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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For The Quarterly Period Ended September 30, 2006

or

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

For the Transition Period from _____ to _____

Commission File Number: 000-51173

Targacept, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**56-2020050**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
200 East First Street, Suite 300 Winston-Salem, North Carolina **(Address of Principal Executive Offices)**	**27101** **(Zip Code)**

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

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

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, 2006, the registrant had 19,119,745 shares of common stock, $0.001 par value per share, outstanding.

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TARGACEPT, INC.

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PART I. Financial Information

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of 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 regarding the timing for completion of additional safety and product characterization studies of TC-1734 (AZD3480) conducted by AstraZeneca, a decision by AstraZeneca whether to initiate a Phase II clinical trial of TC-1734 (AZD3480) following the completion of the safety and product characterization studies, our development plans for the treatment combination that we refer to as TRIDMAC, the progress, timing and scope of our research and development programs and related regulatory filings and clinical trials, our strategy, future operations, financial position, projected future revenues or costs, prospects, plans, expectations and objectives, other than statements of historical fact, 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," "ongoing" 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 dependence on the success of our collaboration with AstraZeneca; the amount and timing of resources that AstraZeneca devotes to the conduct of its safety and product characterization studies of TC-1734 (AZD3480) and to any subsequent development of TC-1734 (AZD3480); AstraZeneca's right to terminate our agreement based on the results of the safety and product characterization studies and all other available information with respect to TC-1734 (AZD3480); AstraZeneca's right in the future to terminate the preclinical research collaboration that we and AstraZeneca are currently conducting prior to the end of the planned four-year term; the receptivity of applicable regulatory authorities to a treatment combination that includes mecamylamine hydrochloride, which is a racemic compound, as opposed to one of its constituent enantiomers such as TC-5214; the results of clinical trials with respect to our current and future product candidates in development; the conduct of nonclinical studies and assessments and of clinical trials, including the performance of third parties that we engage to execute the trials and difficulties or delays in the completion of patient enrollment or data analysis; the timing and success of submission, acceptance and approval of regulatory filings; our ability to obtain substantial additional funding; our ability to establish additional strategic collaborations; and our ability to obtain, maintain and enforce patent and other intellectual property protection for our product candidates and discoveries. These and other risks and uncertainties are described in more detail under the caption "Risk Factors" in Item 1A of Part II of this Quarterly Report on Form 10-Q. 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.

Any forward-looking statements in this quarterly report represent 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, whether as a result of new information, future events or otherwise, we specifically disclaim any obligation to do so, except as required by applicable law. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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Item 1. Financial Statements

TARGACEPT, INC.

BALANCE SHEETS

	September 30, 2006 (unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,513,931	$ 24,851,302
Short-term investments	12,271,369	—
Research fees and accounts receivable	1,179,833	118,163
Inventories	121,855	41,940
Prepaid expenses	1,263,910	729,241
Total current assets	61,350,898	25,740,646
Property and equipment, net	2,105,069	1,747,524
Intangible assets, net of accumulated amortization of $157,350 and $129,027 at September 30, 2006 and December 31, 2005, respectively	484,650	512,973
Total assets	$ 63,940,617	$ 28,001,143
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,208,118	$ 1,173,545
Accrued expenses	2,110,392	2,849,747
Current portion of long-term debt	562,359	783,895
Current portion of deferred rent incentive	335,538	402,647
Current portion of deferred license fee revenue	3,010,539	—
Total current liabilities	7,226,946	5,209,834
Long-term debt, net of current portion	972,910	1,409,402
Deferred rent incentive, net of current portion	—	234,877
Deferred license fee revenue, net of current portion	7,916,667	—
Total liabilities	16,116,523	6,854,113
Commitments		
Redeemable convertible preferred stock:		
Series A, $0.001 par value, 0 and 5,000,000 shares authorized, issued and outstanding at September 30, 2006 and December 31, 2005, respectively; aggregate liquidation preference of $0 and $31,836,985, or $4.65 per share plus accreted redemption value, at September 30, 2006 and December 31, 2005, respectively	—	31,836,985
Series B, $0.001 par value, 0 and 6,567,567 shares authorized, issued and outstanding at September 30, 2006 and December 31, 2005, respectively; aggregate liquidation preference of $0 and $41,759,905, or $4.65 per share plus accreted redemption value, at September 30, 2006 and December 31, 2005, respectively	—	41,759,905
Series C, $0.001 par value, 0 and 81,747,965 shares authorized and 0 and 76,937,998 issued and outstanding at September 30, 2006 and December 31, 2005, respectively; aggregate liquidation preference of $0 and $110,031,263, or $1.21 per share plus accreted redemption value, at September 30, 2006 and December 31, 2005, respectively	—	110,031,263
Total redeemable covertible preferred stock	—	183,628,153
Stockholders' equity (deficit):		
Common stock, $0.001 par value, 100,000,000 and 16,666,666 shares authorized at September 30, 2006 and December 31, 2005, respectively; 19,119,410 and 270,427 shares issued and outstanding at September 30, 2006 and December 31, 2005, respectively	19,119	270
Capital in excess of par value	200,783,683	12,287,904
Common stock warrants	—	213,710
Accumulated deficit	(152,978,708)	(174,983,007)
Total stockholders' equity (deficit)	47,824,094	(162,481,123)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 63,940,617	$ 28,001,143

See accompanying notes

TARGACEPT, INC.

STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenue:				
Collaborative research and development	$ 86,985	$ —	$ 149,209	$ —
License fees	312,500	—	833,333	—
Product sales	161,375	163,234	469,001	503,585
Grant revenue	437,433	175,076	742,281	437,604
Net revenue	998,293	338,310	2,193,824	941,189
Operating expenses:				
Research and development (stock-based compensation of $211,732 and $71,888 for the three months ended September 30, 2006 and 2005, respectively, and $409,779 and $373,970 for the nine months ended September 30, 2006 and 2005, respectively)	5,297,059	6,226,301	14,653,497	18,607,830
General and administrative (stock-based compensation of $86,482 and $32,572 for the three months ended September 30, 2006 and 2005, respectively, and $173,794 and $195,386 for the nine months ended September 30, 2006 and 2005, respectively)	1,220,980	1,158,625	3,719,989	3,620,297
Transaction charges	—	—	—	1,634,973
Cost of product sales	131,951	123,466	300,566	243,822
Total operating expenses	6,649,990	7,508,392	18,674,052	24,106,922
Loss from operations	(5,651,697)	(7,170,082)	(16,480,228)	(23,165,733)
Other income (expense):				
Interest income	806,742	300,271	1,828,390	898,347
Interest expense	(20,647)	(50,389)	(68,682)	(196,078)
Total other income (expense)	786,095	249,882	1,759,708	702,269
Net loss	(4,865,602)	(6,920,200)	(14,720,520)	(22,463,464)
Preferred stock accretion	—	(2,813,899)	(3,332,705)	(8,424,080)
Net loss attributable to common stockholders	$ (4,865,602)	$ (9,734,099)	$ (18,053,225)	$ (30,887,544)
Basic and diluted net loss attributable to common stockholders per share	$ (0.25)	$ (37.02)	$ (1.54)	$ (118.30)
Weighted average common shares outstanding—basic and diluted	19,118,854	262,973	11,731,445	261,094

See accompanying notes

TARGACEPT, INC.

STATEMENTS OF CASH FLOWS
(unaudited)

	Nine Months Ended September 30,	
	2006	2005
Operating activities		
Net loss	$(14,720,520)	$(22,463,464)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	615,821	603,125
Non-cash compensation expense	583,573	569,356
Recognition of deferred rent incentive	(301,986)	(301,986)
Changes in operating assets and liabilities, excluding the effects from acquired assets and liabilities:		
Research fees and accounts receivable	(1,061,670)	368,228
Inventories	(79,915)	10,156
Prepaid expenses and accrued interest receivable	(806,038)	803,124
Accounts payable and accrued expenses	(704,782)	(246,009)
Deferred license fee revenue	10,927,206	—
Net cash used in operating activities	(5,548,311)	(20,657,470)
Investment activities		
Purchase of investments	(29,000,000)	(10,500,000)
Proceeds from sale of investments	17,000,000	10,500,000
Purchase of property and equipment	(945,043)	(236,803)
Net cash used in investing activities	(12,945,043)	(236,803)
Financing activities		
Proceeds from issuance of notes payable	406,967	—
Principal payments on notes payable and long-term debt	(1,064,995)	(2,073,714)
Proceeds from issuance of redeemable convertible preferred stock, net of transaction costs	—	612,281
Proceeds from issuance of common stock	40,814,011	20,385
Net cash provided by (used in) financing activities	40,155,983	(1,441,048)
Net increase (decrease) in cash and cash equivalents	21,662,629	(22,335,321)
Cash and cash equivalents at beginning of period	24,851,302	53,075,348
Cash and cash equivalents at end of period	$ 46,513,931	$ 30,740,027

See accompanying notes

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS
September 30, 2006

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 to treat multiple diseases and disorders of the central nervous system by selectively targeting a class of receptors known as neuronal nicotinic receptors, or NNRs. The Company's 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 accounting principles generally accepted in the United States ("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 Prospectus dated April 11, 2006 and filed on April 12, 2006. 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, 2006 and 2005 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 judgments that affect the amounts of assets, liabilities, revenues and expenses reported in the financial statements and accompanying notes. Actual results and experiences could differ materially from these estimates.

Revenue Recognition

The Company uses revenue recognition criteria included in Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* ("SAB 101"), as amended by Staff Accounting Bulletin No. 104, *Revenue Recognition (replacement of SAB 101)* ("SAB 104"). The Company considers a variety of factors in determining the appropriate method of revenue recognition under its collaboration agreements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with a particular element. Research fee revenue that is non-refundable is earned and recognized as research is performed and related expenses are incurred. License fees for access to the Company's intellectual property are recognized ratably over the contracted period in accordance with the provisions of the agreement.

Upfront fees, or amounts received in advance of performance, are recorded as deferred revenue and amortized in the statement of operations into license fee revenue over the estimated research and development period. Revenue based on the achievement of development and regulatory milestones that carry substantive performance risk are only recognized upon achievement of the milestone event. Revenue for specific research and development costs reimbursable under the Company's collaboration agreement with AstraZeneca AB, such as third-party manufacturing costs for drug material, is recorded in compliance with Emerging Issues Task Force ("EITF") Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF Issue 01-14, *Income Statement Characterization of Reimbursements Received for "Out-of-Pocket" Expenses Incurred*. According to the criteria established by these EITF Issues, in transactions where the Company acts as a principal, with discretion to choose suppliers, bears credit risk and performs part of the services required in the transaction, the Company records revenue for the gross amount of the reimbursement that is non-refundable under the contract. The costs associated

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2006

2. Summary of Significant Accounting Policies (continued)

with these reimbursements are reflected as a component of research and development expense in the statement of operations. Product sales revenues are recorded when goods are shipped, at which point title has passed, and the Company establishes an allowance for estimated returns at that time. Revenue from grants is recognized as the Company performs the work and incurs reimbursable costs in accordance with the award.

Accrued Expenses

The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known to it. This process involves reviewing open contracts and purchase orders, communicating with its applicable personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. Examples of the Company's accrued expenses include fees to contract research organizations in connection with preclinical studies and clinical trials, fees to investigative sites in connection with clinical trials, fees paid to contract manufacturers in connection with the production of clinical trial materials and Inversine and professional service fees.

The Company bases its expenses related to clinical trials on its estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on its behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the achievement of certain events, the enrollment of subjects, the completion of clinical trial milestones or similar conditions. The objective of the Company's accrual policy is to match the recording of expenses in its financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials are recognized based on the Company's estimate of the degree of completion of the event or events specified in the applicable agreement.

Research and Development Expense

Research and development costs are expensed as incurred and include salaries of, and stock-based compensation for, personnel involved in research and development activities, contractor fees, administrative expenses and allocations of research-related overhead costs. Administrative expenses and research-related overhead costs included in research and development expense consist of allocations of facility and equipment lease charges, depreciation and amortization of assets, and insurance, legal and supply costs that are directly related to research and development activities.

Transaction Charges

In the first quarter of 2005, the Company recognized general and administrative expense of $1,635,000 for expenses incurred in connection with a terminated public offering.

Income Taxes

The Company accounts for income taxes using the liability method in accordance with the provisions of Statement of Financial Accounting Standard ("SFAS") No. 109, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of the Company's assets and liabilities and are estimated using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. A valuation allowance is provided when the Company determines that it is more likely than not that some portion or all of a deferred tax asset will not be realized.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2006

2. Summary of Significant Accounting Policies (continued)

Net Loss Per Share Attributable to Common Stockholders

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

Common share equivalents consist of the incremental common shares issuable upon the conversion of preferred stock, the exercise of stock options or the exercise of warrants. For the periods presented, Diluted EPS is identical to Basic EPS because common share equivalents are excluded from the calculation, as their effect would be anti-dilutive.

The Company has excluded all outstanding stock options and warrants from the calculation of net loss per share attributable to common stockholders because such securities are anti-dilutive for the periods presented. Had the Company been in a net income position, these securities may have been included in the calculation. These potentially dilutive securities consist of the following on a weighted-average basis:

	Nine Months Ended September 30,	
	2006	2005
Outstanding stock options	1,739,007	1,414,728
Redeemable convertible preferred stock	5,421,339	13,797,460
Outstanding warrants	84,289	215,054
Total	7,244,635	15,427,242

Initial Public Offering and Pro Forma Information

On April 18, 2006, the Company completed an initial public offering ("IPO") of 5,000,000 shares of its common stock at a price of $9.00 per share. The Company's net proceeds from the IPO, after deducting underwriters' discounts and commissions and offering expenses payable by the Company, were approximately $40.8 million. The Company's common stock began trading on the NASDAQ Global Market (formerly known as the NASDAQ National Market) on April 12, 2006.

All outstanding shares of the Company's Series A, Series B, and Series C convertible preferred stock ("Preferred Stock") automatically converted into shares of common stock upon completion of the IPO. Series A converted at a ratio of approximately 0.133 common share per preferred share, Series B converted at a ratio of approximately 0.133 or 0.318 common share per preferred share and Series C converted at a ratio of approximately 0.144 common share per preferred share. These conversion ratios reflect a 1 for 7.5 share reverse stock split effected February 3, 2005. Under the terms of the preferred stock, accrued dividends totaling $39.8 million were forfeited in connection with the conversion to common stock. In addition, upon completion of the IPO, all outstanding warrants expired unexercised.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2006

2. Summary of Significant Accounting Policies (continued)

As of September 30, 2006, the Company has authorized capital stock of 100,000,000 shares of common stock with a par value of $0.001 per share and 5,000,000 shares of preferred stock with a par value of $0.001 per share. The rights and preferences of the preferred stock may be established from time to time by the Company's board of directors.

The unaudited pro forma balance sheet as of December 31, 2005 reflects the automatic conversion of all outstanding shares of the Company's preferred stock into an aggregate of 13,832,013 shares of common stock as if the conversion had occurred as of December 31, 2005 and gives further effect to the sale of 5,000,000 shares of common stock in the IPO at $9.00 per share, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

	As of September 30, 2006	As of December 31, 2005	
	Actual	Actual	Pro forma
	(unaudited)	(audited)	(unaudited)
Balance Sheet Data (amount in thousands):			
Cash and cash equivalents	$ 46,514	$ 24,851	$ 65,680
Working capital	54,124	20,531	61,261
Total assets	63,941	28,001	68,731
Long-term debt, net of current portion	973	1,409	1,409
Redeemable convertible preferred stock	—	183,628	—
Accumulated deficit	(152,979)	(174,983)	(138,258)
Total stockholders' equity (deficit)	47,824	(162,481)	61,877

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact, if any, of the provisions of SFAS 157.

In September 2006, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* ("SAB 108"). SAB 108 provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in a misstatement that, when all relevant quantitative and qualitative factors are considered, is material and therefore must be quantified. SAB 108 is effective for years ending on or after November 15, 2006.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2006

3. Inventories

Inventories consisted of the following as of the respective dates indicated:

	September 30, 2006	December 31, 2005
Raw materials	$ 6,400	$ 6,400
Finished goods	26,416	35,540
Work-in-progress	89,039	—
	$ 121,855	$ 41,940

4. Stock-Based Compensation

Effective January 1, 2005, the Company adopted the fair value recognition provisions of SFAS No. 123(R), *Share-Based Payment* ("SFAS 123R"), using the modified prospective transition method. Under that transition method, compensation cost recognized in 2005 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of, January 1, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, *Accounting for Stock-Based Compensation*, (b) compensation cost for all share-based payments granted between January 1, 2005 and December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R, and (c) compensation cost for awards modified on April 7, 2005, based on the modification provisions in accordance with SFAS 123R.

The Company's net loss includes approximately $298,000 and $104,000 for the three months ended September 30, 2006 and 2005, respectively, and $584,000 and $569,000 for the nine months ended September 30, 2006 and 2005, respectively, of non-cash compensation costs related to its stock-based compensation arrangements.

The Company has two stock-based incentive plans, the 2000 Equity Incentive Plan of Targacept, Inc., as amended and restated (the "2000 Plan"), and the Targacept, Inc. 2006 Stock Incentive Plan (the "2006 Plan" and, together with the 2000 Plan, the "Plans"). The 2006 Plan became effective in April 2006 and is the successor equity incentive program to the 2000 Plan. All shares previously reserved under the 2000 Plan and not subject to outstanding awards under the 2000 Plan as of the effective date of the 2006 Plan are now reserved for grant under the 2006 Plan. Awards may be made to participants under the Plans in the form of incentive and nonqualified stock options, restricted stock, stock appreciation rights, stock awards, and performance awards. Eligible participants under the Plans include employees, directors and certain independent contractors, consultants or advisors of the Company or a related corporation. Awards made under the Plans have vesting periods that are determined at the discretion of the administrator and range from 0 to 5 years and generally have 10-year contractual terms. The exercise price of incentive options granted under the Plans may not be less than 100% of the fair market value of the common stock on the date of grant, as determined by the administrator.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2006

4. Stock-Based Compensation (continued)

Stock option transactions are summarized as follows:

	Options Granted	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2006	1,610,009	$ 2.88		
Granted	906,863	5.54		
Forfeited	(38,835)	3.07		
Exercised	(16,970)	2.30		
Outstanding at September 30, 2006	2,461,067	$ 3.86	8.2	$4,436,888
Vested and exercisable at September 30, 2006	1,216,434	$ 3.36	7.1	$2,797,556

The weighted-average fair value per share underlying options granted during the nine-month period ended September 30, 2006 was $5.54. The total intrinsic value of options exercised during the nine-month period ended September 30, 2006 was $60,300.

As of September 30, 2006, there was $3,848,000 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of 1.7 years.

5. Collaborative Research and License 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 TC-1734 (AZD3480) as a treatment for Alzheimer's disease, cognitive deficits in schizophrenia and potentially other conditions marked by cognitive impairment such as attention deficit hyperactivity disorder, age associated memory impairment and mild cognitive impairment. The collaboration agreement also provides for a multi-year preclinical research collaboration to be conducted by the Company and AstraZeneca. The collaboration agreement with AstraZeneca became effective on January 20, 2006.

The Company is eligible to receive future research fees, license fees and milestone payments under its collaboration agreement with AstraZeneca. The amount of research fees, license fees and milestone payments will depend on the extent of the Company's research activities and the timing and achievement of development, regulatory and first commercial sale milestone events.

AstraZeneca paid the Company an initial fee of $10.0 million in February 2006. Based on the collaboration agreement terms, the Company allocated $5.0 million of the initial fee to the research collaboration, which the Company expects to recognize as revenue over the planned four-year term of the research collaboration. The Company deferred recognition of the remaining $5.0 million of the initial fee, which was allocated to the TC-1734 (AZD3480) license grants, until AstraZeneca makes a determination whether to conduct Phase II clinical development of TC-1734 (AZD3480) following its completion of additional safety and product characterization studies. If AstraZeneca decides to conduct a Phase II clinical trial of TC-1734 (AZD3480) following the completion

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2006

5. Collaborative Research and License Agreements (continued)

of the safety and product characterization studies, the Company would recognize the deferred $5.0 million of the initial fee as revenue over the expected development period for TC-1734 (AZD3480). The Company expects to recognize any revenue based on the achievement of milestones under the collaboration agreement upon achievement of the milestone event, if the Company determines that the revenue satisfies the revenue recognition requirements of SAB 101, as amended by SAB 104. SAB 101 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed and determinable; and collectability is reasonably assured.

During the period that AstraZeneca conducts its additional safety and product characterization studies, AstraZeneca has agreed to pay the Company research fees equal to 50% of the Company's research expenses in the parties' preclinical research collaboration. If the agreement continues in effect following the completion of the safety and product characterization studies, AstraZeneca has agreed to pay the Company the remaining 50% of its research expenses incurred while the studies were conducted and thereafter research fees equal to 100% of its research expenses in the collaboration, subject to specified limits. The Company records research fees that the Company is eligible to receive from AstraZeneca while it is conducting the safety and product characterization studies of TC-1734 (AZD3480) as deferred revenue. As of September 30, 2006, the Company has recorded $1.76 million, which represents 50% of its research expenses incurred in the research collaboration while AstraZeneca conducted the safety and product characterization studies, as deferred revenue and has not recorded another $1.76 million, which represents the remaining 50%. If the agreement continues following completion of the safety and product characterization studies, the Company will recognize into revenue all research fees previously recorded as deferred revenue, plus the remaining 50% of its research expenses incurred in the research collaboration while AstraZeneca conducted the safety and product characterization studies that the Company would become eligible to receive, and will recognize future research fee revenues as the research is performed and related expenses are incurred.

AstraZeneca has the right to terminate the collaboration agreement if it determines in its sole discretion on or before April 20, 2007 not to proceed with the further development of TC-1734 (AZD3480) based on the results of its safety and product characterization studies and all other available information with respect to TC-1734 (AZD3480). If AstraZeneca were to terminate the collaboration agreement, the Company would be required to reimburse AstraZeneca for the amount of all research fees that it paid to the Company under the research collaboration under the agreement while AstraZeneca conducted the safety and product characterization studies. In addition, the Company would be required to pay AstraZeneca an additional $5.0 million as compensation for assigning to it the data and any intellectual property generated in the studies. In that event, upon final termination by AstraZeneca in accordance with the terms of the agreement, the Company would reduce deferred revenue by the sum of $5.0 million plus the amount of research fees reimbursable to AstraZeneca, which the Company expects to be approximately $2.5 million.

6. Related Party Transactions

As of September 30, 2006, R.J. Reynolds Tobacco Holdings, Inc. ("RJRT") was the holder of 909,094 shares of the Company's common stock. The Company has entered into the following transactions and agreements with RJRT in the ordinary course of business.

During 2002, the Company entered into a facility to borrow $2.5 million from RJRT accruing interest at 6.6%. This borrowing was repayable in monthly installments of $59,000 through the maturity date of May 1, 2006, and has been paid and satisfied in full. In January 2004, the Company amended the facility with RJRT to allow for up to three additional tranches to be advanced to the Company for up to a total of $2.0 million. The Company was advanced an additional tranche on April 1, 2004 in the amount of $1.0 million. This additional tranche accrues interest at 5.87% and is repayable in monthly payments of $24,000 through the maturity date of April 1, 2008. The Company was advanced another additional tranche on December 23, 2004 in the amount of $973,000. This tranche accrues interest at 6.89% and is repayable in monthly payments of $23,000 through the maturity date of January 1, 2009.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2006

6. Related Party Transactions (continued)

In June 2006, the Company amended the facility with RJRT to provide an additional $2.0 million in aggregate borrowing capacity accessible in up to three draws that may be made on or before June 30, 2007. Each future draw would accrue interest at a per annum rate that approximates the hypothetical four-year U.S. Treasury rate, determined as of the date of the draw, plus 2.5% and be payable in equal monthly installments of principal and accrued interest over 48 months beginning on the first day of the month following the draw. As of September 30, 2006, the Company has not been advanced any of the additional $2.0 million in aggregate borrowing capacity under this facility.

Under this related party note payable, the Company paid RJRT $142,000 and $320,000 during the three months ended September 30, 2006 and 2005, respectively, and $723,000 and $939,000 during the nine months ended September 30, 2006 and 2005, respectively.

A member of the Company's board of directors served as an officer of RJRT and its parent company, Reynolds American, Inc., until retiring from RJRT and Reynolds American effective as of August 31, 2006. Equity compensation for such director's service has previously been made, at the director's request, directly to RJRT. The number of shares subject to stock options granted to RJRT in connection with the director's services was 1,000 shares per year. In connection with the issuance of the stock options, the Company recognized compensation expense of $0 and $420 during the three months ended September 30, 2006 and 2005, respectively, and $840 and $4,236 during the nine months ended September 30, 2006 and 2005, respectively.

The Company paid RJRT $0 and $32,000 for copy and print services for the three months ended September 30, 2006 and 2005, respectively, and $0 and $69,000 for the nine months ended September 30, 2006 and 2005, respectively.

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

You should read the following discussion together with our financial statements and accompanying notes included in this quarterly report and our audited financial statements included in our Registration Statement on Form S-1 (No. 333-131050), 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 those indicated by the forward-looking statements due to 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 on Form 10-Q and under "Risk Factors" in Item 1A of Part II of this Quarterly Report on Form 10-Q.

Overview

We are a biopharmaceutical company engaged in the design, discovery and development of NNR Therapeutics, a new class of drugs to treat multiple diseases and disorders of the central nervous system by selectively targeting a class of receptors known as neuronal nicotinic receptors, or NNRs. We have four product candidates in clinical development and multiple preclinical product candidates. Our lead product candidate is a novel small molecule that we refer to as TC-1734. In December 2005, we entered into a collaborative research and license agreement with AstraZeneca AB for the development and worldwide commercialization of TC-1734 as a treatment for Alzheimer's disease, cognitive deficits in schizophrenia and potentially other conditions marked by cognitive impairment such as attention deficit hyperactivity disorder, commonly referred to as ADHD, age associated memory impairment, commonly referred to as AAMI, and mild cognitive impairment, commonly referred to as MCI. The agreement became effective in January 2006. We expect AstraZeneca initially to develop TC-1734, which it refers to as AZD3480, for mild to moderate Alzheimer's disease and cognitive deficits in schizophrenia.

In addition to TC-1734 (AZD3480), our most advanced product candidates are:

- Mecamylamine hydrochloride, which we are currently developing as an augmentation treatment to citalopram hydrobromide for major depression. We refer to this treatment combination as TRIDMAC. Mecamylamine hydrochloride is the active ingredient in Inversine, our only product approved by the U.S. Food and Drug Administration, or FDA, for marketing. TC-5214 is one of the enantiomers of mecamylamine hydrochloride and a separate preclinical product candidate.
- TC-2696, which is a product candidate for acute post-operative pain that is currently in a Phase I multiple rising dose clinical trial.
- TC-2216, which is a product candidate for depression and anxiety disorders for which we have filed a Clinical Trial Authorization application to initiate a Phase I clinical trial in Europe.
- TC-5619, which is a preclinical product candidate selective for the NNR known as a7 with potential application for conditions such as schizophrenia, cognitive impairment and inflammation.

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 and the function of nicotinic receptors. 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 devoted substantially all of our resources to the discovery and development of our product candidates and technologies, including the design, conduct and management of preclinical and clinical studies and related manufacturing, regulatory and clinical affairs, as well as intellectual property prosecution.

We acquired rights to Inversine in August 2002. Inversine is approved for the management of moderately severe to severe essential hypertension, a high blood pressure disorder with an unknown cause. However, we believe that Inversine is prescribed predominantly for the treatment of neuropsychiatric disorders, such as Tourette's syndrome, autism and bipolar disorder, in children and adolescents. Sales of Inversine generated revenue of $681,000 for the year ended December 31, 2005 and $469,000 for the nine months ended September 30, 2006.

We have never been profitable. As of September 30, 2006, we had an accumulated deficit of $153.0 million. We expect to continue to incur substantial losses for the foreseeable future. We expect our research and development expenses to increase substantially over the next several years as we expand our clinical trial activity, as our product candidates advance through the development cycle and as we invest in additional product opportunities and research programs. We also expect our general and administrative expenses to increase substantially due to costs associated with being a public company. 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 for the next several years will depend on the conduct of research and the successful achievement of milestone events in the development of TC-1734 (AZD3480) under our agreement with AstraZeneca. Our revenue may vary substantially from quarter to quarter and year to year. We believe that period-to-period comparisons of our results of operations are not meaningful and should not be relied upon as indicative of our future performance.

Recent Developments

In November 2006, we announced results of our Phase II clinical trial of TRIDMAC in major depression. The trial evaluated the effects of TRIDMAC in patients who did not respond adequately to citalopram hydrobromide alone. Citalopram hydrobromide is a commonly prescribed treatment for depression marketed as Celexa in the United States.

The trial included two primary endpoints, group mean change from baseline and achievement of remission, in each case as measured by the Hamilton Depression Rating Scale (HAM-D) and compared to continued citalopram therapy plus placebo. The secondary outcome measures for the trial included five other rating scales that assess symptoms of depression and anxiety, disability, irritability, global improvement or severity of illness. Data from the trial were evaluated on both an intent to treat and per protocol basis. The intent to treat data set included all patients who received at least one dose of blinded study medication and were assessed at least once post baseline. The per protocol data set included patients who were at least 80% compliant with the dosing regimen called for by the protocol and were assessed at the end of the dosing period.

Patients receiving TRIDMAC showed greater improvement on symptoms of depression, as measured by group mean change from baseline on the HAM-D scale, than patients receiving placebo with continued citalopram therapy. This result was statistically significant on an intent to treat basis ($p=0.041$) and showed a strong trend on a per protocol basis ($p=0.059$). The result on the achievement of remission endpoint favored the TRIDMAC group over the placebo group, although this result was not statistically significant. In addition, the results on all five rating scales favored the TRIDMAC group over the placebo group with statistical significance ($p<0.05$) on a per protocol basis. On an intent to treat basis, the results on three of the five rating scales were statistically significant.

TRIDMAC was generally well tolerated in the trial. There was one serious adverse event reported in each of the TRIDMAC and placebo groups. In the TRIDMAC group, a patient experienced an upper respiratory tract infection and irregular heartbeat and discontinued participation in the trial.

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 accounting principles generally accepted in the United States. 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, including those described below. 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 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 for the year ended December 31, 2005 included in our Registration Statement on Form S-1 (File No. 333-131050) 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 both 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2006.

Financial Operations Overview

Revenue

Inversine is our only approved product. Sales of Inversine generated revenue of $681,000 for the year ended December 31, 2005 and $469,000 for the nine months ended September 30, 2006. We have an exclusive distribution agreement with Cord Logistics, Inc., a Cardinal Health company, for the distribution of Inversine. We do not have or use a sales force or promote Inversine. Accordingly, we do not anticipate any significant increase in Inversine sales. If any of the very

limited number of physicians that most often prescribe Inversine were to cease to do so, our revenue generated by Inversine sales would likely be substantially less. We have no other commercial products for sale and do not anticipate that we will have any other commercial products for sale for at least the next several years.

Our collaboration agreement with AstraZeneca became effective in January 2006. AstraZeneca paid us an initial fee of $10 million in February 2006. AstraZeneca has agreed to make an additional payment to us of $20 million if it decides to conduct a Phase II clinical trial of TC-1734 (AZD3480) following its completion of additional safety and product characterization studies conducted at its expense to generate further data with respect to TC-1734 (AZD3480). We expect AstraZeneca to complete these safety and product characterization studies in or before the first quarter of 2007. We are eligible to receive other payments of up to $249 million, contingent upon the achievement of development, regulatory and first commercial sale milestones for TC-1734 (AZD3480) for Alzheimer's disease, cognitive deficits in schizophrenia and ADHD, and royalties on future product sales. If TC-1734 (AZD3480) is developed under the agreement for indications other than Alzheimer's disease, cognitive deficits in schizophrenia and ADHD, we would also be eligible to receive payments contingent upon the achievement of development, regulatory and first commercial sale milestones for TC-1734 (AZD3480) for those indications. Under the terms of a sponsored research agreement and a subsequent license agreement between us and the University of Kentucky Research Foundation, or UKRF, we are required to pay to UKRF a low single digit percentage of any of these amounts that we may receive from AstraZeneca. If AstraZeneca terminates our agreement upon completion of any or all of its safety and product characterization studies, we would be required to reimburse AstraZeneca for the amount of all research fees that it paid to us for our work performed in the a4ß2 research collaboration while it conducted the studies, which we expect to be approximately $2.5 million. In that event, we would also be required to pay AstraZeneca an additional $5 million as compensation for assigning to us the data and any intellectual property generated in the studies, but we would not be required to refund the $10 million initial fee that AstraZeneca paid us.

We and AstraZeneca are conducting a preclinical research collaboration that is designed to discover and develop additional compounds that, like TC-1734 (AZD3480), act on the NNR known as a4ß2. During the period that AstraZeneca conducts its safety and product characterization studies, AstraZeneca has agreed to pay us research fees equal to 50% of our research expenses. If our agreement with AstraZeneca continues in effect following the completion of the safety and product characterization studies, AstraZeneca has agreed to pay us the remaining 50% of our research expenses incurred while those studies were conducted and thereafter research fees equal to 100% of our research expenses in the collaboration, subject to specified limits. In that event, based on the current budget for the a4ß2 research collaboration, we would expect to receive approximately $26.4 million in aggregate research fees assuming the planned four-year research term. The research fees that AstraZeneca has agreed to pay us are based on a negotiated rate designed to approximate our costs to conduct the research.

In 2003, we were awarded a cooperative agreement from the National Institute of Standards and Technology through its Advanced Technology Program. Under the agreement we received $1.8 million over a three-year period to help fund the development of sophisticated new computer simulation software designed to more accurately predict biological and toxicological effects of drugs. In addition, we are a named subcontractor under a grant awarded to The California Institute of Technology by the National Institute on Drug Abuse, part of the National Institutes of Health, to fund

research on innovative NNR-based approaches to the development of therapies for smoking cessation. We expect to receive approximately $1.1 million in the aggregate over the five-year term of the grant. We recognize grant revenue as we perform the work and incur reimbursable costs. 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 Expense

Since our inception, we have focused our activities on our drug discovery and development programs. We expense research and development expenses as they are incurred. Research and development expenses represented approximately 78% of our total operating expenses for both the year ended December 31, 2005 and the nine months ended September 30, 2006.

Research and development expense includes expenses associated with:

- the employment of personnel involved in our drug discovery and development activities;
- research and development facilities and equipment;
- the screening, identification and optimization of product candidates;
- the development and enhancement of our proprietary databases and computer-based molecular design technologies, which we refer to collectively as Pentad;
- formulation and chemical development;
- production of clinical materials, including fees paid to contract manufacturers;
- preclinical animal studies, including the costs to engage third-party research organizations;
- clinical trials, including fees paid to contract research organizations to monitor and oversee some of our trials;
- quality assurance activities;
- compliance with FDA regulatory requirements;
- consulting, license and sponsored research fees paid to third parties;
- depreciation of capital assets used to develop our products; and
- stock options or other stock-based compensation granted to personnel in research and development functions.

We use our employee and infrastructure resources across several programs. Consistent with our focus on the development of a class of drugs with potential uses in multiple indications, many of our costs are not attributable to a specifically identified program. Instead, these costs are directed to

broadly applicable research efforts. Accordingly, we do not account for internal research and development costs on a program-by-program basis. As a result, we cannot state precisely the total costs incurred for each of our clinical and preclinical programs on a program-by-program basis.

The following table shows, for the periods presented, total payments that we made to third parties for preclinical study support, clinical supplies and clinical trial services for our most advanced product candidates, TC-1734 (AZD3480), TC-2696, mecamylamine hydrochloride, TC-2216 and TC-5619.

Product Candidate	Three months ended September 30,		Nine months ended September 30,		Cumulative From Inception
	2006	2005	2006	2005	
	(in thousands)				
TC-1734 (AZD3480)	$ 80	$ 2,408	$ 172	$ 5,953	$ 15,552
TC-2696	302	52	500	751	3,417
Mecamylamine hydrochloride	141	258	382	450	1,662
TC-2216	296	—	1,312	—	2,210
TC-5619	169	—	434	—	453
	$ 988	$ 2,718	$ 2,800	$ 7,154	$ 23,294

At the end of 2004, we discontinued the development of mecamylamine hydrochloride for attention deficit hyperactivity disorder and another of our product candidates for ulcerative colitis following the completion of Phase II clinical trials. We made total payments to third parties of $70,000 for the nine months ended September 30, 2005 in connection with these discontinued programs. The cumulative from inception amount shown above for mecamylamine hydrochloride does not include payments made to third parties in connection with the discontinued development for attention deficit hyperactivity disorder.

Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. We test compounds in numerous preclinical studies for safety, toxicology and efficacy. We then conduct clinical trials for those product candidates that we determine to be the most promising. If we do not establish a collaboration covering the development of a particular product candidate, we fund these trials ourselves. As we obtain results from clinical trials, we may elect to discontinue or delay trials for some product candidates in order to focus our resources on more promising product candidates. Completion of clinical trials by us or our collaborators may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a program as a result of a variety of factors, including:

- the number of patients who participate in the trials;
- the number and locations of sites included in the trials;
- the length of time required to enroll trial participants;

- the duration of patient follow-up;
- the costs of producing supplies of the product candidates needed for clinical trials and regulatory submissions;
- the efficacy and safety profile of the product candidate; and
- the costs and timing of, and the ability to secure, regulatory approvals.

We have not received FDA or foreign regulatory marketing approval for any of our product candidates that are in development. In order to achieve marketing approval, the FDA or foreign regulatory agencies must conclude that our or our collaborators' clinical data establishes the safety and efficacy of the product candidates. Furthermore, our strategy includes entering into collaborations with third parties to participate in the development and commercialization of some of our product candidates. In situations in which third parties have decision-making authority over the preclinical development or clinical trial process for a product candidate, the estimated completion date is largely under control of that third party and not under our control. We cannot forecast with any degree of certainty which of our product candidates will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development programs or whether or when we will generate revenues from the commercialization and sale of any of our development stage product candidates. Our failure to complete our research and development programs could have a material adverse effect on our financial position and results of operations.

General and Administrative Expense

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

Cost of Product Sales

Cost of product sales are those costs related directly to the sale of Inversine and are principally comprised of cost of goods sold, FDA product and establishment fees, distribution expenses, product royalty obligations and product liability insurance.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and short-term investments.

Interest Expense

Interest expense consists of interest incurred to finance equipment, office furniture and fixtures.

Income Taxes

We have incurred net operating losses since our incorporation in 1997 and consequently have not paid federal, state or foreign income taxes in any period. As of September 30, 2006, we had net operating loss carryforwards of approximately $101.3 million for state income tax purposes and $93.6 million for federal income tax purposes. We also had $2.5 million in research and development federal income tax credits as of September 30, 2006. 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. 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.

Results of Operations

Three Months ended September 30, 2006 and 2005

Revenue

Revenue increased by $660,000 to $998,000 for the three months ended September 30, 2006, from $338,000 for the corresponding three-month period in 2005. The increase was principally attributable to recognition of $313,000 of the $10.0 million initial fee that we received from AstraZeneca in February 2006 and $87,000 in payments that we made to third parties for research and manufacturing services that are reimbursable under our agreement with AstraZeneca. Based on the agreement terms, we allocated $5.0 million of the initial fee to the a4ß2 research collaboration, which we expect to recognize as license fee revenue over the planned four-year term of the research collaboration. We began to recognize this allocated portion of the initial fee as license fee revenue in February 2006 at the rate of $104,000 per month. We deferred recognition of any of the remaining $5.0 million of the initial fee, which we allocated to the TC-1734 (AZD3480) license grants, until AstraZeneca makes a determination whether to conduct Phase II clinical development of TC-1734 (AZD3480) following its completion of additional safety and product characterization studies. We had no research fee revenue or license fee revenue in the comparable 2005 period.

In future periods, we are eligible to receive research fees, license fees and milestone payments under our collaboration agreement with AstraZeneca. The amount of research fees, license fees and milestone fees will depend on the extent of our research activities and the timing and achievement of development, regulatory and first commercial sale milestone events.

The increase in revenue was also attributable to an increase in grant revenue by $262,000 to $437,000 for the three months ended September 30, 2006, from $175,000 for the comparable three-month period in 2005. The grant revenue for the 2006 period related to work performed under the

cooperative agreement awarded to us in the third quarter of 2003 by the National Institute of Standards and Technology through its Advanced Technology Program, or ATP, to fund the development of sophisticated molecular simulation software and to work performed in connection with our subcontract under the 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. In contrast, the grant revenue for the 2005 period related only to work performed in connection with the ATP award. The increase for the 2006 period reflects $72,000 in additional research activity by us under the cooperative agreement, as compared to the 2005 period, and revenue of $190,000 for work performed in connection with the NIDA grant. The term of the ATP award expired September 30, 2006. Due to the expiration of the term of the ATP award, we expect that our grant revenue will decrease in future periods.

Net sales of Inversine decreased by $2,000 to $161,000 for the three months ended September 30, 2006, from $163,000 for the comparable three-month period in 2005. We believe that the substantial majority of Inversine sales are derived from prescriptions written by a very limited number of physicians. If any of these physicians were to change their prescribing habits, it would likely cause sales of Inversine to decrease. We do not promote sales of Inversine.

Research and Development Expense

Research and development expense decreased by $929,000 to $5.3 million for the three months ended September 30, 2006, from $6.2 million for the comparable three-month period in 2005. The lower research and development expense was primarily attributable to a decrease of $2.3 million in expense relating to TC-1734 (AZD3480) for the 2006 period, as compared to the 2005 period, as a result of the assumption by AstraZeneca of development costs for that product candidate under our collaboration agreement. This decrease was partially offset by an increase in expense relating to TC-2696 of $250,000 for the 2006 period as compared to the 2005 period in connection with the resumption of our Phase I multiple rising dose clinical trial of and formulation work for that product candidate. The decrease was also partially offset by an increase in expense relating to TC-2216 and TC-5619 of $296,000 and $169,000, respectively, for the 2006 period as compared to the 2005 period to conduct additional preclinical safety studies and by increased salary and benefit expense for research and development personnel and increased third-party service, supply and infrastructure costs incurred in connection with our a4ß2 research collaboration with AstraZeneca that we initiated in January 2006.

Research and development expense for the three months ended September 30, 2006 includes our costs to conduct research activities under the a4ß2 research collaboration with AstraZeneca. We believe that our research activities during the three-month period qualify us for $1.4 million in research fee revenue from AstraZeneca that we would recognize if the agreement continues in effect following AstraZeneca’s completion of the additional safety and product characterization studies of TC-1734 (AZD3480). During the period that AstraZeneca conducts the safety and product characterization studies, AstraZeneca has agreed to pay us 50% of our research expenses, subject to a specified limit. Accordingly, we have recorded 50% of $1.4 million, or $701,000, as deferred revenue and have not recorded the remaining $701,000 that we are not yet entitled to receive. We expect AstraZeneca to complete the safety and product characterization studies in or before the first quarter of 2007.

General and Administrative Expense

General and administrative expense was $1.2 million for both the three months ended September 30, 2006 and 2005. We expect that our general and administrative expense will increase in future periods due to increased payroll, expanded infrastructure and increased insurance, consulting, legal, accounting and investor relations costs associated with being a public company.

Cost of Product Sales

Cost of product sales increased by $9,000 to $132,000 for the three months ended September 30, 2006, from $123,000 for the comparable three-month period in 2005. The increase primarily reflects our recognition into cost of product sales during the 2006 period of a pro rata portion of FDA product fees with respect to Inversine that we paid in 2005.

The FDA assesses product and establishment fees for marketed products each year for the twelve-month period beginning October 1. Payment is required in advance, but companies can request a waiver after making payment. In assessing waiver requests, the FDA considers whether the company is pursuing innovative drug products or technology and whether the fees would present a significant barrier to the company's ability to develop, manufacture or market innovative drug products or technology. We have historically requested a waiver of the FDA fees with respect to Inversine. We pay the fees, record our payment as a prepaid item and then recognize the prepaid amount as cost of product sales ratably over the twelve-month period. Although the FDA granted our request for waivers of both the product and establishment fees that we paid in 2004 and our request for a waiver of the establishment fees that we paid in 2005, the FDA denied our request for a waiver of $42,000 in product fees that we paid in 2005. As a result, we recognized $10,500 of the fees as cost of product sales for the three months ended September 30, 2006. As permitted by the FDA, we have requested a reconsideration of our request for a waiver of the product fees that we paid in 2005 with respect to Inversine.

We plan to petition the FDA for a waiver of product and establishment fees with respect to Inversine in future years. Historically, the award that we received from the National Institute of Standards and Technology through its Advanced Technology Program to fund the development of sophisticated molecular simulation software has been significant in supporting our waiver requests. Our funding under the award concluded in the third quarter of 2006, and the likelihood that our pending or future fee waiver requests will be allowed is uncertain. If any future fee waiver request is not allowed, our cost of product sales for Inversine would increase.

Interest Income

Interest income increased by $507,000 to $807,000 for the three months ended September 30, 2006, from $300,000 in the comparable three-month period in 2005. The increase was attributable to a substantially higher average cash balance during the 2006 period following completion of our initial public offering in April 2006 in which we received net proceeds of approximately $40.8 million and, to a lesser extent, higher short-term interest rates.

Interest Expense

Interest expense decreased by $29,000 to $21,000 for the three months ended September 30, 2006, from $50,000 for the comparable three-month period in 2005. The decrease was attributable to

reduced indebtedness for the 2006 period, as compared to the 2005 period, resulting from our payment in August 2005 of the outstanding balance on a $1.3 million convertible promissory note to The Stanley Medical Research Institute and a lower principal balance under a loan facility used to finance laboratory and other capital equipment purchases. In June 2006, we amended our existing loan facility to provide us with an additional $2.0 million in aggregate borrowing capacity available to us on or before June 30, 2007. As of September 30, 2006, we have not yet made draws against this additional borrowing capacity, but expect to do so during the first half of 2007. Additionally, beginning in April 2007 following expiration of a five-year grace period, we will begin to recognize interest expense on a $500,000 loan from the City of Winston-Salem. We expect that these items will increase our interest expense beginning in 2007.

Nine Months ended September 30, 2006 and 2005

Revenue

Revenue increased by $1.3 million to $2.2 million for the nine months ended September 30, 2006, from $941,000 for the corresponding nine-month period in 2005. The increase was principally attributable to recognition of $833,000 of the $10.0 million initial fee that we received from AstraZeneca in February 2006 and $149,000 in payments that we made to third parties for research and manufacturing services that are reimbursable under our agreement with AstraZeneca. We had no research fee revenue or license fee revenue in the comparable 2005 period.

The increase in revenue was also attributable to an increase in grant revenue by $304,000 to $742,000 for the nine months ended September 30, 2006, from $438,000 for the comparable nine-month period in 2005. The increase for the 2006 period reflects $114,000 in additional research activity by us under the ATP cooperative agreement, as compared to the 2005 period, and revenue of $190,000 for work performed in connection with the NIDA grant.

Net sales of Inversine decreased by $35,000 to $469,000 for the nine months ended September 30, 2006, from $504,000 for the comparable nine-month period in 2005. The decrease was due to lower sales volume.

Research and Development Expense

Research and development expense decreased by $3.9 million to $14.7 million for the nine months ended September 30, 2006, from $18.6 million for the comparable nine-month period in 2005. The lower research and development expense was primarily attributable to a decrease of $5.8 million in research and development expense relating to TC-1734 (AZD3480) for the 2006 period, as compared to the 2005 period, as a result of the assumption by AstraZeneca of development costs for that product candidate under our collaboration agreement, and a decrease of $251,000 in research and development expense for TC-2696 due to the temporary suspension of our Phase I multiple rising dose clinical trial. These decreases were partially offset by an increase in research and development expense relating to TC-2216 and TC-5619 of $1.3 million and $434,000, respectively, for the 2006 period as compared to the 2005 period to conduct additional preclinical safety studies and formulation work. The decreases were also partially offset by increased salary and benefit expense for research and development personnel for the 2006 period as compared to the 2005 period, and increased third-party service, supply and infrastructure costs incurred in connection with our a4ß2 research collaboration with AstraZeneca that we initiated in January 2006.

Research and development expense for the nine months ended September 30, 2006 includes our costs to conduct research activities under the a4ß2 research collaboration with AstraZeneca. We believe that our research activities during the nine-month period qualify us for $3.5 million in research fee revenue from AstraZeneca that we would recognize if the agreement continues in effect following AstraZeneca's completion of the additional safety and product characterization studies of TC-1734 (AZD3480). We have recorded 50% of $3.5 million, or $1.76 million, as deferred revenue and have not recorded the remaining $1.76 million that we are not yet entitled to receive.

General and Administrative Expense

General and administrative expense was $3.7 million for the nine months ended September 30, 2006 and $3.6 million for the comparable period in 2005.

Transaction Charge

In the nine months ended September 30, 2005, we recorded expense of $1.6 million in connection with a public offering that we terminated in March 2005. There were no similar expenses for the 2006 period as all costs that we incurred in connection with our initial public offering that we completed in April 2006 were recorded as prepaid expenses pending the completion of the offering and were offset against the proceeds from the offering upon completion.

Cost of Product Sales

In the nine months ended September 30, 2006, our cost of product sales increased by $57,000 to $301,000 from $244,000 for the comparable nine-month period in 2005. All of these costs related to sales of Inversine. The increase for the 2006 period primarily reflects the FDA's denial in June 2006 of our request for a waiver of product fees of $42,000 that we paid in 2005. In contrast, our request for a waiver of the product fees that we paid in 2004 was allowed by the FDA in 2005.

Interest Income

Interest income increased by $930,000 to $1.8 million for the nine months ended September 30, 2006, from $898,000 in the comparable nine-month period in 2005. The increase was attributable to a substantially higher average cash balance during the 2006 period following completion of our initial public offering in April 2006 and, to a lesser extent, higher short-term interest rates.

Interest Expense

Interest expense decreased by $127,000 to $69,000 for the nine months ended September 30, 2006, from $196,000 for the comparable nine-month period in 2005. The decrease was attributable to reduced indebtedness for the 2006 period, as compared to the 2005 period, resulting from our payment in August 2005 of the outstanding balance on a $1.3 million convertible promissory note to The Stanley Medical Research Institute and a lower principal balance under a loan facility used to finance laboratory and other capital equipment purchases.

Accretion of Preferred Stock

We recorded charges of $3.3 million for accretion of our preferred stock to its redemption value for the nine months ended September 30, 2006, as compared to $8.4 million for the nine months ended September 30, 2005. Upon completion of our initial public offering in April 2006, all of our outstanding shares of convertible preferred stock converted into shares of common stock, eliminating the potential that the convertible preferred stock would be redeemed. Accordingly, we recorded charges for accretion of preferred stock only until the date of completion of our initial public offering and, as of that date, reversed all previously recorded charges for accretion of preferred stock.

Liquidity and Capital Resources

Sources of Liquidity

From August 2000 when we became an independent company until completion of our initial public offering in April 2006, we financed our operations and internal growth primarily through private placements of convertible preferred stock. We derived aggregate net proceeds of $121.8 million from these private placements. In April 2006, we completed an initial public offering of our common stock, consisting of 5.0 million shares of our common stock at a price of $9.00 per share. After deducting underwriting discounts and commissions and other offering expenses, our net proceeds from the offering were approximately $40.8 million. We have also received additional funding from upfront license fees and payments for research and development services under collaboration agreements, equipment and building lease incentive financing, government grants and interest income. We began generating revenues from product sales of Inversine in December 2002. To date, the net contribution from Inversine sales has not been a significant source of cash and we do not expect it to be a significant source in the future.

Under our collaboration agreement with AstraZeneca, AstraZeneca paid us an initial fee of $10.0 million in February 2006. AstraZeneca has agreed to make an additional payment to us of $20.0 million if it decides to conduct a Phase II clinical trial of TC-1734 (AZD3480) following its completion of additional safety and product characterization studies conducted at its expense to generate further data with respect to TC-1734 (AZD3480). We expect AstraZeneca to complete these safety and product characterization studies in or before the first quarter of 2007. If AstraZeneca terminates our agreement upon completion of any or all of its additional safety and product characterization studies, we would be required to reimburse AstraZeneca for the amount of all research fees that it paid to us for our work performed in the a4ß2 research collaboration while AstraZeneca conducted the studies. In addition, we would be required to pay AstraZeneca an additional $5.0 million as compensation for assigning to us the data and any intellectual property generated in the studies.

In April 2002, we received a $500,000 loan from the City of Winston-Salem. Under the terms of this borrowing, there is no interest accrual or payment due until the fifth anniversary of the loan. Beginning in April 2007, following expiration of the five-year grace period, the outstanding principal balance of the loan will bear interest at a fixed interest rate of 5% and the loan will be payable in 60 equal monthly installments of $9,000.

In May 2002, we borrowed $2.5 million from R.J. Reynolds Tobacco Holdings, Inc. to finance equipment and other fixed assets that we had previously purchased. This borrowing was paid and satisfied in full in May 2006. In January 2004, we amended the terms of the facility to permit us to borrow up to an additional $2.0 million in 2004 in up to three separate borrowings. We borrowed $1.0 million in April 2004 and $973,000 in December 2004 under the amended facility to finance equipment. The April 2004 borrowing bears a fixed interest rate of 5.87%, is payable in 48 equal monthly installments and matures in April 2008. The December 2004 borrowing bears a fixed interest rate of 6.89%, is payable in 48 monthly installments and matures in January 2009. In June 2006, we further amended the facility to permit us to borrow an additional $2.0 million on or before June 30, 2007 in up to three separate borrowings. Each borrowing would accrue interest at a per annum rate that approximates the hypothetical four-year U.S. Treasury rate, determined as of the date of the borrowing, plus 2.5% and be payable in equal monthly installments of principal and accrued interest over 48 months beginning on the first day of the month following the borrowing. All borrowings under the facility are, and all future borrowings under the facility will be, secured by specified tangible fixed assets determined sufficient by the lender at the time of disbursement. As of September 30, 2006, the outstanding principal balance under the loan facility was $1.0 million.

Our cash, cash equivalents and short-term investments were $58.8 million as of September 30, 2006.

Cash Flows

Net cash used in operating activities was $5.5 million for the nine months ended September 30, 2006, as compared to $20.7 million for the comparable nine-month period in 2005. The decrease for the 2006 period was principally due to a reduction in net loss of $7.7 million for the 2006 period as compared to the 2005 period and to our receipt in February 2006 of the initial fee of $10.0 million from AstraZeneca under our collaboration agreement, net of the $833,000 portion of the initial fee recognized as of September 30, 2006. The decrease was partially offset by an increase of $1.4 million in research fees and accounts receivable for the 2006 period, resulting primarily from our receipt of $1.1 million from AstraZeneca for work performed in the a4ß2 research collaboration that we have not recognized as revenue because it may become reimbursable to AstraZeneca.

Net cash used in investing activities was $12.9 million for the nine months ended September 30, 2006, as compared to $237,000 for the comparable nine-month period in 2005. The increase for the 2006 period was primarily due to our investment of $12.0 million in short-term certificate of deposits following completion of our initial public offering in April 2006, as compared to the 2005 period when we held our cash primarily in a money market account. In addition, we purchased $945,000 of equipment during the nine months ended September 30, 2006 to support our activities under our a4ß2 research collaboration with AstraZeneca, an increase of $708,000 over our equipment purchases during the comparable 2005 period.

Net cash provided by financing activities was $40.2 million for the nine months ended September 30, 2006, as compared to net cash used for financing activities of $1.4 million for the comparable nine-month period in 2005. The increase for the 2006 period was principally due to our receipt of $40.8 million in net proceeds from our initial public offering completed in April 2006 and to our payment in August 2005 of the outstanding balance on a $1.3 million convertible promissory note to The Stanley Medical Research Institute.

Funding Requirements

We have incurred significant losses since our inception. As of September 30, 2006, we had an accumulated deficit of $153.0 million. We expect to continue 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 III clinical development of TRIDMAC;
- the scope, progress, results and cost of preclinical development and laboratory testing and clinical trials;
- the timing, receipt and amount of milestone and other payments from AstraZeneca and potential future collaborators;
- the costs, timing and outcome of regulatory review;
- 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 establishing sales and marketing functions and of establishing arrangements for manufacturing;
- the rate of technological advancements for the indications that we target;
- our ability to establish strategic collaborations and licensing or other arrangements on terms favorable to us;
- the costs to satisfy our obligations under existing and potential future 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 increases in our capital requirements as we expand our clinical trial activity, as our product candidates advance through the development cycle, and as we invest in additional product opportunities and research programs and expand our infrastructure. In particular, we anticipate that we will purchase additional equipment over the next several quarters, and that we will incur additional costs beginning in or about the fourth quarter of 2006 in connection with the expansion and lease of our laboratory space, to support our activities under our a4ß2 research collaboration with AstraZeneca. 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 other product candidates. We expect that our existing capital resources will be sufficient to fund our operations through mid-2008. However, our operating plan may change as a result of many factors, including those described above. In particular, our operating plan may change if

AstraZeneca decides not to proceed with the further development of TC-1734 following its completion of any or all of the safety and product characterization studies that it conducts and terminates our agreement. In that event, we would be required to reimburse AstraZeneca for the amount of all research fees that it paid to us for our work performed in the a4ß2 research collaboration while it conducted the studies. We would also be required to pay to AstraZeneca an additional $5.0 million as compensation for assigning to us the data and any intellectual property generated in the studies, but we would not be required to refund the $10.0 million initial fee that AstraZeneca paid us. 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 to result in increases in our cash required to fund operations over the next several quarters and years. To the extent our capital resources are insufficient to meet future capital requirements, we will need to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if 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, reduce our planned commercialization efforts, 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.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 157, *Fair Value Measurements* (“SFAS 157”). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact, if any, of the provisions of SFAS 157.

In September 2006, the Securities and Exchange Commission (“SEC”) issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (“SAB 108”). SAB 108 provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in a misstatement that, when all relevant quantitative and qualitative factors are considered, is material and therefore must be quantified. SAB 108 is effective for years ending on or after November 15, 2006.

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 short-term investments in a variety of securities of high credit quality. As of September 30, 2006, we had cash,

cash equivalents and short-term investments of $58.8 million. A portion of 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, 2006 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, investigational sites and 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 exchange rate or the average Indian Rupee/U.S. dollar exchange rate were to strengthen or weaken by 10% against the respective exchange rates as of September 30, 2006, 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

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 Securities and Exchange Commission’s rules and forms.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors.

Risks Related to Our Financial Results and Need for Additional Financing

We have incurred losses since our inception and anticipate that we will continue to incur substantial losses for the foreseeable future. We may never achieve or sustain profitability.

We were incorporated in 1997 and operated as a wholly owned subsidiary of R.J. Reynolds Tobacco Company until August 2000. We have a limited operating history and have incurred substantial net losses since our inception. As of September 30, 2006, we had an accumulated deficit of $153.0 million. Our net loss was $14.7 million for the nine months ended September 30, 2006 and $29.0 million for the year ended December 31, 2005. Our losses have resulted principally from costs incurred in connection with our research and development activities, including clinical trials, and from general and administrative expenses associated with our operations. We expect to continue to incur substantial losses for the foreseeable future. We expect our research and development expenses to increase substantially over the next several years as we expand our clinical trial activity and as our product candidates advance through the development cycle. We also expect our general and administrative expenses to increase substantially as we expand our infrastructure. As a result, we will need to generate significant revenues to pay these expenses and achieve profitability.

Inversine is our only current source of product revenue. We acquired the rights to Inversine in August 2002. Sales of Inversine generated revenues of only $469,000 for the nine months ended September 30, 2006 and $681,000 for the year ended December 31, 2005. Inversine is approved in the United States for the management of moderately severe to severe essential hypertension, a high blood pressure disorder. However, we believe that the substantial majority of Inversine sales are derived from prescriptions written by a very limited number of physicians for the treatment of neuropsychiatric disorders, such as Tourette's syndrome, autism and bipolar disorder, in children and adolescents. If any of these physicians were to change their prescribing habits, Inversine sales would suffer. We do not expect that sales of Inversine will increase substantially in the future.

If we are unable to develop and commercialize any of our product candidates, if development is delayed or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never become profitable. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

We will require substantial additional financing and our failure to obtain additional funding when needed could force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will require substantial future capital in order to continue to conduct the research and development and clinical and regulatory activities necessary to bring our product candidates to market and to establish marketing and sales capabilities. Our future capital requirements will depend on many factors, including:

- whether we conduct Phase III clinical development of mecamylamine hydrochloride as an augmentation treatment to citalopram hydrobromide, a treatment combination that we refer to as TRIDMAC;

- the scope, progress, results and cost of preclinical development and laboratory testing and clinical trials;
- the timing, receipt and amount of milestone and other payments from AstraZeneca and potential future collaborators;
- the costs, timing and outcomes of regulatory reviews;
- 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 establishing sales and marketing functions and of establishing arrangements for manufacturing;
- the rate of technological advancements for the indications that we target;
- our ability to establish strategic collaborations and licensing or other arrangements on terms favorable to us;
- the costs to satisfy our obligations under existing and potential future 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.

In addition, we may seek additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that are not favorable to us.

Our current operating plan provides for us to continue, either alone or with a collaborator, to advance our product candidates through the development process. Our net cash used in operating activities for 2005 was $26.2 million, or approximately $2.2 million per month. Our net cash used in operating activities for the nine months ended September 30, 2006 was $5.5 million, which reflects the $10 million initial fee that we received from AstraZeneca in February 2006. If the initial fee paid by AstraZeneca were excluded, our net cash used in operating activities would have been $15.5

million, or approximately $1.7 million per month. We are including net cash used in operating activities for the nine months ended September 30, 2006 exclusive of the initial fee paid by AstraZeneca, a non-GAAP financial measure, because we believe that including only net cash used in operating activities would not be a true reflection of our monthly operating cash flows.

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 expect that our existing capital resources will enable us to maintain currently planned operations through mid-2008. 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 and commercialization. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may:

- terminate or delay clinical trials for one or more of our product candidates;
- delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates; or
- curtail significant drug development programs that are designed to identify new product candidates.

If AstraZeneca does not proceed with a Phase II clinical trial of TC-1734 (AZD3480) and terminates our collaboration agreement, we may need additional capital sooner than planned.

Our collaboration agreement with AstraZeneca provides for AstraZeneca to conduct additional safety and product characterization studies of TC-1734 (AZD3480) before deciding whether to proceed with planned Phase II clinical trials to evaluate the efficacy of TC-1734 (AZD3480) in mild to moderate Alzheimer's disease and cognitive deficits in schizophrenia. Upon completion of any or all of the safety and product characterization studies, AstraZeneca has the right to terminate our agreement based on the results of the studies and all other available information with respect to TC-1734 (AZD3480). In that event, we would be required to reimburse AstraZeneca for the amount of all research fees that it paid to us for our work performed in the a4ß2 research collaboration that we and AstraZeneca are conducting under the agreement while AstraZeneca conducted the studies. We would also be required to pay AstraZeneca $5 million as compensation for assigning to us the data and any intellectual property generated in the studies, but we would not be required to refund the $10 million initial fee that AstraZeneca paid us. If AstraZeneca terminates our agreement, we may need additional capital sooner than planned.

AstraZeneca's safety and product characterization studies consist of:

- in vitro studies to assess whether TC-1734 (AZD3480), when administered at a therapeutically relevant dose, activates a particular protein that can activate an enzyme known as CYP1A1 that is considered by some scientists to increase susceptibility to cancer;

- a clinical trial to characterize the cardiovascular effects of various doses of TC-1734 (AZD3480) in persons who break down and eliminate, or metabolize, TC-1734 (AZD3480) at varying rates;
- a single-dose study in dogs to further assess the cardiovascular effects of TC-1734 (AZD3480); and
- small clinical trials to evaluate the interaction and combined effects of TC-1734 (AZD3480) with paroxetine, a known inhibitor of a key enzyme involved in the primary metabolic pathway of TC-1734 (AZD3480), and with multiple commonly prescribed treatments for schizophrenia.

In addition, during the period in which AstraZeneca conducts these safety and product characterization studies, we expect that AstraZeneca will conduct other research and development activities with TC-1734 (AZD3480) customary for its stage of development, such as studies to characterize its mechanism of action and pharmaceutical development and formulation work. We also expect that during this period AstraZeneca will conduct one or more Phase I clinical trials in healthy volunteers of Japanese descent to support the potential future pursuit of regulatory approval of TC-1734 (AZD3480) in Japan.

In a study in rats conducted by a former collaborator of ours, TC-1734 (AZD3480) was found to activate the enzyme CYP1A1, but at a dose substantially higher than the doses at which we and AstraZeneca plan to pursue development of TC-1734 (AZD3480) for Alzheimer's disease and cognitive deficits in schizophrenia. If AstraZeneca determines that TC-1734 also activates CYP1A1 in humans at a therapeutically relevant dose, AstraZeneca may terminate our agreement.

In addition, the study design for AstraZeneca's single-dose cardiovascular study of TC-1734 (AZD3480) in dogs was substantially similar to a study previously conducted by a former collaborator of ours as part of the preclinical evaluation of TC-1734 (AZD3480) in which cardiovascular effects were observed. However, we believe that the cardiovascular effects observed in the prior study were not related to TC-1734 (AZD3480), but resulted from the presence of a substance that was used to facilitate the administration and delivery of TC-1734 (AZD3480) and that is now known to cause cardiovascular effects in dogs. AstraZeneca did not use that substance in its study. We did not observe cardiovascular effects in subsequent studies that we conducted in dogs in which we administered TC-1734 (AZD3480) over 90 days and 180 days. If the results of AstraZeneca's single-dose study in dogs are not favorable, AstraZeneca may terminate our agreement.

Risks Related to the Development and Regulatory Approval of Our Product Candidates

Our success depends substantially on our most advanced product candidates, which are still under development. If we are unable to bring any or all of these product candidates to market, or experience significant delays in doing so, our ability to generate product revenue and our likelihood of success will be harmed.

We and AstraZeneca have agreed to develop TC-1734 (AZD3480) for Alzheimer's disease and cognitive deficits in schizophrenia. However, TC-1734 (AZD3480) has not yet been evaluated in any clinical trial in patients suffering from Alzheimer's disease or cognitive deficits in

schizophrenia. In March 2006, we independently completed a Phase II clinical trial of TC-1734 (AZD3480) in AAMI that was designed to further assess the effects of TC-1734 (AZD3480) on cognition in a cognitively impaired older adult population. Our ability to generate product revenue in the future will depend heavily on the successful development and commercialization of TC-1734 (AZD3480).

Inversine is our only approved product and generates limited revenues. Mecamylamine hydrochloride is the active ingredient in Inversine. We have completed a Phase II clinical trial of TRIDMAC, which is a treatment combination comprised of mecamylamine hydrochloride as an augmentation treatment to citalopram hydrobromide, for major depression. We have also completed a Phase I single rising dose clinical trial for TC-2696, our product candidate for the treatment of pain, and are currently conducting a Phase I multiple rising dose clinical trial for TC-2696. In a single rising dose clinical trial, each subject in a dose group receives a dosage of the drug being evaluated only one time, with subjects in each subsequent dose group receiving a pre-determined higher dosage than subjects in the preceding dose group. In a multiple rising dose clinical trial, each subject in a dose group receives a dosage of the drug being evaluated multiple times, with subjects in each subsequent dose group receiving a pre-determined higher dosage than subjects in the preceding dose group. In addition, we have filed a Clinical Trial Authorization application to initiate a Phase I clinical trial of TC-2216, our product candidate for depression and anxiety disorders, in Europe. Our other product candidates are in various stages of preclinical development.

Any of our product candidates could be unsuccessful if it:

- does not demonstrate acceptable safety and efficacy in preclinical studies or clinical trials or otherwise does not meet applicable regulatory standards for approval;
- does not offer therapeutic or other improvements over existing or future drugs used to treat the same conditions;
- is not capable of being produced in commercial quantities at acceptable costs; or
- is not accepted in the medical community and by third-party payors.

We do not expect any of our current product candidates to be commercially available for at least the next several years, if at all. If we are unable to make our product candidates commercially available, we will not generate substantial product revenues and we will not be successful.

If safety studies conducted by AstraZeneca demonstrate that TC-1734 (AZD3480) is not safe for individuals that metabolize the drug slowly or when the primary means by which the body metabolizes TC-1734 (AZD3480) is blocked, AstraZeneca could cease development of TC-1734 (AZD3480) and terminate its agreement with us. Poor results from these safety studies or termination of our agreement with AstraZeneca would make it more difficult for us to advance development and obtain the regulatory approvals required to market and sell TC-1734 (AZD3480).

Metabolism of a drug refers to a process in which a drug is broken down and then eliminated from the body. The means by which the body metabolizes a drug is referred to as the metabolic pathway. Due to genetic differences, individuals can metabolize drugs through the same metabolic pathway at different rates. For any particular metabolic pathway, an individual can be a poor,

intermediate or extensive metabolizer. Drugs that are metabolized through a particular metabolic pathway may remain in the body at higher concentrations and for longer periods of time in people who are poor metabolizers than in people who are intermediate or extensive metabolizers through that metabolic pathway. As a result, a drug that is determined to be safe when metabolized efficiently by an extensive metabolizer may not be safe or may not be as safe when metabolized inefficiently by a poor metabolizer.

As discussed in greater detail above under "—Risks Related to Our Financial Results and Need for Additional Financing," our agreement with AstraZeneca provides for AstraZeneca to conduct additional safety and product characterization studies of TC-1734 (AZD3480) before deciding whether to proceed with further development of TC-1734 (AZD3480). In particular, our agreement with AstraZeneca provides that AstraZeneca will assess the safety of TC-1734 (AZD3480) in both extensive metabolizers and poor metabolizers, as well as in combination with another drug that may block the primary metabolic pathway of TC-1734 (AZD3480). We expect AstraZeneca to conduct a clinical trial to characterize the cardiovascular effects of TC-1734 (AZD3480) in both extensive metabolizers and poor metabolizers and that the trial may potentially involve doses of up to 200mg. The highest dose at which we have assessed the safety of TC-1734 (AZD3480) in persons over the age of 65 is 150mg, in the first Phase II clinical trial in AAMI that we conducted. In that trial, three out of eight subjects treated with 150mg of TC-1734 (AZD3480) while fasting experienced side effects such as headache, lightheadedness, dizziness and vomiting and dropped out of the trial. However, in a Phase I single rising dose clinical trial of TC-1734 (AZD3480) that we conducted, TC-1734 (AZD3480) was well tolerated at a dose of up to 320mg in young adults. We also expect AstraZeneca to conduct a small clinical trial to characterize the cardiovascular effects of TC-1734 (AZD3480) when administered in combination with paroxetine, a known inhibitor of a key enzyme involved in the primary metabolic pathway of TC-1734 (AZD3480).

If the safety studies conducted by AstraZeneca demonstrate that TC-1734 (AZD3480) is not safe in poor metabolizers or is not safe when the primary metabolic pathway for TC-1734 (AZD3480) is blocked, AstraZeneca could decide not to conduct a Phase II clinical trial of TC-1734 (AZD3480) and terminate its agreement with us. If AstraZeneca terminates our agreement, it would delay our development of TC-1734 (AZD3480). In addition, poor results from these studies would make it more likely that we would not receive the regulatory approvals required to market and sell TC-1734 (AZD3480). Even if we were to receive the required regulatory approvals, the regulatory authorities could limit the patient population for which TC-1734 (AZD3480) is approved to those who are extensive or intermediate metabolizers through the primary metabolic pathway of TC-1734 (AZD3480). If regulatory authorities limit the patient population for which TC-1734 (AZD3480) is approved in this manner, it would have an adverse effect on the commercial potential of TC-1734 (AZD3480).

If the combination of TC-1734 (AZD3480) administered together with other drugs that are commonly prescribed for schizophrenia is not considered to be safe, the commercial potential of TC-1734 (AZD3480) would be adversely affected.

A drug that is generally safe when taken alone may not be safe or may not be as safe when taken together with other drugs. We expect AstraZeneca to conduct a small clinical trial of TC-1734 (AZD3480) administered together with multiple commonly prescribed treatments for schizophrenia in healthy volunteers to evaluate the interaction of the drugs and the combined effects on metabolism and safety. If the interaction of TC-1734 (AZD3480) and any or all of the commonly prescribed

treatments for schizophrenia adversely affects the metabolism of TC-1734 (AZD3480) such that TC-1734 (AZD3480) and any of those treatments are determined to be unsafe together, it could limit the commercial potential of TC-1734 (AZD3480) as a treatment for cognitive deficits in schizophrenia. Moreover, AstraZeneca could decide not to advance TC-1734 (AZD3480) as a treatment for cognitive deficits in schizophrenia, which would limit the overall commercial potential of TC-1734 (AZD3480). Furthermore, if the interaction of TC-1734 (AZD3480) with any of these commonly prescribed treatments adversely affects the metabolism of TC-1734 (AZD3480), AstraZeneca could decide not to conduct any Phase II clinical trials of TC-1734 (AZD3480) and terminate its agreement with us. If AstraZeneca terminates our agreement, it would delay our development of TC-1734 (AZD3480).

If we do not obtain the regulatory approvals required to market and sell our product candidates, our ability to generate product revenue will be materially impaired and our business will not be successful.

The preclinical laboratory testing, development, manufacturing and clinical trials of product candidates that we develop, whether independently or in collaboration with a third party, as well as their distribution, sale and marketing, are regulated by the FDA and other federal, state and local governmental authorities in the United States and by similar agencies in other countries. We must receive regulatory approval of each product candidate before we can market and sell it. We have only limited experience in pursuing regulatory approvals. Securing FDA approval requires the submission of extensive preclinical and clinical data and information about the chemistry and manufacture of, and control procedures for, each potential product. In addition, the supporting information submitted to the FDA must establish the safety and efficacy of the product candidate for each indicated use. The drug development and marketing approval process takes many years, requires the expenditure of substantial resources, is subject to delays and can vary substantially based upon the type, complexity and novelty of the product candidates involved. In addition to the time and expense involved, the process is uncertain and we may never receive the required regulatory approvals. In addition, the FDA, the U.S. Congress and foreign regulatory authorities may from time to time change approval policies or adopt new laws or regulations, either of which could prevent or delay our receipt of required approvals. Even if we receive regulatory approval to market a particular product candidate, the approval will be subject to limitations on the indicated uses for which it may be marketed and may not permit labeling claims that are necessary or desirable for its promotion.

According to the FDA, a Phase I clinical trial program typically takes several months to complete, a Phase II clinical trial program typically takes several months to two years to complete and a Phase III clinical trial program typically takes one to four years to complete. Industry sources report that the preparation and submission of a new drug application, or NDA, which is required for regulatory approval in the United States, generally takes six months to one year to complete after completion of a pivotal clinical trial. The Pharmaceutical Research and Manufacturers of America reports that only one out of five product candidates that enter clinical trials will ultimately be approved by the FDA for commercial sale.

The FDA may delay, limit or deny approval of any of our product candidates for many reasons. For example:

- clinical trial results may indicate that the product candidate is not safe or effective;

- the FDA may interpret our clinical trial results to indicate that the product candidate is not safe or effective, even if we interpret the results differently; or
- the FDA may deem the processes and facilities that we, our collaborative partners or our third-party manufacturers propose to use in connection with the manufacture of the product candidate to be unacceptable.

In addition, mecamylamine hydrochloride, our product candidate as an augmentation treatment for major depression, is the active ingredient in Inversine, which was approved by the FDA more than 50 years ago. The scope of preclinical safety information for mecamylamine previously submitted to the FDA in connection with its approval of Inversine is not as extensive as is required today. If we elect to conduct additional development of mecamylamine and ultimately pursue regulatory approval, the FDA or foreign regulatory authorities are likely to require us to conduct additional preclinical safety studies prior to considering or granting approval. These studies may include routine carcinogenicity studies, which are lengthy studies designed to evaluate any potential to cause cancer. If we conduct carcinogenicity or other lengthy studies before filing applications for regulatory approval, our receipt of regulatory approval may be delayed and, if the results of the studies are not favorable, may not occur at all.

Because drugs that target NNRs are a new class of drugs, the FDA and other applicable regulatory authorities may require more preclinical or clinical data for our product candidates or more time to evaluate that data than we currently anticipate. If we obtain the requisite regulatory approval for a particular product candidate, the approval may not extend to all indications for which we have sought approval, which could limit the use of the product and adversely impact our potential revenues.

Even if the FDA approves a product candidate for marketing and sale in the United States, applicable regulatory authorities in other countries may not approve the product candidate or may subject their approval to conditions such as additional product testing or otherwise cause delays. The regulatory approval process varies among countries, but generally includes all of the risks associated with obtaining FDA approval. In addition, many countries require a separate review process prior to marketing to determine whether their respective national health insurance schemes will pay for newly approved products, as well as the price that may be charged for a product. This process will cause delays in the marketing of any of our product candidates that receives marketing approval and could adversely impact our revenues and results of operations.

If clinical trials for our product candidates are not successful, we will not obtain the regulatory approvals required to market and sell them.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical studies and clinical trials, that the product candidate is safe and effective in humans. The number of clinical trials required to obtain approval varies depending on the particular product candidate, the disease or condition for which it is in development and the regulations applicable to it. Preclinical studies and clinical trials are lengthy and expensive, difficult to design and implement and subject to a historically high rate of failure. The development of each of our product candidates involves significant risks at each stage of testing. A failure of one or more of our clinical trials could occur at any stage of testing. In 2004, we completed Phase II clinical trials for product candidates that we had been developing for attention deficit hyperactivity disorder and ulcerative colitis. Because we determined that these product

candidates failed to meet defined endpoints of the Phase II clinical trials, we discontinued the development of these product candidates for these indications. If we experience similar difficulties or failures in our ongoing or future clinical trials, or if we are not able to design our clinical trials with clear criteria to determine the efficacy of our product candidates, our product candidates may never be approved for sale or become commercially available.

We may not be able to obtain authority or approval from the FDA, other applicable regulatory authorities or the institutional review boards at our intended investigational sites to commence or complete our clinical trials. Before a clinical trial may commence in the United States, we must submit an investigational new drug application, or IND, containing preclinical studies, chemistry, manufacturing, control and other information and a study protocol to the FDA. If the FDA does not object within 30 days after submission of the IND, then the trial may commence. If commenced, we, the FDA, other applicable regulatory authorities or institutional review boards may delay, suspend or terminate clinical trials of a product candidate at any time if, among other reasons, we or they believe the subjects or patients participating in the clinical trials are being exposed to unacceptable health risks or for other reasons.

If we do not prove in clinical trials that our product candidates are safe and effective, we will not obtain marketing approvals from the FDA and other applicable regulatory authorities. In particular, one or more of our product candidates may not exhibit the expected medical benefits in humans, may cause harmful side effects or may have other unexpected characteristics that preclude regulatory approval for any or all indications of use or limit commercial use if approved. For example, in the 100mg dose group of our Phase I multiple rising dose trial of TC-2696, our product candidate for pain, we suspended further dosing after two of three volunteers discontinued participation in the trial due to dizziness, nausea and, in one case, vomiting. Both of these volunteers had received a single dose of TC-2696 prior to discontinuing participation in the trial. We did not see comparable effects at 100mg in our completed single rising dose trial of TC-2696. Based on in vitro metabolism studies of TC-2696 that we subsequently conducted, we currently believe that genetic differences in the primary metabolic pathway of TC-2696 may have played a key role in the different effects of 100mg observed in our single rising dose trial and our multiple rising dose trial. We have not yet determined definitively the dose range in which positive medical effects, if any, are achieved with TC-2696. If following further evaluation we determine that the different effects observed are in fact due to the primary metabolic pathway of TC-2696, that TC-2696 is not safe in poor metabolizers or is not safe when the primary metabolic pathway for TC-2696 is blocked and that the dose range in which positive medical effects are achieved with TC-2696 is not sufficiently below 100mg so as to provide an acceptable margin of safety, we may not receive the regulatory approvals required to market and sell TC-2696. Even if we do receive the required regulatory approvals, the regulatory authorities may limit the patient population for which TC-2696 is approved to those who are extensive or intermediate metabolizers through TC-2696's primary metabolic pathway.

We and AstraZeneca have agreed to develop TC-1734 (AZD3480) as a treatment for Alzheimer's disease and for cognitive deficits in schizophrenia. We and AstraZeneca may also in the future pursue the development of TC-1734 (AZD3480) as a treatment for AAMI. AAMI is a condition that is characterized by gradual memory loss or other cognitive impairment that generally occurs with normal aging. Because AAMI accompanies normal aging, is not a disease state and does not prevent a person from functioning on a daily basis, the FDA or foreign regulatory authorities may require that we establish that TC-1734 (AZD3480) meets a higher threshold of safety than the FDA or foreign regulatory authorities would require for diseases and more severe disorders. If we or

AstraZeneca is unable to demonstrate that TC-1734 (AZD3480) meets this higher safety threshold, the FDA or foreign regulatory authorities may not grant approval to market TC-1734 (AZD3480) for the treatment of AAMI.

Our research and preclinical programs and product candidates target diseases or disorders that are not well understood. For example, there is only limited scientific understanding of the causes of Alzheimer's disease, AAMI, schizophrenia, including cognitive deficits in schizophrenia, and depression and anxiety. In addition, there are no approved drugs that target NNRs to treat these diseases, and there is only limited scientific understanding of the relationships between these diseases and the neurological pathways targeted by our product candidates and research and preclinical programs. These uncertainties increase the risk that one or more of our clinical trials will not be successful.

If we and AstraZeneca do not have success in clinical trials of TC-1734 (AZD3480) for Alzheimer's disease or cognitive deficits in schizophrenia, we and AstraZeneca will not obtain the regulatory approvals required to market TC-1734 (AZD3480) for Alzheimer's disease or cognitive deficits in schizophrenia notwithstanding positive results in clinical trials of TC-1734 (AZD3480) in other indications.

We and AstraZeneca have agreed to develop TC-1734 (AZD3480) for Alzheimer's disease and cognitive deficits in schizophrenia. We and AstraZeneca may in the future also seek to develop TC-1734 (AZD3480) for other conditions marked by various degrees of cognitive impairment, such as ADHD, AAMI or MCI. Successful results in clinical trials of TC-1734 (AZD3480) in a condition marked by one degree of cognitive impairment may not be predictive of successful results in clinical trials of TC-1734 (AZD3480) in a condition marked by more severe cognitive impairment or in cognitive impairment resulting from a different condition. Neither we nor AstraZeneca has conducted any clinical trial of TC-1734 (AZD3480) in Alzheimer's disease or cognitive deficits in schizophrenia. The findings in any of our completed Phase II trials of TC-1734 (AZD3480) in AAMI or MCI may not be predictive of the effect of TC-1734 (AZD3480) in Alzheimer's disease or cognitive deficits in schizophrenia.

The CDR test battery that we have used in our clinical trials of TC-1734 (AZD3480) is different from the Alzheimer's Disease Assessment Scale-cognitive subscale, or ADAS-Cog, the test battery that is most often used to assess the efficacy of drugs for Alzheimer's disease. ADAS-Cog is designed to measure improvement in persons who are severely impaired and is generally less sensitive than the CDR test battery in measuring improvement in persons who are less impaired. We expect that AstraZeneca will use ADAS-Cog, and not the CDR test battery, as the primary endpoint in future clinical trials of TC-1734 (AZD3480) in Alzheimer's disease. The findings in our completed trials as to the effect of TC-1734 (AZD3480) on various aspects of cognition as measured by the CDR test battery may not be predictive of the effect of TC-1734 (AZD3480) on cognition as measured by ADAS-Cog. If future clinical trials of TC-1734 (AZD3480) in Alzheimer's disease are not successful, we and AstraZeneca will not obtain the regulatory approvals required to market TC-1734 (AZD3480) for Alzheimer's disease.

If positive results of completed clinical trials of our product candidates are not replicated in any future clinical trials, we will not obtain the regulatory approvals required to market and sell them.

Positive findings in preclinical studies of a product candidate may not be predictive of similar results in clinical trials in humans. In addition, positive results in early clinical trials of a product candidate may not be replicated in later clinical trials. In particular, in our Phase II clinical trial of TRIDMAC in major depression, we observed a statistically significant result in favor of TRIDMAC on one of two co-primary endpoints in the trial, group mean change from baseline on the Hamilton Depression Rating Scale, on an intent to treat basis and a strong trend in favor of TRIDMAC on a per protocol basis. The result on the other co-primary endpoint, achievement of remission, favored the TRIDMAC group over the placebo group, although this result was not statistically significant. To support an application for regulatory approval in the United States or elsewhere, we would need to conduct additional clinical trials of TRIDMAC. We have not determined whether we will conduct additional clinical development of TRIDMAC. If we do elect to conduct additional clinical development of TRIDMAC, our positive findings in our Phase II trial may not replicated in any future clinical trials. Furthermore, we have not yet determined the primary endpoints that we would use in any future clinical trials of TRIDMAC. If we conduct any additional clinical trials of TRIDMAC in the future but do not use group mean change on the HAM-D scale as a primary endpoint, it would be more likely that the positive finding in our completed Phase II trial would not be replicated. Also, we may elect to advance TC-5214 into clinical development in lieu of further development of mecamylamine hydrochloride as a component of TRIDMAC. The results that we observed with mecamylamine hydrochloride in our completed Phase II clinical trial may not be replicated in future trials of TC-5214.

In addition, we completed a Phase II clinical trial of TC-1734 (AZD3480) in AAMI in March 2006. We previously completed two other Phase II clinical trials of TC-1734 (AZD3480), one in AAMI and one in mild cognitive impairment, commonly referred to as MCI. In those trials, TC-1734 (AZD3480) demonstrated positive effects on cognition. However, our findings in those trials on cognition may not be replicated in future clinical trials of TC-1734 (AZD3480) in Alzheimer's disease, cognitive deficits in schizophrenia or other indications that involve a large number of subjects and a long duration of dosing. In addition, although TC-1734 (AZD3480) demonstrated positive effects at some dose levels with respect to some measures of cognition tested in the first Phase II clinical trial in AAMI that we conducted, TC-1734 (AZD3480) did not demonstrate positive effects as to all measures at all dose levels and placebo showed superior effects to TC-1734 (AZD3480) as to some measures at some dose levels in that trial.

Like most drugs, the active component of TC-1734 (AZD3480) must be combined with an inactive component to form a powder, known as a salt, that is suitable for commercialization as a pharmaceutical product. We anticipate that we or AstraZeneca may use a different salt form of TC-1734 (AZD3480) in the planned Phase II trials in mild to moderate Alzheimer's disease and cognitive deficits in schizophrenia and in future clinical trials of TC-1734 (AZD3480) than we used in our completed trials. The results of our completed clinical trials of TC-1734 (AZD3480) in the initial salt form may not be replicated in any future clinical trials of TC-1734 (AZD3480) in a different salt form.

In our completed clinical trials of TC-1734 (AZD3480) in AAMI and MCI, we used a battery of tests developed by CDR Ltd. to assess each subject's cognitive function. However, if we or

AstraZeneca use an additional or a different test battery for any future AAMI or MCI trials, there would be a greater risk that the results of our completed Phase I and Phase II clinical trials of TC-1734 (AZD3480) will not be replicated in those future clinical trials and that the future trials will not provide a sufficient basis for further development or regulatory approval.

If we elect to pursue development of TC-5214 as a treatment for major depression in lieu of further development of mecamylamine hydrochloride, our future development costs would be greater, our development timelines would be extended and our receipt of revenues from potential product sales may be delayed.

We have not determined whether we will conduct additional clinical development of mecamylamine hydrochloride as an augmentation treatment for major depression. Having completed our Phase II clinical trial, we plan to pursue a dialogue with the FDA. Because mecamylamine is a racemate, it is possible that the FDA will discourage further development of mecamylamine in favor of TC-5214, which is one of the chemical components, called enantiomers, of mecamylamine. A racemate is a mixture of two different enantiomers that are mirror images of each other and have the same chemical but potentially different biological properties. Single enantiomers may cause a different biological response, have different absorption, distribution, metabolism and excretion, known as pharmacokinetic, properties or have different degrees of toxicity, in each case as compared to each other or to the racemate that is comprised of both enantiomers. Current FDA policy provides that, assuming that it is technologically feasible to separate a racemate into its component enantiomers, the pharmacokinetic activity of each enantiomer and, if evaluation of the racemate indicates unexpected toxicity, the toxicity of each enantiomer should be independently characterized and compared to each other and to the racemate. The FDA's policy also suggests that, where characterization of the separate enantiomers shows that one enantiomer has undesirable effects or that both enantiomers are pharmacologically active as opposed to one being inert, consideration should be given to developing a single enantiomer rather than the racemate. We have determined in preliminary animal testing that both enantiomers of mecamylamine have pharmacological activity. In addition, we believe that the preliminary animal testing suggests that the toxicity profiles of the two enantiomers of mecamylamine may be different.

If we elect to pursue development of TC-5214 as a treatment for major depression in lieu of further development of mecamylamine hydrochloride, whether based on feedback from the FDA or for any other reason, we would need to conduct a Phase I clinical program and potentially at least one Phase II clinical trial of TC-5214 before initiating a Phase III clinical trial. As a result, our development costs would be increased. Moreover, our development timeline would be extended, potentially by several years, delaying our receipt of any revenues from potential product sales.

If clinical trials for our product candidates are prolonged or delayed, we would be unable to commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenues from potential product sales.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of our ongoing and planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular product candidate:

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in recruiting and enrolling subjects and patients into clinical trials;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply or deficient quality of our product candidates or other materials necessary to conduct our clinical trials;
- lower than anticipated retention rate of subjects and patients in clinical trials;
- negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical study;
- serious and unexpected drug-related side effects experienced by subjects and patients in clinical trials; or
- failure of our third-party contractors to comply with regulatory requirements or otherwise meet their contractual obligations to us in a timely manner.

Clinical trials require sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial. Delays in patient enrollment can result in increased costs and longer development times. We previously experienced delays in patient enrollment for our Phase II clinical trial of TC-1734 (AZD3480) in persons with MCI. In that trial, we limited the eligible patient population to persons whose condition was sufficiently severe to qualify for a diagnosis of MCI, but not severe enough to qualify for a diagnosis of dementia. Similarly, we expect that the eligible patient population for the Phase II clinical trial of TC-1734 (AZD3480) for mild to moderate Alzheimer's disease planned to be conducted by AstraZeneca will be limited to Alzheimer's disease patients for whom the disease has not yet progressed to the severe stage. As a result of these inclusion limits, there could be delays in recruitment for this trial similar to those that we experienced in our MCI trial. In addition, this trial would require some of the Alzheimer's disease patients to be assigned randomly into a dosing group that would receive placebo instead of TC-1734 (AZD3480). Those patients would not receive any medication for the duration of the trial. As a result, Alzheimer's disease patients or their caregivers may be unwilling or unable to give informed consent to participate in the trial, which would result in delays in patient enrollment. The failure to enroll patients in a clinical trial could delay the completion of the clinical trial beyond our current

expectations. In addition, the FDA could require us and AstraZeneca to conduct clinical trials with a larger number of subjects than we have projected for any of our product candidates. We and AstraZeneca may not be able to enroll a sufficient number of patients in a timely or cost-effective manner. Furthermore, enrolled patients may drop out of clinical trials, which could impair the validity or statistical significance of those clinical trials.

Prior to commencing clinical trials in the United States, we must submit an IND to the FDA and the IND must become effective. We plan to conduct our Phase I clinical trial for our product candidate TC-2216 outside the United States. We have not submitted an IND to enable us to conduct clinical trials of TC-2216 in the United States.

We do not know whether our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Delays in our clinical trials will result in increased development costs for our product candidates. In addition, if our clinical trials are delayed, our competitors may be able to bring products to market before we do and the commercial viability of our product candidates could be limited.

If we are unable to successfully develop and manufacture a salt form of TC-2696 acceptable for use as a pharmaceutical product, clinical development may be delayed and we will not be able to commercialize TC-2696.

In our completed Phase I single rising dose trial of TC-2696 and in our ongoing Phase I multiple rising dose trial of TC-2696, we used a particular salt form of TC-2696 that we refer to as the hemigalactarate salt. We do not expect that the hemigalactarate salt form of TC-2696 will ultimately be viable for marketing as a pharmaceutical product because it accumulates moisture. We are currently conducting additional work to develop a salt form of this product candidate that is acceptable for use as a pharmaceutical product. If we are unable to develop a pharmaceutically acceptable salt form of TC-2696, we may have to terminate or substantially delay development of this product candidate.

If the FDA or foreign regulatory authorities do not consider AAMI or MCI to be a clinical indication appropriate for the approval of a drug, we and AstraZeneca will not receive the regulatory approvals required to market and sell TC-1734 (AZD3480) for AAMI or MCI.

We and AstraZeneca have agreed to develop TC-1734 (AZD3480) for Alzheimer’s disease and cognitive deficits in schizophrenia. In addition, we and AstraZeneca may in the future pursue the development of TC-1734 (AZD3480) for other conditions, such as one or both of AAMI and MCI. Neither the FDA nor, to our knowledge, any foreign regulatory authority has approved a drug indicated for use in the treatment of AAMI or MCI. Furthermore, neither AAMI nor MCI is listed in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*, or DSM-IV, the manual published by the American Psychiatric Association to establish diagnostic criteria. We do not know if the FDA or any foreign regulatory authority will be willing to recognize AAMI or MCI as a distinct clinical condition, or in the FDA’s terminology, a clinical entity, for which approval of a drug is possible. If neither the FDA nor any foreign regulatory authority recognizes AAMI or MCI as a clinical entity, we and AstraZeneca will not obtain the regulatory approval required to market TC-1734 (AZD3480) for AAMI or MCI even if our clinical trials show that TC-1734 (AZD3480) is safe and provides a medical benefit for the persons treated.

When the FDA assesses whether a proposed clinical entity justifies labeling, it generally requires that the existence of the clinical entity be broadly accepted by medical experts in the relevant clinical discipline and that the clinical entity can be defined in practice. This means that the clinical entity must be able to be diagnosed using valid and reliable criteria that are widely accepted by those medical experts. The FDA imposes these requirements to assure that both the population for whom a drug is intended and the effects of the drug in that population can be adequately described in labeling for the drug. The FDA has informed us that it believes it is questionable whether AAMI satisfies these criteria. In three letters that we received from the FDA in connection with the protocol submission for the Phase II trial of TC-1734 (AZD3480) for the treatment of AAMI that we completed in March 2006 and subsequent protocol amendment submissions, the FDA informed us that, in its view, because varying methodologies and criteria have historically been used by medical experts to define AAMI, the requisite consensus in the medical community has not been established. The FDA also informed us that it is not clear that our Phase II clinical trial design and efficacy endpoints are appropriate for measuring the clinical effect of TC-1734 (AZD3480) in AAMI. In particular, the FDA characterized it as unclear whether the power of attention factor of the CDR test battery, which we used as one of our co-primary endpoints for that AAMI trial, is an appropriate outcome measure to use for assessing the effect of a drug on AAMI, in which the only claimed deficit is an impairment of memory. In addition, the FDA indicated that we would need to demonstrate statistically significant improvement on a global measure of overall cognitive improvement to show that the effects of TC-1734 (AZD3480) in AAMI are clinically meaningful. We do not have, and we do not believe that AstraZeneca has, any current plan to develop TC-1734 (AZD3480) for the treatment of AAMI beyond the Phase II clinical trial that we completed in March 2006. However, if in the future we and AstraZeneca develop TC-1734 (AZD3480) for the treatment of AAMI and are unable to establish to the satisfaction of the FDA or foreign regulatory authorities that AAMI can be identified using criteria that are accepted in the medical community, that both the deficit in cognitive performance associated with the condition and its subsequent improvement can be measured and that the improvement is clinically meaningful, we and AstraZeneca will not obtain the regulatory approval required to market TC-1734 (AZD3480) for AAMI.

Our product candidates will remain subject to ongoing regulatory review even if they receive marketing approval. If we fail to comply with continuing regulations, we could lose these approvals and the sale of our products could be suspended.

Even if we receive regulatory approval to market a particular product candidate, the approval could be conditioned on us conducting additional costly post-approval studies or could limit the indicated uses included in our labeling. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will remain subject to extensive regulatory requirements. We may be slow to adapt, or we may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements.

If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities or previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

Because we have a number of compounds and are considering a variety of target indications, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Through 2004, we spent managerial and financial resources on clinical trials for two product candidates that we have ceased developing. We may in the future spend our resources on other research programs and product candidates for specific indications that ultimately do not yield any commercially viable products. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

We may not be successful in our efforts to identify or discover additional product candidates.

A key element of our strategy is to develop and commercialize drugs that selectively target specific NNR subtypes. We seek to do so through our understanding of the role of specific NNRs in the nervous system, our scientific expertise and the use of Pentad.

A significant portion of the research that we are conducting involves new and unproven compounds. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be effective products.

If we are unable to develop suitable product candidates through internal research programs, we will not be able to increase our revenues in future periods, which could result in significant harm to our financial position and adversely impact our stock price. Any additional product candidates that we are able to develop through our internal research programs will require the commitment of substantial time and financial resources for further preclinical research and clinical development.

Risks Related to Our Dependence on Third Parties

The successful development and commercialization of our lead product candidate, TC-1734 (AZD3480), depends substantially on our recently established collaboration with AstraZeneca. If AstraZeneca is unable to further develop or commercialize TC-1734 (AZD3480), or experiences significant delays in doing so, our business will be materially harmed.

In December 2005, we entered into our collaborative research and license agreement with AstraZeneca for the development and worldwide commercialization of TC-1734 (AZD3480) for the treatment of Alzheimer's disease, cognitive deficits in schizophrenia and potentially other indications marked by cognitive impairment. We do not have a history of working together with AstraZeneca and cannot predict the success of the collaboration. The collaboration involves a complex allocation of rights, provides for milestone payments to us based on the achievement of specified development, regulatory and first commercial sale milestones and provides us with royalty-based revenue if TC-1734 (AZD3480) or another product candidate is successfully commercialized. AstraZeneca has decision-making authority for most matters in our collaboration. In addition, AstraZeneca has the right to assume control of patent matters with respect to TC-1734 (AZD3480) if it decides to initiate a Phase II clinical trial of TC-1734 (AZD3480) following its completion of additional safety and product characterization studies.

AstraZeneca is generally responsible for conducting and funding substantially all future development and regulatory approval activities for TC-1734 (AZD3480) and will have significant control over the conduct and timing of development efforts with respect to TC-1734 (AZD3480). Although we have had discussions with AstraZeneca regarding its current plans and intentions, AstraZeneca may change its development plans for TC-1734 (AZD3480). We have little control

over the amount and timing of resources that AstraZeneca devotes to the development of TC-1734 (AZD3480). If AstraZeneca fails to devote sufficient financial and other resources to the development plan for TC-1734 (AZD3480), the development and potential commercialization of TC-1734 (AZD3480) would be delayed. This would result in a delay in milestone payments and, if regulatory approval to market and sell TC-1734 (AZD3480) is obtained, royalties that we could receive on commercial sales.

If we lose AstraZeneca as a collaborator in the development or commercialization of TC-1734 (AZD3480) at any time, it would materially harm our business.

Our agreement with AstraZeneca provides for AstraZeneca to conduct additional safety and product characterization studies of TC-1734 (AZD3480) before deciding whether to proceed with planned Phase II clinical trials to evaluate the efficacy of TC-1734 (AZD3480) in mild to moderate Alzheimer's disease and cognitive deficits in schizophrenia. AstraZeneca can terminate our collaboration agreement if it determines in its sole discretion on or before April 20, 2007 not to proceed with the further development of TC-1734 (AZD3480) based on the results of the studies and all other available information with respect to TC-1734 (AZD3480).

In addition, we and AstraZeneca are conducting preclinical research under our agreement that is designed to identify and develop additional compounds that act on the a4ß2 NNR and enhance cognitive function. The agreement provides for a four-year research term, which began in January 2006. AstraZeneca has the right to terminate the a4ß2 research collaboration effective three years after the research term began upon at least six months notice. AstraZeneca has the right to terminate the agreement upon 90 days notice after the earlier of the end of the research term or four years after the research term began.

If AstraZeneca terminates our agreement at any time, whether on the basis of any of the safety and product characterization studies of TC-1734 (AZD3480) or for any other reason, it would delay our development of TC-1734 (AZD3480) and materially harm our business and could accelerate our need for additional capital. In particular, we would have to fund the clinical development and commercialization of TC-1734 (AZD3480) on our own, seek another collaborator or licensee for clinical development and commercialization or abandon the development and commercialization of TC-1734 (AZD3480).

We will depend on collaborations with third parties for the development and commercialization of some of our product candidates. If these collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

In addition to our collaboration with AstraZeneca, we intend to selectively enter into collaboration agreements with leading pharmaceutical and biotechnology companies where our potential collaborator has particular therapeutic expertise in a target indication or where the target indication represents a large, primary care market. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development of our licensed product candidates. Our ability to generate revenues from our collaborators will depend on our collaborators' abilities to establish the safety and efficacy of our product candidates, to obtain regulatory approvals and to achieve market acceptance.

Strategic collaborations involving our product candidates, including our collaboration with AstraZeneca, pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue further development and commercialization of our product candidates or may elect not to continue or renew research and development programs based on preclinical or clinical trial results, changes in their strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive;
- a collaborator with marketing and distribution rights to one or more products may not commit enough resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between us and the collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development of the applicable product candidates.

Collaboration agreements may not lead to development of product candidates in the most efficient manner or at all. For example, a collaborative research and development agreement that we entered into with Aventis Pharma SA for the development of our compounds for the treatment or prevention of Alzheimer's disease terminated effective January 2, 2005 without any compound having been advanced into clinical development in the collaboration.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development program could be delayed, diminished or terminated.

If we do not establish additional collaborations, we may have to alter our development plans.

Our drug development programs and potential commercialization of our product candidates will require substantial additional cash to fund expenses. Our strategy includes selectively collaborating with leading pharmaceutical and biotechnology companies to assist us in furthering development and potential commercialization of some of our product candidates. We intend to do so especially for target indications in which our potential collaborator has particular therapeutic expertise or that involve a large, primary care market that must be served by large sales and marketing organizations.

We have the right to offer to AstraZeneca the right to license any compound that acts on any NNR other than the a4ß2 NNR that we may in the future seek to exploit for Alzheimer's disease, cognitive deficits in schizophrenia, other conditions marked by cognitive impairment or schizophrenia. However, if we do not offer the compound to AstraZeneca, we are generally not permitted to develop or commercialize the compound for any of these indications. As a result, our ability to seek additional collaborations for these indications is substantially limited during the term of our collaboration with AstraZeneca. We have also granted AstraZeneca a right of first negotiation for the development and commercialization of compounds for depression, anxiety and bipolar disorder.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

If our contract manufacturers fail to devote sufficient resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed or there may be a shortage of commercial supply.

Our product candidates require precise, high quality manufacturing. We have limited internal manufacturing capability. We have historically manufactured our product candidates only in small quantities for preclinical testing and have contracted with third parties to manufacture, in collaboration with us, our product candidates for clinical trials and, in the case of Inversine, for commercial sale. If any of our product candidates is approved by the FDA or by foreign regulatory authorities for marketing and sale, it will need to be manufactured in substantially larger, commercial quantities. Our experience in the manufacture of drugs in commercial quantities is limited to our contractual arrangements with third parties to manufacture Inversine and its active ingredient.

We currently rely on various third-party contract manufacturers, including Siegfried Ltd., for our product candidates and we intend to continue to rely on third-party manufacturers to supply, store and distribute our product candidates for our clinical trials and to manufacture commercial supplies

of any product candidate that is approved for sale. Our reliance on third-party manufacturers will expose us to risks that could delay or prevent the initiation or completion of our clinical trials, the submission of applications for regulatory approvals, the approval of our products by the FDA or the commercialization of our products or result in higher costs or lost product revenues. In particular, contract manufacturers:

- could encounter difficulties in achieving volume production, quality control and quality assurance and suffer shortages of qualified personnel, which could result in their inability to manufacture sufficient quantities of drugs to meet our clinical schedules or to commercialize our product candidates;
- could terminate or choose not to renew the manufacturing agreement, based on their own business priorities, at a time that is costly or inconvenient for us;
- could fail to establish and follow FDA-mandated current good manufacturing practices, or cGMPs, required for FDA approval of our product candidates or fail to document their adherence to cGMPs, either of which could lead to significant delays in the availability of material for clinical study and delay or prevent filing or approval of marketing applications for our product candidates; and
- could breach, or fail to perform as agreed under, the manufacturing agreement.

We expect to rely initially on a single contract manufacturer for each of our product candidates. Currently, we have separate arrangements with third-party manufacturers, each of which is a sole supplier to us, for mecamylamine hydrochloride, the active ingredient of Inversine, and for the finished tablets of Inversine. Changing these or any manufacturer that we subsequently engage for a particular product or product candidate may be difficult, as the number of potential manufacturers is limited and we will have to compete with third parties for access to those manufacturing facilities. cGMP manufacturing processes and procedures typically must be reviewed and approved by the FDA and changing manufacturers may require re-validation of any new facility for cGMP compliance, which would likely be costly and time-consuming. We may not be able to engage replacement manufacturers on acceptable terms quickly or at all. In addition, our contract manufacturers located in foreign countries may be subject to import limitations or bans. As a result, if any of our contract manufacturers is unable, for whatever reason, to supply the contracted amounts of Inversine or any other product that we successfully bring to market, a shortage would result which would have a negative impact on our revenues.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the United States Drug Enforcement Agency and corresponding state and foreign agencies to ensure strict compliance with cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit the performance of third-party contractors, we do not have control over our third-party manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions.

If third parties on which we rely for clinical trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our product candidates. We depend on independent clinical investigators and, in some cases, contract research organizations and other third-party service providers to conduct the clinical trials of our product candidates and expect to continue to do so. We rely heavily on these parties for successful execution of our clinical trials, but we do not control many aspects of their activities. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the respective trial plans and protocols. The failure of these third parties to carry out their obligations could impair the credibility or reliability of the data generated in clinical trials of our product candidates, delay or prevent the development, approval and commercialization of our product candidates or result in enforcement action against us.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property effectively, our competitors may develop and market similar products and the value of our technology and our ability to compete would be damaged.

Our continued success depends significantly on our ability, or our present or future collaborators' ability, to obtain and maintain meaningful intellectual property protection for our product candidates, technology and know-how. We generally seek to protect our compounds and technologies by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology that is important to the development of our business. We file patent applications directed to our product candidates in an effort to establish intellectual property positions regarding new chemical entities and uses in the treatment of disease.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective patent claims and enforcing claims that are granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Moreover, our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated, rendered unenforceable or circumvented, any of which could limit our ability to stop competitors from marketing related products. In addition, the rights granted under any issued patents may not provide us with competitive advantages against competitors with similar compounds or technologies. Furthermore, our competitors may independently develop similar technologies in a manner that does not infringe our patents or other intellectual property.

Although we own or otherwise have rights to a number of patents, these patents may not effectively exclude competitors from engaging in activities that compete with us. Furthermore, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. Because patent applications in the United States and many foreign countries are confidential for a period of time after filing, and because publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued U.S. patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in the foreign patents or patent applications. It is possible that a competitor may successfully challenge our patents or that challenges will result in the elimination or narrowing of patent claims and, therefore, reduce our patent protection.

Because of the extensive time required for development, testing and regulatory review of a new drug, it is possible that any related patent may expire before any of our product candidates can be commercialized or remain in force for only a short period following commercialization. In either case, this would reduce any advantages of the patent. The patent laws of various foreign countries in which we intend to compete may not protect our intellectual property to the same extent as the laws of the United States. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

If we are unable to protect the confidentiality of our proprietary information and know-how, the commercial value of our technology and product candidates could be reduced.

In addition to patents, we rely on protection of trade secrets, know-how and confidential and proprietary information to maintain our competitive position. For example, we generally do not seek patent protection for the computer-based molecular design technologies that form part of Pentad and instead seek to maintain those technologies as trade secrets.

To maintain the confidentiality of trade secrets and proprietary information, we generally enter into confidentiality agreements with our employees, consultants, contractors and collaborative partners upon the commencement of our relationship with them. These agreements typically require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Even if obtained, these agreements may not provide meaningful protection for our trade secrets or other proprietary information or an adequate remedy in the event of their unauthorized use or disclosure. The loss or exposure of our trade secrets or other proprietary information could impair our competitive position.

We also typically enter into agreements with employees that provide inventions conceived by them in the course of rendering services to us are our exclusive property and, where appropriate, we enter into similar agreements with consultants and contractors. To the extent that our employees, consultants or contractors use technology or know-how owned by others in their work for us, disputes may arise as to the rights in related inventions.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to various license agreements. In particular, we license patent rights for a method of use of our product candidate for pain, TC-2696, and two of our product candidates for depression, mecamylamine hydrochloride and one of its molecular components, TC-5214. We may enter into additional licenses in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

Our patent protection for mecamylamine hydrochloride is, and our patent protection for any other particular compound may be, limited to a specific method of use or indication. If a third party were to obtain approval of mecamylamine hydrochloride or other particular compound for use in another indication, we could be subject to competition arising from off-label use.

Although we generally seek the broadest patent protection available for our proprietary compounds, we may not be able to obtain patent protection for the actual composition of any particular compound and may be limited to protecting a new method of use for the compound or otherwise restricted in our ability to prevent others from exploiting the compound. For example, we currently rely on method of use patent coverage in the United States for mecamylamine hydrochloride. If we are unable to obtain patent protection for the actual composition of any compound that we seek to develop and commercialize and must rely on method of use patent coverage, we would likely be unable to prevent others from manufacturing or marketing that compound for any use that is not protected by our patent rights. We are aware of one company, Athenagen, Inc., that has announced its initiation of a clinical trial of mecamylamine hydrochloride in an eye drop formulation as a treatment for age-related macular degeneration, a condition characterized by degeneration of the retina in the eye. If a third party were to receive marketing approval for mecamylamine hydrochloride or any other compound for which we rely on method of use patent coverage for another use, physicians could nevertheless prescribe it for indications that are not described in the product's labeling or approved by the FDA or other regulatory authorities. Even if we have patent protection for the prescribed indication, as a practical matter, we would have little recourse as a result of this off-label use. In that event, our revenues from the commercialization of the compound would likely be adversely affected.

If the development of TRIDMAC for major depression infringes the intellectual property of a third party, we may be required to pay license fees or cease our development activities, which could significantly harm our business.

We have completed a Phase II clinical trial of TRIDMAC and we may conduct additional clinical development of TRIDMAC in the future. We are aware of a patent application that has been filed that, if issued as a patent in the form published, could present an obstacle if in the future we pursue the commercialization of TRIDMAC for major depression. We believe that, even if this patent application issues as a patent, the development or commercialization of TRIDMAC for major depression by the patent holder or any other third party would infringe our intellectual property rights. However, if this patent application issues as a patent, we could be required to obtain a license and pay license fees if we continue to develop and commercialize TRIDMAC for major depression. The owner of the patent application has granted to us an option to negotiate an exclusive license. However, we may not be able

to negotiate acceptable terms. If we are unable to obtain a license on acceptable terms, we may be required to cease further development or commercialization of TRIDMAC for major depression, which could significantly harm our business.

We may be involved in lawsuits to protect or enforce our patents that could be expensive and time-consuming.

We may initiate patent litigation against third parties to protect or enforce our patent rights and we may be similarly sued by third parties. We may also become subject to interference or opposition proceedings conducted in the patent and trademark offices of various countries to determine our entitlement to patents. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings, if necessary, would be costly and divert our technical and management personnel from conducting our business. Moreover, we may not prevail in any of these suits. An adverse determination of any litigation or proceeding could put our patents at risk of being invalidated or narrowly interpreted and our patent applications at risk of not being issued and could prevent us from protecting our rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that disclosure of some of our confidential information could be compelled and the information compromised. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments that, if perceived as negative by securities analysts or investors, could have a substantial adverse effect on the trading price of our common stock.

Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our development and commercialization efforts.

Our success depends in part on avoiding the infringement of other parties' patents and proprietary rights. Patents may issue from patent applications of which we are unaware, and avoiding patent infringement may be difficult. We may infringe or it may be alleged that we infringe third-party patents. If a third party were to file a patent infringement suit against us, we could be forced to stop or delay research, development, manufacturing or sales of any infringing product in the country or countries covered by the patent infringed, unless we can obtain a license from the patent holder. Any necessary license may not be available on acceptable terms or at all, particularly if the third party is developing or marketing a product competitive with the infringing product. Even if we are able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property.

We also may be required to pay substantial damages to the patent holder in the event of an infringement. These damages could in some circumstances be triple the actual damages the patent holder incurs. If we have supplied infringing products to third parties for marketing or have licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for any damages they may be required to pay to the patent holder and for any losses they may sustain themselves as a result.

Any successful infringement action brought against us may also adversely affect marketing of the infringing product in other markets not covered by the infringement action, as well as our marketing of other products based on similar technology. Furthermore, we may suffer adverse

consequences from a successful infringement action against us even if the action is subsequently reversed on appeal, nullified through another action or resolved by settlement with the patent holder. The damages or other remedies awarded, if any, may be significant. As a result, any infringement action against us would likely delay the regulatory approval process, harm our competitive position, be very costly and require significant time and attention of our key management and technical personnel.

Risks Related to Commercialization

Even if approved for marketing, our product candidates may not gain market acceptance and may fail to generate significant revenues.

The commercial success of any of our product candidates for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost-effective and safe. Many of the product candidates that we are developing are based upon technologies or methods of treatment that are relatively new and unproven. As a result, it may be more difficult for us to achieve market acceptance of our products.

The degree of market acceptance of any drug depends on a number of factors, such as:

- its demonstration of efficacy and safety in clinical trials;
- its superior efficacy as compared to alternative treatment methods and its side effect profile;
- its cost-effectiveness and the availability of insurance or other third-party reimbursement;
- its convenience and ease of administration;
- the timing of its market entry relative to competitive treatments;
- the extent and success of marketing and sales efforts; and
- the product labeling or product insert required by the FDA or regulatory authorities in other countries.

In addition, perceptions about the relationship or similarity between our product candidates and nicotine could limit their market potential. Our product candidates derive their medical effects by interacting with NNRs. Nicotine, which can have significantly negative health effects, also interacts with NNRs. Accordingly, our product candidates may be perceived by some to be nicotine or to be closely related to nicotine, particularly in light of the shared derivative names, “nicotine” and neuronal “nicotinic” receptors, and the fact that our company was launched originally as a research group within, and then as a subsidiary of, R.J. Reynolds Tobacco Company. This potential perception could result in a reluctance by patients to take, or by physicians to prescribe, any of our product candidates that receives marketing approval, which would affect our revenues.

We currently have limited sales, marketing and distribution experience and no internal sales or distribution capabilities. If we are unable to enter into collaborations or other arrangements with third parties to market and sell our product candidates or to develop our own internal marketing capability, we may not be successful in commercializing our products.

We currently have limited sales, marketing and distribution experience. Our experience is limited to a contractual arrangement with a third party to distribute Inversine, which we acquired in 2002 and which generates only limited sales. We currently have no internal sales or distribution capabilities. Although we intend to build an internal sales force and expand our marketing capabilities in areas where specialists heavily influence our target markets, such as neurology and psychiatry, we also intend to seek to further augment our sales, marketing and distribution capabilities through arrangements with third parties. In particular, our strategy includes selectively entering into collaborations and other strategic alliances with respect to product candidates for disease indications with sales and distribution characteristics requiring a large sales force. There are risks involved with establishing our own sales force and marketing and distribution capabilities, as well as in entering into arrangements with third parties to perform these services. Developing our own sales force will be expensive and time-consuming and could delay any product launch. We may not be successful in entering into arrangements with third parties on terms that are favorable to us or at all. Also, we would have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell, market or distribute our products effectively. If we do not establish sales and distribution capabilities successfully, either on our own or in collaboration with third parties, we may not successfully commercialize our products.

Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives applicable to our product candidates could limit our potential product revenue.

The regulations governing drug pricing and reimbursement vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed and, in many of these countries, the pricing review period begins only after approval is granted. In some countries, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Although we monitor these regulations, our product candidates are currently in the development stage and we will not be able to assess the impact of price regulations for at least several years. As a result, we may obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay the commercial launch of the product and may negatively impact the revenues we are able to derive from sales in that country.

Successful commercialization of our products will also depend in part on the extent to which coverage and adequate payment for our products will be available from government health administration authorities, private health insurers and other third-party payors. If we succeed in bringing a product candidate to the market, it may not be considered cost-effective and reimbursement to the patient may not be available or sufficient to allow us to sell it at a satisfactory price. Because our product candidates are in the development stage, we are unable at this time to determine their cost-effectiveness. We may need to conduct expensive studies in order to demonstrate cost-effectiveness. Moreover, third-party payors frequently require that drug companies provide them with predetermined discounts from list prices and are increasingly challenging the prices charged for medical products. Because our product candidates are in the development stage, we do not know the level of reimbursement, if any, we will receive for any products that we are able to successfully develop. If the reimbursement for any of our product candidates is inadequate in light of our development and other costs, our ability to achieve profitability could be affected.

We believe that the efforts of governments and third-party payors to contain or reduce the cost of healthcare will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. A number of legislative and regulatory proposals to change the healthcare system in the United States and other major healthcare markets have been proposed and adopted in recent years. For example, the U.S. Congress has enacted a limited prescription drug benefit for Medicare recipients as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. While the program established by this statute may increase demand for any products that we are able to successfully develop, if we participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than prices we might otherwise obtain. If successfully developed, TC-1734 (AZD3480), our product candidate for Alzheimer's disease, cognitive deficits in schizophrenia and other conditions marked by cognitive impairment, could be particularly affected by this law because Alzheimer's disease is a disease that affects the elderly. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries. In addition, ongoing initiatives in the United States have and will continue to increase pressure on drug pricing. The announcement or adoption of any such initiative could have an adverse effect on potential revenues from any product candidate that we may successfully develop.

If our competitors develop and market drugs that are less expensive, more effective or safer than ours, if they develop and market products faster than we do, or if they have better sales and marketing capabilities than we do, any products we are able to commercialize may not generate initial or ongoing revenues.

The development and commercialization of new drugs is highly competitive. Our business is characterized by extensive research efforts and rapid developments. We expect intense competition in our target markets as new products and advanced technologies become available. Our competitors include large pharmaceutical, biotechnology and other companies and research institutions, many of which have greater financial, technical and other resources and personnel and more experience in research, clinical development, regulatory and drug commercialization than we have. Our competitors may:

- develop products that are more effective, safer, more convenient or less costly than our product candidates;
- obtain FDA or other regulatory approval for their products more rapidly than we do;
- adapt more quickly to new technologies and scientific advances;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled scientific workers from the limited pool of available talent;
- obtain more effective intellectual property protection than we have;

- negotiate third-party licensing and collaboration arrangements more effectively than we do; and
- take advantage of acquisition or other opportunities more readily than we do.

Competitive products may render our product candidates obsolete or noncompetitive before we can recover our development or commercialization expenses.

We also face substantial competition from therapies designed to target NNRs. Pfizer's product Chantix targets NNRs and is approved in the United States for smoking cessation. In addition, we believe that several prominent pharmaceutical companies have product candidates that target NNRs in development, including as examples Sanofi-Aventis, with a compound in Phase III for smoking cessation, and Abbott Laboratories, with one compound in Phase I for pain and another in Phase II for Alzheimer's disease, ADHD and schizophrenia. We expect that we will face increased competition in the future if therapies that target NNRs are further validated and companies initiate or expand programs focused on NNRs, whether independently or by collaboration or acquisition.

Any products that we are able to successfully develop and commercialize in the future could be subject to competition from lower priced generic drugs. The manufacturer of a generic product could challenge our patents as invalid or not infringed and subject us to expensive litigation. We do not know if we would prevail in litigation and succeed in keeping the generic product out of the market until our patent protection expires.

If we successfully develop and obtain approval for our product candidates, we will face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective or more affordable products, or obtain more effective patent protection, than we do. Accordingly, our competitors may commercialize products more rapidly or effectively than we do.

If approved, our product candidates will compete for a share of the existing market with numerous approved products. There is currently no approved product for cognitive deficits in schizophrenia. We believe that the primary competitive products for use in indications that we are currently targeting include:

- for mild to moderate Alzheimer's disease, acetylcholinesterase inhibitors such as Aricept from Pfizer/Eisai, Reminyl from Johnson & Johnson and Exelon from Novartis and for moderate to severe Alzheimer's disease, Namenda from Forest Laboratories, which acts by regulating the neurotransmitter glutamate;
- for pain, non-steroidal anti-inflammatory drugs such as Celebrex from Pfizer and opioids such as OxyContin from Purdue Pharma;
- for depression, selective serotonin reuptake inhibitors such as Prozac from Eli Lilly, Paxil from GlaxoSmithKline, Zoloft from Pfizer, Celexa and Lexapro from Forest Laboratories and the dual uptake inhibitor Effexor from Wyeth;

- for schizophrenia, anti-psychotics such as Seroquel from AstraZeneca, Zyprexa from Eli Lilly, Risperdal from Johnson & Johnson, Geodon from Pfizer and Abilify from Bristol-Myers Squibb; and
- for smoking cessation, Zyban from GlaxoSmithKline and Chantix from Pfizer.

We may have substantial exposure to product liability claims and may not have adequate insurance to pay them.

We face an inherent business risk of exposure to product liability claims if the use of our products is alleged to have resulted in harm to others. This risk exists for product candidates in clinical trials, whether or not the product candidate is subsequently approved for commercial sale, as well as for products in commercial distribution. Any product liability claim arising in the future against us or any third party that we have agreed to indemnify, regardless of its merit or eventual adjudication, could be costly and significantly divert management's attention from conducting our business or adversely affect our reputation and the demand for our products.

We have secured product liability insurance coverage with limits of $10 million per occurrence and $10 million in the aggregate. Our current insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may incur. We intend to expand our coverage with respect to any products for which we obtain marketing approval. However, additional insurance may not be available to cover our potential liabilities fully or may be prohibitively expensive. In addition, some potential product liability claims may be excluded from coverage under the terms of the policy. Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or impede the commercialization of our product candidates.

Our business activities involve hazardous materials, which could subject us to significant liability.

Our research and development activities involve, and any future manufacturing processes that we conduct may involve, the use of hazardous materials, including hazardous chemicals and radioactive materials. Accordingly, we are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. We incur significant costs to comply with these laws and regulations. Moreover, despite precautionary procedures that we implement, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages. We do not carry insurance against the risk of contamination or injury from hazardous materials.

If our promotional activities fail to comply with the regulations and guidelines of the FDA and other applicable regulatory authorities, we may be subject to warnings or enforcement actions that could harm our business.

Physicians may prescribe drugs for uses that are not described in the product's labeling or for uses that differ from those tested in clinical studies and approved by the FDA or similar regulatory authorities in other countries. Regulatory authorities generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications on the subject of off-label use. Companies cannot actively promote approved drugs for off-label uses

but, in some countries outside of the European Union, they may under specified conditions disseminate articles published in peer-reviewed journals that discuss off-label uses of approved products to physicians. To the extent allowed, we may in the future disseminate peer-reviewed articles on our products to physicians. We do not currently promote Inversine for off-label use in the treatment of any neuropsychiatric disorder. However, if we undertake any promotional activities in the future for Inversine or any other product candidate that we are able to commercialize and our activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities.

Risks Related to Employees and Managing Growth

If we lose our key personnel or are unable to attract and retain additional skilled personnel, we may be unable to successfully develop and commercialize our product candidates or effectively compete in our industry.

Our performance depends substantially on the performance of our senior management and key scientific, technical and managerial personnel, including our Chief Executive Officer and President, J. Donald deBethizy, and our Vice President, Clinical Development and Regulatory Affairs, Geoffrey C. Dunbar. Our executive officers, including these individuals, can terminate their employment agreements with us at any time. The loss of the services of any of our executive officers may significantly delay or prevent the achievement of product research and development and other business objectives. We maintain key man life insurance policies on Dr. deBethizy and Dr. Dunbar, among other executive officers. We also rely on consultants and advisors to assist us in formulating our research and development strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have other commitments, including consulting or advisory contracts with other organizations, that may affect their ability to contribute to us.

Our ability to operate successfully and manage our potential future growth will depend on our ability to identify, recruit and retain additional qualified scientific, technical, financial and managerial personnel. There is currently a shortage of skilled executives in our industry, and we face intense competition for such personnel. We may not be able to continue to attract and retain personnel with the advanced qualifications necessary for the growth of our business.

We may encounter difficulties in managing our growth, which could increase our losses.

We expect the number of our employees and the scope of our operations to grow over the next several years. Continued growth may place a significant strain on our managerial, operational and financial resources, in particular as we expand our focus beyond drug discovery and development to commercialization. To manage our anticipated growth, we must continue to implement and improve our managerial, operational and financial systems and controls and reporting processes and procedures, to expand our facilities and to continue to recruit and train additional qualified personnel. We may not be able to manage our growth effectively. Moreover, we may experience deficiencies in existing systems and controls that could expose us to an increased risk of incurring financial or accounting irregularities or fraud.

Risks Related to Our Common Stock

The market price of our common stock may be highly volatile.

We expect that the trading price of our common stock is likely to be highly volatile in response to factors that are beyond our control. The stock market in general has previously experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of shares held by any stockholder.

If our operating results fluctuate significantly, our stock price may decline.

Our operating results are likely to fluctuate significantly from quarter to quarter and year to year. These fluctuations could cause our stock price to decline. Some of the factors that could cause our operating results to fluctuate include:

- our inability, or the inability of AstraZeneca or any of our potential future collaborators, to successfully complete preclinical studies and clinical trials in a timely manner or at all, resulting in a delay in receiving, or a failure to receive, the required regulatory approvals to commercialize our product candidates;
- the timing of regulatory approvals or other regulatory actions;
- general and industry-specific economic conditions that may affect the research and development expenditures of AstraZeneca or any of our potential future collaborators;
- the timing of receipt of milestone payments from AstraZeneca or any of our potential future collaborators; and
- the expiration or termination of agreements with AstraZeneca or any of our potential future collaborators or the execution of new agreements.

Due to fluctuations in our operating results, a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors and our stock price could decline.

If our stockholders sell a substantial number of shares of our common stock in the public market, our stock price may decline.

Sales of a substantial number of shares of our common stock in the public market could cause the market price to decline. Such sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. If there are more shares of our common stock offered for sale than buyers are willing to purchase, the market price of our common stock may decline to a market price at which buyers are willing to purchase the offered shares and sellers remain willing to sell the shares. The number of shares of our common stock owned by our stockholders and available for sale in the public market is limited only to the extent

provided under applicable federal securities laws. In addition, we may, in the future, issue additional shares of our common stock to our employees, directors or consultants as compensation, in connection with corporate alliances or acquisitions or to raise capital. Accordingly, sales of a substantial number of shares of our common stock in the public market could occur at any time.

Concentration of ownership among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and their affiliates beneficially own or control approximately 34.9% of the outstanding shares of our common stock, based on the shares outstanding as of October 31, 2006. Accordingly, our current executive officers, directors and their affiliates have substantial control over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions, as well as our management and affairs. The concentration of ownership may also delay or prevent a change of control of us at a premium price if these stockholders oppose it, even if it would benefit our other stockholders.

Provisions of our charter, bylaws and Delaware law may make an acquisition of us or a change in our management more difficult.

Provisions of our certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions:

- allow the authorized number of directors to be changed only by resolution of our board of directors;
- establish a classified board of directors, providing that not all members of the board be elected at one time;
- authorize our board of directors to issue without stockholder approval blank check preferred stock that, if issued, could operate as a “poison pill” to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and

- require the approval of the holders of 66 2/3% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our certificate of incorporation and bylaws.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a prescribed period of time.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Initial Public Offering and Use of Proceeds from Sales of Registered Securities

On April 18, 2006, we sold 5,000,000 shares of our common stock in our initial public offering at a price to the public of $9.00 per share. As part of the offering, we granted the underwriters an over-allotment option to purchase up to an additional 750,000 shares of our common stock from us, which was not exercised. The offer and sale of all of the shares in the offering were registered under the Securities Act of 1933, as amended, pursuant to a registration statement on Form S-1 (File No. 333-131050), which was declared effective by the Securities and Exchange Commission on April 11, 2006.

After deducting underwriting discounts and commissions of $3.15 million and other offering expenses of approximately $1.1 million payable by us in connection with the offering, our net proceeds from the offering were approximately $40.8 million. Between April 11, 2006 and September 30, 2006, we used approximately $8.4 million of the net proceeds to fund our operating activities, including activities relating to the development of our clinical and preclinical product candidates and for working capital, capital expenditures and other general corporate purposes. During this period, our research and development expenses comprised approximately 79% of our operating expenses. The remaining approximately $32.4 million in net proceeds have been deposited in a highly rated financial institution in the United States. None of the net proceeds of the offering have been paid by us, directly or indirectly, to any director, officer or general partner of us, to any of their associates, to any person owning ten percent or more of any class of our equity securities, or to any of our affiliates.

There has been no material change in our planned use of proceeds from our initial public offering as described in our final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b).

Item 6. Exhibits.

The exhibits listed in the accompanying exhibit index are filed as part of this Quarterly Report on Form 10-Q.

Our trademarks include Targacept®, Inversine®, Pentad™, NNR Therapeutics™ and TRIDMAC™. 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 13, 2006

/s/ J. Donald deBethizy

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

Date: November 13, 2006

/s/ Alan A. Musso

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

EXHIBIT INDEX

Exhibit Number	Description
10.1	Amendment No. 1 dated November 10, 2006 to Collaborative Research and License Agreement between the Company and AstraZeneca AB dated December 27, 2005.
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit 10.1

AMENDMENT NO. 1 TO
COLLABORATIVE RESEARCH AND LICENSE AGREEMENT

This Amendment No. 1 to Collaborative Research and License Agreement (this "**Amendment**"), dated November 10, 2006, amends the Collaborative Research and License Agreement entered into as of December 27, 2005 (the "**Agreement**") 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**").

WHEREAS AstraZeneca and Targacept desire to amend the Agreement in accordance with Section 17.6 thereof;

NOW, THEREFORE, AstraZeneca and Targacept, intending to be legally bound, hereby agree as follows:

1. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Agreement.

2. Section 1.80 is hereby amended by deleting the text in its entirety and replacing it with the following.

"**"Contract Quarter"** means, for each Contract Year, each of the periods from (a) February 1 (or, for the first Contract Year, the Effective Date) through March 31, (b) April 1 through June 30, (c) July 1 through September 30 and (d) October 1 through January 31."

3. Section 1.134 of the Agreement is hereby amended by deleting the text in its entirety and replacing it with the following.

"**"Framework"** means the structural framework of a compound determined in accordance with the guidelines set forth in Schedule 1.134."

4. Section 1.236 is hereby amended by deleting the text in its entirety and replacing it with the following.

"**"Pre-Phase IIb Program"** means (a) the non-clinical and clinical development program as set forth in the Pre-Phase IIb Plan and (b) in the event that either (i) this Agreement is terminated by AstraZeneca in accordance with Section 11.2.1(a), by Targacept in accordance with Section 11.2.1(b) or by mutual agreement upon completion of the Pre-Phase IIb Plan or (ii) Section 3.3.2(b) and Section 3.3.2(b)(2) apply, all other non-clinical and clinical research and development activities (including Manufacturing (as defined in Section 16.18.1(f)) activities, but excluding all non-clinical and clinical research and development activities, if any, evaluating the combined effects or combined activity of Ispronicline and any compound outside of the Collaboration that is Controlled by AstraZeneca) conducted with respect to Ispronicline during the period beginning on the Effective Date and ending on the effective date of such termination (including for purposes of Sections 1.42 and 11.3.1).""

5. Section 1.263 is hereby amended by deleting the text in its entirety and replacing it with the following.

"**"ROFN Collaboration"** means any transaction between Targacept or any of its Affiliates and a Third Party for the purpose of collaborating, or licensing such Third Party, to research, develop, commercialize or otherwise Exploit compounds or products for which prophylactic or therapeutic activity is known to be derived in any material respect through any Exclusivity Mechanism for one or more ROFN Indications in the Territory, but excluding any transaction with (a) a Third Party involving (i) an agreement or arrangement (A) with a contract manufacturer solely to manufacture or (B) with a contract sales organization solely to promote products, (ii) any fee-for-service or sponsored research agreement or arrangement where Targacept retains rights to any resulting Technology or Patent Rights, or (iii) any other agreement or arrangement involving the payment to Targacept or any of its Affiliates of governmental research or grant funding or research or grant funding from a non-profit organization or (b) The Stanley Medical Research Institute."

6. Section 4.1.1 is hereby amended by deleting the penultimate sentence thereof and replacing it with the following:

"For purposes of further clarity, (i) in addition to AstraZeneca Research Activities, AstraZeneca shall have the right, in its sole discretion, to conduct research and development activities other than AstraZeneca Research Activities with respect to Collaboration Compounds, Candidate Drugs and Products during the Term, including by generating Derivatives with respect thereto, and (ii) the Research Program (or, if applicable, an Additional Research Program) shall include research activities, if any, specified in the Research Plan, any Annual Research Plan or any Additional Research Plan, or in an amendment to any of the foregoing, or approved by the JRC (including specifically by both Targacept's and AstraZeneca's representatives on the JRC, voting collectively in accordance with Section 2.2.3, without resort to the dispute resolution procedures set forth in Section 2.1.5), to be performed by or on behalf of Targacept, alone or jointly with Third Parties, with respect to any Collaboration Compound, Candidate Drug (including Ispronicline) or Product or Licensed Derivative or Additional Compound with respect to any of the foregoing (including TC-1827)."

7. Section 8.2.3(a) and Section 8.2.3(b) are hereby amended by deleting each reference therein to "Development or Commercialization" and replacing it with a reference to "research, development or commercialization."

8. Section 9.1.3 is hereby amended by deleting the first sentence in its entirety and replacing it with the following:

"Subject to the license grants and assignments under Article 8 and except as provided in Section 9.1.4, the Parties shall each own an equal, undivided interest in (a) any and all (i) Technology conceived, discovered, developed or otherwise made, as necessary to establish authorship, inventorship or ownership under Applicable Laws in the United States, by or on behalf of a Party (or its Affiliates), jointly by or on behalf of Targacept (or its Affiliates or, to the extent permitted by their agreements therewith, their respective licensees and Sublicensees), on the one hand, and AstraZeneca (or its Affiliates or, to the extent permitted by their agreements therewith, their respective licensees and Sublicensees) on the other hand, in connection with the work conducted under or in connection with this Agreement, whether or not patented or patentable, and (ii) data and results (including any negative results) generated in the conduct by either Targacept or AstraZeneca, alone or jointly with Third

Parties, of research or development activities with respect to compounds that are Controlled neither by Targacept nor by AstraZeneca, in each case or any Affiliate thereof, that are approved by the JRC or JDC ((i) and (ii), collectively, "**Joint Technology**"), and (b) Patent Rights that contain one or more claims that cover Joint Technology (the "**Joint Patent Rights**").

9. Section 11.3.1(c) is hereby amended by deleting "Pre-Phase IIb Program Patent Rights" and replacing it with "AstraZeneca Pre-Phase IIb Program Patent Rights."

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

[signature page follows]

IN WITNESS WHEREOF, AstraZeneca and Targacept have executed this Amendment as of the date first written above.

TARGACEPT, INC.

By: /s/ J. Donald deBethizy
Name: J. Donald deBethizy
Title: President and CEO

ASTRAZENECA AB (publ)

By: /s/ Martin Nicklasson
Name: Martin Nicklasson
Title: President & CEO

EXHIBIT 31.1

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)) 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) 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

c) 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 13, 2006

By: /s/ J. Donald deBethizy
J. Donald deBethizy
President and Chief Executive Officer

EXHIBIT 31.2

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)) 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) 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

c) 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 13, 2006

By: /s/ Alan A. Musso
Alan A. Musso
Vice President, Chief Financial Officer, Secretary and Treasurer

EXHIBIT 32.1

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, 2006 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:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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 13, 2006

By: /s/ J. Donald deBethizy
J. Donald deBethizy
President and Chief Executive Officer

EXHIBIT 32.2

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, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Alan A. Musso, Vice President, Chief Financial Officer, Secretary 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:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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 13, 2006

By: /s/ Alan A. Musso
Alan A. Musso
Vice President, Chief Financial Officer,
Secretary and Treasurer