfront payment from AstraZeneca.

As discussed above under the caption “—Overview— Revenue,” we are eligible to receive substantial additional payments from AstraZeneca, contingent on the achievement of specified milestone events related to TC-5214, AZD3480, AZD1446, and, if AstraZeneca licenses TC-5619, TC-5619 and from GlaxoSmithKline, contingent on the achievement of specified milestone events in the specified therapeutic focus areas of the alliance. There is no assurance that we will achieve any particular milestone event in 2010, in any future period or at all. In particular, in February 2010, GlaxoSmithKline announced plans to cease discovery research in selected neuroscience areas. Although the overall impact of GlaxoSmithKline’s strategic change on our alliance has not yet been finally determined, we anticipate that at least several therapeutic focus areas in the alliance will be discontinued. In that event, we would no longer be eligible to receive milestone payments from GlaxoSmithKline for those therapeutic focus areas, which would diminish the alliance as a potential source of future funds.

In July 2010, we entered into a loan agreement with a bank that provides aggregate borrowing capacity of \$4.0 million to be provided in up to three individual term loans that we may take at any time on or prior to June 30, 2011 to fund the purchase of equipment, furnishings, software

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and other fixed assets. In September 2010, we borrowed \$1.2 million under this loan facility at a fixed interest rate of 3.4% per annum. We are obligated only to pay interest through the remainder of 2010. Beginning January 1, 2011 and continuing through the maturity date of December 1, 2014, the loan is repayable in equal monthly installments of \$28,000. We granted to the bank a first priority security interest in the assets acquired with the proceeds of the loan. Any future loan under the facility would, at our discretion on a loan-by-loan basis, bear interest at either a variable rate equal to the thirty-day LIBOR plus 2.15%, adjusted monthly on the first day of each month, or a fixed rate equal to the bank's fixed rate cost of funds index corresponding to the term of the loan plus 2.15%. Any additional loan that we take during 2010 would be interest only through 2010 and then would be re-payable in equal monthly installments of principal and interest over 48 months. Any loan that we take during the first half of 2011 would be interest only through June 30, 2011 and then would be re-payable in equal monthly installments of principal and interest over the next 48 months.

In March 2008, we entered into a loan agreement with a bank that provided borrowing capacity of \$5.3 million to fund the purchase of equipment, furnishings, software and other fixed assets and enable the refinancing of our then-existing loan facility with R.J. Reynolds Tobacco Holdings, Inc. We borrowed \$4.8 million upon entering into the loan agreement and borrowed the remaining \$489,000 in September 2008. Pursuant to the loan agreement, we granted a first priority security interest in favor of the bank in the assets acquired with the proceeds of the loan facility or the previous facility that it replaced. The March 2008 loan bears interest at a fixed rate of 5.231% per annum and is repayable in equal monthly installments of \$112,000 beginning April 1, 2008 and continuing through the maturity date of March 1, 2012. The September 2008 loan bears interest at a fixed rate of 6.131% per annum and is repayable in equal monthly installments of \$11,000 beginning October 1, 2008 and continuing through the maturity date of September 1, 2012. As of September 30, 2010, the outstanding principal balance under the loan facility was \$2.2 million. There is no additional borrowing capacity remaining available to us under the loan agreement.

In April 2002, we received a \$500,000 loan from the City of Winston-Salem. Under the terms of the loan, there was no interest accrual or payment due until the fifth anniversary of the loan. Following expiration of the five-year grace period in April 2007, the outstanding principal balance of the loan began to bear interest at an annual interest rate of 5% and became payable in 60 equal monthly installments of \$9,000. As of September 30, 2010, the outstanding principal balance under the loan was \$161,000.

Our cash, cash equivalents and investments in marketable securities were \$268.0 million as of September 30, 2010 and \$111.1 million as of December 31, 2009. As of September 30, 2010, the majority of our cash, cash equivalents and investments were invested in bank depository accounts and institutional money market funds at Branch Banking and Trust Company, RBC Bank and Wells Fargo & Company. In addition, as of September 30, 2010, we had cash of \$98.2 million that we do not expect to need to fund our short-term liquidity requirements invested in U.S. Treasury notes and bonds, U.S. federal and state agency-backed certificates, corporate debt securities that are rated at least A quality or equivalent and certificates of deposit.

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Cash Flows

| | Nine Months ended September 30, | | Change |
|--|------------------------------------|------------------------|------------|
| | 2010 | 2009 (in thousands) | |
| Net cash provided by (used in) operating activities | \$ 154,012 | \$ (12,544) | \$ 166,556 |
| Net cash (used in) provided by investing activities | (56,563) | 9,848 | (66,411) |
| Net cash provided by (used in) financing activities | 4,441 | (277) | 4,718 |
| Net increase (decrease) in cash and cash equivalents | \$ 101,890 | \$ (2,973) | |

Net cash provided by operating activities for the nine months ended September 30, 2010 was \$154.0 million and net cash used in operating activities for the nine months ended September 30, 2009 was \$12.5 million, a difference of \$166.6 million.

For the nine months ended September 30, 2010, net cash provided by operating activities was principally the result of our receipt of:

- the \$200.0 million upfront payment under our TC-5214 agreement with AstraZeneca in January 2010;
- the \$11.0 million payment under an amendment to our cognitive disorders agreement with AstraZeneca to modify the terms applicable to TC-5619 in April 2010; and
- \$397,000 under our grants with MJFF.

These cash inflows were partially offset by:

- our payments in January 2010 of \$16.0 million to USFRF based on our receipt of the \$200.0 million upfront payment under our TC-5214 agreement with AstraZeneca and \$350,000 to University of Kentucky Research Foundation as a result of the \$10.0 million milestone payment we received from AstraZeneca in July 2009 for achievement of a milestone event under our cognitive disorders agreement with AstraZeneca;
- our payment of \$1.5 million to Cornerstone Therapeutics Inc. upon entering into an exclusive worldwide license agreement in August 2010; and
- aggregate payments of \$39.1 million made for operating charges, including costs incurred for third-party research and development services in connection with clinical-stage product candidates and preclinical programs and personnel and infrastructure costs.

For the nine months ended September 30, 2009, net cash used in operating activities was principally the result of aggregate payments of \$30.5 million made for operating charges, including costs incurred for third-party research and development services in connection with clinical-stage product candidates and preclinical programs and personnel and infrastructure costs, and was partially offset by our receipt of:

- the \$10.0 million payment from AstraZeneca in July 2009;

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- \$4.0 million in collaboration research and development revenue under our preclinical research collaboration with AstraZeneca, which ended in January 2010;
- \$2.5 million in aggregate payments from GlaxoSmithKline upon achievement of milestone events under our alliance agreement;
- \$473,000 in net product sales of Inversine, which we discontinued effective September 30, 2009; and
- \$321,000 under a grant from MJFF.

Net cash used in investing activities for the nine months ended September 30, 2010 was \$56.6 million and net cash provided by investing activities for the nine months ended September 30, 2009 was \$9.8 million, a difference of \$66.4 million. Cash used in investing activities primarily reflects the portion of our cash that we allocate to, and the timing of purchases and maturities of, our investments in marketable securities. The net purchases of investments in marketable securities for the nine months ended September 30, 2010 were \$54.9 million and occurred primarily as a result of our receipt of the upfront payment under our TC-5214 agreement with AstraZeneca. The net sales of investments in marketable securities for the nine months ended September 30, 2009 were \$10.0 million. Additionally, we purchased \$1.7 million of property and equipment for the 2010 period, an increase of \$1.5 million from \$152,000 for the 2009 period, to expand our internal research and development capacity.

Net cash provided by financing activities for the nine months ended September 30, 2010 was \$4.4 million and net cash used in financing activities for the nine months ended September 30, 2009 was \$277,000, a difference of \$4.7 million. The change was principally attributable to an increase for the 2010 period of \$1.4 million in proceeds from the issuance of common stock upon the exercise of stock options, the related income tax effect of \$2.4 million for the 2010 period and our receipt of \$1.2 million in September 2010 under a loan facility.

Funding Requirements

As of September 30, 2010, we had an accumulated deficit of \$216.2 million. We may incur operating losses in future periods as our clinical-stage and preclinical product candidates advance into later-stage development and as we progress our programs, invest in additional product opportunities and expand our research and development infrastructure. However, we may generate operating income for any particular reporting period as a result of the recognition into revenue of amounts previously received under our agreements with AstraZeneca and GlaxoSmithKline, including in particular our TC-5214 agreement with AstraZeneca, the timing of milestone events that may be achieved under those agreements and the timing of costs incurred related to development of our clinical-stage and preclinical product candidates. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- whether and to what extent milestone events are achieved for TC-5214 under our TC-5214 agreement with AstraZeneca and for AZD3480 and AZD1446 under our cognitive disorders agreement with AstraZeneca;

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- the progress of, and outcomes from, Phase 3 clinical development of TC-5214 and the amount and timing of development costs for TC-5214 payable by us;
- whether AstraZeneca exercises its right to license TC-5619 when exercisable;
- the scope, progress, duration, results and cost of clinical trials, as well as non-clinical studies and assessments, of our other product candidates;
- the impact on our alliance of GlaxoSmithKline's shift in discovery research focus announced in February 2010 and whether any of our programs in the therapeutic focus areas of the alliance continue and research and development-related milestone events are achieved;
- the extent to which we retain development or commercialization rights or responsibilities for our product candidates that are not subject to our collaborations with AstraZeneca or our alliance with GlaxoSmithKline and incur associated development costs, manufacturing costs or costs to establish sales and marketing functions;
- whether we establish strategic alliances, collaborations and licensing or other arrangements on terms favorable to us;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions;
- the number and characteristics of product candidates that we pursue;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending patents and other intellectual property rights;
- the costs of manufacturing-related services for our product candidates in clinical and late preclinical development;
- the rate of technological advancements for the indications that we target;
- the costs to satisfy our obligations under existing and potential future alliances and collaborations;
- the timing, receipt and amount of sales or royalties, if any, from our potential products; and
- the extent and scope of our general and administrative expenses.

Implementing our strategy may require additional capital as our clinical-stage and preclinical product candidates advance into later-stage development and as we progress our programs, invest in additional product opportunities and expand our research and development infrastructure. Our existing capital resources may not be sufficient to enable us to fund the completion of the

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development of any of our product candidates. We currently expect our existing capital resources to be sufficient to fund our operations at least through the end of 2013, without taking into account any amounts that we would be entitled to receive if milestone events are achieved under either of our collaboration agreements with AstraZeneca or our alliance agreement with GlaxoSmithKline. However, our operating plan may change as a result of many factors, including those described above, and we may need additional funds sooner than planned to meet operational needs and capital requirements for product development.

To the extent our capital resources are insufficient to meet future capital requirements, we may need to finance future cash needs through alliances, collaborations or licensing or other arrangements, public or private equity or debt offerings or other financings. The global credit and financial markets continue to be negatively impacted by the recessionary environment. This, coupled with other factors, may dramatically limit our access to additional equity or debt financing in the future on acceptable terms or at all. Also, additional strategic alliances, collaborations or licensing or other arrangements may not be available on acceptable terms or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently. Additionally, any future equity funding may dilute the ownership of our stockholders.

We cannot determine precisely the completion dates and related costs of our research and development programs due to inherent uncertainties in outcomes of clinical trials and regulatory approvals of our product candidates. We cannot be certain that we will be able to successfully complete our research and development projects or establish strategic alliances, collaborations or licensing or other arrangements for our product candidates. Our failure, or the failure of any of our licensees or collaborators, to complete research and development programs for our product candidates could have a material adverse effect on our financial position or results of operations.

Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board issued Accounting Standards Update No. 2010-17, *Milestone Method of Revenue Recognition*, or ASU 2010-17. ASU 2010-17 defines a milestone event and permits an entity to make an accounting policy election to recognize a payment that is contingent upon achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. ASU 2010-17 is effective for fiscal years beginning on or after June 15, 2010, and for interim periods within those years, and may be applied prospectively to milestones achieved after the adoption date or retrospectively for all periods presented. Early adoption is permitted. We do not expect ASU 2010-17 to have a material impact on our financial results.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objectives of our investment activities are to preserve our capital and meet our liquidity needs to fund our operations. We also seek to generate competitive rates of return from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in marketable securities that are of high credit quality. As of September 30, 2010, we had cash, cash equivalents and investments in marketable securities of \$268.0 million. Our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our cash equivalents are invested in accounts with market interest rates and short term in nature and our investments in marketable securities are traded in active markets, we believe that our exposure to interest rate risk is not significant and estimate that an immediate and uniform 10% increase in market interest rates from levels as of September 30, 2010 would not have a material impact on the total fair value of our portfolio.

We contract for the conduct of some of our clinical trials and other research and development and manufacturing activities with contract research organizations, clinical trial sites and contract manufacturers in Europe and India. We may be subject to exposure to fluctuations in foreign currency exchange rates in connection with these agreements. If the average Euro/U.S. dollar or Indian Rupee/U.S. dollar exchange rate were to strengthen or weaken by 10% against the corresponding exchange rate as of September 30, 2010, we estimate that the impact on our financial position, results of operations and cash flows would not be material. We do not hedge our foreign currency exposures.

We have not used derivative financial instruments for speculation or trading purposes.

Item 4. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures in accordance with Rule 13a-15 under the Exchange Act as of the end of the period covered by this quarterly report. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures

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as of the end of the period covered by this quarterly report, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (a) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure and (b) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

(b) *Changes in Internal Controls*. No change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2010 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 6. Exhibits

The exhibits listed in the accompanying exhibit index are filed as part of this quarterly report.

Our trademarks include Targacept®, Pentad™, NNR Therapeutics™, TRIDMAC™ and Building Health, Restoring Independence™. Any other service marks, trademarks and trade names appearing in this quarterly report are the property of their respective owners.

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 thereunto duly authorized.

TARGACEPT, INC.

Date: November 5, 2010

/s/ J. DONALD DEBETHIZY

J. Donald deBethizy
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2010

/s/ ALAN A. MUSSO

Alan A. Musso
Senior Vice President, Finance and Administration,
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|---|
| 10.1 | Amendment No. 4, effective as of September 28, 2010, to Collaborative Research and License Agreement between the Company and AstraZeneca AB dated as of December 27, 2005 [^] . |
| 31.1 | Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

[^] Portions of this Exhibit have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Exchange Act.

The registrant hereby undertakes to furnish to the SEC, upon its request, a copy of any instrument defining the rights of holders of indebtedness of the registrant incurred during the third quarter ended September 30, 2010 and not filed herewith pursuant to Item 601(b)(4)(v) of Regulation S-K.

[*****] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.

**AMENDMENT NO. 4 TO
COLLABORATIVE RESEARCH AND LICENSE AGREEMENT**

This Amendment No. 4 to Collaborative Research and License Agreement (this “**Amendment**”), effective as of the date of signature of the last Party to sign below, amends the Collaborative Research and License Agreement entered into as of December 27, 2005 by and between AstraZeneca AB, a company limited by shares organized and existing under the laws of Sweden (“**AstraZeneca**”), and Targacept, Inc., a Delaware (USA) corporation (“**Targacept**”), as amended by Amendment No. 1 dated November 10, 2006, Amendment No. 2 effective July 8, 2009, and Amendment No. 3 effective April 30, 2010 (the “**Agreement**”). Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Agreement.

WHEREAS AstraZeneca and Targacept desire to amend, in accordance with Section 17.6 of the Agreement, various aspects of the Agreement to provide (i) terms on which Targacept would [*****] a human clinical trial of Ispronicline as a treatment for AD and (ii) for certain other rights and obligations with respect to the Development of Ispronicline as a treatment for AD.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and for other good and valuable consideration, AstraZeneca and Targacept, intending to be legally bound, hereby agree as follows:

1. Section 5.10.1 of the Agreement is hereby amended by deleting the text thereof in its entirety and replacing it with the following:

“Except (a) in the conduct of the Research Program or any Additional Research Program as provided in Sections 4.1, 4.3, 4.4 and 4.8, (b) subject to Section 5.10.2(c)(1), for the identification, research and development of potential Back-Up Option Compounds (which, for purposes of clarity, are Additional Compounds with respect to the corresponding Option Compound Candidate Drugs) that have not yet themselves become Option Compound Candidate Drugs, (c) as provided in Section 5.2.2, (d) for the Targacept Development Activities, and (e) for the [*****] the TRGT Ispronicline AD Trial (as defined in Section 5.14) and activities incidental thereto, notwithstanding anything else in this Agreement to the contrary, AstraZeneca shall have the sole and exclusive right during the Term to research, develop, manufacture, commercialize and otherwise Exploit all Collaboration Compounds, Candidate Drugs and Products (including to Develop Candidate Drugs and Commercialize Products) in the Territory for use in the Field and in Schizophrenia.”

2. The Agreement is hereby amended by adding the following new Section 5.14.

“5.14 **TRGT Ispronicline AD Trial.**

(a) Contingent upon the execution by the Parties of the Agreement relating to AZD3480 Clinical Study in AD dated on or about September 28, 2010 (the “**TRGT Ispronicline AD Trial Agreement**”) and subject to the other terms of this Agreement, AstraZeneca shall, and hereby does, grant to Targacept and its Affiliates a non-exclusive, royalty-free, worldwide license during the Term, without the right to grant sublicenses (except as reasonably necessary in connection with the

engagement by Targacept of any Third Party to conduct the TRGT Ispronicline AD Trial (as defined below) or any activity incidental thereto), under AstraZeneca Technology and AstraZeneca Patent Rights and AstraZeneca's interest in Joint Technology and Joint Patent Rights solely to conduct as contemplated by the TRGT Ispronicline AD Trial Agreement a human clinical trial of Ispronicline as a treatment for AD (the "TRGT Ispronicline AD Trial") and activities incidental thereto.

(b) Notwithstanding any terms of the Agreement to the contrary (including Section 5.3 (Product Development Plans) and Section 6.4 (R&D Funding)), unless otherwise expressly provided in the TRGT Ispronicline AD Trial Agreement or agreed in writing by the Parties, all costs and expenses incurred by Targacept to conduct the TRGT Ispronicline AD Trial shall be borne by Targacept and shall not be reimbursed by AstraZeneca.

(c) Unless and until AstraZeneca in its sole discretion were to determine [*****] to conduct another Clinical Trial of Ispronicline in AD at a [*****] (the "Internal AZ AD Advancement Action"): (i) the TRGT Ispronicline AD Trial shall not be [*****] for purposes of [*****]; and (ii) consistent with clause (i), AstraZeneca shall not be required to [*****] for [*****] based on [*****] in the TRGT Ispronicline AD Trial. For clarity and without limitation of any [*****] that [*****] under the Agreement (including [*****]), if the Internal AZ AD Advancement Action occurs, AstraZeneca shall thereupon be required to [*****]. For purposes of this Section 5.14(c) and Section 5.14(d), a [*****] is [*****] if such [*****], be reasonably expected to [*****] or, together with [*****]; provided that the designation of [*****] shall not create any implication that [*****].

(d) Notwithstanding anything in the Agreement to the contrary, including the provisions of [*****], and regardless of [*****] the TRGT Ispronicline AD Trial, AstraZeneca [*****]; provided that (i) if AstraZeneca [*****], or [*****] Targacept [*****], AstraZeneca's [*****] shall thereafter apply in accordance with such Section [*****] and (ii) nothing in this Section 5.14(d) is intended to modify [*****] with respect to Ispronicline and ADHD or any other Primary Indication."

3. The Agreement is hereby amended by adding the following new Section 6.1A.

"6.1A **AD Program Achievement Payments.** AstraZeneca shall pay Targacept the following non-refundable and non-creditable fees (each, an "AD Program Achievement Payment") in immediately available funds:

[*****] Five Hundred Thousand Dollars (US \$500,000) on or before October 5, 2010;

[*****] within [*****] Business Days after receipt of a Targacept invoice therefor after [*****];

[*****] within [*****] Business Days after receipt of a Targacept invoice therefor after [*****]

[*****] within [*****] Business Days after receipt of a Targacept invoice therefor after [*****].

As used in this Section 6.1(A), the term [*****] means the [*****] and is [*****]."

4. Section 8.1.3 of the Agreement is hereby amended by (a) deleting the “and” before clause (E) in the proviso at the end thereof and (b) adding the following to the end of such proviso (before the period):

“; and (F) to conduct (or have conducted) the TRGT Ispronidine AD Trial and activities incidental thereto”

5. Except as expressly amended by this Amendment, all of the terms and conditions of the Agreement shall remain in full force and effect.

[remainder of page intentionally left blank]

IN WITNESS WHEREOF AstraZeneca and Targacept have executed this Amendment as of the respective dates set forth below.

TARGACEPT, INC.

ASTRAZENECA AB (publ.)

By: /s/ J. Donald deBethizy

By: /s/ Anders Burén

Name: J. Donald deBethizy

Name: Anders Burén

Title: President & CEO

Title: Authorised Signatory

Date: September 28, 2010

Date: September 28, 2010

[Signature Page to Amendment No. 4]

CERTIFICATION

I, J. Donald deBethizy, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Targacept, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2010

/s/ J. Donald deBethizy

J. Donald deBethizy

President and Chief Executive Officer

CERTIFICATION

I, Alan A. Musso, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Targacept, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2010

/s/ Alan A. Musso

Alan A. Musso
Senior Vice President, Finance and Administration,
Chief Financial Officer and Treasurer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Targacept, Inc. (the "Company") for the period ended September 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, J. Donald deBethizy, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2010

/s/ J. Donald deBethizy

J. Donald deBethizy
President and Chief Executive Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Targacept, Inc. (the "Company") for the period ended September 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Alan A. Musso, Senior Vice President, Finance and Administration, Chief Financial Officer and Treasurer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2010

/s/ Alan A. Musso

Alan A. Musso
Senior Vice President, Finance and Administration,
Chief Financial Officer and Treasurer