
**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, 2014

or

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

For the transition period from _____ to _____

Commission File Number: 000-51173

Targacept, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

56-202050
(I.R.S. Employer
Identification No.)

100 North Main Street, Suite 1510
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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

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

As of October 31, 2014, the registrant had 34,311,435 shares of common stock, \$0.001 par value per share, outstanding.

TARGACEPT, INC.
FORM 10-Q
TABLE OF CONTENTS

	Page
<u>PART I – FINANCIAL INFORMATION</u>	1
Cautionary Note Regarding Forward-Looking Statements	1
Item 1. Financial Statements	3
Balance Sheets as of September 30, 2014 and December 31, 2013 (Unaudited)	3
Statements of Comprehensive Income (Loss) for the Three and Nine Months Ended September 30, 2014 and 2013 (Unaudited)	4
Statements of Cash Flows for the Nine Months Ended September 30, 2014 and 2013 (Unaudited)	5
Notes to Unaudited Financial Statements	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	16
Item 3. Quantitative and Qualitative Disclosures About Market Risk	27
Item 4. Controls and Procedures	27
<u>PART II – OTHER INFORMATION</u>	28
Item 1A. Risk Factors	28
Item 6. Exhibits	51
SIGNATURES	52
EXHIBIT INDEX	53

PART I. Financial Information

Cautionary Note Regarding Forward-Looking Statements

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

- the progress, scope or duration of the development of our product candidates or programs, such as the target indication(s) for development, the size, design, population, location, conduct, objective, duration or endpoints of any clinical trial, or the timing for initiation or completion of or availability of results from any clinical trial, for submission or approval of any regulatory application, for interactions with regulatory authorities;
- the benefits that may be derived from any of our product candidates or the commercial opportunity in any target indication;
- our operations, financial position, revenues, costs or expenses; or
- our strategies, prospects, plans, expectations or objectives

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

- whether our previous findings from clinical and nonclinical studies and assessments of TC-6499 in indications other than diabetic gastroparesis are predictive of a benefit for TC-6499 as a treatment for diabetic gastroparesis;
- the conduct and results of clinical trials and non-clinical studies and assessments of any of our product candidates, including the performance of third parties engaged to execute them, delays resulting from any changes to the applicable protocols or difficulties or delays in subject enrollment or data analysis;
- our ability to establish additional strategic alliances, collaborations or licensing or other strategic arrangements or transactions on favorable terms;
- our ability to protect our intellectual property; and
- the timing and success of submission, acceptance and approval of regulatory applications for our product candidates.

[Table of Contents](#)

Risks and uncertainties that we face are described in greater detail under the caption “Risk Factors” in Item 1A of Part II of this quarterly report and in other filings that we make with the Securities and Exchange Commission, or SEC. As a result of the risks and uncertainties to which our business is subject, the results or events indicated by any forward-looking statement may not occur. We caution you not to place undue reliance on any forward-looking statement.

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

Item 1. Financial Statements

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

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 45,707	\$ 54,485
Investments in marketable securities – short term	52,209	37,844
Current receivables	57	278
Prepaid expenses	1,016	999
Total current assets	98,989	93,606
Investments in marketable securities – long term	16,630	51,448
Property and equipment, net	483	682
Intangible assets	—	97
Other assets	19	40
Total assets	<u>\$ 116,121</u>	<u>\$ 145,873</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 364	\$ 1,296
Accrued expenses	2,370	8,830
Current portion of long-term debt	478	853
Total current liabilities	3,212	10,979
Long-term debt, net of current portion	—	283
Total liabilities	3,212	11,262
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value, 100,000,000 shares authorized and 33,793,735 and 33,718,179 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	34	34
Preferred stock, \$0.001 par value, 5,000,000 shares authorized and 0 shares issued and outstanding at September 30, 2014 and December 31, 2013	—	—
Capital in excess of par value	421,448	415,123
Accumulated other comprehensive income	55	87
Accumulated deficit	(308,628)	(280,633)
Total stockholders' equity	112,909	134,611
Total liabilities and stockholders' equity	<u>\$ 116,121</u>	<u>\$ 145,873</u>

See accompanying notes.

TARGACEPT, INC.
STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Operating revenues:				
License fees and milestones from collaborations	\$ —	\$ —	\$ —	\$ 3,536
Grant and other revenue	25	—	148	—
Net operating revenues	25	—	148	3,536
Operating expenses:				
Research and development (including stock-based compensation of \$372 and \$610 for the three months ended September 30, 2014 and 2013, respectively; and \$1,220 and \$1,985 for the nine months ended September 30, 2014 and 2013, respectively)	2,655	10,312	17,143	28,086
General and administrative (including stock-based compensation of \$435 and \$682 for the three months ended September 30, 2014 and 2013, respectively; and \$1,397 and \$2,172 for the nine months ended September 30, 2014 and 2013, respectively)	2,358	2,834	7,988	9,358
Total operating expenses	5,013	13,146	25,131	37,444
Loss from operations	(4,988)	(13,146)	(24,983)	(33,908)
Other income (expense):				
Interest income	144	257	476	612
Interest expense	(5)	(13)	(20)	(43)
Total other income (expense)	139	244	456	569
Loss before taxes	(4,849)	(12,902)	(24,527)	(33,339)
Income tax expense	(11)	—	(3,468)	—
Net loss	\$ (4,860)	\$ (12,902)	\$ (27,995)	\$ (33,339)
Basic and diluted net loss per share	\$ (0.14)	\$ (0.38)	\$ (0.83)	\$ (0.99)
Weighted average common shares outstanding – basic and diluted	33,793,735	33,644,256	33,775,951	33,629,295
Net loss	\$ (4,860)	\$ (12,902)	\$ (27,995)	\$ (33,339)
Unrealized (loss) gain on available-for-sale securities, net	(55)	109	(32)	(106)
Comprehensive loss	\$ (4,915)	\$ (12,793)	\$ (28,027)	\$ (33,445)

See accompanying notes.

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

	Nine Months Ended	
	September 30,	
	2014	2013
Operating activities		
Net loss	\$(27,995)	\$(33,339)
Adjustments to reconcile net loss to net cash used in operating activities:		
Recognition of deferred revenue	(148)	(3,536)
Amortization of premium on marketable securities, net	633	680
Depreciation and amortization	286	522
Stock-based compensation expense	2,617	4,157
Income tax expense from other comprehensive income	56	—
Changes in operating assets and liabilities:		
Current receivables	220	322
Other assets	144	128
Accounts payable and accrued expenses	(7,392)	1,622
Deferred revenue	148	—
Net cash used in operating activities	(31,431)	(29,444)
Investing activities		
Purchase of investments in marketable securities	(7,169)	(47,004)
Proceeds from sale of investments in marketable securities	26,747	55,406
Purchase of property and equipment	(4)	(92)
Proceeds from sale of property and equipment	29	1,163
Net cash provided by investing activities	19,603	9,473
Financing activities		
Principal payments on long-term debt	(658)	(636)
Excess tax benefits from stock-based compensation	3,412	—
Proceeds from issuance of common stock, net	296	106
Net cash provided by (used in) financing activities	3,050	(530)
Net decrease in cash and cash equivalents	(8,778)	(20,501)
Cash and cash equivalents at beginning of period	54,485	82,240
Cash and cash equivalents at end of period	<u>\$ 45,707</u>	<u>\$ 61,739</u>

See accompanying notes.

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS
September 30, 2014

1. The Company and Nature of Operations

Targacept, Inc., or the Company, is a Delaware corporation formed on March 7, 1997. The Company is a biopharmaceutical company that has historically been engaged in the development of novel NNR Therapeutics™ to treat patients suffering from serious nervous system and gastrointestinal/ genitourinary diseases and disorders. The Company's NNR Therapeutics selectively target neuronal nicotinic receptors, which it refers to as NNRs. Its facilities are located in Winston-Salem, North Carolina.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information, the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's audited financial statements and notes thereto included in its Annual Report on Form 10-K for the year ended December 31, 2013. 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, 2014 are not necessarily indicative of the results that may be expected for the full year, for any other interim period or for any future year.

Use of Estimates

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

Fair Value Measurement

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

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2014

2. Summary of Significant Accounting Policies (continued)

The valuation techniques required by ASC 820 may be based on either observable or unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, and unobservable inputs reflect the Company's market assumptions. These inputs are classified into the following hierarchy:

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

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

Level 3 Inputs – unobservable inputs for the assets.

The following tables present the Company's investments in marketable securities (including, if applicable, those classified on the Company's balance sheet as cash equivalents) that are measured at fair value on a recurring basis as of September 30, 2014 and December 31, 2013, respectively:

<u>September 30, 2014</u>	<u>Quoted Prices in Active Markets (Level 1)</u>	<u>Other Observable Inputs (Level 2)</u>	<u>Unobservable Inputs (Level 3)</u>
		(in thousands)	
U.S. Treasury and U.S. or state government agency-backed securities	\$25,937	\$ —	\$ —
Corporate debt securities	—	36,048	—
Municipal bonds	—	1,577	—
Certificates of deposit	5,023	—	—
Accrued interest	254	—	—
Total investments in marketable securities	<u>\$31,214</u>	<u>\$ 37,625</u>	<u>\$ —</u>
		(in thousands)	
<u>December 31, 2013</u>	<u>Quoted Prices in Active Markets (Level 1)</u>	<u>Other Observable Inputs (Level 2)</u>	<u>Unobservable Inputs (Level 3)</u>
U.S. Treasury and U.S. or state government agency-backed securities	\$37,029	\$ —	\$ —
Corporate debt securities	—	43,347	—
Municipal bonds	—	3,509	—
Certificates of deposit	5,000	—	—
Accrued interest	407	—	—
Total investments in marketable securities	<u>\$42,436</u>	<u>\$ 46,856</u>	<u>\$ —</u>

Corporate debt securities and municipal bonds are valued based on various observable inputs such as benchmark yields, reported trades, broker/dealer quotes, benchmark securities and bids.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2014

2. Summary of Significant Accounting Policies (continued)

Investments in Marketable Securities

Consistent with its investment policy, the Company invests its cash allocated to fund its short-term liquidity requirements with prominent financial institutions in bank depository accounts and institutional money market funds and the Company invests the remainder of its cash in corporate debt securities and municipal bonds rated at least A quality or equivalent, U.S. Treasury notes and bonds, U.S. and state government agency-backed securities and certificates of deposit.

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates its classification as of each balance sheet date. All marketable securities owned during the nine months ended September 30, 2014 and 2013 were classified as available-for-sale. The cost of securities sold is based on the specific identification method. Investments in marketable securities are recorded as of each balance sheet date at fair value, with unrealized gains and, to the extent deemed temporary, unrealized losses included in stockholders' equity. Interest and dividend income on investments in marketable securities, accretion of discounts and amortization of premiums and realized gains and losses are included in interest income in the statement of comprehensive income (loss).

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

Revenue Recognition

The Company uses the revenue recognition guidance established by ASC Topic 605, *Revenue Recognition*, or ASC 605. In determining the accounting for collaboration and alliance agreements, the Company follows the provisions of ASC 605, Subtopic 25, *Multiple Element Arrangements*, or ASC 605-25. ASC 605-25 provides guidance on whether an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes and, if division is required, how the arrangement consideration should be allocated among the separate units of accounting. If the arrangement constitutes separate units of accounting according to the separation criteria of ASC 605-25, the consideration received is allocated among the separate units of accounting and the applicable revenue recognition criteria must be applied to each unit. If the arrangement constitutes a single unit of accounting, the revenue recognition policy must be determined for the entire arrangement and the consideration received is recognized over the period of inception through the date on which the last deliverable within the single unit of accounting is expected to be delivered. Revisions to the estimated period of recognition are reflected in revenue prospectively.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2014

2. Summary of Significant Accounting Policies (continued)

Collaboration research and development revenue is earned and recognized as research or development is performed and related expenses are incurred. Non-refundable upfront fees, which may include, for example, an initial payment upon effectiveness of the contractual relationship, payment representing a common stock purchase premium or payment to secure a right for a future license, are recorded as deferred revenue and recognized into revenue as license fees and milestones from collaborations on a straight-line basis over the estimated period of the Company's substantive performance obligations. If the Company does not have substantive performance obligations, it recognizes non-refundable upfront fees into revenue through the date the deliverable is satisfied.

Revenue for non-refundable payments based on the achievement of milestone events under collaboration agreements is recognized in accordance with ASC 605, Subtopic 28, *Milestone Method*, or ASC 605-28. Milestone events under the Company's collaboration agreements may include research, development, regulatory, commercialization or sales events. Under ASC 605-28, a milestone payment is recognized as revenue when the applicable event is achieved if the event meets the definition of a milestone and the milestone is determined to be substantive. ASC 605-28 defines a milestone event as an event having all of the following characteristics: (1) there is substantive uncertainty regarding achievement of the milestone event at the inception of the arrangement; (2) the event can only be achieved based, in whole or in part, on either the company's performance or a specific outcome resulting from the company's performance; and (3) if achieved, the event would result in additional payment due to the company. The Company also treats events that can only be achieved based, in whole or in part, on either a third party's performance or a specific outcome resulting from a third party's performance as milestone events if the criteria of ASC 605-28 are otherwise satisfied. A milestone is considered substantive if it meets all of the following criteria: (A) the payment is commensurate with either the Company's performance to achieve the milestone or with the enhancement of the value of the delivered item; (B) the payment relates solely to past performance; and (C) the payment is reasonable relative to all of the deliverables and payment terms within the arrangement. If any of these conditions is not met, the milestone payment is deferred and recognized on a straight-line basis over a period determined as discussed above.

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

Grant payments received prior to the Company's performance of work required by the terms of the award are recorded as deferred revenue and recognized as grant revenue as the Company performs the work and incurs qualifying costs.

Income Taxes

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

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2014**2. Summary of Significant Accounting Policies (continued)**

allowance is recorded to reduce the carrying amounts of deferred tax assets unless it is more likely than not that the assets will be realized. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC 740 requires interim income tax expense or benefit to be calculated using an estimated annual effective tax rate. If a reliable estimate of the annual effective tax rate cannot be made, the Company considers the effective tax rate for the year to date to be the best estimate. Accordingly, the income tax provisions for the three and nine months ended September 30, 2014 were determined based on the actual year-to-date effective tax rate because a reliable estimate of the annual effective tax rate cannot be made. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosures and transition. The Company's policy is to classify any interest recognized in accordance with ASC 740 as interest expense and to classify any penalties recognized in accordance with ASC 740 as an expense other than income tax expense.

Net Income or Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Basic and diluted:				
Net loss	\$ (4,860)	\$ (12,902)	\$ (27,995)	\$ (33,339)
Weighted average common shares – basic and diluted	33,793,735	33,644,256	33,775,951	33,629,295
Basic and diluted EPS	\$ (0.14)	\$ (0.38)	\$ (0.83)	\$ (0.99)

Common share equivalents consist of the incremental common shares that would be outstanding upon the exercise of stock options, calculated using the treasury stock method. For the three- and nine-month periods ended September 30, 2014 and 2013, the Company excluded all common share equivalents from the calculation of Diluted EPS because the Company had a net loss in those periods. As a result, Diluted EPS is identical to Basic EPS for those periods. If the Company had been in a net income position for the three months ended September 30, 2014 and 2013, 4,687,285 and 4,808,429 shares subject to outstanding stock options, respectively, may have been included in the calculation of common share equivalents using the treasury stock method. If the Company had been in a net income position for the nine months ended September 30, 2014 and 2013, 4,810,606 and 4,765,095 shares subject to outstanding stock options, respectively, may have been included in the calculation of common share equivalents using the treasury stock method.

TARGACEPT, INC.**NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)**
September 30, 2014**2. Summary of Significant Accounting Policies (continued)*****Common Stock and Stock-Based Compensation***

The Company issued 75,556 shares of common stock upon the exercise of stock options during the nine months ended September 30, 2014. The Company issued 103,098 shares of common stock upon the exercise of stock options during the year ended December 31, 2013.

During the nine months ended September 30, 2014, the Company granted to employees options to purchase an aggregate of 849,118 shares of common stock. These stock options have an estimated aggregate fair value, using the Black-Scholes-Merton formula, of \$3,311,000. The Company is recording this amount, as adjusted for forfeitures, as stock-based compensation on a straight line basis over 16 quarters beginning on the last day of the respective quarters in which the grants were made. In October 2014, the Company granted to employees 517,700 unvested stock awards. These stock awards have an estimated fair value of \$1,222,000. The Company will record this amount, as adjusted for forfeitures, as stock-based compensation on a straight line basis over the vesting period, which ends December 31, 2016.

Accumulated Other Comprehensive Income or Loss

Accumulated other comprehensive income or loss, as presented in stockholders' equity on the Company's balance sheet, reflects the cumulative net unrealized gains or losses on available-for-sale securities for all periods. The table below reflects changes in accumulated other comprehensive income for the nine months ended September 30, 2014, in thousands.

Accumulated other comprehensive income, January 1, 2014	\$ 87
Unrealized loss on available-for-sale securities, net	(82)
Net realized gains on available-for-sale securities reclassified out of other comprehensive income	(6)
Income taxes	56
Accumulated other comprehensive income, September 30, 2014	<u>\$ 55</u>

Intellectual Property

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

The Company assesses the net realizable value of its long-lived assets, including capitalized intellectual property, and evaluates these assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment charge would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. An impairment charge, if recognized, would be based on the excess of the carrying value of the impaired asset over its estimated fair value. As a result of the decision to discontinue development of TC-5214, the Company determined during the three months ended September 30, 2014 the carrying value of the related capitalized intellectual property was not recoverable and, accordingly, recorded an impairment charge for its full carrying value, which was \$89,000 as of June 30, 2014.

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2014

2. Summary of Significant Accounting Policies (continued)

Commitments and Contingencies

Under an employment agreement with a former executive officer and a related separation agreement and release, the Company paid severance equal to the departing executive's regular base salary as of March 31, 2013 for nine months, a pro rata percentage of the departing executive's target bonus for 2013, and the departing executive's health and life insurance benefits coverage provided to him as of March 31, 2013 for nine months. These payments and benefits, which represent an aggregate amount of \$306,000, were recorded as general and administrative expense for the nine months ended September 30, 2013.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09. ASU 2014-09 develops a common revenue standard for GAAP and International Financial Reporting Standards and supersedes most current revenue recognition guidance. ASU 2014-09 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and requires a company to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. ASU 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. The Company is currently evaluating the impact that the implementation of ASU 2014-09 will have on the Company's financial statements.

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2014

3. Investments in Marketable Securities

The following is a reconciliation of amortized cost to fair value of available-for-sale marketable securities (including those classified on the Company's balance sheet as cash equivalents) held at September 30, 2014 and December 31, 2013:

<u>September 30, 2014</u>	<u>Amortized</u>	<u>Gross</u>	<u>Gross</u>	<u>Fair</u>
<i>Security type</i>	<u>Cost</u>	<u>Unrealized</u>	<u>Unrealized</u>	<u>Value</u>
	(in thousands)			
<u>Marketable Securities – Short term</u>				
U.S. Treasury and U.S. or state government agency-backed securities	\$ 22,297	\$ 23	\$ —	\$22,320
Corporate debt securities	23,378	46	—	23,424
Municipal bonds	1,280	3	—	1,283
Certificates of deposit	5,023	—	—	5,023
Accrued interest	159	—	—	159
<u>Marketable Securities – Long term</u>				
U.S. Treasury and U.S. or state government agency-backed securities	3,615	2	—	3,617
Corporate debt securities – long term	12,604	23	(3)	12,624
Municipal bonds	295	—	(1)	294
Accrued interest	95	—	—	95
Total available-for-sale marketable securities	<u>\$ 68,746</u>	<u>\$ 97</u>	<u>\$ (4)</u>	<u>\$68,839</u>
<u>December 31, 2013</u>	<u>Amortized</u>	<u>Gross</u>	<u>Gross</u>	<u>Fair</u>
<i>Security type</i>	<u>Cost</u>	<u>Unrealized</u>	<u>Unrealized</u>	<u>Value</u>
	(in thousands)			
<u>Marketable Securities – Short term</u>				
U.S. Treasury and U.S. or state government agency-backed securities	\$ 16,352	\$ 39	\$ —	\$16,391
Corporate debt securities	14,307	35	—	14,342
Municipal bonds	1,910	3	—	1,913
Certificates of deposit	5,000	—	—	5,000
Accrued interest	198	—	—	198
<u>Marketable Securities – Long term</u>				
U.S. Treasury and U.S. or state government agency-backed securities	20,628	14	(4)	20,638
Corporate debt securities	28,909	101	(5)	29,005
Municipal bonds	1,598	4	(6)	1,596
Accrued interest	209	—	—	209
Total available-for-sale marketable securities	<u>\$ 89,111</u>	<u>\$ 196</u>	<u>\$ (15)</u>	<u>\$89,292</u>

As of September 30, 2014, the Company held investments in marketable securities with unrealized gains of \$97,000 and unrealized losses of \$4,000. For the investments in an unrealized loss position, the duration of the loss was less than 12 months and the investments are not considered to be other-than-temporarily impaired. The Company's investments in marketable securities as of September 30, 2014, will reach maturity between October 2014 and December 2016, with a weighted average maturity date in May 2015.

TARGACEPT, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)
September 30, 2014

4. Income Taxes

Because the Company has incurred cumulative net operating losses since inception, all tax years remain open to examination by U.S. federal, North Carolina and Massachusetts tax authorities. An examination of the Company's 2010 federal income tax return was completed in 2014 and resulted in an adjustment that increased taxable income for 2010 by \$15,064,000, decreased taxable income for 2011 by \$1,076,000, and decreased taxable income for 2012 by \$13,988,000. The examination adjustment had no cumulative effect on federal net operating loss carryforwards. Exercises of stock options may result in tax deductions for stock-based compensation in excess of expense recorded for the stock options under GAAP. For interim periods within years for which taxable net income is forecasted, the Company recognizes the income tax benefit related to the excess tax deductions as an increase to capital in excess of par value, which based on ASC 740 results in an offsetting charge in the same amount to income tax expense. The examination adjustment to the Company's 2010 federal income tax return resulted in the realization of an additional \$3,412,000 of excess tax deductions and an offsetting charge to income tax expense for the nine months ended September 30, 2014. The Company did not recognize any income tax expense for the nine months ended September 30, 2013.

As of September 30, 2014, the Company had \$3,915,000 remaining of cumulative tax deductions for periods of net loss from exercises of stock options in excess of expense recorded for the stock options under GAAP. The benefit of these excess tax deductions had not begun to be realized as of September 30, 2014 because the Company incurred operating losses in the years in which the respective stock options were exercised and has incurred cumulative net operating losses since inception. Accordingly, the tax benefit will not be recognized as an increase to capital in excess of par value until the excess deductions reduce income taxes payable.

5. Collaboration Agreement

AstraZeneca AB

In December 2005, the Company entered into a collaborative research and license agreement with AstraZeneca AB, or AstraZeneca, that was initially focused in cognitive disorders. In October 2014, AstraZeneca terminated the agreement in its entirety, effective January 2015. When termination of the agreement becomes effective, all remaining rights and licenses to compounds granted by the Company under the agreement to AstraZeneca will terminate and revert to the Company, including the rights and license relating to the Company's product candidate TC-6683 (also known as AZD1446).

AstraZeneca paid the Company an initial fee of \$10,000,000 under the agreement in February 2006. The initial fee included \$5,000,000 for grants of licenses to develop and commercialize the Company's product candidate TC-1734 (formerly known also as AZD3480), which the Company recognized on a straight-line basis over the estimated development period for TC-1734. In September 2010, the Company and AstraZeneca amended the agreement to enable the Company to conduct a clinical trial of TC-1734 in mild to moderate Alzheimer's disease and to provide for

TARGACEPT, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS (continued)

September 30, 2014

5. Collaboration Agreement (continued)

respective roles and responsibilities and associated financial terms for such a study. Under the 2010 amendment, the Company received from AstraZeneca cumulative payments of \$6,000,000 during 2010 and 2011. At that time, the Company began recognizing the portion of the \$5,000,000 received for grants of licenses not yet recognized and the payments received under the 2010 amendment into revenue on a straight-line basis over the period of the Company's substantive performance obligations under the agreement as amended.

In March 2013, the Company and AstraZeneca amended the agreement to permit AstraZeneca to pursue development and commercialization of compounds it had licensed from the Company in any therapeutic area. Also in March 2013, AstraZeneca exercised its right to terminate TC-1734 from the collaboration. As a result, the Company recognized into revenue during the first quarter of 2013 all of the initial fee and payments received under the 2010 amendment that had not yet been recognized as of the date of AstraZeneca's action, totaling \$3,142,000. The Company recognized an aggregate of \$3,536,000 of the initial fee and the payments received under the 2010 amendment into revenue during the nine months ended September 30, 2013.

Under the agreement, AstraZeneca paid the Company an aggregate of \$88,120,000, including the initial fee and payments upon the achievement of milestone events, to maintain option rights and for research services rendered in the completed preclinical research collaboration. This entire amount had been fully recognized into revenue in previous periods.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes included in this quarterly report and our audited financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2013, which is on file with the SEC. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results, performance or experience could differ materially from what is indicated by any forward-looking statement due to various important factors, risks and uncertainties, including, but not limited to, those set forth in Part I of this quarterly report under the heading "Cautionary Note Regarding Forward-Looking Statements", in Part II, Item 1A of this quarterly report under the heading "Risk Factors," or in other filings that we make with the SEC.

Overview

Background

We are a biopharmaceutical company that has historically been engaged in the development of novel NNR Therapeutics™ to treat patients suffering from serious nervous system and gastrointestinal/genitourinary diseases and disorders. Our NNR Therapeutics selectively target a class of receptors known as neuronal nicotinic receptors, which we refer to as NNRs. NNRs are found on nerve cells throughout the nervous system and serve as key regulators of nervous system activity. However, due to the recent clinical trial outcomes in our development programs for TC-5214, TC-1734 and TC-5619, and the resulting development discontinuation decisions, we are now focused on strategic arrangements or transactions that would fortify our pipeline with non-nicotinic opportunities.

As described briefly below, we have multiple clinical-stage nicotinic product candidates that we believe could address significant medical needs.

- *TC-6499*. TC-6499 is a novel small molecule that modulates the activity of the $\alpha 3\beta 4$ and other NNRs as an agonist. We are currently conducting an exploratory study of TC-6499 as a treatment for diabetic gastroparesis, a disorder that is often debilitating and chronic, and that slows or stops the passage of food from the stomach to the small intestine.
- *TC-6683 (formerly AZD1446)*. TC-6683 is a novel small molecule that modulates the activity of the $\alpha 4\beta 2$ NNR. TC-6683 is subject to our collaboration agreement with AstraZeneca that AstraZeneca has terminated, effective January 2015. Upon termination of the agreement, all rights to TC-6683 will revert to Targacept. We do not have current plans to pursue additional development of TC-6683.
- *TC-5619 and TC-6987*. TC-5619 and TC-6987 are novel small molecules that are highly selective for the $\alpha 7$ NNR. The $\alpha 7$ NNR has been shown to play a role in a variety of biological pathways associated with various diseases and disorders. We previously conducted clinical studies of TC-5619 as a potential treatment for schizophrenia and attention deficit hyperactivity disorder and exploratory studies of TC-6987 as a treatment for inflammatory disorders. We do not have plans to pursue additional development of these compounds in these therapeutic areas.

[Table of Contents](#)

- *TC-1734*. TC-1734 (also referred to in previous filings as AZD3480) is a wholly owned novel small molecule that modulates the activity of the $\alpha 4\beta 2$ NNR. In July 2014, we announced that our Phase 2b clinical trial of TC-1734 as a treatment for mild to moderate Alzheimer's disease did not meet its primary endpoint. We have no further plans for development of TC-1734.
- *TC-5214*. TC-5214 acts as an antagonist on the $\alpha 3\beta 4$ NNR. We previously conducted clinical studies of TC-5214 as a treatment for major depressive disorder and for overactive bladder. Most recently, in July 2014, we announced that a Phase 2b trial of TC-5214 as a treatment for overactive bladder did not meet one of the trial's two co-primary endpoints. We do not have plans to pursue additional development of this compound in these therapeutic areas.

We are party to a collaboration agreement with AstraZeneca focused on compounds that act on the $\alpha 4\beta 2$ NNR, which AstraZeneca terminated in October 2014, effective January 2015. Under the agreement AstraZeneca was granted an exclusive license to TC-6683 and an earlier-stage compound that arose from the preclinical research collaboration conducted under the agreement from January 2006 to January 2010. The rights to TC-6683 and the other compound will revert to Targacept upon effectiveness of termination of the collaboration agreement in January 2015.

Since our inception, we have funded our operations principally through public and private offerings of equity securities, payments under collaboration and alliance agreements, grants and equipment financing. We have historically devoted substantially all of our resources to the discovery (prior to our 2012 reductions in force) and development of our product candidates and technologies, including the design, conduct and management of non-clinical and clinical studies and related manufacturing, regulatory and clinical affairs, as well as intellectual property prosecution.

Except for a small number of periods in which we generated net income due primarily to the recognition into revenue of amounts received under collaboration agreements, we have not been profitable. As of September 30, 2014, we had an accumulated deficit of \$308.6 million. We expect that we will incur losses in future periods as we progress our current program and invest in additional product or other strategic opportunities. Drug development, including clinical trials in particular, is time-consuming, expensive and may never yield a product that will generate revenue.

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

Revenue

As of September 30, 2014, we had received \$61.6 million in aggregate upfront fees and milestone payments under our collaboration agreement with AstraZeneca and recognized an additional \$26.5 million in collaboration research and development revenue for research services that we provided in the preclinical research collaboration conducted under that agreement. We

[Table of Contents](#)

immediately recognized an aggregate of \$32.6 million of the amounts received under the agreement for achievement of milestone events, because each event met the conditions required for immediate recognition under our revenue recognition policy. We deferred recognition of an aggregate of \$29.0 million received under the agreement. In March 2013, AstraZeneca exercised its right to terminate TC-1734 from our collaboration agreement. As a result, we recognized the remaining unrecognized deferred amount of \$3.5 million into revenue during the first quarter of 2013. All deferred amounts have been fully recognized into revenue over the respective periods determined by our revenue recognition policy discussed in Note 2 to our unaudited financial statements included in this quarterly report.

From time to time we seek and are awarded grants or perform work under grants awarded to third-party collaborators from which we derive revenue. We are a subcontractor under a grant awarded to The California Institute of Technology by the National Institute on Drug Abuse, or NIDA, part of the National Institutes of Health, to fund research on innovative NNR-based approaches to the development of therapies for smoking cessation. Based on the terms of this arrangement, we were granted \$148,000 in March 2014. Funding for awards under federal grant programs is subject to the availability of funds as determined annually in the federal appropriations process. In September 2014, we entered into a services agreement with a biopharmaceutical company, under which we will provide certain clinical development and regulatory consulting services. Under the agreement, we may receive up to \$252,000 for our services over the term of the agreement, which expires on December 31, 2014. We do not expect ongoing revenue from this agreement or other similar agreements.

Research and Development Expenses

Since our inception, we have focused our activities on drug discovery and development programs. Research and development expenses consist principally of charges for third-party services associated with our clinical-stage programs and preclinical research, salaries and other related costs for personnel in research and development functions and depreciation and other facility costs related to research and development functions. We record research and development expenses as they are incurred. Research and development expenses represented approximately 53% and 78% of our total operating expenses for the three months ended September 30, 2014 and 2013, respectively, and 68% and 75% of our total operating expenses for the nine months ended September 30, 2014 and 2013, respectively.

We have historically utilized our research and development personnel and infrastructure resources across several programs, and many of our costs are not specifically attributable to a single program. Accordingly, we cannot state precisely our total costs incurred on a program-by-program basis.

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

[Table of Contents](#)

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

General and Administrative Expenses

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

Income Taxes

We have incurred cumulative net operating losses through September 30, 2014 and have not paid federal, state or foreign income taxes for any period. An examination of our 2010 federal income tax return was completed in 2014 and resulted in an adjustment that increased taxable income for 2010 by \$15.1 million, decreased taxable income for 2011 by \$1.1 million and decreased taxable income for 2012 by \$14.0 million. The cumulative adjustment had no effect on our federal net operating loss carryforwards. The application of U.S. generally accepted accounting principles, or GAAP, may for some periods result in non-cash income tax expense or benefit being reflected in our Statement of Comprehensive Income (Loss). Exercises of stock options in periods of net income may result in tax deductions for stock-based compensation in excess of expense recorded for the stock options under GAAP. For interim periods within years for which net income is forecasted, we recognize the income tax benefit related to the excess tax deductions as an increase to capital in excess of par value and, based on Accounting Standards Codification ASC Topic 740, *Income Taxes*, record an offsetting charge in the same amount to income tax expense. The examination adjustment to our 2010 federal income tax return resulted in the realization of an additional \$3.4 million of excess tax deductions and an offsetting charge to income tax expense for the nine months ended September 30, 2014.

As of September 30, 2014, we had \$3.9 million remaining of cumulative tax deductions for periods of net loss from exercises of stock options in excess of expense recorded for the stock options under GAAP. The benefit of these excess tax deductions had not begun to be realized as of September 30, 2014 because we have incurred cumulative net operating losses since inception. This benefit will not be recognized as an increase to capital in excess of par value until the excess deductions reduce income taxes payable.

As of September 30, 2014, we had net operating loss carryforwards of \$255.3 million for federal income tax purposes and \$241.0 million for state income tax purposes and we had research and development income tax credit carryforwards of \$12.8 million for federal income tax purposes and \$587,000 for state income tax purposes. The federal net operating loss carryforwards begin to expire in 2024. The state net operating loss carryforwards begin to expire in 2019. The federal and state research and development tax credits begin to expire in 2021. As a result of various factors, including the subjectivity of measurements used in the calculation of particular tax positions taken or that may in the future be taken in our tax returns, it is uncertain whether or to what extent we will be eligible to use the tax credits.

[Table of Contents](#)

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. A series of stock issuances by us gave rise to such an ownership change in December 2004. As a result, an annual limitation is imposed on our use of net operating loss and credit carryforwards that are attributable to periods before the change. In addition, a portion of the net operating loss carryforwards described above may potentially not be usable by us if we experience further ownership changes in the future.

For financial reporting purposes, we have recorded a valuation allowance to fully offset the deferred tax assets related to the carryforwards and tax credits discussed above until it is more likely than not that we will realize any benefit from them.

Fair Value

The carrying amounts of our cash and cash equivalents, investments in marketable securities, accounts receivable, accounts payable and accrued expenses are considered to be representative of their respective fair values due to their short-term natures and, in the case of short-term investments, their market interest rates. Likewise, the carrying amounts of our long-term debts are considered to be representative of their fair value due to their market interest rates. Cash that we do not expect to use to fund our short-term liquidity requirements is invested in corporate debt securities and municipal bonds rated at least A quality or equivalent, U.S. Treasury notes and bonds, U.S. and state government agency backed certificates and certificates of deposit. Our investments in marketable securities, which would include marketable securities classified on our balance sheet as cash equivalents, are recorded at quoted market prices or observable market inputs and totaled \$68.8 million at September 30, 2014.

Critical Accounting Policies and Estimates

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

Our significant accounting policies are described in Note 2 to our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2013 and in the notes to our unaudited 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

[Table of Contents](#)

financial condition and results of operations and require us to make judgments and estimates on matters that are inherently uncertain and may change in future periods. These policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2013.

Results of Operations

Three Months ended September 30, 2014 and 2013

Net Operating Revenues

	Three Months Ended September 30,		Change
	2014	2013	
	(in thousands)		
Operating revenues:			
License fees and milestones from collaborations	\$—	\$—	\$ —
Grant and other revenue	25	—	25
Net operating revenues	<u>\$ 25</u>	<u>\$—</u>	<u>\$ 25</u>

Net operating revenues for the three months ended September 30, 2014 increased by \$25,000 as compared to the three months ended September 30, 2013, as a result of the grant we were awarded in March 2014 as a subcontractor under a grant to the California Institute of Technology.

Research and Development Expenses

	Three Months Ended September 30,		Change
	2014	2013	
	(in thousands)		
Research and development expenses	\$2,655	\$10,312	\$(7,657)

Research and development expenses for the three months ended September 30, 2014 decreased by \$7.7 million as compared to the three months ended September 30, 2013. The lower research and development expenses were principally attributable to a decrease of \$6.7 million in costs incurred for third-party services associated with our clinical-stage programs to \$856,000 for the 2014 period, from \$7.6 million for the 2013 period. This decrease was principally due to lower costs related to our Phase 2b study of TC-5619 in schizophrenia, which we completed in the fourth quarter of 2013, and lower costs related to the Phase 2b study of TC-5214 in overactive bladder, which we completed in the third quarter of 2014. The lower research and development expenses were also attributable to a decrease of \$767,000 in research and development-related operating costs, including infrastructure and compensation-related expenses for research and development personnel, to \$1.8 million for the 2014 period, from \$2.6 million for the 2013 period.

The costs that we incurred for the three months ended September 30, 2014 and 2013 for third-party services in connection with research and development of clinical-stage product candidates are shown in the table below.

[Table of Contents](#)

	Three Months Ended September 30,		Change
	2014	2013	
	(in thousands)		
TC-5214 overactive bladder	\$ 83	\$5,548	\$(5,465)
TC-6499	493	123	370
TC-1734	307	595	(288)
TC-5619	—	1,316	(1,316)
TC-6683	—	—	—

With the completion in mid-2014 of the Phase 2b clinical trials of TC-5214 in overactive bladder and TC-1734 in Alzheimer's disease, we expect that our expenses for these programs in the second half of 2014 will be substantially less than in the first half of 2014 and in the comparable 2013 periods.

General and Administrative Expenses

	Three Months Ended September 30,		Change
	2014	2013	
	(in thousands)		
General and administrative expenses	\$2,358	\$2,834	\$(476)

General and administrative expenses for the three months ended September 30, 2014 decreased by \$476,000 as compared to the three months ended September 30, 2013. The lower general and administrative expenses were primarily attributable to a decrease of \$489,000 in compensation related expenses for general and administrative personnel resulting principally from fewer general and administrative employees and a lower value assigned to our stock-based compensation awards that vested during the period.

Nine Months ended September 30, 2014 and 2013

Net Operating Revenues

	Nine Months Ended September 30,		Change
	2014	2013	
	(in thousands)		
Operating revenues:			
License fees and milestones from collaborations	\$—	\$3,536	\$(3,536)
Grant revenue	148	—	148
Net operating revenues	<u>\$148</u>	<u>\$3,536</u>	<u>\$(3,388)</u>

Net operating revenues for the nine months ended September 30, 2014 decreased by \$3.4 million as compared to the nine months ended September 30, 2013, primarily as a result of a decrease in license fees and milestones from collaborations. License fees and milestones from collaborations for the 2013 period reflected recognition of the remaining \$3.5 million balance of deferred revenue from payments previously received under our collaboration agreement with AstraZeneca, triggered by AstraZeneca's decision to terminate TC-1734 from the collaboration.

Research and Development Expenses

	Nine Months Ended September 30,		Change
	2014	2013	
		(in thousands)	
Research and development expenses	\$17,143	\$28,086	\$(10,943)

Research and development expenses for the nine months ended September 30, 2014 decreased by \$10.9 million as compared to the nine months ended September 30, 2013. The lower research and development expenses were principally attributable to a decrease of \$8.7 million in costs incurred for third-party services associated with our clinical-stage programs to \$10.7 million for the 2014 period, from \$19.4 million for the 2013 period. This decrease was principally due to lower costs related to our Phase 2b study of TC-5619 in schizophrenia, which we completed in the fourth quarter of 2013, and lower costs related to the Phase 2b studies of TC-5214 in overactive bladder and TC-1734 in Alzheimer's disease, both of which we completed in the third quarter of 2014, and which were partially offset by increased costs related to our ongoing exploratory study of TC-6499 in diabetic gastroparesis, which we initiated in the second quarter of 2014. The lower research and development expenses were also attributable to a decrease of \$2.3 million in research and development-related operating costs, including infrastructure and compensation-related expenses for research and development personnel, to \$6.2 million for the 2014 period, from \$8.5 million for the 2013 period.

The costs that we incurred for the nine months ended September 30, 2014 and 2013 for third-party services in connection with research and development of clinical-stage product candidates are shown in the table below.

	Nine Months Ended September 30,		Change
	2014	2013	
		(in thousands)	
TC-5214 overactive bladder	\$7,384	\$8,449	\$(1,065)
TC-1734	1,847	2,815	(968)
TC-6499	1,713	151	1,562
TC-5619	—	7,952	(7,952)
TC-6683	—	—	—

[Table of Contents](#)

General and Administrative Expenses

	Nine Months Ended September 30,		Change
	2014	2013	
		(in thousands)	
General and administrative expenses	\$7,988	\$9,358	\$(1,370)

General and administrative expenses for the nine months ended September 30, 2014 decreased by \$1.4 million as compared to the nine months ended September 30, 2013. The lower general and administrative expenses were partly attributable to a decrease of \$788,000 in compensation related expenses for general and administrative personnel due principally to fewer general and administrative employees and a lower value assigned to our stock-based compensation awards that vested during the period. The lower general and administrative expenses were also attributable to the non-recurrence of \$467,000 in non-cash stock-based compensation charges resulting from the partial accelerated vesting of, and extended exercise periods for, certain outstanding stock options held by a former executive officer who departed Targacept in March 2013, and \$309,000 in severance and other charges resulting from the departure of the former executive officer.

Liquidity and Capital Resources

Sources of Liquidity

We have historically financed our operations and internal growth principally through public and private offerings of equity securities, payments received under collaboration and alliance agreements, grants and equipment financing.

In November 2013, we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission that became effective December 11, 2013. Pursuant to this Form S-3, we may sell shares of common stock and other forms of securities having an aggregate offering price of up to \$200.0 million. Under an At-the-Market Issuance Sales Agreement, or ATM, with MLV & Co., LLC, filed concurrently with the Form S-3, we may offer and sell shares of common stock having an aggregate offering price of up to \$40.0 million.

Our cash, cash equivalents and investments in marketable securities were \$114.5 million as of September 30, 2014 and \$143.8 million as of December 31, 2013. As of September 30, 2014, we had \$41.8 million of cash in bank depository accounts and institutional money market funds at Branch Banking and Trust Company, PNC Bank and Wells Fargo & Company. Substantially all of our remaining cash, cash equivalents and investments were invested as of September 30, 2014 in corporate debt securities and municipal bonds rated at least A quality or equivalent, U.S. Treasury notes and bonds, U.S. and state government agency-backed securities and certificates of deposit.

We have borrowed amounts under a loan agreement with a bank that we entered into in July 2010 to fund the purchase of equipment, furnishings, software and other fixed assets. As of September 30, 2014, the aggregate outstanding principal balance under the loan facility was \$478,000 and there is no additional borrowing capacity remaining available to us.

[Table of Contents](#)

Cash Flows

	Nine Months Ended September 30,		Change
	2014	2013	
	(in thousands)		
Net cash used in operating activities	\$(31,431)	\$(29,444)	\$ (1,987)
Net cash provided by investing activities	19,603	9,473	10,130
Net cash provided by (used in) financing activities	3,050	(530)	3,580
Net decrease in cash and cash equivalents	<u>\$ (8,778)</u>	<u>\$ (20,501)</u>	

Net cash used in operating activities for the nine months ended September 30, 2014 increased by \$2.0 million as compared to the nine months ended September 30, 2013. For the nine months ended September 30, 2014, net cash used in operating activities was principally attributable to \$29.6 million in payments made for research and development and general and administrative charges, and realization of \$3.4 million of excess tax deductions, which is reflected as an increase to our net loss for the nine months ended September 30, 2014, recorded upon the completion during 2014 of an examination of our 2010 federal income tax return. These cash outflows were partially offset by \$1.3 million of amortization of premiums paid for available-for-sale securities, interest income from available-for-sale securities and other investment-related operating activities. For the nine months ended September 30, 2013, net cash used in operating activities was primarily attributable to \$30.8 million in payments made for research and development and general and administrative charges. These cash payments were partially offset by \$1.4 million of investment-related cash receipts.

Net cash provided by investing activities for the nine months ended September 30, 2014 increased by \$10.1 million over the same period in 2013. Cash provided by or used in investing activities reflects the portion of our cash that we allocate to, and the timing of purchases and maturities of, our investments in marketable securities and equipment purchases or dispositions. Our net sales of investments in marketable securities were \$19.6 million and \$8.4 million for the 2014 period and 2013 period, respectively. The remaining \$1.1 million of net cash provided by investing activities for the 2013 period reflects proceeds received in January 2013 from the sale of laboratory equipment and office furniture and fixtures in December 2012.

Net cash provided by financing activities for the nine months ended September 30, 2014 was \$3.1 million. Net cash used in financing activities for the nine months ended September 30, 2013 was \$530,000, a change of \$3.6 million. The change reflects the realization of \$3.4 million of stock-based compensation excess tax deductions for the nine months ended September 30, 2014.

Funding Requirements

As of September 30, 2014, we had an accumulated deficit of \$308.6 million and our cash and investments in marketable securities totaled \$114.5 million. We expect our cash and investments in marketable securities balance at December 31, 2014 to be approximately \$107.0 million. We currently expect our existing capital resources to be sufficient to fund our operations through the entry into one or more strategic transactions; and, if we are successful in entering into a strategic transaction, our objective is to have sufficient capital to fund our operations through projected milestones that have potential for value creation. Our existing capital resources may not be

[Table of Contents](#)

sufficient to enable us to fund the completion of the development of any of our product candidates. We may require additional capital in future periods as our product candidates advance into later-stage development and as we progress our programs and invest in additional product opportunities. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- whether and to what extent we in-license, acquire or risk-share in developing product candidates from external sources, and the terms and scope of any related agreements;
- whether we establish additional strategic alliances, collaborations and licensing or other comparable arrangements, or whether we pursue and complete any merger, acquisition or other significant corporate transaction, and, if we do, the associated terms in each case;
- the costs to satisfy our obligations under potential future alliances, collaborations or licensing or other comparable arrangements;
- the scope, progress, duration, results and cost of clinical trials, as well as non-clinical studies and assessments, of our product candidates and programs;
- the extent to which we retain development or commercialization rights or responsibilities for our product candidates and incur associated development costs, manufacturing costs or costs to establish sales and marketing functions;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending patents and other intellectual property rights;
- the number and characteristics of product candidates that we pursue and programs that we conduct;
- the costs of manufacturing-related services for our product candidates in development;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions;
- the timing, receipt and amount of sales or royalties, if any, from our potential products;
- the extent of our general and administrative expenses; and
- the rate of technological advancements for the indications that we target.

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. To the extent our capital resources are insufficient to meet future capital requirements or to the extent the conditions for raising capital are favorable, we may seek to finance future cash needs through public or private equity or debt offerings or other financings (whether using our currently effective registration statement on Form S-3, including our ATM, or otherwise). Our access in the future to additional equity or debt financing, on acceptable terms or at all, is uncertain. We may also seek to finance future cash needs through alliances, collaborations or licensing or other comparable arrangements. Strategic alliances, collaborations or licensing or other comparable arrangements may not be available on acceptable terms or at all. If adequate funds are not available,

[Table of Contents](#)

we may be required to delay, reduce the scope of or eliminate our development programs or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently. Additionally, any future equity funding may significantly dilute the ownership of our stockholders.

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

To date, inflation has not had a material effect on our business.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objectives of our investment activities are to preserve our capital and meet our liquidity needs to fund operations. We also seek to generate competitive rates of return from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities that are of high credit quality based on ratings from commonly relied upon rating agencies. As of September 30, 2014, we had cash, cash equivalents and investments in marketable securities of \$114.5 million. Our cash, cash equivalents and investments in marketable securities may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our cash is invested in accounts with market interest rates and because our cash equivalents and investments in marketable securities are traded in active markets, we believe that our exposure to interest rate risk is not significant and estimate that an immediate and uniform 10% increase in market interest rates from levels as of September 30, 2014 would not have a material impact on the total fair value of our portfolio.

We sometimes contract for the conduct of clinical trials or other research and development and manufacturing activities with contract research organizations, clinical trial sites and contract manufacturers in Europe or elsewhere outside of the United States. We may be subject to exposure to fluctuations in foreign currency exchange rates in connection with these agreements. If the average exchange rate between the currency of our payment obligations under any of these agreements and the U.S. dollar were to strengthen or weaken by 10% against the corresponding exchange rate as of September 30, 2014, we estimate that the impact on our financial position, results of operations and cash flows would not be material. We do not hedge our foreign currency exposures.

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

Item 4. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our chief executive officer and our 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

[Table of Contents](#)

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 our 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 our chief financial officer, as appropriate to allow timely decisions regarding required disclosure and (b) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

(b) *Changes in Internal Controls.* No change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2014 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

The following risk factors section amends, restates and supersedes the risk factors section included in Part I, Item 1A of our 2013 Annual Report on Form 10-K. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual results of operations and financial condition to vary materially from past, or from anticipated future, results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations and common stock price.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding any statement in this quarterly report or elsewhere. The following information should be read in conjunction with the condensed consolidated financial statements and related notes in Part I, Item 1, "Financial Statements" and Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this quarterly report.

Because of the following factors, as well as other factors affecting our financial condition and operating results, past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.

Risks Related to our Business

We are exploring and evaluating multiple strategic alternatives for our company; this process may have an adverse impact on our business and may not result in the consummation of any transaction.

[Table of Contents](#)

We, in collaboration with our board of directors and in consultation with several of our significant shareholders, are in the process of exploring and evaluating strategic alternatives for our business, which could result in, among other things, a sale of the company, a merger, the disposition of a substantial portion of our assets, a partial or full liquidation, or a combination of two or more of these alternatives. In connection with this process, we may incur considerable expenses associated with identifying and evaluating potential strategic alternatives. The process of exploring strategic alternatives may be disruptive to our business operations and will consume significant time and attention of our management, and may not result in the consummation of any transaction, on beneficial terms or at all. If we are unable to effectively manage this process, our business, financial condition and results of operations could be materially and adversely affected.

No decision has been made with respect to any transaction and we cannot assure you that we will be able to identify and undertake a transaction that allows our shareholders to realize an increase in the value of their stock. We are currently unable to provide any guidance on the timing of any such action. We also cannot assure you that any potential transaction or other strategic alternative, if identified, evaluated and consummated, will provide greater value to our shareholders than that reflected in the current stock price. Any potential transaction would be dependent upon a number of factors that may be beyond our control, including, among other factors, our ability to negotiate acceptable terms with a third party, market conditions, industry trends, the interest of third parties in our business or in out-licensing technology to us, and the availability of financing to potential buyers or other third parties on reasonable terms.

We do not intend to comment regarding the process of evaluation of these strategic alternatives until such time as our board of directors has determined the outcome of the process or otherwise has deemed that disclosure is appropriate or required by federal securities laws. As a consequence, perceived uncertainties related to the future of our company may result in a decrease in stock price and may make it more difficult for us to attract and retain qualified personnel.

We currently have only one product candidate in clinical development, and our recent clinical trials have resulted in significant clinical pipeline attrition. As we have closed our laboratory operations and no longer have the capability to discover new internal product candidates, we may not be able to overcome this attrition without adding new product candidates.

In 2012, we completed two workforce reductions and closed our laboratory operations. Following these actions, we do not have internal discovery and research capabilities or the ability to identify and discover new internal product candidates. We have no current plan to resume discovery or research activities. If in the future we were to resume these activities, we would need to recruit additional scientific and technical personnel and obtain access to laboratory facilities.

Further, we currently have only one product candidate in clinical trials and, without internal discovery and research, we may not be able to expand our pipeline with internal candidates or at all. If we are unable to expand our portfolio of product candidates through acquisitions, in-licensing or internal development, which we may be unable to do on reasonable terms or at all, our business would be materially and adversely affected, which would materially and adversely impact our stock price.

A small number of our stockholders beneficially own a substantial amount of our common stock and have substantial control over us; therefore, your ability to influence corporate matters may be limited.

Significant stockholders, acting together, will have the ability to affect matters submitted to our stockholders for approval, potentially including the approval of a significant transaction. This concentration of ownership may have the effect of delaying, deferring or preventing a strategic transaction, even if such a transaction would benefit other stockholders.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of prior or future offerings of our stock or other transactions.

Section 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of the company's stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long term tax exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset future taxable income, if any, with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability.

In addition, it is possible that future transactions will cause us to undergo one or more additional ownership changes. In that event, we generally would not be able to use our pre-change loss or credit carryovers or certain built-in losses prior to such ownership change to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383 and those attributes already subject to limitations as a result of our prior ownership changes may be subject to more stringent limitations.

Risks Related to Our Financial Results

We have a substantial accumulated deficit and may incur losses for future periods. We may not achieve profitability for any future period or, if we do achieve profitability for a future period, we may not sustain or grow our profitability.

As of September 30, 2014, we had an accumulated deficit of \$308.6 million. We had a net loss of \$28 million for the nine months ended September 30, 2014, and net losses of \$46.7 million and \$7.0 million for the years ended December 31, 2013 and 2012, respectively. Our losses for other periods have historically 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 may incur losses for future periods as we progress our programs and invest in or evaluate additional strategic opportunities. As a result, we will need to generate significant revenues to achieve profitability in the future or, if we do achieve profitability for any particular period, to sustain or grow our profitability on a quarterly or annual basis.

[Table of Contents](#)

We derived a substantial portion of our revenue for 2013 and 2012 from our strategic alliances and collaborations. We expect that a substantial portion of our operating cash flow in the next few years will depend on the following:

- whether we establish additional strategic alliances, collaborations or licensing or other comparable arrangements, or whether we pursue and complete any merger, acquisition or other significant corporate transaction, and, if we do, the associated terms in each case; and
- the scope, progress, duration, results and cost of clinical trials, as well as non-clinical studies and assessments, of our product candidates and programs.

Sources that have contributed to our revenue for any particular year may not continue. For example, we received \$245 million in aggregate payments under two collaborations with global pharmaceutical companies that are now terminated and no longer sources of future revenue. Additionally, we do not currently have any source of product revenue.

If we are unable to develop and commercialize one or more of our product candidates, if development is delayed or if revenue from sales of any product candidate that receives marketing approval is insufficient, we may not achieve profitability in the future. Even if we are profitable for any particular period, we may not be able to sustain or grow our profitability on a quarterly or annual basis.

Our failure to obtain additional capital when needed could force us to delay, reduce or eliminate our product development programs or future commercialization efforts.

Successful drug development and commercialization requires significant amounts of capital. It is foreseeable that we will in the future require substantial additional capital in order to continue to conduct the development and regulatory activities necessary to bring our product candidates to market (or, where applicable for a particular product candidate, to the stage of development when a potential future collaborator may assume responsibility under the terms of the applicable agreement for funding further development and subsequent commercialization) and potentially to establish sales and marketing capabilities. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the scope, progress, duration, results and costs of clinical trials, as well as non-clinical studies and assessments, of our product candidates and programs;
- whether we establish additional strategic alliances, collaborations or licensing or other comparable arrangements, or whether we pursue and complete any merger, acquisition or other significant corporate transaction, and, if we do, the associated terms in each case;
- the extent to which we retain development or commercialization rights or responsibilities for our product candidates and incur associated development costs, manufacturing costs or costs to establish sales and marketing functions;
- the number and characteristics of product candidates that we pursue and programs that we conduct;

Table of Contents

- the costs to satisfy our obligations under potential future alliances and collaborations;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending patents and other intellectual property rights;
- the costs of manufacturing-related services for our product candidates in development;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions;
- the timing, receipt and amount of sales or royalties, if any, from our potential products;
- the extent of our general and administrative expenses; and
- the rate of technological advancements for the indications that we target.

In addition, we may seek additional capital, whether through offerings of securities utilizing our currently effective Registration Statement on Form S-3, our at the market sales agreement or otherwise, if the conditions for raising capital are favorable or based on 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 may be diluted, and the terms of the securities may include liquidation or other preferences that materially and 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 alliance, collaboration or 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.

We plan to continue, whether alone or with potential future collaborators, to advance TC-6499 through the development process as a treatment for diabetic gastroparesis. We currently expect that we will have approximately \$107 million of cash, cash equivalents and investments at December 31, 2014, which, based on our current scope of operations, would be sufficient to fund our current operations for several years. However, there is substantial uncertainty associated with our ongoing evaluation of strategic alternatives and the potential costs associated with those alternatives, which may fundamentally change our business and capital requirements. As a result, we may need additional funds sooner than planned to meet operational needs and capital requirements for product development and commercialization, or to fund strategic transactions, pipeline diversification or other business and corporate development initiatives. Our ability to raise additional funds if and when needed on terms that are acceptable to us, or at all, is uncertain. If adequate funds are not available on a timely basis, we may:

- terminate, delay or downsize clinical trials or manufacturing or other development activities for one or more of our product candidates;
- delay establishment of any sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates; or
- scale back or eliminate programs that are designed to expand our product pipeline.

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

Our success depends substantially on the advancement of our product candidates, only one of which remains under active development. If we are unable to bring any product candidates to market, or experience significant delays in doing so, our ability to generate product or royalty revenue and our likelihood of success will be harmed.

Our ability to generate product or royalty revenue in future periods will depend substantially on the successful development and commercialization of our clinical-stage product candidates, including in particular TC-6499, which is our only product candidate under active development.

Any of our product candidates could be unsuccessful if it:

- does not demonstrate acceptable safety and efficacy in nonclinical 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 condition;
- 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 revenue and we will not be successful.

TC-6499 has not yet demonstrated efficacy in clinical trials in diabetic gastroparesis, and our previous findings from clinical and nonclinical studies and assessments may not be predictive of a benefit for TC-6499 as a treatment for diabetic gastroparesis. If our ongoing and any future clinical trials of TC-6499 in diabetic gastroparesis are not successful, we will not obtain the regulatory approvals required to market and sell TC-6499.

We are conducting an exploratory study of TC-6499 as a treatment for diabetic gastroparesis. Our decision to conduct this study was based primarily on various findings from a previous clinical trial of TC-6499 in another indication and nonclinical studies and assessments of TC-6499 that we believe may indicate potential benefits of TC-6499 as a diabetic gastroparesis therapy. We have not previously conducted any clinical trials of TC-6499 in patients with diabetic gastroparesis, and our previous findings may not be predictive of clinical success in this patient population. If our ongoing and any future clinical trials of TC-6499 in diabetic gastroparesis are not successful, we will not obtain the regulatory approvals required to market and sell TC-6499 as a treatment for diabetic gastroparesis.

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.

[Table of Contents](#)

The nonclinical 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 and regulatory 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 nonclinical 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 or foreign governmental or regulatory authorities may from time to time change approval policies or adopt new laws or regulations that 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.

A Phase 1 clinical trial program typically takes several months to complete, a Phase 2 clinical trial program typically takes several months to two years to complete and a Phase 3 clinical trial program typically takes one to four years to complete. Moreover, Phase 3 clinical trials may not follow successful completion of Phase 2 clinical trials directly, as additional non-clinical assessments or clinical trials may first be required. Industry sources have reported that the preparation and submission of an NDA, which is required for regulatory approval in the United States, generally takes six months to one year to complete after completion of pivotal clinical trials. However, additional clinical trials may be required by the FDA or foreign regulatory authorities following completion of pivotal clinical trials and prior to seeking approval. Precise estimates vary, but a great majority of investigational drugs that enter clinical trials will never 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;
- clinical trial results may indicate that the product candidate is not effective, whether because the product candidate does not have its intended effects in the clinical trial, because subjects given an inactive comparator (i.e., placebo) in the clinical trial experience benefits comparable to the benefits experienced by subjects given the product candidate, which obscures the effects of the product candidate, or for any other reason;
- the product candidate may not have a favorable risk/benefit profile;
- the FDA (or any advisory committee on which the FDA relies) may interpret results of clinical trials or manufacturing or other non-clinical studies or assessments to indicate that the product candidate is not safe, effective or acceptable for commercial use, even if we interpret the same results differently;

[Table of Contents](#)

- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval;
- the FDA may deem the processes or facilities that we, our collaborators or our third-party manufacturers propose to use in connection with the manufacture of the product candidate to be unacceptable, or the facilities of our third party manufacturers may not pass inspection by the FDA; or
- the FDA may change its approval policies or adopt new regulations.

If we obtain the requisite regulatory approval for a particular product candidate, the approval may not extend to all indications for which approval was sought, which could limit the use of the product and materially and adversely impact our revenue.

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. This process is likely to cause delays in the marketing of any of our product candidates that receives approval and could materially and adversely impact our revenue 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 nonclinical 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. Nonclinical 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 clinical trials of any of our product candidates could occur at any stage of testing. For example, TC-5214 did not achieve the primary endpoint in multiple Phase 3 clinical trials in major depressive disorder completed in 2011 and 2012, nor did it meet one of the co-primary endpoints in the Phase 2b clinical trial in overactive bladder earlier this year. As a consequence, we no longer have plans to pursue additional development of this compound in these therapeutic areas. If we experience failures in our ongoing or future clinical trials, or if we are not able to design clinical trials to establish the safety and efficacy of our product candidates and otherwise achieve the objectives of the trials, 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, applicable foreign regulatory authorities or the institutional review boards at our intended investigational sites to

[Table of Contents](#)

commence or complete our clinical trials. Before the initial clinical trial for a product candidate may commence in the United States, we must submit an IND containing nonclinical 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 a clinical trial is commenced, we, the FDA, applicable foreign regulatory authorities and 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 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 or applicable foreign 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.

Our product candidates target diseases or disorders that are not well understood. For example, there is only limited scientific understanding of the causes of diabetic gastroparesis. In addition, there are no approved drugs that target NNRs to treat diabetic gastroparesis, and there is only limited scientific understanding of the relationships between diabetic gastroparesis and the pathway targeted by our product candidates. These uncertainties increase the risk that our ongoing and future clinical trials will not be successful.

If clinical trials for any of our product candidates are prolonged or delayed, we would experience a delay in the commercialization of the affected product candidates, which may require us to incur additional costs and delay our receipt of any revenue from potential product sales.

We cannot predict whether we will encounter problems with any ongoing or planned clinical trials of our product candidates 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 those described below, could delay the initiation or completion of any ongoing or planned clinical trial of any of our product candidates or otherwise negatively impact our ability to obtain regulatory approval for, and to market and sell, the product candidate:

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of the clinical trial;
- delays in recruiting and enrolling subjects into the clinical trial;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards, ethics committees or other reviewing entities at clinical sites selected for participation in the clinical trial;
- insufficient supply or deficient quality of the product candidate or other materials necessary to conduct the clinical trial;
- lower than anticipated retention rate of subjects in the clinical trial;

[Table of Contents](#)

- negative or inconclusive results from the clinical trial, or results that are inconsistent with earlier results, that necessitate additional study;
- serious and unexpected drug-related side effects experienced by subjects in the clinical trial; 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 subject enrollment, which is a function of many factors — including the size of the patient population, the extent to which other clinical trials are being conducted concurrently that involve the same patient population, the number of participating clinical sites, the proximity of subjects to clinical sites, the nature of the trial protocol, the availability of effective treatments for the relevant disease, the eligibility criteria for the clinical trial and the emphasis placed on ensuring a rigorous adherence to the eligibility criteria. Delays in subject enrollment can result in increased costs and longer development times. The failure to enroll subjects in a clinical trial could delay the completion of the clinical trial beyond our current expectations.

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

We do not know whether any clinical trial of any of our product candidates will begin as planned, will need to be restructured or will be completed on schedule, if at all. Delays in clinical trials may 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.

Each of our product candidates will remain subject to ongoing regulatory review even if it receives marketing approval. If we fail to comply with continuing regulations or if patients taking our products experience adverse health effects, we could lose the approval or the sale of the affected products could be suspended or otherwise adversely affected.

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. In addition, if any of our product candidates becomes an approved product, 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. We may be slow to adapt, or may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements. If we fail to comply with the requirements of the FDA and other applicable U.S. or foreign governmental or regulatory authorities or previously unknown problems with our products or product candidates, 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 or untitled letters;
- civil or criminal penalties;

[Table of Contents](#)

- 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 multiple nicotinic compounds in our pipeline that we are focused on selectively supplementing with externally sourced non-nicotinic opportunities, we may apply our finite resources to pursue a particular product candidate or indication, fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success, or relinquish valuable rights to our disadvantage.

Because we have finite financial and managerial resources, we must focus on product candidates and 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. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, or if we incorrectly conclude that utilizing the expertise and resources of a collaborator in the development or potential commercialization of a particular product candidate would benefit us, we may relinquish valuable rights to that product candidate through strategic alliances, collaborations or licensing or other comparable arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. Any of these decisions or conclusions could have a material adverse effect on our business.

Risks Related to Our Dependence on Third Parties

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

We intend to selectively enter into alliances and collaborations, particularly for target indications for which a potential collaborator has unique expertise or that represent large primary care markets that must be served by large sales and marketing organizations. Our ability to generate revenue from our alliances and collaborations 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 alliances and collaborations involving our product candidates pose many risks to us, including:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these alliances and collaborations or to the development of our licensed product candidates;

[Table of Contents](#)

- collaborators may interpret clinical trial or non-clinical study results differently than we do, may pursue further development and commercialization of our product candidates for indications that we do not believe are optimal, may not pursue further development and commercialization of our product candidates at all or may elect not to continue or renew research and development programs based on nonclinical 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;
- collaborators 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 collaborators that result in the delay or termination of the research, development or commercialization of our product candidates, that result in costly litigation or arbitration that diverts management attention and resources or that, if resolved unfavorably to us, result in adverse financial consequences for us under the terms of the applicable agreements; and
- alliances and collaborations may be terminated, either in their entirety or as to particular product candidates or programs, which may result in a need for a reallocation of internal funds or additional capital to pursue further development of the applicable product candidates. As examples, we previously had a collaborative research and license agreement with AstraZeneca which included a multi-year preclinical research collaboration and a license granted to AstraZeneca to develop and commercialize TC-1734, an additional collaboration agreement with AstraZeneca for the development and commercialization of TC-5214 in major depressive disorder, and a product development and commercialization agreement with GlaxoSmithKline that have all been terminated. Some of these terminations caused us to reallocate internal resources.

[Table of Contents](#)

Alliances and collaborations may not lead to development of product candidates or commercialization of products in the most efficient manner or at all.

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 alliances and 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 seeking alliances and collaborations to assist us in furthering development and potential commercialization of some of our product candidates. We intend to do so particularly for target indications for which a potential collaborator has unique expertise or that involve large primary care markets that must be served by large sales and marketing organizations.

We face significant competition in seeking appropriate alliances and collaborations. Alliances and collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate them on acceptable terms, or at all. If we cannot, 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 any 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 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 many 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 and foreign regulatory authorities require us to comply with regulations and guidelines, commonly referred to as good clinical practice, or GCP, 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. These risks may

[Table of Contents](#)

be heightened for clinical trials that we conduct outside of North America and Western Europe. In particular, we have previously conducted trials of multiple product candidates at sites in India and Eastern Europe, as well as in the United States.

Language barriers and the limited experience of some clinical investigators in Eastern Europe or other countries in conducting clinical trials in accordance with standards set forth by the FDA and applicable regulatory authorities may increase the risk of non-compliance. The failure of third parties to carry out their obligations could impair the credibility or reliability of the data generated in clinical trials of our product candidates, require a trial to be repeated and increase the overall cost of a development program, delay or prevent the development, approval and commercialization of our product candidates or result in enforcement action against us.

If the performance of our contract manufacturers or any present or future collaborator of ours with manufacturing responsibility for a particular product candidate 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 no longer have internal manufacturing capability. We have historically manufactured our product candidates only in small quantities for early-stage preclinical testing and have contracted with third parties to manufacture, in collaboration with us, our product candidates for clinical trials. 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 our now discontinued product Inversine and its active ingredient.

For each of our product candidates, we typically rely on single third-party contract manufacturers for manufacturing in drug substance form and single third-party contract manufacturers for manufacturing in a formulation for use in clinical trials. We intend to continue to rely on third-party manufacturers (or, where applicable, potential future collaborators) 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 or collaborators 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 receipt of regulatory approvals or the commercialization of our products or result in higher costs or lost product revenue. In particular, any contract manufacturer or applicable collaborator of ours could:

- encounter difficulties in achieving volume production, laboratory testing, quality control or quality assurance or suffer shortages of qualified personnel, any of which could result in its inability to manufacture sufficient quantities to meet clinical timelines for a particular product candidate, obtain approval to market and sell the product candidate or to commercialize the product candidate; or
- fail to establish and follow cGMP or fail to document its adherence to cGMP, 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.

In addition, any contract manufacturer could:

- terminate or not renew its manufacturing agreement with us, based on its own business priorities, at a time that is costly or inconvenient for us; or
- breach or fail to perform as agreed under the applicable manufacturing agreement.

We expect to rely initially on a single contract manufacturer for any product candidate that we successfully bring to market. Changing any manufacturer that we 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 are described in an NDA or supplement that typically must be reviewed and approved by the FDA or foreign regulatory authorities and the facilities typically must pass inspection by the FDA or foreign regulatory authorities before such approval. 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, contract manufacturers located in foreign countries may be subject to import limitations or bans. As a result, if any contract manufacturer is unable, for whatever reason, to supply the contracted amounts of any product that is successfully brought to market, a shortage would result which would have a negative impact on our revenue.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Administration (in the case of controlled substances) and corresponding state and foreign agencies to ensure strict compliance with cGMP, other government regulations and corresponding foreign standards. While we are ultimately responsible for ensuring the quality of any products manufactured by third party contractors and obligated to audit the performance of such third-party contractors, we do not have control over third-party manufacturers' compliance with these regulations and standards. Failure by us or any third-party manufacturers 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.

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 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, pharmaceutical compositions, formulations and uses in the treatment of diseases and disorders.

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 product candidates and technology will depend on the success that we have in obtaining valid 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.

[Table of Contents](#)

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. If we are unable to obtain, enforce or defend the patents with respect to our product candidates, our ability to commercialize our product candidates would be materially and adversely affected and our business would suffer.

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. The Leahy-Smith America Invents Act was signed into U.S. law September 26, 2011, and includes significant changes to patent law. One of the most notable changes is the transition from a “first-to-invent” to a “first-inventor-to-file” patent system. This is effective for patent applications filed on or after March 16, 2013. 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 invent the inventions claimed in our issued U.S. patents or patent applications filed on or before March 16, 2013, or that we were or will be the first to file for protection of the inventions claimed in any of our U.S. patent applications filed after March 16, 2013 or in any of our issued foreign patents or pending foreign 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 patent covering one of our product candidates may expire before the product candidate can be commercialized or remain in force for only a short period following initial commercialization. In either case, any advantages of the patent would be limited. 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 either in patent laws or in interpretations or enforcement 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 collaborators 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

[Table of Contents](#)

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 that 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 and, if we have sublicensed our license rights to a third party, the loss of the license rights may breach our obligations to our sublicensee.

We are a party to various license agreements. As an example, we license patent rights covering the pharmaceutical composition and methods of use of TC-5214 from University of South Florida Research Foundation. 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, whether as a result of actions or inactions by us or by any potential future collaborator of ours to which we out-license patent rights that we have in-licensed from a third party, the licensor may have the right to terminate the license, in which event we may not be able to market any product that is covered by the licensed patents.

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

Although we generally seek the broadest patent protection available for our 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. 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. If a third party were to receive marketing approval of any 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 foreign regulatory authorities. Even if we have patent protection for the indication for which the product is prescribed, as a practical matter, we would have little recourse as a result of this off-label use. In that event, our revenue from the commercialization of the compound would likely be materially and adversely affected.

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 similarly be sued by third parties. We may also become subject to interference, review or opposition proceedings conducted in the patent and trademark offices of various countries to

[Table of Contents](#)

determine our entitlement to patents. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings, regardless of their merit, lack of merit or eventual outcome, would be costly and a significant diversion of our technical personnel's and management's attention from conducting our business, which would harm 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 material 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 and development, manufacturing or sales of any infringing product in the country or countries covered by the patent allegedly 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 allegedly 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 materially and 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 material 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 and sale, our product candidates may not gain market acceptance and may fail to generate significant revenue.

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.

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 foreign regulatory authorities.

We currently have limited sales, marketing and distribution experience and no internal sales or distribution capabilities. If we are unable to enter into alliances and collaborations or other arrangements with third parties to market and sell our product candidates or to develop our own internal marketing capability, or if we enter into such arrangements with third parties who do not perform well, we may not be successful in commercializing any products for which we receive regulatory approval.

We currently have limited sales, marketing and distribution experience and no internal sales or distribution capabilities. 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. 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 would 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. We may also have little control over the performance of potential future collaborators, any of which may fail to devote the necessary resources and attention to sell, market or distribute our products effectively.

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

Successful commercialization of any of our product candidates for which regulatory approval is obtained will depend in part on the extent to which coverage and adequate payment is available from government health programs, such as Medicare and Medicaid, 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 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 cannot yet determine their cost-effectiveness. We may need to conduct expensive studies in order to demonstrate cost-effectiveness. Moreover, third-party payors frequently require that pharmaceutical companies provide predetermined discounts from list prices and frequently challenge the prices charged for medical products. Because our product candidates are in the development stage, we do not yet know the level of reimbursement, if any, for any product candidates 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 or sustain profitability could be materially and adversely affected.

We believe that the government and third party payors will continue to look for ways to contain or reduce the cost of health care in ways that are likely to affect the business and financial condition of pharmaceutical companies. We cannot predict the impact of these efforts on the coverage of, or prices for, any of our product candidates if they are approved.

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 revenue.

The development and commercialization of new drugs is highly competitive. Our business is characterized by extensive research and development 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, biopharmaceutical, biotechnology and other companies and research institutions, many of which have greater financial, technical and other resources and personnel and more experience in research and development, regulatory and drug commercialization than we have. Our competitors may:

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

[Table of Contents](#)

- 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.

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.

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, lack of merit or eventual outcome, would be a significant diversion of our management's attention from conducting our business and could be costly or materially and adversely affect our reputation or the demand for our products.

We have secured product liability insurance coverage in amounts that we believe to be appropriate for our current operations. 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 expect that we will expand our coverage with respect to any products for which we successfully 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.

If any promotional activities that we undertake fail to comply with the regulations and guidelines of the FDA and applicable foreign 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 foreign regulatory

[Table of Contents](#)

authorities. 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 may in some jurisdictions and 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. If we undertake any promotional activities in the future for any product candidate for which we receive regulatory approval 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

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 team, including our President and Chief Executive Officer, Stephen A. Hill, as well as our other scientific, technical and managerial personnel. Our key personnel, including Dr. Hill, can terminate their employment with us at any time. The loss of the services of any of our senior management team or other key personnel may significantly delay or prevent the achievement of product development and other business objectives. In addition, we rely on consultants and advisors, including scientific and clinical advisors, from time to time 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 consulting or advisory contracts with other organizations or other commitments that could limit their availability or otherwise affect their ability to contribute to us.

Potential future growth of our business and replacement of any key personnel that may terminate their employment with us will depend on our ability to identify, recruit and retain the appropriate personnel. We may have difficulty attracting senior management, scientific and technical personnel as a result of previous workforce reductions and a perceived risk of future workforce reductions. We face intense competition for skilled executives and individuals with relevant scientific and technical expertise in our industry, and this competition is likely to continue. We may not be able to continue to attract and retain personnel with the advanced qualifications necessary for the success of our business.

Risks Related to Our Common Stock

The market price of our common stock has historically been highly volatile.

The trading price of our common stock has historically been highly volatile, and the stock market in general has experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical, biopharmaceutical and biotechnology companies have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to operating performance. 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:

- the scope, progress, duration, results and cost of clinical trials, as well as non-clinical studies and assessments, of our product candidates and programs;
- our inability, or the inability of any current or potential future collaborator, to successfully complete clinical trials or non-clinical studies and assessments 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;
- whether we establish additional strategic alliances, collaborations or licensing or other comparable arrangements, or whether we pursue and complete any merger, acquisition or other significant corporate transaction, and, if we do, the associated terms in each case;
- the expiration or termination of agreements with any potential future collaborator;
- the cost, timing and outcomes of regulatory approvals or other regulatory actions;
- the extent of our general and administrative expenses;
- general and industry-specific economic conditions that may affect the research and development expenditures of any potential future collaborator of ours; and
- general conditions in the pharmaceutical, biopharmaceutical or biotechnology industries or in the U.S. or global credit or financial markets.

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. For 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.

Our current trading volumes are modest, and 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 as compensation to our employees, directors or consultants, in connection with strategic alliances, collaborations, acquisitions or other transactions 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.

Provisions of our charter and bylaws and Delaware law may discourage or 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. As a result, stockholders who wish to participate in these transactions may not have the opportunity to do so. 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. Furthermore, these provisions could also 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 are 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 or otherwise 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 $\frac{2}{3}$ % of the outstanding shares of our capital stock entitled to vote in order for the stockholders 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 6. Exhibits

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

Targacept® and NNR Therapeutics™ are trademarks of Targacept, Inc. Any other service marks, trademarks and trade names appearing in this quarterly report are the property of their respective owners.

SIGNATURES

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

TARGACEPT, INC.

Date: November 6, 2014

/s/ Stephen A. Hill
Stephen A. Hill
President and Chief Executive Officer
(*Principal Executive Officer*)

Date: November 6, 2014

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
31.1	Certification of the Principal 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 Principal 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 Principal 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 Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) the Balance Sheets as of September 30, 2014 and December 31, 2013 (Unaudited); (ii) the Statements of Comprehensive Income (Loss) for the three and nine months ended September 30, 2014 and 2013 (Unaudited); (iii) the Statements of Cash Flows for the nine months ended September 30, 2014 and 2013 (Unaudited); and (iv) the Notes to Unaudited Financial Statements.

CERTIFICATION 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

I, Stephen A. Hill, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Date: November 6, 2014

/s/ Stephen A. Hill
Stephen A. Hill
President and Chief Executive Officer
(*Principal Executive Officer*)

CERTIFICATION 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

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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Date: November 6, 2014

/s/ Alan A. Musso

Alan A. Musso

Senior Vice President, Finance and Administration, Chief Financial Officer and Treasurer

(Principal Financial and Accounting Officer)

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

In connection with the Quarterly Report on Form 10-Q of Targacept, Inc. (the "Company") for the period ended September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen A. Hill, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

Date: November 6, 2014

/s/ Stephen A. Hill
Stephen A. Hill
President and Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Quarterly Report on Form 10-Q of Targacept, Inc. (the "Company") for the period ended September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Alan A. Musso, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

Date: November 6, 2014

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