
**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 **June 30, 2009**

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 checked="" type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> (do not check if a smaller reporting company) | Smaller reporting company | <input 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 July 31, 2009, the registrant had 25,072,253 shares of common stock, \$0.001 par value per share, outstanding.

TARGACEPT, INC.
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 statements contained in this quarterly report, other than statements of historical fact, regarding: the progress, scope or duration of the development of TC-5214, AZD3480 (TC-1734), AZD1446 (TC-6683), TC-5619 or any of our other product candidates, such as the size, design, conduct or objective of any clinical trial, the timing for initiation or completion of or availability of results from any clinical trial or the indication(s) for which the product candidate may be developed; the benefits that may be derived from any of our product candidates; a strategic alliance, collaboration, licensing or other arrangement with respect to TC-5214; the period of our preclinical research collaboration with AstraZeneca; any payments that AstraZeneca or GlaxoSmithKline may make to us; the period over which we will conduct grant-funded research; the discontinuation of the sale of Inversine®; our future operations, financial position, revenues, costs or expenses; or our strategies, prospects, plans, expectations or objectives are forward-looking statements 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,” “scheduled” or other comparable words identify forward-looking statements. Actual results, performance or experience may differ materially from those expressed or implied by forward-looking statements as a result of various important factors, including our critical accounting policies and risks and uncertainties relating to: our ability to establish a strategic alliance, collaboration or licensing or other arrangement with respect to TC-5214 and the time and complexity involved; our dependence on the success of our collaboration with AstraZeneca and our alliance with GlaxoSmithKline; the significant control that AstraZeneca has over the development of AZD3480 and AZD1446, including as to the conduct of any further development of AZD3480 in attention deficit/hyperactivity disorder or AZD1446 in Alzheimer’s disease and the scope and design of any future clinical trial of AZD3480 or AZD1446; the conduct and results of clinical trials and non-clinical studies and assessments of TC-5214, AZD3480, AZD1446, TC-5619 and our other product candidates, including the performance of third parties engaged to execute such trials, studies and assessments, delays resulting from any changes to the applicable protocols and difficulties or delays in the completion of subject enrollment or data analysis; and the timing and success of submission, acceptance and approval of regulatory filings. These and other risks and uncertainties are described in greater detail under the caption “Risk Factors” in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2008, in Item 1A of Part II of this quarterly report and in other filings that we make with the Securities and Exchange Commission, or SEC. As a result of the risks and uncertainties, the results or events indicated by the forward-looking statements 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.

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Item 1. Financial Statements

TARGACEPT, INC.

BALANCE SHEETS

(in thousands, except share and par value amounts)

| | <u>June 30, 2009</u> (unaudited) | <u>December 31, 2008</u> |
|--|-------------------------------------|--------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 45,919 | \$ 51,202 |
| Short-term investments | 27,193 | 37,161 |
| Collaboration revenue and accounts receivable | 1,687 | 2,073 |
| Inventories | 31 | 100 |
| Prepaid expenses | 1,459 | 1,430 |
| Total current assets | 76,289 | 91,966 |
| Property and equipment, net | 5,584 | 6,401 |
| Intangible assets, net of accumulated amortization of \$120 and \$112 at June 30, 2009 and December 31, 2008, respectively | 176 | 184 |
| Total assets | <u>\$ 82,049</u> | <u>\$ 98,551</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,003 | \$ 1,500 |
| Accrued expenses | 4,258 | 4,381 |
| Current portion of long-term debt | 1,404 | 1,390 |
| Current portion of deferred rent incentive | 42 | 42 |
| Current portion of deferred license fee revenue | 5,101 | 6,479 |
| Total current liabilities | 12,808 | 13,792 |
| Long-term debt, net of current portion | 2,695 | 3,408 |
| Deferred rent incentive, net of current portion | 88 | 109 |
| Deferred license fee revenue, net of current portion | 22,222 | 23,869 |
| Total liabilities | 37,813 | 41,178 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock, \$0.001 par value, 100,000,000 shares authorized at June 30, 2009 and December 31, 2008 and 24,967,048 and 24,964,373 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively | 25 | 25 |
| Capital in excess of par value | 248,437 | 247,244 |
| Accumulated deficit | (204,226) | (189,896) |
| Total stockholders' equity | 44,236 | 57,373 |
| Total liabilities and stockholders' equity | <u>\$ 82,049</u> | <u>\$ 98,551</u> |

See accompanying notes.

TARGACEPT, INC.

STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|-----------------------------|------------|---------------------------|-------------|
| | 2009 | 2008 | 2009 | 2008 |
| Operating revenues: | | | | |
| Collaboration research and development | \$ 1,121 | \$ 2,637 | \$ 2,665 | \$ 4,895 |
| Milestones and license fees from collaborations | 1,605 | 2,320 | 5,725 | 3,939 |
| Product sales, net | 104 | 199 | 355 | 387 |
| Grant revenue | — | — | 226 | 211 |
| Net operating revenues | 2,830 | 5,156 | 8,971 | 9,432 |
| Operating expenses: | | | | |
| Research and development (including stock-based compensation of \$293 and \$292 for the three months ended June 30, 2009 and 2008, respectively, and \$580 and \$554 for the six months ended June 30, 2009 and 2008, respectively) | 11,049 | 10,518 | 20,544 | 19,599 |
| General and administrative (including stock-based compensation of \$279 and \$233 for the three months ended June 30, 2009 and 2008, respectively, and \$566 and \$473 for the six months ended June 30, 2009 and 2008, respectively) | 1,377 | 1,894 | 2,848 | 3,585 |
| Cost of product sales | 258 | 178 | 485 | 381 |
| Total operating expenses | 12,684 | 12,590 | 23,877 | 23,565 |
| Loss from operations | (9,854) | (7,434) | (14,906) | (14,133) |
| Other income (expense): | | | | |
| Interest income | 258 | 700 | 620 | 1,669 |
| Interest expense | (57) | (69) | (117) | (120) |
| Total other income (expense) | 201 | 631 | 503 | 1,549 |
| Loss before provision for income taxes | (9,653) | (6,803) | (14,403) | (12,584) |
| Income tax benefit | — | — | 73 | — |
| Net loss | \$ (9,653) | \$ (6,803) | \$ (14,330) | \$ (12,584) |
| Basic and diluted net loss per share | \$ (0.39) | \$ (0.27) | \$ (0.57) | \$ (0.52) |
| Weighted average common shares outstanding - basic and diluted | 24,966,347 | 24,905,965 | 24,965,632 | 24,370,195 |

See accompanying notes.

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

| | Six Months Ended June 30, | |
|---|------------------------------|------------------|
| | 2009 | 2008 |
| Operating activities | | |
| Net loss | \$(14,330) | \$(12,584) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Recognition of deferred license fee revenue | (3,025) | (3,239) |
| Depreciation and amortization | 947 | 836 |
| Stock-based compensation expense | 1,146 | 1,027 |
| Recognition of deferred rent incentive | (21) | (21) |
| Impairment of inventory | 52 | — |
| Changes in operating assets and liabilities: | | |
| Collaboration revenue and accounts receivable | 386 | 1,357 |
| Inventories | 17 | 21 |
| Prepaid expenses and accrued interest receivable | (61) | (967) |
| Accounts payable and accrued expenses | 380 | (1,571) |
| Net cash used in operating activities | (14,509) | (15,141) |
| Investing activities | | |
| Purchase of investments | (18,000) | (67,800) |
| Proceeds from sale of investments | 28,000 | 63,934 |
| Purchase of property and equipment | (122) | (1,759) |
| Net cash provided by (used in) investing activities | 9,878 | (5,625) |
| Financing activities | | |
| Proceeds from issuance of long-term debt | — | 4,811 |
| Principal payments on long-term debt | (699) | (2,339) |
| Proceeds from issuance of common stock | 47 | 29,257 |
| Net cash (used in) provided by financing activities | (652) | 31,729 |
| Net (decrease) increase in cash and cash equivalents | (5,283) | 10,963 |
| Cash and cash equivalents at beginning of period | 51,202 | 53,403 |
| Cash and cash equivalents at end of period | <u>\$ 45,919</u> | <u>\$ 64,366</u> |

See accompanying notes

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS

June 30, 2009

1. The Company and Nature of Operations

Targacept, Inc., a Delaware corporation (the Company), was formed on March 7, 1997. The Company is a biopharmaceutical company engaged in the design, discovery and development of NNR Therapeutics™, a new class of drugs for the treatment of diseases and disorders primarily of the central 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 and 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, 2008. 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 six months ended June 30, 2009 and 2008 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

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.

Fair Value Measurement

Effective January 1, 2008, the Company adopted Statement of Financial Accounting Standard, or SFAS, No. 157, *Fair Value Measurements*, or SFAS 157, for application to financial assets. SFAS 157 defines fair value, provides a consistent framework for measuring fair value under GAAP and expands fair value financial statement disclosure requirements. SFAS 157 does not require any new fair value measurements. SFAS 157 applies only to accounting pronouncements that already require or permit fair value measurements, except for standards that relate to share-based payments such as SFAS No. 123 (revised 2004), *Share-Based Payment*, and related interpretations.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

June 30, 2009

2. Summary of Significant Accounting Policies (continued)

The valuation techniques of SFAS 157 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. SFAS 157 classifies these inputs into the following hierarchy:

Level 1 Inputs— Quoted prices for identical instruments in active markets.

Level 2 Inputs— Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and valuations for which inputs are observable or for which significant value drivers are observable.

Level 3 Inputs— Primarily unobservable value drivers.

As of June 30, 2009, the Company had \$27,193,000 invested in available-for-sale marketable securities, comprised entirely of certificates of deposit and the related accrued interest receivable. The Company determines fair value for certificates of deposit through quoted market prices, or Level 1 inputs. The Company has also previously invested in student loan auction rate securities, or ARS. Prior to January 1, 2008, the Company determined fair value for student loan ARS based on quoted market prices in active markets for identical assets. However, based on failures of student loan ARS to settle at auction during the six months ended June 30, 2008, the Company determined fair value for student loan ARS based on a discounted cash flow model at March 31, 2008. This model considered, among other things, the expected timing for successful auctions or refinancings in the future, the composition and quality of the underlying collateral and the creditworthiness of the issuer, and resulted in a fair value adjustment of \$297,000. Because these inputs were not observable, they were classified as Level 3 inputs under SFAS 157. All of the Company's previously owned ARS were redeemed by the issuers of the underlying securities at full par value in June and July 2008. Based on the June 2008 redemption and then-expected future redemptions, the Company reversed the fair value adjustment as of June 30, 2008.

The adoption of SFAS No. 157 had no effect on the valuation of the Company's available-for-sale marketable securities as of June 30, 2009 or December 31, 2008.

The Company valued non-financial assets using previously issued Financial Accounting Standards Board, or FASB, standards in accordance with FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, as of December 31, 2008.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

June 30, 2009

2. Summary of Significant Accounting Policies (continued)

Short-Term Investments

Consistent with the Company's investment policy, cash is invested with prominent financial institutions in bank depository accounts, certificates of deposit, and institutional money market funds. The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation as of each balance sheet date. All marketable securities owned during the three and six months ended June 30, 2009 and 2008 were classified as available for sale. Interest and dividend income on investments are included in "Interest income." The cost of securities sold is based on the specific identification method.

During the six months ended June 30, 2008, the Company had investments in student loan ARS as discussed above under "Fair Value Measurement." The Company had no investments in student loan ARS during the six months ended June 30, 2009.

Revenue Recognition

The Company uses revenue recognition criteria in Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, or SAB 101, as amended by Staff Accounting Bulletin No. 104, *Revision of Topic 13*, or SAB 104, which are referred to together as SEC Topic 13, *Revenue Recognition*, or Topic 13.

In determining the accounting for collaboration and alliance agreements, the Company follows the provisions of Emerging Issues Task Force, or EITF, Issue 00-21, *Revenue Arrangements with Multiple Deliverables*, or EITF 00-21, for multiple element revenue arrangements. EITF 00-21 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 EITF's separation criteria, 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.

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 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 license fee revenue and recognized into revenue as milestones and license fees from collaborations on a straight-line basis over the estimated development period, to the extent such fees are attributable to a specific licensed product candidate, or otherwise over the expected period of the Company's performance obligations or, where its collaborator has substantially all research and development responsibility, over the estimated research and development period.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

June 30, 2009

2. Summary of Significant Accounting Policies (continued)

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 into revenue on a straight-line basis over a period determined as described in the preceding paragraph.

Revenues for specific research and development costs that are reimbursable under collaboration agreements are recognized in accordance with EITF Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF Issue 01-14, *Income Statement Characterization of Reimbursements Received for "Out-of-Pocket" Expenses Incurred*. The revenues associated with these reimbursable amounts are reflected as a component of collaboration research and development revenue and the costs associated with these reimbursable amounts are reflected as a component 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 grants is recognized as the Company performs the work and incurs reimbursable costs in accordance with the objectives of the award.

Income Taxes

The Company uses the liability method in accounting for income taxes as required by SFAS No. 109, *Accounting for Income Taxes*, or SFAS 109. The Company follows Financial Accounting Standards Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48, which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109. Under SFAS 109, 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 on deferred tax assets and liabilities of a change in tax rates 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 than not that such assets will be realized. FIN 48 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. FIN 48 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 FIN 48 as interest expense and to classify any penalties recognized in accordance with FIN 48 as an expense other than income tax expense.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

June 30, 2009

2. Summary of Significant Accounting Policies (continued)

Because the Company has incurred taxable losses since inception, all tax years remain open to examination by major jurisdictions. The Company is eligible to receive a refundable research and development tax credit provided initially under the Housing Assistance Tax Act of 2008 and extended by the American Recovery and Reinvestment Act of 2009 in lieu of claiming "bonus depreciation," and has recorded a corresponding income tax benefit of \$73,000 for the six months ended June 30, 2009.

Net Loss Per Share

The Company computes net loss per share in accordance with SFAS No. 128, *Earnings Per Share*, or SFAS 128. Under the provisions of SFAS 128, basic net loss per share attributable to common stockholders, or Basic EPS, is computed by dividing the net loss by the weighted average number of common shares outstanding. Diluted net loss per share, or Diluted EPS, is computed by dividing the net loss by the weighted average number of common shares and dilutive common share equivalents outstanding.

Common share equivalents consist of the incremental common shares issuable upon the exercise of stock options. The Company has excluded all outstanding stock options from the calculation of Diluted EPS because their effect is antidilutive for the periods presented. As a result, Diluted EPS is identical to Basic EPS for the periods presented.

Had the Company been in a net income position, potentially dilutive outstanding stock options of 3,826,598 and 3,091,002 for the three months ended June 30, 2009 and 2008, respectively, and 3,791,707 and 3,097,277 for the six months ended June 30, 2009 and 2008, respectively, in each case calculated on a weighted-average basis, may have been included in the calculation.

Common Stock and Stock-Based Compensation

On January 23, 2008, the Company completed a public offering of 4,370,000 shares of its common stock at a price of \$7.07 per share. The Company's net proceeds from the offering, after deducting underwriters' discounts and commissions and offering expenses payable by the Company, were \$29,114,000. The Company issued 1,875 and 2,675 shares of common stock upon the exercise of stock options during the three and six months ended June 30, 2009, respectively. The Company issued 90,954 shares of common stock upon the exercise of stock options during the year ended December 31, 2008.

On January 9, 2009, the Company granted to employees options to purchase 700,250 shares of common stock with an estimated aggregate fair value using the Black-Scholes-Merton formula of \$1,352,000. The Company is recording this amount, as adjusted for estimated forfeitures, as stock-based compensation on a straight line basis over an expected period of 16 quarters.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

June 30, 2009

2. Summary of Significant Accounting Policies (continued)**Comprehensive Loss**

For the three and six months ended June 30, 2009 and for the six months ended June 30, 2008, the Company's comprehensive loss equaled its reported net loss. For the three months ended June 30, 2008, the Company's comprehensive loss was \$6,506,000, which included a net loss of \$6,803,000 and the recovery of a fair value adjustment to student loan ARS of \$297,000, as discussed above under "Fair Value Measurement."

Recent Accounting Pronouncements

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles—a replacement of FASB Statement No. 162*, or SFAS 168. SFAS 168 replaces SFAS No. 162 and establishes *The FASB Accounting Standards Codification* as the source of authoritative accounting principles recognized by the FASB to be applied by non-governmental entities in the preparation of financial statements in conformity with GAAP. SFAS 168 is effective for financial statements issued for periods ending after September 15, 2009. The Company does not expect SFAS 168 to have a material impact on its financial results.

3. Inventories

As of the respective dates shown, inventories consisted of the following:

| | <u>June 30,</u> <u>2009</u> | <u>December 31,</u> <u>2008</u> |
|----------------|--------------------------------|------------------------------------|
| | (In thousands) | |
| Raw materials | \$ — | \$ 52 |
| Finished goods | 31 | 48 |
| | <u>\$ 31</u> | <u>\$ 100</u> |

In March 2009, the Company notified the U.S. Food and Drug Administration that it will discontinue Inversine effective as of September 30, 2009. Because the Company has no further plans to manufacture Inversine, the Company recorded a charge of \$52,000 in cost of product sales related to the impairment of its raw materials inventory during the three months ended June 30, 2009. The Company does not expect the discontinuation of Inversine to have a material impact on its cash flows or results of operations in future periods.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

June 30, 2009

4. Strategic Alliance and Collaboration Agreements

AstraZeneca AB

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 Alzheimer's disease, cognitive dysfunction in schizophrenia and attention deficit/hyperactivity disorder. The agreement also provides for a multi-year preclinical research collaboration between the Company and AstraZeneca. The Company is eligible to receive research fees, license fees and milestone payments under the agreement. The amount of research fees, license fees and milestone payments depends on the extent of the Company's research activities and the timing and achievement of development, regulatory and 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 is recognizing as revenue on a straight-line basis over the planned 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 AstraZeneca had informed the Company that it plans to conduct further development of AZD3480 for attention deficit/hyperactivity disorder, or ADHD (see Note 5). Based on AstraZeneca's plans to conduct further Phase 2 clinical development prior to the planned initiation of Phase 3 clinical development, the Company changed its estimate of the development period for AZD3480 to continue through 2013 and began recognizing the portion of the \$5,000,000 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 \$457,000 and \$563,000 of the initial fee as revenue for the three months ended June 30, 2009 and 2008, respectively, and \$1,020,000 and \$1,125,000 of the initial fee as revenue for the six months ended June 30, 2009 and 2008, respectively.

Under the agreement, the Company is also eligible to receive (1) additional payments of up to \$103,000,000 contingent upon achievement of development, regulatory, first commercial sale and first detail milestones for AZD3480 in ADHD, (2) other payments if development, regulatory, first commercial sale and first detail milestones for AZD3480 are achieved for other target indications 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. 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 the Company's revenue recognition policy (see Note 2). Under the terms of a sponsored research agreement and a subsequent license agreement between the Company and the University of Kentucky

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

June 30, 2009

4. Strategic Alliance and Collaboration Agreements (continued)

Research Foundation, or UKRF, the Company is required to pay UKRF a low single digit percentage of any payments that are received from AstraZeneca related to AZD3480. No fees were paid to UKRF during the six months ended June 30, 2009 or 2008.

The Company is eligible to receive payments from AstraZeneca for research services performed in the parties' preclinical research collaboration. The Company recognizes collaboration research and development revenue as the research is performed and related expenses are incurred. The Company recognized collaboration research and development revenue of \$1,121,000 and \$2,637,000 for the three months ended June 30, 2009 and 2008, respectively, and \$2,665,000 and \$4,895,000 for the six months ended June 30, 2009 and 2008, respectively.

In October 2007, the Company provided notice under its agreement with AstraZeneca 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 proof of concept clinical trial in accordance with a mutually acceptable development plan, following which AstraZeneca would have the right to license TC-5619. The Company is recognizing the \$2,000,000 payment as revenue on a straight-line basis over the estimated development period for TC-5619 to reach Phase 2 clinical proof of concept. Accordingly, the Company recognized \$122,000 and \$231,000 of the payment as revenue for the three months ended June 30, 2009 and 2008, respectively, and \$353,000 and \$462,000 of the payment as revenue for the six months ended June 30, 2009 and 2008, respectively.

The Company received a \$200,000 payment from AstraZeneca in each of May 2008 and June 2009 and a \$2,000,000 payment from AstraZeneca in December 2008. Each payment was made upon achievement of a milestone event related to the development of a product candidate arising under the parties' preclinical research collaboration. The Company recognized the full amount of each payment as revenue upon achievement of the corresponding milestone event because the event met each of the conditions required for immediate recognition under the Company's revenue recognition policy (see Note 2).

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: smoking cessation, pain, obesity, addiction and Parkinson's disease.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

June 30, 2009

4. Strategic Alliance and Collaboration Agreements (continued)

Under the agreement, the Company has agreed, for specified periods of time, to use diligent efforts to conduct research activities designed to discover product candidates that target specified NNR subtypes, to develop the product candidate identified as the lead for each therapeutic focus area of the alliance through a Phase 2 proof of concept trial and to develop up to two other product candidates for each therapeutic focus area to a specified stage of preclinical development. 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 AB.

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 contingent milestone payments from GlaxoSmithKline as product candidates subject to the alliance advance through preclinical and clinical development.

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 the 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 them into revenue on a straight-line basis over the estimated term of the Company's research and early development obligations under the agreement. Currently, the Company estimates the term of such obligations to be nine years from effectiveness of the agreement. The Company recognized \$653,000 of the initial payment and deemed premium as revenue for each of the three-month periods ended June 30, 2009 and 2008 and \$1,307,000 of the initial payment and deemed premium as revenue for each of the six-month periods ended June 30, 2009 and 2008.

The Company is also eligible to receive up to approximately \$1.1 billion in additional payments from GlaxoSmithKline, contingent upon achievement of specified discovery, development, regulatory and commercial milestones across the five therapeutic focus areas of the alliance, as well as stepped double-digit royalties dependent on sales achieved following regulatory approval 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 the Company's revenue recognition policy (see Note 2). The amounts that the Company may receive depends on the success of the Company's research and

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

June 30, 2009

4. Strategic Alliance and Collaboration Agreements (continued)

development activities, the timing and achievement of the discovery, development, regulatory and commercial milestone events and whether GlaxoSmithKline exercises any options that are triggered under the agreement.

In December 2007, the Company received a \$6,000,000 payment from GlaxoSmithKline upon the Company's initiation of a Phase 1 clinical trial of TC-6499, a 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 license fee revenue and is recognizing it into revenue on a straight-line basis over the estimated term 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 June 30, 2009 and 2008 and \$346,000 of the payment as revenue for each of the six-month periods ended June 30, 2009 and 2008.

The Company has received an aggregate of \$4,000,000 in payments from GlaxoSmithKline for achievement of various preclinical milestone events under the agreement, including \$2,500,000 and \$500,000 for the six months ended June 30, 2009 and 2008, respectively. 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 the Company's revenue recognition policy (see Note 2).

5. Subsequent Event

On July 8, 2009, the Company announced that AstraZeneca plans to conduct further development of AZD3480 for ADHD, agreed to make a \$10,000,000 milestone payment to the Company and, for Alzheimer's disease, is prioritizing development of AZD1446 over further development of AZD3480. The Company received the \$10,000,000 milestone payment in July 2009 and, following receipt, recorded a license fee payable of \$350,000 to UKRF. The milestone payment and license fee payable were recorded by the Company in July 2009 and will be reflected in its results of operations for the three months ending September 30, 2009. Subsequent events have been evaluated through August 7, 2009, the date the Company's financial statements as of and for the three and six-month periods ended June 30, 2009 were issued.

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, 2008, 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, 2008, Item 1A of Part II of this quarterly report and other filings that we make with the SEC.

Overview

Background

We are a biopharmaceutical company engaged in the design, discovery and development of NNR Therapeutics, a new class of drugs for the treatment of diseases and disorders primarily of the central 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 a cognition-focused collaboration with AstraZeneca and a strategic alliance with GlaxoSmithKline. Our most advanced product candidates are described below.

- *TC-5214.* TC-5214 is a product candidate that we are developing as an augmentation therapy for major depressive disorder, or MDD. TC-5214, which is the S(+) enantiomer of mecamylamine hydrochloride, is a nicotinic channel blocker that inhibits the activity of a form of the $\alpha 4\beta 2$ NNR and positively modulates the activity of another form of the $\alpha 4\beta 2$ NNR. In July 2009, we announced positive top-line results from a Phase 2b clinical trial of TC-5214 as an augmentation (add-on) treatment in subjects with MDD who did not respond adequately to first-line treatment with citalopram hydrobromide, a selective serotonin reuptake inhibitor marketed as Celexa® in the United States.

In addition, we initiated a Phase 2 exploratory study of TC-5214 as an augmentation treatment for resistant hypertension in the second quarter of 2009. In light of the favorable outcome of the completed MDD trial and slow enrollment in the resistant hypertension study, we have determined to allocate resources to preparation for Phase 3 MDD development of TC-5214 and not to continue the resistant hypertension study.

- *AZD3480 (TC-1734).* AZD3480 is a novel small molecule that acts as an agonist of one or more forms of the $\alpha 4\beta 2$ NNR. We have a collaborative research and license agreement with AstraZeneca AB for the development and worldwide

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commercialization of AZD3480 as a treatment for various conditions characterized by cognitive impairment. In July 2009, following results from a Phase 2 clinical trial of AZD3480 in adults with ADHD in May 2009 and from Phase 2b clinical trials of AZD3480 in mild to moderate Alzheimer's disease and cognitive dysfunction in schizophrenia in the second half of 2008, we announced that AstraZeneca plans to conduct further development of AZD3480 for ADHD.

- *AZD1446 (TC-6683)*. AZD1446 is a novel small molecule that acts as an agonist of one or more forms of the $\alpha 4\beta 2$ NNR and is the most advanced product candidate to arise from our preclinical research collaboration with AstraZeneca described below. AZD1446 is planned for development in Alzheimer's disease and potentially one or more other conditions characterized by cognitive impairment. AstraZeneca is currently conducting Phase 1 clinical development of AZD1446.
- *TC-5619*. TC-5619 is a novel small molecule that we plan to develop for cognitive dysfunction in schizophrenia or potentially one or more other conditions characterized by cognitive impairment. TC-5619 modulates the activity of the $\alpha 7$ NNR. We have completed a Phase 1 single rising dose clinical trial and a Phase 1 multiple rising dose clinical trial of TC-5619 in healthy volunteers. Following our completion of a planned Phase 2 clinical proof of concept trial of TC-5619, AstraZeneca has the right to license TC-5619 on terms specified in our agreement.
- *TC-5685*. TC-5685 is a preclinical product candidate for depression and anxiety disorders. TC-5685 inhibits the activity of one or more forms of the $\alpha 4\beta 2$ NNR and is one of the constituent enantiomers of the racemate TC-2216. We completed a Phase 1 single rising dose clinical trial of TC-2216 in healthy volunteers in the first quarter of 2008. Based on our current budget management plans, we do not expect that we will progress the development of TC-5685 or TC-2216 in 2009. If we elect to continue development in the future, we are likely to elect to develop TC-5685 instead of conducting further clinical development of TC-2216.

Under our collaboration agreement with AstraZeneca, we and AstraZeneca are conducting a preclinical research collaboration that is designed to discover and develop additional compounds that act on the $\alpha 4\beta 2$ NNR as treatments for conditions characterized by cognitive impairment. The preclinical research collaboration has a planned four-year term, which began in January 2006 and is scheduled to expire in January 2010. AstraZeneca pays us research fees, based on a reimbursement rate specified under the agreement, for research services rendered in the preclinical research collaboration, subject to specified limits.

In addition to our collaboration with AstraZeneca, we have a strategic alliance with GlaxoSmithKline that is designed to discover, develop and market product candidates that selectively target specified NNR subtypes in five therapeutic focus areas – smoking cessation, pain, obesity, addiction and Parkinson's disease.

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

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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.

We generated net income for the fourth quarter and year ended December 31, 2006 due primarily to the achievement of a milestone event related to AZD3480 under our agreement with AstraZeneca. Except for these periods, we have never been profitable. As of June 30, 2009, we had an accumulated deficit of \$204.2 million. We expect to incur substantial losses for the foreseeable future as our clinical-stage and preclinical product candidates advance through the development cycle, as we progress our programs in the therapeutic focus areas of our alliance with GlaxoSmithKline and as we invest in additional product opportunities and research programs. 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 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

As of June 30, 2009, we had received \$34.4 million in aggregate upfront fees and milestone payments under our collaboration agreement with AstraZeneca and had recognized an additional \$23.9 million in collaboration research and development revenue for research services that we provided in the preclinical research collaboration that we are conducting with AstraZeneca under the agreement. In July 2009, under an amendment to the agreement, we received a \$10.0 million payment from AstraZeneca as a result of the achievement of the objective in the completed Phase 2 trial of AZD3480 in adults with ADHD. The \$10.0 million payment will be reflected in our results of operations for the three months ending September 30, 2009. As of June 30, 2009, we had also received \$45.0 million in aggregate payments under our alliance agreement with GlaxoSmithKline. We initially deferred recognition of \$41.5 million of the amounts received from AstraZeneca and GlaxoSmithKline and are recognizing such amounts into revenue over the periods discussed in Note 2 and Note 4 to our unaudited financial statements included in this quarterly report. As of June 30, 2009, we had \$27.3 million of these deferred amounts remaining to be recognized in future periods.

We acquired rights to Inversine in August 2002. Inversine is our only product approved for marketing by the U.S. Food and Drug Administration, or FDA. Inversine is approved for the management of moderately severe to severe essential hypertension and in uncomplicated cases of malignant hypertension, which are high blood pressure disorders. Sales of Inversine generated net revenue of \$104,000 and \$199,000 for the three months ended June 30, 2009 and 2008, respectively, and \$355,000 and \$387,000 for the six months ended June 30, 2009 and 2008, respectively. We instituted a price increase of 19% for Inversine at the beginning of 2009 and a price increase of 62% for Inversine at the beginning of 2008 to help offset the impact of increased cost of product sales resulting primarily from FDA product and establishment fees. We experienced decreased sales volume during 2008 and through June 30, 2009. Product sales of Inversine resulted in a net loss of \$130,000 for the six months ended June 30, 2009 and \$31,000 for the year ended December 31, 2008. As a result of increased FDA fees and declining prescriptions for Inversine in recent years, we notified the FDA in March 2009 that we will discontinue Inversine effective as of September 30, 2009. Because we have no further plans to

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manufacture Inversine, we recorded a charge of \$52,000 in cost of product sales related to the impairment of our raw materials inventory during the three months ended June 30, 2009. We do not expect the discontinuation of Inversine to have a material impact on our cash flows or results of operations in future periods.

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 June 30, 2009, 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 expect to receive approximately \$1.1 million in the aggregate over a five-year period 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.

In July 2009, we were awarded a grant from The Michael J. Fox Foundation for Parkinson's Research. The grant is designed to fund preclinical research involving the use of compounds that modulate NNRs to address Levodopa-induced abnormal involuntary movements, known as dyskinesias. The terms of the award provide for us to receive \$641,000 in aggregate payments as we conduct the funded research over an expected period of one year.

A substantial portion of our revenue depends on the successful achievement of milestone events under our agreements with AstraZeneca and GlaxoSmithKline. Our revenue may vary substantially from quarter to quarter and year to year.

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 87% and 84% of our total operating expenses for the three months ended June 30, 2009 and 2008, respectively, and 86% and 83% of our total operating expenses for the six months ended June 30, 2009 and 2008, 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 the preclinical or clinical development of a particular product candidate, the estimated completion date is largely under the control of that third party and not under our control. We cannot forecast with certainty whether AstraZeneca or GlaxoSmithKline will exercise any options to license particular product candidates that become exercisable under the terms of our respective agreements, which of our product candidates, if any, 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, accounting, business development, legal and human resource functions. Other general and administrative expenses include expenses associated with stock options and other stock-based awards 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 recognized an income tax benefit of \$73,000 for the six months ended June 30, 2009 as a result of our election to forgo certain “bonus depreciation” for federal income tax purposes in exchange for a refundable research and development tax credit provided initially under the Housing Assistance Tax Act of 2008 and extended by the American Recovery and Reinvestment Act of 2009.

We generated net income for the three months and year ended December 31, 2006 primarily due to the achievement of a milestone event related to AZD3480 under our agreement with AstraZeneca. We have incurred net operating losses for each other period since inception and consequently have not paid federal, state or foreign income taxes in any period. As of June 30, 2009, we had net operating loss carryforwards of \$128.7 million for federal income tax purposes and \$128.6 million for state income tax purposes. The federal net operating loss carryforwards begin to expire in 2020. The state net operating loss carryforwards begin to expire in 2015. We also had \$6.0 million in research and development federal income tax credits as of June 30, 2009. The federal research and development tax credits begin to expire in 2023. 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 and a portion of the net operating loss carryforwards described above may potentially not be usable by us. We could experience additional 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 because realization of the benefit is uncertain.

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Fair Value

The carrying amounts of our cash and cash equivalents, short-term investments, accounts receivable, accounts payable, accrued expenses and long-term debt are considered to be representative of their respective fair values due to the short-term nature of our cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses and the market interest rates of our short-term investments and long-term debt. Our short-term investments in certificates of deposit of \$27.2 million at June 30, 2009 are recorded at quoted prices of an active market.

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, 2008 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, 2008.

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Results of Operations

Three Months ended June 30, 2009 and 2008

Net Operating Revenues

| | <u>Three Months ended June 30,</u> | | <u>Change</u> |
|---|------------------------------------|-----------------|------------------|
| | <u>2009</u> | <u>2008</u> | |
| | | (in thousands) | |
| Operating revenues: | | | |
| Collaboration research and development | \$ 1,121 | \$ 2,637 | \$(1,516) |
| Milestones and license fees from collaborations | 1,605 | 2,320 | (715) |
| Product sales, net | 104 | 199 | (95) |
| Grant revenue | — | — | — |
| Net operating revenues | <u>\$ 2,830</u> | <u>\$ 5,156</u> | <u>\$(2,326)</u> |

Net operating revenues for the three months ended June 30, 2009 decreased by \$2.3 million as compared to the three months ended June 30, 2008. The lower net operating revenues for the 2009 period as compared to the 2008 period were principally attributable to a decrease of \$1.5 million in collaboration research and development revenue and a decrease of \$715,000 in milestones and license fees from collaborations revenue. The decrease in collaboration research and development revenue for the 2009 period reflects reduced services rendered by us in our preclinical research collaboration with AstraZeneca as a result of progress previously made towards meeting the objectives of the research plan. We expect collaboration research and development revenue for future 2009 periods to continue to be lower than the corresponding 2008 periods. The preclinical research collaboration with AstraZeneca is scheduled to expire in January 2010.

The decrease in milestones and license fees from collaborations revenue for the 2009 period was principally attributable to the timing of our achievement of milestone events under our alliance agreement with GlaxoSmithKline related to progress in preclinical programs, as well as recognition of less deferred license fee revenue. We recognized less deferred license fee revenue for the 2009 period as a result of an extension of the estimated development period for AZD3480, based on AstraZeneca's plans to conduct further Phase 2 clinical development prior to the planned initiation of Phase 3 clinical development, and an extension of the estimated development period for TC-5619 to reach Phase 2 clinical proof of concept.

Research and Development Expenses

| | <u>Three Months ended June 30,</u> | | <u>Change</u> |
|-----------------------------------|------------------------------------|----------------|---------------|
| | <u>2009</u> | <u>2008</u> | |
| | | (in thousands) | |
| Research and development expenses | \$ 11,049 | \$ 10,518 | \$ 531 |

Research and development expenses for the three months ended June 30, 2009 increased by \$531,000 as compared to the three months ended June 30, 2008. The higher research and development expenses were principally attributable to an increase of \$596,000 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 \$3.2 million for the 2009 period, from \$2.6 million for the 2008 period. The increase was primarily due to

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costs associated with the conduct of the Phase 2b clinical trial of TC-5214 as an augmentation therapy for MDD, which we initiated in July 2008. The higher research and development expenses were also attributable to an increase of \$215,000 in costs incurred for third-party research and development services in connection with our preclinical programs, primarily in the therapeutic focus areas of our alliance with GlaxoSmithKline, to \$1.7 million for the 2009 period, from \$1.4 million for the 2008 period. These increases were partially offset by a decrease of \$280,000 in supply and other non-program specific research and development costs resulting from planned budget reductions.

The costs that we incurred for the three-month periods ended June 30, 2009 and 2008 for third-party research and development services in connection with clinical-stage product candidates are shown in the table below:

| | <u>Three months ended June 30,</u> | | <u>Change</u> |
|-------------------|------------------------------------|-------------|---------------|
| | <u>2009</u> | <u>2008</u> | |
| | (in thousands) | | |
| TC-5214 | \$ 2,025 | \$ 1,106 | \$ 919 |
| TC-5619 | 687 | 614 | 73 |
| AZD3480 (TC-1734) | 191 | 133 | 58 |

In addition to the product candidates shown in the table above, for the three months ended June 30, 2009 and 2008, we incurred \$254,000 and \$707,000, respectively, in expenses for third-party research and development services in connection with TC-2696, TC-6499 and TC-2216, which are clinical-stage compounds for which we have either terminated development or are not currently progressing. AstraZeneca is responsible for funding all future development costs for AZD3480 and AZD1446.

General and Administrative Expenses

| | <u>Three months ended June 30,</u> | | <u>Change</u> |
|-------------------------------------|------------------------------------|-------------|---------------|
| | <u>2009</u> | <u>2008</u> | |
| | (in thousands) | | |
| General and administrative expenses | \$ 1,377 | \$ 1,894 | \$ (517) |

General and administrative expenses for the three months ended June 30, 2009 decreased by \$517,000 as compared to the three months ended June 30, 2008. The lower general and administrative expenses were principally attributable to decreases in professional fees, patent-related costs and travel-related expenses.

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Interest Income and Interest Expense

| | <u>Three months ended June 30,</u> | | <u>Change</u> |
|------------------|------------------------------------|----------------|---------------|
| | <u>2009</u> | <u>2008</u> | |
| | | (in thousands) | |
| Interest income | \$ 258 | \$ 700 | \$ (442) |
| Interest expense | 57 | 69 | (12) |

Interest income for the three months ended June 30, 2009 decreased by \$442,000 as compared to the three months ended June 30, 2008. The decrease was attributable to lower short-term interest rates and a lower average cash and investment balance during the 2009 period. Interest expense for the three months ended June 30, 2009 decreased by \$12,000 as compared to the three months ended June 30, 2008.

Six Months ended June 30, 2009 and 2008

Net Operating Revenues

| | <u>Six Months ended June 30,</u> | | <u>Change</u> |
|---|----------------------------------|-----------------|-----------------|
| | <u>2009</u> | <u>2008</u> | |
| | | (in thousands) | |
| Operating revenues: | | | |
| Collaboration research and development | \$ 2,665 | \$ 4,895 | \$(2,230) |
| Milestones and license fees from collaborations | 5,725 | 3,939 | 1,786 |
| Product sales, net | 355 | 387 | (32) |
| Grant revenue | 226 | 211 | 15 |
| Net operating revenues | <u>\$ 8,971</u> | <u>\$ 9,432</u> | <u>\$ (461)</u> |

Net operating revenues for the six months ended June 30, 2009 decreased by \$461,000 as compared to the six months ended June 30, 2008. The lower net operating revenues for the 2009 period were primarily attributable to a decrease of \$2.2 million in collaboration research and development revenue, partially offset by an increase of \$1.8 million in milestones and license fees from collaborations revenue. The decrease in collaboration research and development revenue for the 2009 period reflects reduced services rendered by us in our preclinical research collaboration with AstraZeneca as a result of progress previously made towards meeting the objectives of the research plan. The increase in milestones and license fees from collaborations revenue reflects an increase of \$2.0 million to \$2.5 million for the 2009 period, from \$500,000 for the 2008 period, in aggregate payments that became payable from GlaxoSmithKline upon achievement of milestone events under our alliance agreement related to progress in preclinical programs, partially offset by recognition of less deferred license fee revenue as a result of an extension of the estimated development period for AZD3480 and an extension of the estimated development period for TC-5619 to reach Phase 2 clinical proof of concept.

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Research and Development Expenses

| | <u>Six Months ended June 30,</u> | | <u>Change</u> |
|-----------------------------------|----------------------------------|-------------|---------------|
| | <u>2009</u> | <u>2008</u> | |
| | <u>(in thousands)</u> | | |
| Research and development expenses | \$ 20,544 | \$ 19,599 | \$ 945 |

Research and development expenses for the six months ended June 30, 2009 increased by \$945,000 as compared to the six months ended June 30, 2008. The higher research and development expenses were principally attributable to an increase of \$800,000 in costs incurred for third-party research and development services in connection with our preclinical programs, primarily in the therapeutic focus areas of our alliance with GlaxoSmithKline, to \$2.8 million for the 2009 period, from \$2.0 million for the 2008 period and an increase of \$379,000 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 \$5.4 million for the 2009 period, from \$5.0 million for the 2008 period. The higher costs incurred for third-party research and development services in connection with our clinical-stage product candidates were primarily due to costs associated with the conduct of the Phase 2b clinical trial of TC-5214 as an augmentation therapy for MDD. These increases were partially offset by a decrease of \$234,000 in supply and other non-program specific research and development costs resulting from planned budget reductions.

The costs that we incurred for the six-month periods ended June 30, 2009 and 2008 for third-party research and development services in connection with clinical-stage product candidates are shown in the table below:

| | <u>Six months ended June 30,</u> | | <u>Change</u> |
|-------------------|----------------------------------|-------------|---------------|
| | <u>2009</u> | <u>2008</u> | |
| | <u>(in thousands)</u> | | |
| TC-5214 | \$ 3,368 | \$ 1,870 | \$1,498 |
| TC-5619 | 1,566 | 1,636 | (70) |
| AZD3480 (TC-1734) | 208 | 135 | 73 |

In addition to the product candidates shown in the table above, for the six months ended June 30, 2009 and 2008, we incurred \$234,000 and \$1.4 million, respectively, in expenses for third-party research and development services in connection with TC-2696, TC-6499 and TC-2216.

General and Administrative Expenses

| | <u>Six months ended June 30,</u> | | <u>Change</u> |
|-------------------------------------|----------------------------------|-------------|---------------|
| | <u>2009</u> | <u>2008</u> | |
| | <u>(in thousands)</u> | | |
| General and administrative expenses | \$ 2,848 | \$ 3,585 | \$ (737) |

General and administrative expenses for the six months ended June 30, 2009 decreased by \$737,000 as compared to the six months ended June 30, 2008. The lower general and administrative expenses were principally attributable to decreases in professional fees, patent-related costs and travel-related expenses.

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Interest Income and Interest Expense

| | <u>Six months ended June 30,</u> | | <u>Change</u> |
|------------------|----------------------------------|--------------------------------------|---------------|
| | <u>2009</u> | <u>2008</u> <u>(in thousands)</u> | |
| Interest income | \$ 620 | \$ 1,669 | \$(1,049) |
| Interest expense | 117 | 120 | (3) |

Interest income for the six months ended June 30, 2009 decreased by \$1.0 million as compared to the six months ended June 30, 2008. The decrease was attributable to lower short-term interest rates and a lower average cash and investment balance during the 2009 period. Interest expense for the three months ended June 30, 2009 decreased by \$3,000 as compared to the three months ended June 30, 2008.

Liquidity and Capital Resources

Sources of Liquidity

In July 2009, after the end of the second quarter ended June 30, 2009, we received a \$10.0 million payment from AstraZeneca as a result of the achievement of the objective in the completed Phase 2 trial of AZD3480 in adults with ADHD, a milestone event under an amendment to our collaboration agreement. We also received a \$200,000 payment from AstraZeneca in June 2009 upon achievement of a milestone event under our collaboration agreement related to progress of a compound arising in our preclinical research collaboration. In addition, we received a \$2.0 million payment in April 2009 and a \$500,000 payment in March 2009 from GlaxoSmithKline upon achievement of milestone events under our alliance agreement related to progress in preclinical programs.

We made our final monthly payment of \$23,000 on a loan facility that we had with R.J. Reynolds Tobacco Holdings, Inc., or RJRT, on the maturity date of January 1, 2009.

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 RJRT. 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. 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. We used \$1.7 million of the proceeds from the March 2008 loan to pay and satisfy in full the principal and interest outstanding on two of the tranches under the loan facility with RJRT and granted a first priority security interest in favor of the bank in assets previously acquired with the proceeds of those tranches. 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 June 30, 2009, the outstanding principal balance under the loan facility was \$3.8 million. There is no additional borrowing capacity remaining available to us under the loan agreement.

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As a result of increased FDA fees and declining prescriptions for Inversine in recent years, we notified the FDA in March 2009 that we will discontinue Inversine effective as of September 30, 2009. The net contribution from Inversine sales has not historically been a significant source of cash.

Our cash, cash equivalents and short-term investments were \$73.1 million as of June 30, 2009 and \$88.4 million as of December 31, 2008. As of June 30, 2009, substantially all of our cash, cash equivalents and short-term investments were invested in bank depository accounts, certificates of deposit, and institutional money market funds at Branch Banking and Trust Company, RBC Bank and Evergreen Investments, which is affiliated with Wells Fargo & Company. Approximately 90% of our \$17.1 million invested in institutional money market funds as of June 30, 2009 were invested in funds that invest 100% in U.S. Treasury bills and notes. In addition, our investments in Evergreen money market funds are currently subject to the U.S. Treasury Department's Temporary Guarantee Program for Money Market Funds initiated in September 2008. The program is expected to be in effect through September 18, 2009, at which time the Secretary of the Treasury is expected to review the need and terms for the program. There is no assurance that the program will continue through any particular date.

Cash Flows

| | <u>Six Months ended June 30,</u> | | <u>Change</u> |
|--|----------------------------------|-------------------------------|---------------|
| | <u>2009</u> | <u>2008</u> (in thousands) | |
| Net cash used in operating activities | \$ (14,509) | \$ (15,141) | \$ 632 |
| Net cash provided by (used in) investing activities | 9,878 | (5,625) | 15,503 |
| Net cash (used in) provided by financing activities | (652) | 31,729 | (32,381) |
| Net (decrease) increase in cash and cash equivalents | <u>\$ (5,283)</u> | <u>\$ 10,963</u> | |

Net cash used in operating activities for the six months ended June 30, 2009 decreased by \$632,000 as compared to the six months ended June 30, 2008. Our net loss increased by \$1.7 million for the six months ended June 30, 2009 to \$14.3 million, from \$12.6 million for the six months ended June 30, 2008. This increased net loss was:

- supplemented by a difference of \$971,000 in the change in our collaboration revenue and accounts receivable balance for the six months ended June 30, 2009 (a decrease of \$386,000) as compared to the change in our collaboration revenue and accounts receivable balance for the three months ended June 30, 2008 (a decrease of \$1.4 million), primarily as a result of the timing of our achievement of milestone events and receipt of the associated payments from GlaxoSmithKline and AstraZeneca;
- partially offset by a difference of \$2.0 million in the change in accounts payable and accrued expenses for the six months ended June 30, 2009 (an increase of \$380,000) as compared to the change in accounts payable and accrued expenses for the six months ended June 30, 2008 (a decrease of \$1.6 million), which was principally attributable to the timing of third-party research and development services and lower employee bonuses paid in January 2009 than in January 2008;

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- partially offset by a difference of \$906,000 in the change in our prepaid expenses and accrued interest receivable balance for the six months ended June 30, 2009 (an increase of \$61,000) as compared to the change in our prepaid expenses and accrued interest receivable balance for the six months ended June 30, 2008 (an increase of \$967,000), which was primarily attributable to the timing of nonrefundable advance payments made for research and development services and the timing of performance of the services; and
- partially offset by a decrease of \$214,000 in recognition of deferred license fee revenue to \$3.0 million for the six months ended June 30, 2009 from \$3.2 million for the six months ended June 30, 2008 as a result of an extension of the estimated development periods for AZD3480 and for TC-5619 to reach Phase 2 clinical proof of concept.

Net cash provided by investing activities for the six months ended June 30, 2009 was \$9.9 million as compared to net cash used in investing activities for the six months ended June 30, 2008 of \$5.6 million, a change of \$15.5 million. Cash provided by (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. The net sales of our investments for the six months ended June 30, 2009 were \$10.0 million. The net purchases of our investments for the six months ended June 30, 2008 were \$3.9 million and occurred primarily upon our receipt of proceeds from a public stock offering that we completed in January 2008. Additionally, we purchased \$122,000 of property and equipment for the six months ended June 30, 2009, a decrease of \$1.6 million from \$1.8 million in property and equipment purchases for the six months ended June 30, 2008.

Net cash used in financing activities for the six months ended June 30, 2009 was \$652,000 and net cash provided by financing activities for the six months ended June 30, 2008 was \$31.7 million, a difference of \$32.4 million. The change was principally attributable to our receipt of \$29.1 million in net proceeds from a public stock offering that we completed in January 2008 and a difference of \$3.2 million in proceeds from borrowings under our loan facilities, net of payments, for the six months ended June 30, 2009 as compared to the six months ended June 30, 2008.

Funding Requirements

As of June 30, 2009, we had an accumulated deficit of \$204.2 million. We expect to incur substantial operating losses for the foreseeable future. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- whether we conduct Phase 3 clinical development of TC-5214 without having established a strategic alliance, collaboration, licensing or other arrangement with respect to TC-5214;
- our ability to establish additional strategic alliances, collaborations and licensing or other arrangements with third parties on terms favorable to us;
- the extent to which we retain development or commercialization rights or responsibilities for our product candidates that are not subject to our collaboration with AstraZeneca or our alliance with GlaxoSmithKline and incur associated development costs, manufacturing costs or costs to establish sales and marketing functions;

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- the scope, progress, duration, results and cost of clinical trials, as well as non-clinical studies and assessments, of our product candidates;
- the timing, receipt and amount of milestone and other payments from AstraZeneca, GlaxoSmithKline and potential future collaborators;
- the extent to which our research and development activities in the programs that are the therapeutic focus areas of our alliance with GlaxoSmithKline result in the achievement of milestone events under our alliance agreement;
- the duration of our preclinical research collaboration with AstraZeneca;
- 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 intellectual property-related claims;
- 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.

We anticipate that implementing our strategy will require substantial additional capital as our clinical-stage and preclinical product candidates advance into later-stage development, as we progress our programs in the therapeutic focus areas of our alliance with GlaxoSmithKline and as we invest in additional product opportunities and research programs. We do not expect our existing capital resources to be sufficient to enable us to fund the completion of the 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 first half of 2011. Our expectation does not take into account any amounts that we would be entitled to receive if clinical development milestone events are achieved under our agreement with AstraZeneca or our agreement with GlaxoSmithKline, does not take into account any amounts that we might receive in the future if we were to establish a strategic alliance, collaboration or licensing or other arrangement with respect to TC-5214 and assumes that the funds required for Phase 3 clinical development of TC-5214 would be obtained through a potential future strategic alliance, collaboration, licensing or other arrangement with respect to TC-5214. 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.

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We do not expect to generate sufficient cash from our operations to sustain our business for the foreseeable future. We expect our continuing operating losses to result in increases in our cash required to fund operations over the next several quarters and years. To the extent our capital resources are insufficient to meet future capital requirements, we will need to finance future cash needs through alliances, collaborations or licensing arrangements, public or private equity or debt offerings or other financings. The global credit and financial markets have recently experienced a period of unusual volatility and illiquidity. 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 accurately determine 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 to complete our research and development projects could have a material adverse effect on our financial position or results of operations.

Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standard No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles - a replacement of FASB Statement No. 162*, or SFAS 168. SFAS 168 replaces SFAS No. 162 and establishes *The FASB Accounting Standards Codification* as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with U.S. generally accepted accounting principles. SFAS 168 is effective for financial statements issued for periods ending after September 15, 2009. We do not expect SFAS 168 to have a material impact on our financial results.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities that are of high credit quality. Our investments are typically short term in nature. As of June 30, 2009, we had cash, cash equivalents and short-term investments of \$73.1 million. Our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are short term in duration, 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 June 30, 2009 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 June 30, 2009, 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 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 June 30, 2009 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors.

Regulatory authorities may require more data for any of our product candidates than we currently anticipate, which could cause us to incur additional costs, extend our development timelines or delay our receipt of any revenue from potential product sales.

The FDA or other applicable regulatory authorities may require more preclinical or clinical data for any of our product candidates or more time to evaluate that data than we currently anticipate because drugs that act on NNRs are not a well established class of drugs or because of experiences with drugs that act on NNRs that are developed or marketed by third parties. In particular, in February 2008, the FDA issued a public health advisory with regard to Pfizer's aid to smoking cessation product, Chantix. In July 2009, the FDA announced that it would require each of Chantix and Zyban, which is GlaxoSmithKline's aid to smoking cessation product, to include a boxed warning on its prescribing information. The warning makes more prominent the risk of serious mental health events, including changes in behavior, depressed mood, hostility, agitation and suicide-related events, that have been reported in some patients attempting to quit smoking while taking these drugs. The warning also states that the health benefits of quitting smoking are immediate and substantial and that the risks of the drug should be weighed against the benefits of use. Chantix acts on several NNR subtypes, as well as other molecular targets in the body. All of our product candidates currently in development affect the activity of one or more NNR subtypes. If the FDA or any foreign regulatory authority determines that any adverse medical experiences associated with Chantix have relevance to one or more of our product candidates, it may require us or a collaborator of ours to generate more clinical data than we currently anticipate to establish the safety of the affected product candidate, which could increase the cost of the development program for the affected product candidate, extend the development timeline for the affected product candidate or delay our receipt of revenue from potential product sales of the affected product candidate.

Item 4. Submission of Matters to a Vote of Security Holders

The following matters were submitted to a vote of our stockholders at our 2009 Annual Meeting of Stockholders held on June 10, 2009 and approved by the requisite vote of our stockholders as follows:

1. Election of G. Steven Burrill, Errol B. De Souza, Ph.D. and Mark Skaletsky to our board of directors as Class III directors to serve for a term to expire at the 2012 annual meeting of stockholders, with each director to hold office until his successor is duly elected and qualified or until his earlier death, retirement, resignation or removal.

| <u>Nominee</u> | <u>Number of Shares</u> | |
|--------------------------|-------------------------|-----------------|
| | <u>For</u> | <u>Withheld</u> |
| G. Steven Burrill | 22,756,659 | 64,505 |
| Errol B. De Souza, Ph.D. | 22,784,041 | 37,123 |
| Mark Skaletsky | 22,574,193 | 246,971 |

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2. Approval of (a) the amendment of the Targacept, Inc. 2006 Stock Incentive Plan to increase the number of available shares and (b) certain terms of the Targacept, Inc. 2006 Stock Incentive Plan for purposes of Section 162(m) of the Internal Revenue Code of 1986, as amended.

| <u>For</u> | <u>Number of Shares</u> | | <u>Broker Non-Votes</u> |
|------------|-------------------------|----------------|-------------------------|
| | <u>Against</u> | <u>Abstain</u> | |
| 15,446,852 | 3,021,475 | 2,051,735 | 2,301,102 |

3. Ratification of the appointment of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2009.

| <u>For</u> | <u>Against</u> | <u>Abstain</u> |
|------------|----------------|----------------|
| 22,805,519 | 14,411 | 1,232 |

There were 24,965,173 shares of our common stock outstanding as of the record date of April 15, 2009 and eligible to be voted at the meeting.

Item 6. Exhibits

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

Our trademarks include Targacept®, Inversine®, Pentad™, NNR Therapeutics™, TRIDMAC™ and AMPLIXA™. 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: August 7, 2009

/s/ J. Donald deBethizy

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

Date: August 7, 2009

/s/ Alan A. Musso

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

EXHIBIT INDEX

| Exhibit Number | Description |
|-----------------------|---|
| 10.1 | Targacept, Inc. 2006 Stock Incentive Plan, as amended and restated through November 28, 2007 and further amended effective June 10, 2009 (incorporated by reference to Exhibit 99 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 30, 2009 (Registration No. 333-160331)). |
| 10.2 | Letter, dated June 2, 2009, regarding Asset Purchase and Trademark Assignment Agreement, dated March 19, 1998, by and between the Company (as assignee of Layton Bioscience, Inc.) and Merck & Co., Inc. |
| 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. |

[Targacept Letterhead]

May 27, 2009

VIA EMAIL AND U.S. MAIL

Merck & Co., Inc.
Sumneytown Pike
West Point, Pennsylvania 19486
Attn: Larry Senour

Re: *Discontinuation of Inversine® by Targacept*

Dear Mr. Senour:

Reference is made to the Asset Purchase and Trademark Assignment Agreement between Merck & Co., Inc. ("Merck") and, as assignee of Layton Bioscience, Inc., Targacept, Inc. ("Targacept") dated March 19, 1998 (the "Agreement"). Capitalized terms used herein and not otherwise defined shall have the meanings given to them in the Agreement.

Merck understands that Targacept intends (1) that its product Inversine® (NDA #10-251) be identified in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations as a discontinued drug product and (2) to discontinue manufacture of Inversine®, in each case effective as of September 30, 2009 (together, the "Discontinuation"). By the signature of their respective authorized representatives below:

A. Merck hereby: (1) acknowledges and agrees that neither element of the Discontinuation nor any necessary or appropriate action or inaction arising from the Discontinuation shall constitute an Event of Default or otherwise constitute a breach or violation of the Agreement; and (2) confirms that, as of the date of this letter, two (2) Royalty Payments remain to be paid under Section 2.3(a)(ii) of the Agreement, for the Payment Years running from May 1, 2008 through April 30, 2009 ("Payment Year 9") and May 1, 2009 through April 30, 2010 ("Payment Year 10"), and that, upon payment in full by Targacept of the Royalty Payments with respect to Payment Year 9 and Payment Year 10, Targacept shall have no further payment obligation to Merck under the Agreement;

B. Merck and Targacept hereby agree that, solely for purposes of applying Section 2.3(a)(ii)(B) of the Agreement with respect to Payment Year 10 and for no other purpose, Net Sales shall equal the sum of (i) Net Sales for the portion of Payment Year 10 ending September 30, 2009 plus (ii) the average monthly Net Sales for the twenty-four months ending April 30, 2009 multiplied by seven (7); and

C. Targacept hereby agrees to pay the Royalty Payment with respect to Payment Year 10 prior to the end of 2009.

Please indicate your agreement with the foregoing by signing one of the enclosed originals of this letter and returning it to my attention.

Sincerely,

/s/ Jeffrey P. Brennan

Jeffrey P. Brennan
Vice President, Business and
Commercial Development

Acknowledged and agreed:

Merck & Co., Inc.

By: /s/ Robert A. McMahon

Name: Robert A. McMahon

Title: President, US Commercial Operations

Date: Jun 2, 2009

cc: Beth Fordham-Meier
Scott N. Cullison
Peter A. Zorn, Esq.

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: August 7, 2009

/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: August 7, 2009

/s/ Alan A. Musso

Alan A. Musso

Vice President, 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 June 30, 2009 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: August 7, 2009

/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 June 30, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Alan A. Musso, Vice President, 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: August 7, 2009

/s/ Alan A. Musso

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