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

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**FORM 10-Q**

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

For The Quarterly Period Ended September 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

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**Targacept, Inc.**

(Exact Name of Registrant as Specified in its Charter)

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**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

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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 October 31, 2009, the registrant had 27,700,519 shares of common stock, \$0.001 par value per share, outstanding.

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**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 effect of the discontinuation of the sale of Inversine® on our financial results; 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 reliance on third parties for the manufacture of clinical trial material for future development of TC-5214; 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; the timing of discussions with regulatory authorities 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 subsequently filed Quarterly Reports on Form 10-Q 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.

**Item 1. Financial Statements**

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

	September 30, 2009 (unaudited)	December 31, 2008
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 48,229	\$ 51,202
Short-term investments	27,082	37,161
Collaboration revenue and accounts receivable	1,761	2,073
Inventories	—	100
Prepaid expenses	1,502	1,430
Total current assets	78,574	91,966
Property and equipment, net	5,175	6,401
Intangible assets, net of accumulated amortization of \$125 and \$112 at September 30, 2009 and December 31, 2008, respectively	171	184
Total assets	<u>\$ 83,920</u>	<u>\$ 98,551</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,101	\$ 1,500
Accrued expenses	4,922	4,381
Current portion of long-term debt	1,423	1,390
Current portion of deferred rent incentive	42	42
Current portion of deferred revenues	5,053	6,479
Total current liabilities	13,541	13,792
Long-term debt, net of current portion	2,333	3,408
Deferred rent incentive, net of current portion	77	109
Deferred revenues, net of current portion	21,129	23,869
Total liabilities	37,080	41,178
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value, 100,000,000 shares authorized at September 30, 2009 and December 31, 2008 and 25,281,539 and 24,964,373 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively	25	25
Capital in excess of par value	249,708	247,244
Accumulated deficit	(202,893)	(189,896)
Total stockholders' equity	46,840	57,373
Total liabilities and stockholders' equity	<u>\$ 83,920</u>	<u>\$ 98,551</u>

See accompanying notes.

**TARGACEPT, INC.**  
**STATEMENT OF OPERATIONS**  
**(in thousands, except share and per share amounts**  
**(unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
<b>Operating revenues:</b>				
Collaboration research and development	\$ 1,059	\$ 2,352	\$ 3,724	\$ 7,246
Milestones and license fees from collaborations	11,405	1,620	17,131	5,559
Product sales, net	118	164	473	551
Grant revenue	81	—	306	211
Net operating revenues	<u>12,663</u>	<u>4,136</u>	<u>21,634</u>	<u>13,567</u>
<b>Operating expenses:</b>				
Research and development (including stock-based compensation of \$320 and \$270 for the three months ended September 30, 2009 and 2008, respectively, and \$900 and \$824 for the nine months ended September 30, 2009 and 2008, respectively)	9,625	10,717	30,169	30,316
General and administrative (including stock-based compensation of \$233 and \$223 for the three months ended September 30, 2009 and 2008, respectively, and \$799 and \$695 for the nine months ended September 30, 2009 and 2008, respectively)	1,628	1,397	4,477	4,982
Cost of product sales	206	184	691	565
Total operating expenses	<u>11,459</u>	<u>12,298</u>	<u>35,337</u>	<u>35,863</u>
Income (loss) from operations	1,204	(8,162)	(13,703)	(22,296)
<b>Other income (expense):</b>				
Interest income	173	579	793	2,248
Interest expense	(53)	(65)	(170)	(184)
Total other income (expense)	<u>120</u>	<u>514</u>	<u>623</u>	<u>2,064</u>
Income (loss) before provision for income taxes	1,324	(7,648)	(13,080)	(20,232)
Income tax benefit	10	—	83	—
Net income (loss)	<u>\$ 1,334</u>	<u>\$ (7,648)</u>	<u>\$ (12,997)</u>	<u>\$ (20,232)</u>
Basic net income (loss) per share	<u>\$ 0.05</u>	<u>\$ (0.31)</u>	<u>\$ (0.52)</u>	<u>\$ (0.82)</u>
Diluted net income (loss) per share	<u>\$ 0.05</u>	<u>\$ (0.31)</u>	<u>\$ (0.52)</u>	<u>\$ (0.82)</u>
Weighted average common shares outstanding—basic	<u>25,126,823</u>	<u>24,945,523</u>	<u>25,019,953</u>	<u>24,563,371</u>
Weighted average common shares outstanding—diluted	<u>26,943,535</u>	<u>24,945,523</u>	<u>25,019,953</u>	<u>24,563,371</u>

See accompanying notes.

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

	Nine Months Ended	
	September 30,	
	2009	2008
<b>Operating activities</b>		
Net loss	\$(12,997)	\$(20,232)
Adjustments to reconcile net loss to net cash used in operating activities:		
Recognition of deferred revenues	(4,487)	(4,859)
Depreciation and amortization	1,391	1,312
Stock-based compensation expense	1,699	1,520
Recognition of deferred rent incentive	(32)	(32)
Impairment of inventory	77	—
Changes in operating assets and liabilities:		
Collaboration revenue and accounts receivable	312	1,353
Inventories	23	31
Prepaid expenses and accrued interest receivable	7	(1,039)
Accounts payable and accrued expenses	1,142	(1,487)
Deferred revenues	321	—
Net cash used in operating activities	<u>(12,544)</u>	<u>(23,433)</u>
<b>Investing activities</b>		
Purchase of investments	(31,000)	(86,800)
Proceeds from sale of investments	41,000	88,297
Purchase of property and equipment	(152)	(1,944)
Net cash provided by (used in) investing activities	<u>9,848</u>	<u>(447)</u>
<b>Financing activities</b>		
Proceeds from issuance of long-term debt	—	5,300
Principal payments on long-term debt	(1,042)	(2,705)
Proceeds from issuance of common stock	765	29,384
Net cash (used in) provided by financing activities	<u>(277)</u>	<u>31,979</u>
Net (decrease) increase in cash and cash equivalents	(2,973)	8,099
Cash and cash equivalents at beginning of period	51,202	53,403
Cash and cash equivalents at end of period	<u>\$ 48,229</u>	<u>\$ 61,502</u>

See accompanying notes.

**TARGACEPT, INC.**  
**NOTES TO UNAUDITED FINANCIAL STATEMENTS**  
**September 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 nine months ended September 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 Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 820, *Fair Value Measurements and Disclosures*, or ASC 820, for application to financial assets. ASC 820 defines fair value, provides a consistent framework for measuring fair value under GAAP and expands fair value financial statement disclosure requirements. ASC 820 does not require any new fair value measurements, but applies only to accounting standards that already require or permit fair value measurements (except for standards that relate to share-based payments such as ASC Topic 718, *Compensation – Stock Compensation*).

**TARGACEPT, INC.**  
**NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)**  
**September 30, 2009**

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

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

*Level 1 Inputs*— Quoted prices 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 September 30, 2009, the Company had \$27,082,000 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 first half of 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 ASC 820. 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 ASC 820 had no effect on the valuation of the Company's available-for-sale marketable securities as of September 30, 2009 or December 31, 2008.

The Company valued non-financial assets as of December 31, 2008 using other accounting standards in accordance with Section 15, *Scope and Scope Exceptions* of Subtopic 10, *Overall*, of ASC 820.



**TARGACEPT, INC.**  
**NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)**  
**September 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 nine months ended September 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 nine months ended September 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 nine months ended September 30, 2009.

***Revenue Recognition***

The Company uses the revenue recognition guidance established by ASC Topic 605, *Revenue Recognition*, or ASC 605. In determining the accounting for collaboration and alliance agreements, the Company follows the provisions of Subtopic 25, *Multiple Element Arrangements*, of ASC 605, or ASC 605-25. ASC 605-25 provides guidance on whether an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes and, if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. If the arrangement constitutes separate units of accounting according to ASC 605-25 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 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)**  
**September 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 Subtopic 45, *Principal Agent Considerations*, of ASC 605. 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. Payments received from grants prior to the Company's performance of the work required by the terms of the award are recorded as deferred revenue and recognized as grant revenue as the Company performs the work and incurs reimbursable costs.

***Income Taxes***

The Company uses the liability method in accounting for income taxes as required by ASC Topic 740, *Income Taxes*, or ASC 740. Under ASC 740, deferred tax assets and liabilities are recorded for operating loss and tax credit carryforwards and for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect 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. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosures and transition. The Company's policy is to classify any interest recognized in accordance with ASC 740 as interest expense and to classify any penalties recognized in accordance with ASC 740 as an expense other than income tax expense.

**TARGACEPT, INC.**  
**NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)**  
**September 30, 2009**

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

Because the Company has incurred cumulative operating 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 for federal income tax purposes under the Housing Assistance Tax Act of 2008, as extended by the American Recovery and Reinvestment Act of 2009, in lieu of claiming “bonus depreciation” and has recognized corresponding income tax benefits of \$10,000 and \$83,000 for the three and nine months ended September 30, 2009, respectively.

**Net Income (Loss) Per Share**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
<b>Basic:</b>				
Net income (loss)	\$ 1,334	\$ (7,648)	\$ (12,997)	\$ (20,232)
Weighted average common shares—basic	25,126,823	24,945,523	25,019,953	24,563,371
Basic EPS	\$ 0.05	\$ (0.31)	\$ (0.52)	\$ (0.82)
<b>Diluted:</b>				
Net income (loss)	\$ 1,334	\$ (7,648)	\$ (12,997)	\$ (20,232)
Weighted average common shares—basic	25,126,823	24,945,523	25,019,953	24,563,371
Common share equivalents	1,816,712	—	—	—
Weighted average common shares—diluted	26,943,535	24,945,523	25,019,953	24,563,371
Diluted EPS	\$ 0.05	\$ (0.31)	\$ (0.52)	\$ (0.82)

Common share equivalents consist of the incremental common shares issuable upon the exercise of stock options calculated using the treasury stock method. The Company has excluded all outstanding stock options from the calculation of Diluted EPS for the three months ended September 30, 2008 and the nine months ended September 30, 2009 and 2008 because their effect is antidilutive. As a result, Diluted EPS is identical to Basic EPS for those periods.

Dilutive outstanding stock options of 3,120,352 for the three months ended September 30, 2008, 3,768,462 for the nine months ended September 30, 2009 and 3,105,025 for the nine months ended September 30, 2008, in each case calculated on a weighted-average basis, may have been included in the calculation of common share equivalents if the Company had been in a net income position for such period.

**TARGACEPT, INC.**  
**NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)**  
**September 30, 2009**

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

***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 314,491 and 317,166 shares of common stock upon the exercise of stock options during the three and nine months ended September 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.

***Comprehensive Income (Loss)***

For each of the three and nine months ended September 30, 2009 and September 30, 2008, the Company's comprehensive income (loss) equaled its reported net income (loss).

***Recent Accounting Pronouncements***

In October 2009, the FASB issued Accounting Standards Update, or ASU, No. 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements—a consensus of the FASB Emerging Issues Task Force*, or ASU 2009-13. ASU 2009-13 addresses the units of accounting for arrangements involving multiple deliverables and how arrangement consideration should be allocated to the separate units of accounting, when applicable. ASU 2009-13 eliminates the criterion in prior accounting guidance that objective and reliable evidence of the fair value of any undelivered items must exist for the delivered items to be considered a separate unit or separate units of accounting. ASU 2009-13 is effective for financial statements issued for fiscal years beginning after June 15, 2010 and can be applied either prospectively or retrospectively for all periods presented. The Company is in the process of determining the impact of ASU 2009-13 on its financial results.

**TARGACEPT, INC.**  
**NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)**  
**September 30, 2009**

**3. Inventories**

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

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

Effective as of September 30, 2009, the Company discontinued its product Inversine. As a result, the Company recorded a charge of \$25,000 related to impairment of its remaining finished goods inventory to cost of product sales for the three months ended September 30, 2009 and aggregate charges of \$77,000 related to the impairment of its remaining raw materials and finished goods inventory to cost of product sales for the nine months ended September 30, 2009. The discontinuation of Inversine did not have a material impact on the Company's cash flows or results of operations for the periods presented, and the Company does not expect the discontinuation of Inversine to have a material impact on its cash flows or results of operations for future periods.

**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

**TARGACEPT, INC.**

**NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)**

**September 30, 2009**

**4. Strategic Alliance and Collaboration Agreements (continued)**

July 2009, the Company announced that it had been informed by AstraZeneca of AstraZeneca's plans to conduct further development of AZD3480 for attention deficit/hyperactivity disorder, or ADHD. The Company extended 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 September 30, 2009 and 2008, respectively, and \$1,477,000 and \$1,688,000 of the initial fee as revenue for the nine months ended September 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 and first commercial sale 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 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 amount was paid to UKRF during the nine months ended September 30, 2009 or the nine months ended September 30, 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 \$1,059,000 and \$2,352,000 for the three months ended September 30, 2009 and 2008, respectively, and \$3,724,000 and \$7,200,000 for the nine months ended September 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 clinical proof of concept 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

**TARGACEPT, INC.**  
**NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)**  
**September 30, 2009**

**4. Strategic Alliance and Collaboration Agreements (continued)**

revenue for the three months ended September 30, 2009 and 2008, respectively, and \$474,000 and \$692,000 of the payment as revenue for the nine months ended September 30, 2009 and 2008, respectively.

The Company received from AstraZeneca a \$10,000,000 payment in July 2009 based on achievement of the objective in a completed Phase 2 clinical trial of AZD3480 in adults with ADHD, a milestone event under an amendment to its agreement. The Company also received from AstraZeneca a \$200,000 payment in June 2009, a \$2,000,000 payment in December 2008 and a \$200,000 payment in May 2008, in each case based on 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 of the payments described in this paragraph 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). The Company has recorded an accrued expense of \$350,000 payable to UKRF in January 2010 based on the \$10,000,000 milestone payment received from AstraZeneca as described above.

***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.

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.

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.

**TARGACEPT, INC.**

**NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)**

**September 30, 2009**

**4. Strategic Alliance and Collaboration Agreements (continued)**

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 September 30, 2009 and 2008 and \$1,960,000 of the initial payment and deemed premium as revenue for each of the nine-month periods ended September 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 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 achievement of a specified milestone event under the agreement. The Company determined the payment did not meet each of the conditions of its revenue recognition policy (see Note 2) required for recognition of the full amount into revenue upon achievement of the milestone. Specifically, based on the progress of this product candidate as of inception of the agreement, achievement of this milestone was reasonably assured within the meaning of the Company's revenue recognition policy. Accordingly, the Company recorded the payment as deferred revenue and is recognizing it into revenue on a straight-line basis over the estimated 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 September 30, 2009 and 2008 and \$519,000 of the payment as revenue for each of the nine-month periods ended September 30, 2009 and 2008.

In addition to the \$6,000,000 payment discussed above, the Company has received an aggregate of \$4,000,000 in payments from GlaxoSmithKline for achievement of various preclinical milestone events under the agreement, including \$2,500,000 and \$500,000 for the nine months ended September 30, 2009 and 2008, respectively. The Company immediately recognized the full amount of each



**TARGACEPT, INC.**  
**NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)**  
**September 30, 2009**

**4. Strategic Alliance and Collaboration Agreements (continued)**

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 October 13, 2009, the Company completed a public offering of 2,200,000 shares of its common stock at a price to the public of \$21.00 per share. The Company's net proceeds from the offering, after deducting underwriters' discounts and commissions and estimated offering expenses payable by the Company, were \$44,364,000. Subsequent events have been evaluated through November 6, 2009, the date the Company's financial statements as of and for the three and nine months ended September 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, subsequently filed Quarterly Reports on Form 10-Q 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 mecamlamine hydrochloride, is a nicotinic channel blocker that has unique properties in modulating forms of the  $\alpha 4\beta 2$  NNR subtype thought to be involved in the increased cholinergic tone associated with depression. In particular, TC-5214 blocks certain NNR channels, which is believed to help normalize cholinergic tone resulting in antidepressant effects. We expect to initiate Phase 3 clinical development of TC-5214 as an augmentation treatment in subjects with MDD in the second quarter of 2010, following planned discussions with the U.S. Food and Drug Administration and the European Medicines Agency and the production of clinical trial material.*
- *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 commercialization of AZD3480 as a treatment for various conditions characterized by cognitive impairment. We or AstraZeneca has completed Phase 2 clinical trials of AZD3480 in various indications characterized by cognitive impairment, and AstraZeneca has informed us of its plans to conduct further development of AZD3480 for attention deficit/hyperactivity disorder, or ADHD, including clinical studies with both younger subjects and adults.

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- *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 has informed us that it has completed Phase 1 single rising dose and Phase 1 multiple rising dose clinical trials of AZD1446 and plans to initiate Phase 2 clinical development in Alzheimer's disease.
- *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. We expect to initiate a Phase 2 clinical proof of concept trial of TC-5619 in cognitive dysfunction in schizophrenia in the fourth quarter of 2009. Following completion of the planned Phase 2 trial, 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 collaboration agreements, grants and equipment and building lease incentive financing. We have devoted substantially all of our resources to the discovery and development of our product candidates and technologies, including the design, conduct and management of preclinical and clinical studies and related manufacturing, regulatory and clinical affairs, as well as intellectual property prosecution.

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We generated net income for the third quarter ended September 30, 2009 and for the fourth quarter and year ended December 31, 2006, in each case due primarily to the achievement in each period of a single milestone event related to AZD3480 under our agreement with AstraZeneca. Except for these periods, we have never been profitable. As of September 30, 2009, we had an accumulated deficit of \$202.9 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 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.

A substantial portion of our revenue depends on the successful achievement of milestone events under our agreements with AstraZeneca and GlaxoSmithKline and, as a clinical-stage company, our revenues, expenses and results of operations are likely to fluctuate significantly from quarter to quarter and year to year. We believe that period-to-period comparisons of our results of operations should not be relied upon as indicative of our future performance.

### *Revenue*

As of September 30, 2009, we had received \$44.4 million in aggregate upfront fees and milestone payments under our collaboration agreement with AstraZeneca and had recognized an additional \$25.0 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. As of September 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 aggregate 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 September 30, 2009, we had \$25.9 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 \$118,000 and \$164,000 for the three months ended September 30, 2009 and 2008, respectively, and \$473,000 and \$551,000 for the nine months ended September 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 September 30, 2009. Product sales of Inversine resulted in a net loss of \$218,000 for the nine months ended September 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 discontinued Inversine effective as of September 30, 2009. Because we have no further plans to manufacture Inversine, we recorded charges of \$77,000 related to the impairment of our remaining raw materials and finished goods inventory to cost of product sales for the nine months ended September 30, 2009. The discontinuation of Inversine did not have a material impact on our cash flows or results of operations for the periods presented, and we do not expect the discontinuation of Inversine to have a material impact on our cash flows or results of operations in future periods.

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From time to time we seek and are awarded grants or work to be performed under grants awarded to third-party collaborators from which we derive revenue. As of September 30, 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 and have received a grant from The Michael J. Fox Foundation for Parkinson's Research, or MJFF, to fund preclinical research involving the use of compounds that modulate NNRs to address Levodopa-induced abnormal involuntary movements, known as dyskinesias. We expect to receive an aggregate of \$641,000 over a one-year period that began in August 2009 in connection with the MJFF grant. We also 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.

### *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 84% and 87% of our total operating expenses for the three months ended September 30, 2009 and 2008, respectively, and 85% of our total operating expenses for each of the nine-month periods ended September 30, 2009 and 2008.

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 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.

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### *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 income tax benefits of \$10,000 and \$83,000 for the three and nine months ended September 30, 2009, respectively, 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 under the Housing Assistance Tax Act of 2008, as extended by the American Recovery and Reinvestment Act of 2009.

We generated net income for the third quarter ended September 30, 2009 and for the fourth quarter and year ended December 31, 2006, in each case primarily due to the achievement in each period of a single 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, net of refundable credits, in any period. As of September 30, 2009, we had net operating loss carryforwards of \$127.9 million for federal income tax purposes and \$127.8 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 September 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.

### *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 \$27.1 million at September 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.

### ***Results of Operations***

*Three Months ended September 30, 2009 and 2008*

#### *Net Operating Revenues*

	<b>Three Months ended September 30,</b>		<b>Change</b>
	<b>2009</b>	<b>2008</b>	
	<b>(in thousands)</b>		
Operating revenues:			
Collaboration research and development	\$ 1,059	\$2,352	\$(1,293)
Milestones and license fees from collaborations	11,405	1,620	9,785
Product sales, net	118	164	(46)
Grant revenue	81	—	81
Net operating revenues	<u>\$12,663</u>	<u>\$4,136</u>	<u>\$ 8,527</u>

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Net operating revenues for the three months ended September 30, 2009 increased by \$8.5 million as compared to the three months ended September 30, 2008. The higher net operating revenues for the 2009 period as compared to the 2008 period were primarily attributable to an increase of \$9.8 million in milestones and license fees from collaborations revenue and was partially offset by a decrease of \$1.3 million in collaboration research and development revenue. The increase in milestones and license fees from collaborations revenue for the 2009 period reflects a \$10.0 million milestone payment by AstraZeneca based on the achievement of the objective in the completed Phase 2 trial of AZD3480 in adults with ADHD. The increase in milestones and license fees from collaborations revenue was partially offset by our recognition of less deferred revenue for the 2009 period 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. The extent to which we may achieve milestone events under our strategic alliance and collaboration agreements in any particular period is uncertain. Accordingly, we expect the amount of our milestone-based revenue to vary from period to period.

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 the year ending December 31, 2009 to be lower than for the year ended December 31, 2008. Our preclinical research collaboration with AstraZeneca is scheduled to expire in January 2010.

### *Research and Development Expenses*

	Three Months ended September 30,		Change
	2009	2008 (in thousands)	
Research and development expenses	\$9,625	\$10,717	\$(1,092)

Research and development expenses for the three months ended September 30, 2009 decreased by \$1.1 million as compared to the three months ended September 30, 2008. The lower research and development expenses were principally attributable to a decrease of \$2.0 million in costs incurred for third-party research and development services in connection with our clinical-stage product candidates (including costs for clinical trial activities, formulation activities, production of clinical trial materials, and pharmacology, toxicology and other non-clinical studies) to \$1.2 million for the 2009 period, from \$3.2 million for the 2008 period. The decrease in third-party research and development costs in connection with our clinical-stage product candidates for the 2009 period was principally due to the completion of the Phase 2b clinical trial of TC-5214 as an augmentation therapy for MDD in June 2009 and costs for the 2008 period associated with clinical development of TC-6499, a compound that we have since ceased developing. These lower research and development expenses were partially offset by an increase of \$641,000 in costs incurred for third-party research and development services in connection with our preclinical programs, primarily in therapeutic focus areas of our alliance with GlaxoSmithKline, to \$1.9 million for the 2009 period, from \$1.3 million for the 2008 period, and by an accrued expense of \$350,000 payable to the University of Kentucky Research Foundation based on the \$10.0 million milestone payment received from AstraZeneca described above.



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The costs that we incurred for the three months ended September 30, 2009 and 2008 for third-party research and development services in connection with clinical-stage product candidates are shown in the table below. AstraZeneca is responsible for funding all future development costs for AZD3480 and AZD1446.

	Three months ended September 30,		Change
	2009	2008 (in thousands)	
TC-5214	\$ 832	\$ 1,288	\$ (456)
TC-5619	464	731	(267)
AZD3480 (TC-1734)	—	85	(85)
AZD1446 (TC-6683)	—	—	—

In addition to the product candidates shown in the table above, for the three months ended September 30, 2008, we incurred \$1.1 million in aggregate expenses for third-party research and development services in connection with clinical-stage compounds that we have either ceased developing or are not currently progressing, primarily TC-6499.

### *General and Administrative Expenses*

	Three months ended September 30,		Change
	2009	2008 (in thousands)	
General and administrative expenses	\$ 1,628	\$ 1,397	\$ 231

General and administrative expenses for the three months ended September 30, 2009 increased by \$231,000 as compared to the three months ended September 30, 2008. The higher general and administrative expenses were principally attributable to increased professional and consulting fees related to business development activities.

### *Interest Income and Interest Expense*

	Three months ended September 30,		Change
	2009	2008 (in thousands)	
Interest income	\$ 173	\$ 579	\$ (406)
Interest expense	53	65	(12)

Interest income for the three months ended September 30, 2009 decreased by \$406,000 as compared to the three months ended September 30, 2008. The decrease was attributable to lower short-term interest rates and a lower average cash and investment balance during the 2009 period.

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Nine Months ended September 30, 2009 and 2008

### Net Operating Revenues

	Nine Months ended September 30,		Change
	2009	2008 (in thousands)	
Operating revenues:			
Collaboration research and development	\$ 3,724	\$ 7,246	\$ (3,522)
Milestones and license fees from collaborations	17,131	5,559	11,572
Product sales, net	473	551	(78)
Grant revenue	306	211	95
Net operating revenues	<u>\$21,634</u>	<u>\$13,567</u>	<u>\$ 8,067</u>

Net operating revenues for the nine months ended September 30, 2009 increased by \$8.1 million as compared to the nine months ended September 30, 2008. The higher net operating revenues for the 2009 period were primarily attributable to an increase of \$11.6 million in milestones and license fees from collaborations revenue, partially offset by a decrease of \$3.5 million in collaboration research and development revenue. The higher milestones and license fees from collaborations revenue for the 2009 period reflects an increase of \$12.0 million in aggregate payments to us upon achievement of milestone events under our agreements with GlaxoSmithKline and AstraZeneca to \$12.7 million for the 2009 period, from \$700,000 for the 2008 period, primarily attributable to the \$10.0 million milestone payment by AstraZeneca based on the achievement of the objective in the completed Phase 2 trial of AZD3480 in adults with ADHD. The higher milestones and license fees from collaborations revenue was partially offset by reduced recognition of deferred revenue as a result of the extension of the estimated development period for AZD3480 and the extension of the estimated development period for TC-5619 to reach Phase 2 clinical proof of concept. The decrease in collaboration research and development revenue 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.

### Research and Development Expenses

	Nine Months ended September 30,		Change
	2009	2008 (in thousands)	
Research and development expenses	\$30,169	\$30,316	\$ (147)

Research and development expenses for the nine months ended September 30, 2009 decreased by \$147,000 as compared to the nine months ended September 30, 2008. The lower research and development expenses were principally attributable to a decrease of \$1.6 million in costs incurred for third-party research and development services in connection with our clinical-stage product candidates (including costs for clinical trial activities, formulation activities, production of clinical trial materials, and pharmacology, toxicology and other non-clinical studies) to \$6.6 million for the 2009 period, from \$8.2 million for the 2008 period. The decrease in third-party research and development costs in connection with our clinical-stage product candidates was primarily due to costs for

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the 2008 period associated with clinical trials of compounds that we have either ceased developing or are not currently progressing, partially offset by higher costs for the 2009 period associated with the conduct of the Phase 2b clinical trial of TC-5214 as an augmentation therapy for MDD. These lower research and development expenses were partially offset by an increase of \$1.4 million in costs incurred for third-party research and development services in connection with our preclinical programs, primarily in therapeutic focus areas of our alliance with GlaxoSmithKline, to \$4.7 million for the 2009 period, from \$3.3 million for the 2008 period.

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

	Nine months ended September 30,		Change
	2009	2008 (in thousands)	
TC-5214	\$4,200	\$3,158	\$1,042
TC-5619	2,030	2,367	(337)
AZD3480 (TC-1734)	201	220	(19)
AZD1446 (TC-6683)	—	—	—

In addition to the product candidates shown in the table above, for the nine months ended September 30, 2009 and 2008, we incurred \$194,000 and \$2.5 million, respectively, in expenses for third-party research and development services in connection with compounds that we have either ceased developing or are not currently progressing.

### *General and Administrative Expenses*

	Nine months ended September 30,		Change
	2009	2008 (in thousands)	
General and administrative expenses	\$4,477	\$4,982	\$(505)

General and administrative expenses for the nine months ended September 30, 2009 decreased by \$505,000 as compared to the nine months ended September 30, 2008. The lower general and administrative expenses were principally attributable to decreases in professional fees, patent-related costs and travel-related expenses.

### *Interest Income and Interest Expense*

	Nine months ended September 30,		Change
	2009	2008 (in thousands)	
Interest income	\$ 793	\$ 2,248	\$(1,455)
Interest expense	170	184	(14)

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Interest income for the nine months ended September 30, 2009 decreased by \$1.5 million as compared to the nine months ended September 30, 2008. The decrease was attributable to lower short-term interest rates and a lower average cash and investment balance during the 2009 period.

### ***Liquidity and Capital Resources***

#### *Sources of Liquidity*

In October 2009, after the end of the third quarter ended September 30, 2009, we completed a public offering for 2,200,000 shares of our common stock at a price to the public of \$21.00 per share. Our net proceeds from the offering, after deducting underwriters' discounts and commissions and estimated offering expenses payable by us, were \$44.4 million.

In July 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 September 30, 2009, the outstanding principal balance under the loan facility was \$3.5 million. There is no additional borrowing capacity remaining available to us under the loan agreement.

As a result of increased FDA fees and declining prescriptions for Inversine in recent years, we discontinued 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 \$75.3 million as of September 30, 2009 and \$88.4 million as of December 31, 2008. As of September 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.

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### Cash Flows

	Nine Months ended September 30,		Change
	2009	2008 (in thousands)	
Net cash used in operating activities	\$(12,544)	\$(23,433)	\$ 10,889
Net cash provided by (used in) investing activities	9,848	(447)	10,295
Net cash (used in) provided by financing activities	(277)	31,979	(32,256)
Net (decrease) increase in cash and cash equivalents	<u>\$ (2,973)</u>	<u>\$ 8,099</u>	

The change of \$32.3 million in net cash (used in) provided by financing activities between the nine months ended September 30, 2009 and the nine months ended September 30, 2008 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 \$3.6 million in proceeds from borrowings, net of payments, under our loan facilities for the 2009 period as compared to the 2008 period.

The decrease of \$10.9 million in net cash used in operating activities for the nine months ended September 30, 2009 as compared to the nine months ended September 30, 2008 was principally attributable to:

- a reduction in net loss of \$7.2 million for the 2009 period to \$13.0 million, from \$20.2 million for the 2008 period;
- a difference of \$2.6 million in the change in accounts payable and accrued expenses for the 2009 period (an increase of \$1.1 million) as compared to the change in accounts payable and accrued expenses for the 2008 period (a decrease of \$1.5 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;
- a difference of \$1.0 million in the change in prepaid expenses and accrued interest receivable balance for the 2009 period (a decrease of \$7,000) as compared to the change in our prepaid expenses and accrued interest receivable balance for the 2008 period (an increase of \$1.0 million), which was principally attributable to the timing of nonrefundable advance payments made for research and development services, the adoption in 2008 of an accounting standard that requires the capitalization of these payments and the timing of performance of the services; and
- a decrease of \$372,000 in recognition of deferred revenues to \$4.5 million for the 2009 period from \$4.9 million for the 2008 period 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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and was partially offset by a difference of \$1.0 million in the change in our collaboration revenue and accounts receivable balance for the 2009 period (a decrease of \$312,000) as compared to the change in our collaboration revenue and accounts receivable balance for the 2008 period (a decrease of \$1.4 million), principally as a result of 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 and the timing of our achievement of milestone events under our agreements with GlaxoSmithKline and AstraZeneca and receipt of the associated payments.

Net cash provided by (used in) investing activities, which changed by \$10.3 million for the nine months ended September 30, 2009 as compared to the nine months ended September 30, 2008, 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 nine months ended September 30, 2009 were \$10.0 million. The net purchases of our investments for the nine months ended September 30, 2008 were \$1.5 million and occurred primarily upon our receipt of proceeds from a public stock offering that we completed in January 2008. Additionally, we purchased \$152,000 of property and equipment for the nine months ended September 30, 2009, a decrease of \$1.8 million from \$1.9 million in property and equipment purchases for the nine months ended September 30, 2008.

### *Funding Requirements*

As of September 30, 2009, we had an accumulated deficit of \$202.9 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;
- 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;

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- 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, taking into account the \$44.4 million in net proceeds from the October 2009 public offering of our common stock, to be sufficient to fund our operations at least through the first half of 2012. 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.

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 over the next several quarters and years to result in additional capital required to fund future operations. 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 continue to be negatively impacted by the recessionary environment. This, coupled with other factors, may limit our access to additional equity or debt financing in the future on acceptable terms or at all. Also, additional strategic

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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 October 2009, the Financial Accounting Standards Board issued Accounting Standards Update, or ASU, No. 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements—a consensus of the FASB Emerging Issues Task Force*, or ASU 2009-13. ASU 2009-13 addresses the units of accounting for arrangements involving multiple deliverables and how arrangement consideration should be allocated to the separate units of accounting, when applicable. ASU 2009-13 eliminates the criterion in prior accounting guidance that objective and reliable evidence of the fair value of any undelivered items must exist for the delivered items to be considered a separate unit or separate units of accounting. ASU 2009-13 is effective for financial statements issued for fiscal years beginning after June 15, 2010 and can be applied either prospectively or retrospectively for all periods presented. We are in the process of determining the impact of ASU 2009-13 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 September 30, 2009, we had cash, cash equivalents and short-term investments of \$75.3 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 September 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 September 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 September 30, 2009 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 6. Exhibits**

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

Our trademarks include Targacept<sup>®</sup>, Inversine<sup>®</sup>, Pentad<sup>™</sup>, NNR Therapeutics<sup>™</sup>, TRIDMAC<sup>™</sup> and AMPLIXA<sup>™</sup>. Any other service marks, trademarks and trade names appearing in this quarterly report are the property of their respective owners.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**TARGACEPT, INC.**

Date: November 6, 2009

/s/ J. DONALD DEBETHIZY

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

Date: November 6, 2009

/s/ ALAN A. MUSSO

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

**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description</u>
3.1	Bylaws of Targacept, Inc., as amended and restated January 9, 2009 and further amended effective as of August 6, 2009 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 11, 2009).
10.1*	Amendment No. 2, effective July 8, 2009, to Collaborative Research and License Agreement dated December 27, 2005, by and between the Company and AstraZeneca AB, as amended.
10.2*	Amendment No. 1, effective September 21, 2009, to Amended and Restated License Agreement dated March 9, 2004, by and between the Company and University of South Florida Research Foundation, 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.

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\* Portions of this Exhibit have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities Exchange Act of 1934, as amended.

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

**AMENDMENT NO. 2 TO  
COLLABORATIVE RESEARCH AND LICENSE AGREEMENT**

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

WHEREAS AstraZeneca has completed two Phase II Clinical Trials of Ispronicline, one in AD and one in CDS, neither of which resulted in the occurrence of Achievement of Proof of Concept;

WHEREAS the Parties have collaborated to conduct a Phase II Clinical Trial of Ispronicline in ADHD funded by Targacept and, following such trial, AstraZeneca plans to continue Development of Ispronicline; and

WHEREAS AstraZeneca and Targacept desire to amend the Agreement in accordance with Section 17.6 thereof to reflect certain additional or modified terms that shall be or may become applicable to the continued Development of Ispronicline.

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

1. The Agreement is hereby amended by adding the following to the end of Section 6.5.1(a) as the last paragraph.

“The terms of this Section 6.5.1(a) shall be subject to the terms of Section 6.7, if and to the extent applicable.”

2. The Agreement is hereby amended by adding the following new Section 6.7.

“6.7 **Ispronicline ADHD Development Terms**. Each of the Parties hereby agrees as follows.

(a) As a result of the achievement of the objective in the completed Phase II Clinical Trial of Ispronicline in ADHD funded by Targacept, AstraZeneca shall make a milestone payment to Targacept as contemplated by the Parties prior to initiation of such trial, such milestone payment to be in the amount of \$10 million and non-creditable and non-refundable.

(b) With respect to each of milestone event 4 through milestone event 9 (six milestone events) under the heading “Milestone Event” in Section 6.5.1(a) for Ispronicline/ Ispronicline Products (column A) (reproduced under the heading “Milestone Event” below), if the applicable Primary Indication for the first occurrence of such milestone event is ADHD (a “**Subject ADHD Milestone Event**”), then the amount payable to Targacept by AstraZeneca with respect to such Subject ADHD Milestone Event shall be the amount shown below corresponding to such milestone event, if any (and, for clarity, not the amount shown in Section 6.5.1(a), column A, corresponding to such milestone event), subject to Section 6.7(c).

<u>Milestone Event</u>	<u>Amount</u>
4. [*****] of [*****]	[*****]
5. Initiation of [*****]	[*****]
6. [*****] of [*****]	[*****]
7. First Commercial Sale [*****]	[*****]
8. First Commercial Sale [*****]	[*****]
9. First Commercial Sale [*****]	[*****]

(c) With respect to each Subject ADHD Milestone Event, the first time that the same milestone event as such Subject ADHD Milestone Event occurs for Ispronicline or an Ispronicline Product where the applicable indication is any one of Schizophrenia or any Primary Indication besides ADHD (the “**Corresponding PI Milestone Event**”), AstraZeneca shall, within thirty (30) days of such Corresponding PI Milestone Event, make a non-creditable, nonrefundable payment to Targacept in an amount equal to the positive difference between (i) the amount payable under Section 6.5.1(a), column A, with respect to the Corresponding PI Milestone Event as if the occurrence of the Corresponding PI Milestone Event had been the first occurrence of such milestone event (and, for clarity, had preceded the occurrence of the Subject ADHD Milestone Event) and (ii) the amount paid or payable by AstraZeneca with respect to the Subject ADHD Milestone Event in accordance with Section 6.7(b). For clarity, with respect to each Subject ADHD Milestone Event, there can be no more than one (1) Corresponding PI Milestone Event and, as a result, there can be no more than six (6) Corresponding PI Milestone Events in the aggregate.

(d) For clarity: (i) Sections 6.7(b) and 6.7(c) shall apply solely to the application of Section 6.5.1(a) to Ispronicline and Ispronicline Products under the circumstances described therein and for no other purpose (for further clarity, Sections 6.5.1(b) and 6.5.1(c) and the amounts payable to Targacept by AstraZeneca thereunder, if any, are not intended to be affected by this Section 6.7); (ii) any payment obligation of AstraZeneca that arises under Section 6.7(b) or Section 6.7(c) shall be deemed to arise under Section 6.5.1(a) and therefore subject to Sections 6.5.1(a) (excluding the dollar amounts shown in the table therein), 6.5.2, 6.6.1(d)(2), 10.2.4 and 10.2.6 (in each case if and to the extent applicable), except as provided in clause (iv) below; (iii) amounts paid to Targacept by AstraZeneca under Section 6.7(b) or Section 6.7(c) shall be deemed paid under Section 6.5.1(a); and (iv) no payment made by AstraZeneca pursuant to Section 6.7 shall be deemed to violate or be inconsistent with the provisions of Section 6.5.1(a) or any other provision of the Agreement that may restrict the number of times AstraZeneca will make a payment corresponding to any particular milestone event with respect to Ispronicline or an Ispronicline Product under Section 6.5.1(a).”

3. Except as expressly amended by this Amendment, all of the terms and conditions of the Agreement shall remain in full force and effect. This Amendment is not intended and shall not be construed to change AstraZeneca's diligence obligations as set forth in the Agreement (including, without limitation, Section 5.5.1 (AstraZeneca Diligence Obligations)).

4. AstraZeneca shall pay to Targacept the milestone payment required by Section 6.7(a) of the Agreement, as amended, on or before the fifth (5th) Business Day after the effective date of this Amendment.

**[Remainder of page intentionally left blank.]**

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

TARGACEPT, INC.

ASTRAZENECA AB (publ.)

By: /s/ J. Donald deBethizy

By: /s/ Jan M. Lundberg

Name: J. Donald deBethizy

Name: Jan M. Lundberg

Title: President and CEO

Title: President

Date: July 8, 2009

Date: July 6, 2009



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

August 31, 2009

USF Research Foundation, Inc.  
Attention: Business Manager  
USF Box 30445  
Tampa, Florida 33620-3044

Re: *Amendment No. 1 to Amended and Restated License Agreement (this "Amendment")*

Ladies and Gentlemen:

Reference is made to the Amended and Restated License Agreement between Targacept, Inc. ("**Targacept**") and University of South Florida Research Foundation, Inc. ("**USFRF**") dated March 9, 2004 (the "**Agreement**"). Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Agreement.

Paragraph 16.2 of the Agreement provides that the Agreement shall not be subject to any change or modification except by the execution of a written instrument signed by Targacept and USFRF, and each of Targacept and USFRF desires to amend the Agreement as provided herein. Accordingly, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Targacept and USFRF agree as follows:

1. the Agreement is hereby amended by:

a. adding the following new Paragraph 1.17A:

"1.17A "Sublicense Agreement" means any agreement, however characterized, pursuant to which LICENSEE grants a sublicense to any or all of the Patent Rights to a third party.";

b. deleting the text of Paragraph 1.18 in its entirety and replacing it with the following:

""Sublicense Fees" shall mean any fees (including the fair market value of any consideration paid other than in cash) received by LICENSEE from a sublicensee for a sublicense of Patent Rights, excluding (i) royalties on the sale or lease of Licensed Products, (ii) amounts received that are specifically allocated to research and development for, or to the manufacture or supply of, a Licensed Product or Licensed Process, (iii) amounts received that LICENSEE is required to repay (e.g., a loan), (iv) amounts received in exchange for securities of LICENSEE or any of its affiliates (not to exceed the fair market value of such securities), and (v) amounts received as reimbursement for the costs or expenses of filing, prosecuting or maintaining the Patent Rights (but limited to costs and expenses incurred after the effective date of the applicable Sublicense Agreement). For clarity, amounts received based on the achievement by LICENSEE or its sublicensee of specified development events, regulatory events or sales milestones for Licensed Products are Sublicense Fees. For further clarity, and notwithstanding anything in this Agreement to the contrary, Sublicense Fees do not include any payment received by LICENSEE from a sublicensee that is not for a sublicense of Patent Rights.

c. renumbering the second Paragraph 2.7 as Paragraph 2.8.

d. deleting the text of Paragraph 3.1 in its entirety and replacing it with the following:

“LICENSEE shall use commercially reasonable efforts (either alone or through research collaborations or alliances with research organizations, pharmaceutical companies or other third parties) to market and sell, or to develop, one or more Licensed Products or Licensed Processes through a diligent program for exploitation of the Patent Rights, and LICENSEE’s uncured failure to use such efforts shall be grounds for RESEARCH FOUNDATION to terminate this Agreement pursuant to Paragraph 13.3. Without limiting the generality of the foregoing, until the NDA Filing Date, LICENSEE (together with any sublicensees) shall: (i) spend a minimum of [\*\*\*\*\*] related to research and development of one or more Licensed Products; provided that, for the avoidance of doubt, any or all of such amount may [\*\*\*\*\*]; and (ii) deliver to RESEARCH FOUNDATION, at least annually, a brief report summarizing its research and development activities completed since the last report, research and development activities currently in process, planned future research and development activities and research and development work being performed by third parties. If RESEARCH FOUNDATION believes LICENSEE is failing to comply with its obligations under this Paragraph 3.1, RESEARCH FOUNDATION may send notice to the LICENSEE asserting such belief and the basis therefor. LICENSEE shall have sixty (60) days from its receipt of such notice either to (i) commence compliance with its obligations under this Paragraph 3.1 to RESEARCH FOUNDATION’s reasonable satisfaction or (ii) send notice to RESEARCH FOUNDATION requesting that such issue be resolved in accordance with Article XII, in which case the procedures set forth in Article XII shall be followed.”

e. deleting the text of clause (1) of Paragraph 4.1(b) in its entirety and replacing it with the following:

“the obligations in this Paragraph 4.1(b) shall expire with respect to Net Sales of a particular Licensed Product in a particular country on the date of expiration of the last-to-expire patent included in the Patent Rights that includes at least one (1) Valid Claim covering, in whole or in part, such Licensed Product in such country;”

f. deleting the text of Paragraph 3.2 in its entirety and replacing it with “Reserved”:

g. deleting the text of Paragraph 13.6 in its entirety and replacing it with the following:

“If not earlier terminated, this Agreement shall terminate on the date of expiration of the last-to-expire patent included in the Patent Rights that includes at least one (1) Valid Claim covering, in whole or in part, a Licensed Product, and LICENSEE shall thereupon have the rights and licenses set forth in Paragraphs 2.1(a) and 2.4 without any further obligation to RESEARCH FOUNDATION hereunder, which rights and licenses shall survive such termination.”

2. All of the terms and conditions of the Agreement not expressly amended hereby shall continue in full force and effect.

3. This Amendment may be executed in multiple counterparts (which may be exchanged by facsimile or PDF with the same legal effect as if exchanged manually), each of which shall be deemed an original and all of which, taken together, shall be deemed a single instrument.

*[continues on next page]*

Please indicate your acknowledgment of, and agreement with, the foregoing by executing the duplicate copies of this Amendment and returning one fully-executed original to my attention.

Sincerely,

TARGACEPT, INC.

By: /s/ Jeffrey P. Brennan  
Jeffrey P. Brennan  
Vice President, Business and Commercial Development

Acknowledged and agreed:

UNIVERSITY OF SOUTH FLORIDA RESEARCH FOUNDATION, INC.

By: /s/ Rod Casto  
Name: Rod Casto, PhD  
Title: Corporate Secretary

Date: 9/21/09

UNIVERSITY OF SOUTH FLORIDA

By: /s/ Valerie Landrio McDevitt  
Name: Valerie Landrio McDevitt  
Title: Assistant Vice President, Division of Patents & Licensing

Date: 9/2/09

By: /s/ Diego Vazquez  
Name: Diego Vazquez  
Title: Interim Associate Vice President

Date: 9/2/09

## CERTIFICATION

I, J. Donald deBethizy, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 6, 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: November 6, 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 September 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: November 6, 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 September 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: November 6, 2009

/s/ Alan A. Musso

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