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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 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 MARCH 31, 2016**

or

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

Commission File Number 001-36818

**TRACON Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**34-2037594**

(IRS Employer  
Identification No.)

**8910 University Center Lane, Suite 700,  
San Diego CA**

(Address of principal executive offices)

**92122**

(Zip Code)

**(858) 550-0780**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The number of outstanding shares of the registrant's common stock as of May 5, 2016 was 12,203,886.

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**TRACON Pharmaceuticals, Inc.**

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**PART I FINANCIAL INFORMATION****Item 1. Financial Statements**

**TRACON Pharmaceuticals, Inc.**  
**Condensed Consolidated Balance Sheets**  
**(in thousands, except share and per share data)**

	<u>March 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
	<u>(Unaudited)</u>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 43,265	\$ 41,373
Short-term investments	2,225	10,783
Prepaid and other assets	1,305	1,150
Total current assets	46,795	53,306
Property and equipment, net	152	173
Other assets	43	43
Total assets	<u>\$ 46,990</u>	<u>\$ 53,522</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,607	\$ 8,281
Accrued compensation and related expenses	785	1,163
Current portion of deferred revenue	2,389	3,353
Long-term debt, current portion	2,417	1,378
Total current liabilities	14,198	14,175
Other long-term liabilities	886	905
Long-term debt, less current portion	6,586	7,464
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, authorized shares— 10,000,000 at March 31, 2016 and December 31, 2015; issued and outstanding shares—none	—	—
Common stock, \$0.001 par value; authorized shares—200,000,000 at March 31, 2016 and December 31, 2015; issued and outstanding shares —12,185,242 and 12,175,942 at March 31, 2016 and December 31, 2015, respectively	12	12
Additional paid-in capital	90,424	89,556
Accumulated deficit	(65,116)	(58,590)
Total stockholders' equity	25,320	30,978
Total liabilities and stockholders' equity	<u>\$ 46,990</u>	<u>\$ 53,522</u>

See accompanying notes.

**TRACON Pharmaceuticals, Inc.**  
**Unaudited Condensed Consolidated Statements of Operations**  
**(in thousands, except share and per share data)**

	Three Months Ended	
	March 31,	
	2016	2015
Collaboration revenue	\$ 1,210	\$ 1,132
Operating expenses:		
Research and development	5,495	3,831
General and administrative	2,009	1,013
Total operating expenses	7,504	4,844
Loss from operations	(6,294)	(3,712)
Other income (expense):		
Interest expense, net	(293)	(256)
Other income (expense), net	61	(27)
Total other income (expense)	(232)	(283)
Net loss	(6,526)	(3,995)
Accretion to redemption value of redeemable convertible preferred stock	—	(31)
Net loss attributable to common stockholders	\$ (6,526)	\$ (4,026)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.54)	\$ (0.50)
Weighted-average shares outstanding, basic and diluted	12,179,442	8,024,579

See accompanying notes.

**TRACON Pharmaceuticals, Inc.**  
**Unaudited Condensed Consolidated Statements of Cash Flows**  
(in thousands)

	Three Months Ended	
	March 31,	
	2016	2015
<b>Cash flows from operating activities</b>		
Net loss	\$ (6,526)	\$ (3,995)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	857	247
Depreciation and amortization	24	8
Amortization of debt discount	26	34
Amortization of premium/discount on short-term investments	2	—
Noncash interest	135	126
Change in fair value of preferred stock warrant liability	—	65
Deferred rent	(12)	(8)
Deferred revenue	(964)	(805)
Changes in assets and liabilities:		
Prepaid expenses and other assets	(155)	(962)
Accounts payable and accrued expenses	323	842
Accrued compensation and related expenses	(378)	(352)
Net cash used in operating activities	(6,668)	(4,800)
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(3)	(2)
Purchases of available-for-sale short-term investments	(1,445)	—
Proceeds from the maturity of available-for-sale short-term investments	10,001	—
Net cash provided by (used in) investing activities	8,553	(2)
<b>Cash flows from financing activities</b>		
Repayment of long-term debt	—	(1,177)
Proceeds from sale of common stock, net of offering costs paid in the current period	—	36,263
Proceeds from issuance of common stock under equity plans	7	7
Net cash provided by financing activities	7	35,093
Net increase in cash and cash equivalents	1,892	30,291
Cash and cash equivalents at beginning of period	41,373	35,000
Cash and cash equivalents at end of period	<u>\$ 43,265</u>	<u>\$ 65,291</u>

See accompanying notes.

**TRACON Pharmaceuticals, Inc.**  
**Notes to Condensed Consolidated Financial Statements**

**1. Organization and Summary of Significant Accounting Policies**

**Organization and Business**

TRACON Pharmaceuticals, Inc. (formerly Lexington Pharmaceuticals, Inc.) (TRACON or the Company) was incorporated in the state of Delaware on October 28, 2004. TRACON is a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration and fibrotic diseases. The Company's research focuses on antibodies that bind to the endoglin receptor, which is essential to angiogenesis (the process of new blood vessel formation) and a key contributor to fibrosis (tissue scarring).

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, TRACON Pharma Limited, which was formed in September 2015. All significant intercompany accounts and transactions have been eliminated.

**Basis of Presentation**

As of March 31, 2016, the Company has devoted substantially all of its efforts to product development, raising capital, and building infrastructure and has not realized revenues from its planned principal operations. The Company has incurred operating losses since inception. As of March 31, 2016, the Company had an accumulated deficit of \$65.1 million. The Company anticipates that it will continue to incur net losses into the foreseeable future as it: (i) continues the development and commercialization of its product candidates; (ii) works to develop additional product candidates through research and development programs; and (iii) continues to expand its corporate infrastructure. At March 31, 2016, the Company had cash, cash equivalents and short-term investments of \$45.5 million. Based on the Company's current business plan, management believes that existing cash, cash equivalents and short-term investments will be sufficient to fund the Company's obligations for at least the next twelve months. The Company plans to continue to fund its losses from operations and capital funding needs through cash and investments on hand, as well as future debt and equity financing and potential collaboration arrangements. If the Company is not able to secure adequate additional funding, it may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

**Unaudited Interim Financial Information**

The unaudited condensed consolidated financial statements at March 31, 2016, and for the three months ended March 31, 2016 and 2015, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and with accounting principles generally accepted in the United States (GAAP) applicable to interim financial statements. These unaudited condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company's financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year or future periods. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ materially from those estimates. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2015, included in its Annual Report on Form 10-K filed with the SEC on February 19, 2016.

### **Use of Estimates**

The Company's condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of the Company's condensed consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to revenue recognition and the valuation of equity awards. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

### **Cash and Cash Equivalents**

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less at the date of purchase. Cash and cash equivalents include cash in readily available checking and money market funds, as well as certificates of deposit.

### **Concentration of Credit Risk**

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

### **Preferred Stock Warrant Liabilities**

Prior to the completion of the Company's initial public offering in February 2015, the Company had outstanding freestanding warrants to purchase shares of its Series A redeemable convertible preferred stock. Since the underlying Series A redeemable convertible preferred stock was classified outside of permanent equity, these preferred stock warrants were classified as liabilities in the December 31, 2014 balance sheet. The Company adjusted the carrying value of such preferred stock warrants to their estimated fair value at each reporting date, with any related increases or decreases in the fair value recorded as an increase or decrease to other income (expense) in the statements of operations. Upon the completion of the Company's initial public offering, the warrants no longer require liability accounting and the then fair value of the warrant liability was reclassified into stockholders' equity.

The Company performed the final remeasurement of the warrant liability as of the initial public offering date and recorded the \$65,000 change in fair value into other income (expense) for the three months ended March 31, 2015.

### **Revenue Recognition**

The Company's revenue is derived from its license agreement with Santen Pharmaceutical Co., Ltd. (Santen) as described in Note 7. The Company recognizes revenue when all four of the following criteria are met: (1) there is persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured. Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as long-term deferred revenue.

The Company evaluates multiple-element arrangements to determine: (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. Deliverables are considered separate units of accounting provided that: (a) the delivered items have value to the customer on a standalone basis and (b) if the arrangement includes a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and substantially in the Company's control. In assessing whether an item has standalone value, the Company considers factors such as the research, manufacturing and commercialization capabilities of the partner and the availability of the

associated expertise in the general marketplace. In addition, the Company considers whether the partner can use the other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items and whether there are other vendors that can provide the undelivered elements.

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. The Company uses the following hierarchy of values to estimate the selling price of each deliverable: (1) vendor-specific objective evidence of fair value; (2) third party evidence of selling price; and (3) best estimate of selling price (BESP). The BESP reflects the Company's best estimate of what the selling price would be if the Company regularly sold the deliverable on a standalone basis. In developing the BESP for a unit of accounting, the Company considers applicable market conditions and relevant entity-specific factors, including factors that are contemplated in negotiating an arrangement and estimated costs. The Company validates the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting.

The Company then applies the applicable revenue recognition criteria to each of the separate units of accounting in determining the appropriate period and pattern of recognition. If there is no discernible pattern of performance and/or objectively measurable performance measures do not exist, then the Company recognizes revenue under the arrangement on a straight-line basis over the period the Company expects to complete its performance obligations.

With respect to revenue derived from reimbursement of direct, out-of-pocket expenses for research and development costs associated with collaborations, where the Company acts as a principal with discretion to choose suppliers, bear credit risk, and perform part of the services required in the transaction, the Company records revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the statements of operations.

#### **Milestones**

The Company uses the milestone method of accounting and revenue is recognized when earned, as evidenced by written acknowledgement from the collaborator or other persuasive evidence that the milestone has been achieved and the payment is non-refundable, provided that the milestone event is substantive. A milestone event is defined as an event: (1) that can only be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance; (2) for which there is substantive uncertainty at the inception of the arrangement that the event will be achieved; and (3) that would result in additional payments being due to the Company. Events for which the occurrence is either contingent solely upon the passage of time or the result of a counterparty's performance are not considered to be milestone events. A milestone event is substantive if all of the following conditions are met: (a) the consideration is commensurate with either the Company's performance to achieve the milestone, or the enhancement of the value to the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone; (b) the consideration relates solely to past performance; and (c) the consideration is reasonable relative to all the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

The Company assesses whether a milestone is substantive at the inception of each arrangement. If a milestone is deemed non-substantive, the Company will account for that milestone payment in accordance with the multiple element arrangements guidance and recognize it consistent with the related units of accounting for the arrangement over the related performance period.

#### **Clinical Trial Expense Accruals**

As part of the process of preparing the Company's financial statements, the Company is required to estimate expenses resulting from its obligations under contracts with vendors, contract research organizations (CROs), and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

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The Company's objective is to reflect the appropriate trial expenses in its financial statements by recording those expenses in the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of completion of trials. During the course of a clinical trial, the Company adjusts the clinical expense recognition if actual results differ from its estimates. The Company makes estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The Company's clinical trial accruals are dependent upon accurate reporting by CROs and other third-party vendors. Although the Company does not expect its estimates to differ materially from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any particular period. For the three months ended March 31, 2016 and 2015, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

### **Stock-Based Compensation**

Stock-based compensation expense represents the grant date fair value of employee stock option grants, employee restricted stock unit grants and employee stock purchase plan (ESPP) rights recognized as expense over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures. The Company estimates the fair value of stock option grants and ESPP rights using the Black-Scholes option pricing model.

The Company accounts for stock options granted to non-employees using the fair value approach. These option grants, if any, are subject to periodic revaluation over their vesting terms.

### **Comprehensive Loss**

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and comprehensive loss were the same for all periods presented.

### **Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss by the weighted-average shares of common stock outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted-average number of common shares outstanding that are subject to repurchase. The Company has excluded 5,243 and 7,344 weighted-average shares subject to repurchase from the weighted-average number of common shares outstanding for the three months ended March 31, 2016, and 2015, respectively. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	Three Months Ended	
	March 31,	
	2016	2015
Warrants to purchase common stock	57,173	38,758
Common stock options and restricted stock units	2,089,186	1,482,454
ESPP shares	3,000	2,098
	<u>2,149,359</u>	<u>1,523,310</u>

### **Recent Accounting Pronouncements Not Yet Adopted**

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which converges the FASB and the International Accounting Standards Board standard on revenue

recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2017. The Company has not yet selected a transition method and is currently evaluating the impact that the adoption of ASU 2014-09 will have on its financial statements and related disclosures.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate relevant conditions, events and certain management plans that are known or reasonably knowable that when, considered in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management's plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. The Company is currently evaluating the impact that the adoption of ASU 2014-15 will have on its financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends ASC Topic 718, Compensation – Stock Compensation. ASU 2016-09 includes an update which simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 is effective for public entities for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. The Company is evaluating the impact of this standard on its financial statements and related disclosures but does not anticipate a material impact on its financial statements.

### **Recently Adopted Accounting Standards**

In April 2015, the FASB issued ASU 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. ASU 2015-03 requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying value of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 was effective for interim and annual periods beginning on January 1, 2016. The Company applied the amended presentation requirements in the first quarter of 2016, which resulted in no change on its financial statements.

## **2. Short-Term Investments and Fair Value Measurements**

At March 31, 2016, short-term investments consist of certificates of deposit. The Company classifies all investments as available-for-sale, as the sale of such investments may be required prior to maturity to implement management strategies. These investments are carried at amortized cost which approximates fair value, with the unrealized gains and losses reported as a component of other comprehensive income in equity until realized. A decline in the market value of any short-term investment below cost that is determined to be other-than-temporary will result in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. No such impairment charges were recorded for any period presented.

Realized gains and losses from the sale of short-term investments, if any, are determined on a specific identification basis. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense on the consolidated statements of operations. Realized and unrealized gains and losses during the periods presented were immaterial. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method and are included in interest income on the consolidated statements of operations. Interest and dividends on securities classified as available-for-sale are included in interest income on the consolidated statements of operations. At March 31, 2016, the remaining contractual maturities of all available-for-sale investments were less than one year.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to

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transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. No transfers between levels have occurred during the periods presented.

The fair values of the Company's assets and liabilities, which are measured at fair value on a recurring basis, were determined using the following inputs (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>At March 31, 2016</b>				
Certificates of deposit and money market funds, included in Cash equivalents and Short-term investments	\$ 15,024	\$ —	\$ 15,024	\$ —
<b>At December 31, 2015</b>				
Certificates of deposit and money market funds, included in Cash equivalents and Short-term investments	\$ 14,996	\$ —	\$ 14,996	\$ —

The carrying amounts of cash and cash equivalents, prepaid and other assets, accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, which is considered a Level 2 input, the Company believes that the fair value of long-term debt approximates its carrying value.

### 3. Property and Equipment

Property and equipment consist of the following (in thousands):

	March 31, 2016	December 31, 2015
Computer and office equipment	\$ 115	\$ 112
Furniture and fixtures	19	19
Leasehold improvements	124	99
Construction in process	—	25
	258	255
Less accumulated depreciation and amortization	(106)	(82)
	\$ 152	\$ 173

Depreciation expense related to property and equipment totaled approximately \$24,000 and \$8,000 for the three months ended March 31, 2016 and 2015, respectively.

**4. Long-Term Debt**

Long-term debt and unamortized debt discount balances are as follows (in thousands):

	<b>March 31,</b>	<b>December 31,</b>
	<b>2016</b>	<b>2015</b>
Long-term debt	\$ 10,000	\$ 10,000
Less debt discount, net of current portion	(414)	(536)
Long-term debt, net of debt discount	9,586	9,464
Less current portion of long-term debt	(3,000)	(2,000)
Long-term debt, net of current portion	\$ 6,586	\$ 7,464
Current portion of long-term debt	\$ 3,000	\$ 2,000
Current portion of debt discount	(583)	(622)
Current portion of long-term debt, net	\$ 2,417	\$ 1,378

In May 2015, the Company entered into an Amended and Restated Loan and Security Agreement with Silicon Valley Bank (the 2015 Amended SVB Loan) under which the Company could borrow up to \$10.0 million. At December 31, 2015, the Company had borrowed the full \$10.0 million available under the 2015 Amended SVB Loan, of which, borrowings of approximately \$8.0 million were used to refinance amounts outstanding under the prior loan and security agreements, which was first entered into in November 2013 (SVB Loan Agreement) and amended and restated in June 2014 (Amended SVB Loan Agreement). In connection with the 2015 Amended SVB Loan, the Company issued warrants to purchase up to 18,415 shares of common stock at an exercise price of \$10.86 per share. The warrants are fully exercisable and expire on May 13, 2022. The transaction was accounted for as a debt modification.

The 2015 Amended SVB Loan provides for interest to be paid at a rate of 6.5% per annum. Interest-only payments are due monthly through June 2016, which will be extended through September 2016, in the event certain conditions are met. Thereafter, in addition to interest accrued during such period, the monthly payments will include an amount equal to the outstanding principal at July 1, 2016 (or October 1, 2016) divided by 30 months. At maturity (or earlier prepayment), the Company is also required to make a final payment equal to 8.5% of the original principal amount of the amounts borrowed. The 2015 Amended SVB Loan provides for prepayment fees of 3% of the outstanding balance of the loan if the loan is repaid prior to May 13, 2016, 2.0% of the amount prepaid if the prepayment occurs after May 13, 2016 but prior to May 13, 2017 and 1.0% of the amount prepaid if the prepayment occurs thereafter.

The fair value of the warrants and the final payment related to the 2015 Amended SVB Loan were recorded as debt discounts and are being amortized to interest expense using the effective interest method over the term of the debt, in addition to the remaining unamortized discounts related to the SVB Loan and the Amended SVB Loan Agreements.

Consistent with the terms of the SVB Loan and the Amended SVB Loan Agreements, the 2015 Amended SVB Loan is collateralized by substantially all of the Company's assets, other than the Company's intellectual property, and contains customary conditions of borrowing, events of default and covenants, including covenants that restrict the Company's ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of the Company's capital stock. Should an event of default occur, including the occurrence of a material adverse change, the Company could be liable for immediate repayment of all obligations under the 2015 Amended SVB Loan.

In connection with the SVB Loan and the Amended SVB Loan, the Company issued warrants to purchase 37,500 shares and 112,500 shares of Series A redeemable convertible preferred stock, respectively, at an exercise price of \$2.00 per share. The warrants are fully exercisable and expire on November 14, 2023 and June 4, 2024, respectively. The initial fair value of the warrants as of the November 2013 and June 2014 issuance dates was estimated to be \$0.1 million and \$0.2 million, respectively, based on the application of the Black-Scholes option pricing model, and these discounts are being amortized to interest expense using the effective interest method over the term of the debt. Upon completion of the Company's initial public offering in February 2015, the warrants became exercisable for an aggregate of 38,758 shares of common stock at an exercise price of \$7.74 per share.

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Future minimum principal and interest payments under the 2015 Amended SVB Loan, including the final payment, as of March 31, 2016 are as follows (in thousands):

Remaining 2016	\$ 2,469
2017	4,406
2018	4,993
	<u>11,868</u>
Less interest and final payment	<u>(1,868)</u>
Long-term debt	<u>\$ 10,000</u>

**5. Commitments and Contingencies**

***License Agreements***

The Company has entered into various license agreements pursuant to which the Company acquired licenses to certain intellectual property. The agreements generally required an upfront license fee and, in some cases, reimbursement of patent costs. Additionally, under each agreement, the Company may be required to pay annual maintenance fees, royalties, milestone payments and sublicensing fees. Each of the license agreements is generally cancelable by the Company, given appropriate prior written notice. At March 31, 2016, potential future milestone payments under these agreements totaled an aggregate of approximately \$22.1 million.

**6. Stockholders' Equity**

***Initial Public Offering and Related Transactions***

In February 2015, the Company completed its initial public offering in which it sold 3,600,000 shares of common stock at an initial public offering price of \$10.00 per share. In addition, a concurrent private placement to an existing stockholder was completed in which the Company sold 500,000 shares of common stock, also at \$10.00 per share. Proceeds from the initial public offering and concurrent private placement, net of underwriting discounts, commissions and offering costs paid by us of approximately \$6.0 million, were approximately \$35.0 million.

In addition, in connection with the completion of the Company's initial public offering on February 4, 2015, all of the outstanding shares of redeemable convertible preferred stock were converted into 6,369,567 shares of the Company's common stock; outstanding warrants to purchase 150,000 shares of Series A redeemable convertible preferred stock were converted into warrants to purchase 38,758 shares of the Company's common stock, and the Company's certificate of incorporation was amended and restated to authorize 200,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock.

***Redeemable Convertible Preferred Stock***

Prior to its automatic conversion in the initial public offering, the Company classified its redeemable convertible preferred stock outside of permanent equity since such stock was contractually redeemable outside of the Company's control. As a result, the carrying value was increased to its redemption value by periodic accretion charges over the estimated redemption period. In the absence of retained earnings, these accretion charges were recorded against additional paid-in capital.

### Stock-Based Compensation Expense

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants were as follows:

	Three Months Ended	
	March 31,	
	2016	2015
Risk-free interest rate	1.6 %	1.6 %
Expected volatility	77 %	74 %
Expected term (in years)	6.3	6.2
Expected dividend yield	— %	— %

Stock compensation expense for the Employee Stock Purchase Plan was immaterial for the three months ended March 31, 2016 and 2015.

The allocation of stock-based compensation is as follows (in thousands):

	Three Months Ended	
	March 31,	
	2016	2015
Research and development	\$ 353	\$ 153
General and administrative	504	94
	<u>\$ 857</u>	<u>\$ 247</u>

## 7. Collaboration

In March 2014, the Company entered into a license agreement with Santen, under which the Company granted Santen an exclusive, worldwide license to certain patents, information and know-how related to TRC105. Under the agreement, Santen is permitted to use, develop, manufacture and commercialize TRC105 products for ophthalmology indications, excluding systemic treatment of ocular tumors. Santen also has the right to grant sublicenses to affiliates and third party collaborators. In the event Santen sublicenses any of its rights under the agreement, Santen will be obligated to pay the Company a portion of any upfront and certain milestone payments received under such sublicense.

Santen has sole responsibility for funding, developing, seeking regulatory approval for and commercializing TRC105 products in the field of ophthalmology. In the event that Santen fails to meet certain commercial diligence obligations, the Company will have the option to co-promote TRC105 products in the field of ophthalmology in the United States with Santen. If the Company exercises this option, the Company will pay Santen a percentage of certain development expenses, and the Company will receive a percentage of profits from sales of the licensed products in the ophthalmology field in the United States, but will not receive royalties on such sales.

In consideration of the rights granted to Santen under the agreement, the Company received a one-time upfront fee of \$10.0 million. The license agreement provides for various types of payments, including the upfront payment, payment for various technical and regulatory support, payments for delivery of drug substance, reimbursement of certain development costs, milestone payments, and royalties on net product sales. The Company has identified multiple deliverables, which include at inception: (1) a license to patents, information and know-how related to TRC105, (2) technology transfer, (3) collaboration, including technical and regulatory support provided by the Company, (4) manufacturing and supply obligations, and (5) shared chemistry, manufacturing and controls (CMC) development activities. Deliverables 1 and 2 above were substantially delivered at the inception of the agreement, and deliverables 3 through 5 are expected to be delivered during the estimated 34-month period over which the Company will provide technical and regulatory support to Santen. At inception and through March 31, 2016, the Company has identified one single unit of accounting for all the deliverables under the agreement since the delivered elements do not have standalone value. The Company's technical and regulatory expertise, including manufacturing and CMC activities, in the development of biologic therapeutics, specifically TRC105, is a significant component of Santen's ability to utilize the license and know-how related to TRC105. Given the early stage of development of TRC105 for ophthalmology, the Company is the only party capable of performing the level and type of technical and regulatory collaboration services

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required by Santen under the agreement. As a result, the Company has determined that the license, including the ability to sublicense, and know-how related to TRC105 do not have standalone value to a licensee. As such, the Company is recognizing revenue for the fixed or determinable collaboration consideration on a straight-line basis over the estimated 34-month period over which it will deliver its technical and regulatory support.

During the three months ended March 31, 2016, the expected term over which the Company will provide technical and regulatory support to Santen was extended from 31 months to 34 months. The change in the estimated term increased net loss by \$0.4 million, or \$0.03 per share, for the three months ended March 31, 2016.

In addition, the Company is eligible to receive up to a total of \$155.0 million in milestone payments upon the achievement of certain milestones, of which \$20.0 million relates to the initiation of certain development activities, \$52.5 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals and \$82.5 million relates to commercialization activities and the achievement of specified levels of product sales. The Company has determined that \$10.0 million related to the initiation of certain clinical development activities will be based upon its efforts and meet the criteria of substantive milestones and therefore will be recognized as revenue upon achievement of the milestone in accordance with the milestone method of accounting. As of March 31, 2016, the Company had received a \$3.0 million milestone payment related to development activities, revenue for which was recognized in the year ended December 31, 2015. The remaining \$145.0 million of potential milestone payments are not substantive milestones as they do not require the efforts of the Company.

If TRC105 products are successfully commercialized in the field of ophthalmology, Santen will be required to pay the Company tiered royalties on net sales ranging from high single digits to low teens, depending on the volume of sales, subject to adjustments in certain circumstances. In addition, Santen will reimburse the Company for all royalties due by the Company under certain third party agreements with respect to the use, manufacture or commercialization of TRC105 products in the field of ophthalmology by Santen and its affiliates and sublicensees. Royalties will continue on a country-by-country basis through the later of the expiration of the Company's patent rights applicable to the TRC105 products in a given country or 12 years after the first commercial sale of the first TRC105 product commercially launched in such country.

Santen may unilaterally terminate this agreement in its entirety, or on a country-by-country basis, upon written notice to the Company. Either party may terminate the agreement in the event of the other party's bankruptcy or dissolution or for the other party's material breach of the agreement that remains uncured 90 days (or 30 days with respect to a payment breach) after receiving notice from the non-breaching party. Unless earlier terminated, the agreement continues in effect until the termination of Santen's payment obligations.

In connection with the collaboration with Santen, the Company recognized revenue of \$1.2 million and \$1.1 million for the three months ended March 31, 2016 and 2015, respectively. At March 31, 2016, deferred revenue totaled \$2.4 million.

## **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 condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, timing of future events and future financial performance, includes forward-looking statements that are based upon current beliefs, plans and expectations and involve risks, uncertainties and assumptions. You should review the "Risk Factors" section of this Quarterly Report for a discussion of important factors that could cause our actual results and the timing of selected events to differ materially from those described in or implied by the forward-looking statements contained in this Quarterly Report. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this Report or to reflect actual outcomes.*

### **Overview**

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration, or wet AMD, and fibrotic diseases. We are a leader in the field of endoglin biology and are using our expertise to develop antibodies that bind to the endoglin receptor. Endoglin is essential to angiogenesis, the process of new blood vessel formation, and a key contributor to the development of fibrosis, or tissue scarring. Our lead product candidate, TRC105, is an endoglin antibody that is being developed for the treatment of multiple solid tumor types in combination with inhibitors of the vascular endothelial growth factor, or VEGF, pathway. The VEGF pathway regulates vascular development in the embryo, or vasculogenesis, and angiogenesis. TRC105 has been studied in seven completed Phase 2 clinical trials and three completed Phase 1 clinical trials, and is currently being dosed in five Phase 2 clinical trials. Interim data from these trials have shown encouraging rates of durable complete responses in angiosarcoma and choriocarcinoma, orphan drug indications that highly express endoglin, and we expect to initiate a Phase 3 trial in angiosarcoma and a multicenter Phase 2 trial in gestational trophoblastic neoplasia, or GTN, that includes choriocarcinoma and could be registration enabling, in 2016. Furthermore, we expect topline data in four of these ongoing Phase 2 clinical trials by the end of 2016 and, if results are positive, we expect to initiate additional Phase 3 clinical trials for one or more indications of soft tissue sarcoma, renal cell carcinoma, glioblastoma and hepatocellular carcinoma.

During May 2016, we received notice that the European Medicines Agency granted TRC105 orphan drug designation for the treatment of patients with soft tissue sarcoma. This designation, similar to the orphan drug designation for TRC105 in soft tissue sarcoma received from the Food and Drug Administration in January 2016, provides regulatory and financial incentives to develop and market therapies that treat rare diseases.

Our other product candidates are TRC205, an endoglin antibody that is in preclinical development for the treatment of fibrotic diseases, and TRC102, which is a small molecule that is in clinical development for the treatment of lung cancer and glioblastoma. In March 2014, Santen licensed from us exclusive worldwide rights to develop and commercialize our endoglin antibodies for ophthalmology indications.

We recently completed certain preclinical studies of our endoglin antibodies, including TRC205, in three fibrosis models in mice: a model of chemically-induced liver fibrosis, a model of chemically induced pulmonary fibrosis, and a model of non-alcoholic steatohepatitis, or NASH. In each study, one or more endoglin antibodies achieved the primary endpoint of the study compared to control. In the NASH study, the clinical candidate TRC205 significantly reduced the Non-Alcoholic Fatty Liver Disease (NAFLD) Activity Score versus control, and reduced fibrotic gene expression without significantly reducing the fibrotic area by visual inspection. We expect to present data from these three models in the second half of 2016.

We have collaborated with NCI, which has selected TRC105 and TRC102 for federal funding of clinical development, as well as Case Western. Under these collaborations, NCI has sponsored or is sponsoring nine completed or ongoing clinical trials of TRC105 and TRC102, and Case Western sponsored two clinical trials of TRC102. We anticipate that NCI will complete ongoing Phase 2 clinical trials of TRC105 and may initiate other Phase 2 clinical trials in addition to the Phase 2 clinical trials of TRC105 that we are sponsoring. In addition, we expect that Phase 2 clinical

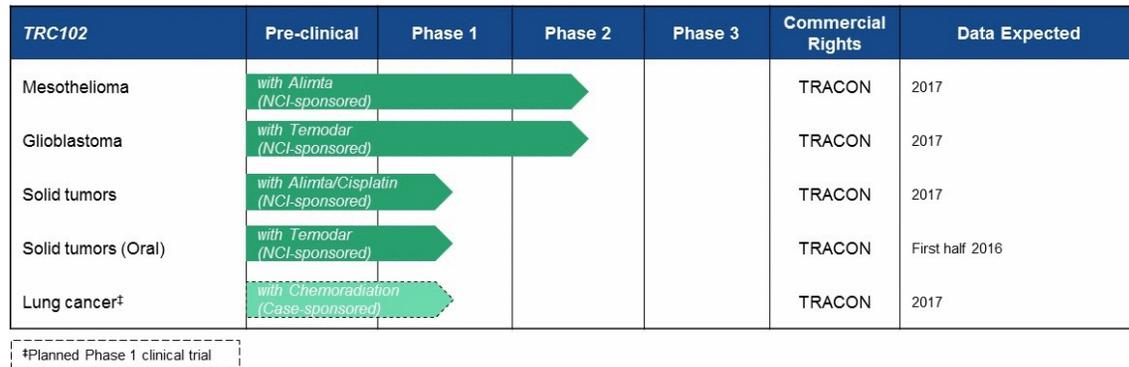
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trials of TRC102 will be completed with NCI funding. If merited by Phase 2 data, we expect to fund initial Phase 3 clinical trials of TRC105 and TRC102 and, based on NCI's past course of conduct with similarly situated pharmaceutical companies in which it has sponsored pivotal clinical trials following receipt of positive Phase 2 data, we anticipate that NCI will sponsor Phase 3 clinical trials in additional indications.

The following chart summarizes key information regarding ongoing and planned development of our TRC105 product candidate:



The following chart summarizes key information regarding ongoing and planned development of our TRC102 product candidate:



Since our inception in 2004, we have devoted substantially all of our resources to research and development efforts relating to our product candidates, including conducting clinical trials and developing manufacturing capabilities, in-licensing related intellectual property, providing general and administrative support for these operations and

protecting our intellectual property. We have not generated any revenue from product sales and, through December 31, 2014, had funded our operations primarily with the aggregate net proceeds of \$79.1 million from the private placement of redeemable convertible preferred stock and common stock, a \$10.0 million one-time upfront fee received in connection with our collaboration with Santen, and \$10.0 million of commercial bank debt under our credit facility with SVB. In February 2015, we completed our initial public offering and a concurrent private placement and raised proceeds, net of underwriting discounts, commissions and offering costs of approximately \$6.0 million, totaling approximately \$35.0 million. At March 31, 2016, we had cash, cash equivalents and short-term investments totaling \$45.5 million.

We have incurred losses from operations in each year since our inception. Our net losses were \$24.4 million and \$6.8 million for the years ended December 31, 2015 and 2014, respectively. At March 31, 2016, we had an accumulated deficit of \$65.1 million.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will increase substantially in connection with our ongoing activities as we:

- continue to conduct clinical trials of our product candidates;
- continue our research and development efforts;
- manufacture preclinical study and clinical trial materials;
- maintain, expand and protect our intellectual property portfolio;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- hire additional staff, including clinical, operational, financial and technical personnel to execute on our business plan and create additional infrastructure to support our operations as a public company; and
- implement operational, financial and management systems.

We do not expect to generate any revenues from product sales until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to raise substantial additional capital. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our preclinical and clinical development efforts and the timing and nature of the regulatory approval process for our product candidates. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and ability to develop our product candidates.

#### **Collaboration and License Agreements**

##### ***Santen Pharmaceutical Co., Ltd.***

In March 2014, we entered into a license agreement with Santen, under which we granted Santen an exclusive, worldwide license to certain patents, information and know-how related to TRC105, or the TRC105 Technology. Under the agreement, Santen is permitted to use, develop, manufacture and commercialize TRC105 products for ophthalmology indications, excluding systemic treatment of ocular tumors. Santen also has the right to grant sublicenses to affiliates and third party collaborators, provided such sublicenses are consistent with the terms of our agreement. Santen has sole responsibility for funding, developing, seeking regulatory approval for and commercializing TRC105 products in the field of ophthalmology.

In consideration of the rights granted to Santen under the agreement, we received a one-time upfront fee of \$10.0 million. In addition, we are eligible to receive up to a total of \$155.0 million in milestone payments upon the achievement of certain milestones, of which \$20.0 million relates to the initiation of certain development activities, \$52.5 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals and \$82.5 million relates to commercialization activities and the achievement of specified levels of product sales. As of March 31, 2016, we had received \$3.0 million in milestones related to development activities. If TRC105 products are successfully commercialized in the field of ophthalmology, Santen will be required to pay us tiered royalties on net sales ranging from high single digits to low teens, depending on the volume of sales, subject to adjustments in certain circumstances. In addition, Santen will reimburse us for all royalties due by us under certain third party agreements with respect to the use, manufacture or commercialization of TRC105 products in the field of ophthalmology by Santen and its affiliates and sublicensees. Royalties will continue on a country-by-country basis through the later of the expiration of our patent rights applicable to the TRC105 products in a given country or 12 years after the first commercial sale of the first TRC105 product commercially launched in such country.

## **Financial Operations Overview**

### ***Revenue***

Our revenue to date has been derived solely from our March 2014 collaboration with Santen. The terms of this arrangement contain multiple deliverables, which include at inception: (1) a license to patents, information and know-how related to TRC105; (2) technology transfer; (3) collaboration, including technical and regulatory support provided by us; (4) manufacturing and supply obligations; and (5) shared CMC development activities. The license agreement provides that we may receive various types of payments, including an upfront payment, payment for various technical and regulatory support, payments for delivery of drug substance, reimbursement of certain development costs, milestone payments, and royalties on net product sales. In accordance with our revenue recognition policy described in detail below, we have identified one single unit of accounting for all the deliverables under the agreement and are recognizing revenue for the fixed or determinable collaboration consideration on a straight-line basis over the estimated development period.

We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing of any future achievement of milestones and the extent to which any of our products are approved and successfully commercialized by us or Santen. If we or Santen fail to develop product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenues, our results of operations and our financial position could be adversely affected.

### ***Research and Development Expenses***

Research and development expenses consist of costs associated with the preclinical and clinical development of our product candidates. These costs consist primarily of:

- costs to acquire, develop and manufacture preclinical study and clinical trial materials;
- salaries and employee-related expenses, including stock-based compensation and benefits for personnel in research and development functions;
- costs associated with conducting our preclinical, development and regulatory activities, including fees paid to third party professional consultants, service providers and our scientific advisory board;
- costs incurred under clinical trial agreements with investigative sites;
- payments related to licensed products and technologies; and
- facilities, depreciation and other expenses, including allocated expenses for rent and maintenance of facilities.

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Research and development costs, including third party costs reimbursed by Santen as part of our collaboration, are expensed as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received.

The following table summarizes our research and development expenses by product candidate for the periods indicated:

	Three Months Ended	
	March 31,	
	2016	2015
	(in thousands)	
Third-party research and development expenses:		
TRC105	\$ 3,552	\$ 2,660
TRC102	227	7
TRC205	23	143
Total third-party research and development expenses	3,802	2,810
Unallocated expenses	1,693	1,021
Total research and development expenses	\$ 5,495	\$ 3,831

Unallocated expenses consist of our internal personnel costs, facility costs and scientific advisory board related expenses.

We plan to substantially increase our current level of research and development expenses for the foreseeable future as we: (1) continue development of TRC105 in orphan indications, including initiating a Phase 3 clinical trial in angiosarcoma and a Phase 2 clinical trial in GTN, (2) expand the development program for TRC105 in our additional oncology indications of soft tissue sarcoma, renal cell carcinoma, hepatocellular carcinoma, and glioblastoma in combination with approved VEGF inhibitors, and (3) expand the development program for TRC105 into large market oncology indications.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

The costs of clinical trials to us may vary significantly based on factors such as:

- the extent to which costs are borne by third parties such as NCI;
- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;

- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

#### ***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance and administration, corporate development and administrative support functions, including stock-based compensation expenses and benefits. Other significant general and administrative expenses include insurance, accounting and legal services, expenses associated with obtaining and maintaining patents, the cost of various consultants and occupancy costs.

We anticipate that our general and administrative expenses will remain relatively constant in the near term.

#### ***Other Income (Expense)***

Other income (expense) primarily consists of interest related to our loan agreements with SVB offset by interest income from our short-term investments and cash equivalents.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on our historical experience and on various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies Involving Management Estimates and Assumptions," included in our Annual Report on Form 10-K for the year ended December 31, 2015.

#### **Recent Accounting Pronouncements Not Yet Adopted**

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which converges the FASB and the International Accounting Standards Board standard on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2017. We have not yet selected a transition method and are currently evaluating the impact that the adoption of ASU 2014-09 will have on our financial statements and related disclosures.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate relevant conditions, events and certain management plans that are known or reasonably knowable that when, considered in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management's plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. We are currently evaluating the impact that the adoption of ASU 2014-15 will have on our financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, an ASU which amends ASC Topic 718, Compensation – Stock Compensation. ASU 2016-09 includes an update which simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 is effective for public entities for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. We are currently evaluating the impact that the adoption of ASU 2016-09 will have on our financial statements and related disclosures but we do not anticipate the adoption to have a material impact.

### Recently Adopted Accounting Standards

In April 2015, the FASB issued ASU 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. ASU 2015-03 requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying value of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 was effective for interim and annual periods beginning on January 1, 2016. We applied the amended presentation requirements in the first quarter of 2016, which resulted in no change to our financial statements.

### Results of Operations

#### *Comparison of the Three Months Ended March 31, 2016 and 2015*

The following table summarizes our results of operations for the three months ended March 31, 2016 and 2015:

	Three Months Ended		
	March 31,		Change
2016	2015		
	(in thousands)		
Collaboration revenue	\$ 1,210	\$ 1,132	\$ 78
Research and development expenses	5,495	3,831	1,664
General and administrative expenses	2,009	1,013	996
Other income (expense)	(232)	(283)	51

*Collaboration revenue.* Collaboration revenue, all of which resulted from our collaboration with Santen, was \$1.2 million and \$1.1 million for the three months ended March 31, 2016 and 2015, respectively.

*Research and development expenses.* Research and development expenses were \$5.5 million and \$3.8 million for the three months ended March 31, 2016 and 2015, respectively. The increase of \$1.7 million was due primarily to increased clinical study expenses and manufacturing related to TRC105, as well as increased compensation related expenses, including stock-based compensation expenses, due to increased headcount.

*General and administrative expenses.* General and administrative expenses were \$2.0 million and \$1.0 million for the three months ended March 31, 2016 and 2015, respectively. The increase of \$1.0 million was due primarily to increased compensation related expenses, including stock-based compensation expenses, due to increased headcount, as well as increased expenses related to being a public company for the entire three months ended March 31, 2016, such as insurance, accounting and legal expenses.

*Other income (expense).* Other income (expense) was (\$0.2) million and (\$0.3) million for the three months ended March 31, 2016 and 2015, respectively.

### **Liquidity and Capital Resources**

We have incurred losses and negative cash flows from operations since our inception. As of March 31, 2016, we had an accumulated deficit of \$65.1 million, and we expect to continue to incur net losses for the foreseeable future. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may seek to obtain through one or more equity offerings, debt financings, government or other third party funding, and licensing or collaboration arrangements.

On February 4, 2015, we completed the initial public offering and a concurrent private placement of our common stock, which resulted in net proceeds to us of approximately \$35.0 million. We anticipate that our existing cash, cash equivalents and short-term investments will fund our operations for at least the next 12 months. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to capital preservation.

### ***Credit Facility with SVB***

In May 2015, we entered into an Amended and Restated Loan and Security Agreement with SVB (the 2015 Amended SVB Loan) under which we could borrow up to \$10.0 million. At December 31, 2015, we had borrowed the full \$10.0 million available, of which, borrowings of approximately \$8.0 million were used to refinance amounts outstanding under the prior loan and security agreements. In connection with the 2015 Amended SVB Loan, we issued warrants to purchase up to 18,415 shares of common stock at an exercise price of \$10.86 per share. The warrants are fully exercisable and expire on May 13, 2022.

The 2015 Amended SVB Loan provides for interest to be paid at a rate of 6.5% per annum. Interest-only payments are due monthly through June 2016, which will be extended through September 2016, in the event certain conditions are met. Thereafter, in addition to interest accrued during such period, the monthly payments will include an amount equal to the outstanding principal at July 1, 2016 (or October 1, 2016) divided by 30 months. At maturity (or earlier prepayment), we are also required to make a final payment equal to 8.5% of the original principal amount of the amounts borrowed. The 2015 Amended SVB Loan provides for prepayment fees of 3.0% of the outstanding balance of the loan if the loan is repaid prior to May 13, 2016, 2.0% of the amount prepaid if the prepayment occurs after May 13, 2016 but prior to May 13, 2017 and 1.0% of the amount prepaid if the prepayment occurs thereafter.

The 2015 Amended SVB Loan is collateralized by substantially all of our assets, other than our intellectual property, and contains customary conditions of borrowing, events of default and covenants, including covenants that restrict our ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of our capital stock. Should an event of default occur, including the occurrence of a material adverse change, we could be required to immediately repay of all obligations under the 2015 Amended SVB Loan.

### **ATM Facility**

In February 2016, we entered into an At-the-Market Equity Offering Sales Agreement, or the Sales Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, pursuant to which we may sell from time to time, at our option, up to an aggregate of \$25.0 million of our shares of our common stock through Stifel, as sales agent. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made on the Nasdaq Global Market under our effective registration statement on Form S-3, by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the Sales Agreement, we may also sell shares of our common stock through Stifel, on the Nasdaq Global Market or otherwise, at negotiated prices or at prices related to the prevailing market price. Stifel will use its commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We are obligated to pay Stifel an aggregate sales agent commission equal to up to 2.5% of the gross proceeds of the sales price for common stock sold under the Sales Agreement.

### **Cash Flows**

The following table summarizes our net cash flow activity for each of the periods set forth below:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2016</b>	<b>2015</b>
	<b>(in thousands)</b>	
Net cash provided by (used in):		
Operating activities	\$ (6,668)	\$ (4,800)
Investing activities	8,553	(2)
Financing activities	7	35,093
Net increase in cash and cash equivalents	<u>\$ 1,892</u>	<u>\$ 30,291</u>

*Operating activities.* Net cash used in operating activities was \$6.7 million for the three months ended March 31, 2016 and was primarily due to our net loss and changes in our assets, liabilities and deferred revenue for this period. Net cash used in operating activities was \$4.8 million for the three months ended March 31, 2015 and was primarily due to our net loss and changes in our accounts payable and accrued expense accounts for this period.

*Investing activities.* Net cash provided by investing activities was \$8.6 million for the three months ended March 31, 2016 and was primarily due to maturities of short-term investments, offset by purchases of these investments. Net cash used in investing activities was \$2,000 for the three months ended March 31, 2015 and was due to the purchase of property and equipment during this period.

*Financing activities.* Net cash provided by financing activities was \$7,000 during the three months ended March 31, 2016 and was due to proceeds received from stock option exercises. Net cash provided by financing activities was \$35.1 million during the three months ended March 31, 2015 and resulted from net proceeds received totaling approximately \$36.3 million from our initial public offering and concurrent private placement, offset in part by \$1.2 million in repayments on borrowings under our SVB loans.

### **Funding Requirements**

At March 31, 2016, we had cash, cash equivalents and short-term investments totaling \$45.5 million. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

- our ability to initiate, and the progress and results of, our planned clinical trials of TRC105;

- Santen’s ability and willingness to continue clinical development of DE-122;
- our ability to enter into and maintain our collaborations, including our collaboration with Santen;
- our ability to achieve, and our obligations to make, milestone payments under our collaboration and license agreements;
- the costs and timing of procuring supplies of our product candidates for clinical trials and regulatory submissions;
- the scope, progress, results and costs of preclinical development, and clinical trials of our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the revenue, if any, received from commercial sales of our product candidates for which we or any of our partners, including Santen, may receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval and do not partner for commercialization; and
- the extent to which we acquire or in-license other products and technologies.

Until we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and licensing arrangements.

#### **Off-Balance Sheet Arrangements**

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the applicable rules of the Securities and Exchange Commission (the SEC).

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

#### ***Interest Rate Risk***

Our cash and cash equivalents consist of cash, money market funds and certificates of deposit. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes. Our long-term debt bears interest at a fixed rate.

#### ***Foreign Currency Exchange Risk***

We incur significant expenses for manufacturing of clinical trial materials outside the United States based on contractual obligations denominated in currencies other than the U.S. dollar, primarily Pounds Sterling. At the end of each reporting period, these liabilities are converted to U.S. dollars at the then-applicable foreign exchange rate. As a result, our business is affected by fluctuations in exchange rates between the U.S. dollar and foreign currencies. We do not enter into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks. Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. However, to date, these fluctuations have not been significant. Based on our purchase commitments for our 2016 fiscal

year, a movement of 1% in the U.S. dollar to Pounds Sterling exchange rate would not have a material effect on our results of operations or financial condition.

***Effects of Inflation***

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations or financial condition during the periods presented.

**ITEM 4. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of March 31, 2016, the end of the period covered by this report.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II OTHER INFORMATION

### Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

### Item 1A. Risk Factors

*Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below with an asterisk (\*) next to the title contain changes to the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.*

#### **Risks Related to our Financial Position and Need for Additional Capital**

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

We are a clinical stage company with limited operating history. All of our product candidates, including our most advanced product candidate, TRC105, will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have incurred losses from operations in each year since our inception, including net losses of \$24.4 million and \$6.8 million for the years ended December 31, 2015 and 2014, respectively. At March 31, 2016, we had an accumulated deficit of \$65.1 million.

We expect to continue to incur substantial and increased expenses as we expand our development activities and advance our clinical programs, particularly with respect to our planned clinical development and manufacturing activities for TRC105. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future.

To become and remain profitable, we or our partners must succeed in developing our product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we or our partners may obtain regulatory approval. We or they may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates or continue our operations.

***We will require substantial additional financing to achieve our goals, and failure to obtain additional financing when needed could force us to delay, limit, reduce or terminate our drug development efforts.\****

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs, including our planned and future clinical trials of TRC105.

At March 31, 2016, we had cash, cash equivalents and short-term investments totaling \$45.5 million. Based upon our current operating plan, we believe that our existing cash will enable us to fund our operating expenses and capital requirements for at least the next 12 months. Regardless of our expectations, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties or we could encounter difficulties obtaining clinical trial material that could increase our development costs more than we expect. In any event, we will require additional capital prior to completing Phase 3 development of, filing for regulatory approval for, or commercializing, TRC105 or any of our other product candidates.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development or commercialization of our product candidates or otherwise significantly curtail, or cease, operations. If we are unable to pursue or forced to delay our planned drug development efforts due to lack of financing, it would have a material adverse effect on our business, operating results and prospects.

***Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.***

We may seek additional capital through a variety of means, including through equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

***Our loan and security agreement with Silicon Valley Bank, or SVB, contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.***

In May 2015, we entered into an amended loan and security agreement with SVB to borrow up to \$10.0 million, \$8.0 million of which was used to refinance amounts outstanding under prior credit facilities with SVB. The agreement, as amended, contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- convey, sell, lease or otherwise dispose of certain parts of our business or property;
- change the nature of our business;
- liquidate or dissolve;
- enter into certain change in control or acquisition transactions;
- incur or assume certain debt;

- grant certain types of liens on our assets;
- maintain certain collateral accounts;
- pay dividends or make certain distributions to our stockholders;
- make certain investments;
- enter into material transactions with affiliates;
- make or permit certain payments on subordinate debt; and
- become an “investment company” as defined under the Investment Company Act of 1940, as amended.

The restrictive covenants of the agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial.

A breach of any of these covenants could result in an event of default under the agreement. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, which could potentially include negative results in clinical trials, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the agreement occurs. In the case of a continuing event of default under the agreement, SVB could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted SVB a security interest under the agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the agreement are secured by all of our existing and future assets, excluding intellectual property, which is subject to a negative pledge arrangement.

#### **Risks Related to Clinical Development and Regulatory Approval of Our Product Candidates**

***We are heavily dependent on the success of our lead product candidate TRC105, which is in a later stage of development than our other product candidates. We cannot give any assurance that TRC105 will successfully complete clinical development or receive regulatory approval, which is necessary before it can be commercialized.***

Our business and future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize our lead product candidate TRC105, which is currently in Phase 2 clinical trials for the treatment of multiple solid tumor types. Any delay or setback in the development of any of our product candidates, particularly TRC105, could adversely affect our business and cause our stock price to decline. We cannot assure you that our planned clinical development for TRC105 will be completed in a timely manner, or at all, or that we or our partner Santen or any additional future partners, will be able to obtain approval for TRC105 from the FDA or any foreign regulatory authority.

***Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.***

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. For example, enrollment was closed for two of our Phase 2 clinical trials sponsored by NCI following interim analyses that did not meet the requirements for continuing enrollment. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials. In particular, the positive results observed in the Phase 1 and 2 clinical trials of TRC105 do not ensure that the ongoing or planned clinical trials of TRC105 will demonstrate similar results. In addition, further interim results or the final results from these trials could be negative.

Even if our product candidates demonstrate favorable results in ongoing or planned Phase 1 and 2 clinical trials, many product candidates fail to show desired safety and efficacy traits in late-stage clinical trials despite having

progressed through earlier trials. In addition to the inherent safety and efficacy traits of our product candidates, clinical trial failures may result from a multitude of factors including flaws in trial design, manufacture of clinical trial material, dose selection and patient enrollment criteria. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or our partners may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval.

If TRC105 or any other product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be materially harmed. For example, if the results of ongoing or planned Phase 1 and 2 clinical trials of TRC105 demonstrate unexpected safety issues or do not achieve the primary efficacy endpoints, as applicable, the prospects for approval of TRC105 as well our stock price would be materially and adversely affected.

***Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.***

We may experience delays in clinical trials of our product candidates. Our ongoing and planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- adverse findings in toxicology studies, including chronic toxicology studies;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers or other third parties to produce and deliver sufficient supply of clinical trial materials.

If initiation or completion of our ongoing or planned clinical trials are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize our product candidates could be materially harmed, which could have a material adverse effect on our business.

***Our product candidates may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.***

Adverse events, or AEs, caused by our product candidates or other potentially harmful characteristics of our product candidates could cause us, our partners, including NCI or other third party clinical trial sponsors, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval.

Phase 1 or Phase 2 clinical trials of TRC105 and TRC102 conducted to date have generated AEs related to the study drug, some of which have been serious. The most common AEs identified to date and related to TRC105 have been anemia, dilated small vessels in the skin and mucosal membranes (which may result in nosebleeds and bleeding of the gums), headache, fatigue and gastrointestinal and other symptoms during the initial infusion of TRC105. While we have not observed an exacerbation of side effects commonly associated with VEGF inhibitors in clinical trials of TRC105 in combination with a VEGF inhibitor, it is possible that future trials, including larger and lengthier Phase 3 clinical trials, may show this effect due to both drugs acting to inhibit angiogenesis simultaneously. Because our development and regulatory approval strategy for TRC105 is focused on combining TRC105 with VEGF inhibitors, if we encountered safety issues associated with combining TRC105 with VEGF inhibitors, it would be a significant setback for our development program and our ability to obtain regulatory approval for TRC105 may be adversely impacted. The most common AE identified in our clinical trials of TRC102 has been anemia.

Further, if any of our approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

***The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.***

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For example, we cannot guarantee that for certain oncology indications where the FDA has traditionally granted approval to therapies that can demonstrate progression-free survival, the agency will not later require us to demonstrate overall survival, which would greatly extend the time and increase the capital required to complete clinical development. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application, or BLA, or a New Drug Application, or NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve our validation methods for detecting TRC105 serum levels and antibodies to TRC105 and assessing TRC105 activity in a biologic release assay; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market TRC105 or our other product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates. For example, we anticipate that if we were to obtain regulatory approval for TRC105 in some or all of the initial oncology indications we are pursuing, we or our partners such as NCI would still need to conduct additional Phase 3 clinical trials in order to obtain approval for additional indications and expand TRC105's market potential. In addition, we believe that TRC105 may be most effective as a treatment of solid tumors, such as angiosarcoma and GTN, that express high levels of endoglin, and we plan to analyze clinical data to determine if there is a correlation between endoglin expression and response to TRC105 treatment. If we are unable to establish such a correlation or to identify additional tumor types that express high levels of endoglin, our ability to successfully identify target patient populations for future clinical development or to expand TRC105's market potential would be limited.

We have not previously submitted a BLA or NDA, or any similar drug approval filing to the FDA or any comparable foreign authority for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market

one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

***We may not receive Fast Track designation for additional product candidates from the FDA, or Fast Track designation may not actually lead to a faster development or regulatory review or approval process.***

We received Fast Track designation for TRC105 in renal cell carcinoma in May 2015 and we intend to seek Fast Track designation or other appropriate expedited development options for our eligible product candidates in other indications. Fast track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. A new drug or biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for the disease or condition. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA will grant it. Despite our receipt of Fast Track designation for TRC105 in renal cell carcinoma, and even if additional product candidates receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

***We may be unsuccessful in our efforts to obtain additional orphan drug designations from the FDA for our product candidates or may not ultimately realize the potential benefits of orphan drug designation.\****

We received orphan drug designation for TRC105 in soft tissue sarcoma in January 2016 and we intend to seek orphan drug designation for our eligible product candidates in other indications. We have applied for orphan drug designation in gestational trophoblastic neoplasia (GTN) and the FDA has requested additional information to further review our application. The FDA grants orphan designation to drugs that are intended to treat rare diseases with fewer than 200,000 patients in the United States or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Orphan drugs do not require prescription drug user fees with a marketing application, may qualify the drug development sponsor for certain tax credits, and may be eligible for a market exclusivity period of seven years. Despite our receipt of orphan drug designation for TRC105 in soft tissue sarcoma, we cannot guarantee that we will be able to receive orphan drug status from the FDA for any other product candidates or indications. If we are unable to secure orphan drug designation for additional product candidates or indications, our regulatory and commercial prospects may be negatively impacted.

Despite orphan drug exclusivity, the FDA can still approve another drug containing the same active ingredient and used for the same orphan indication if it determines that a subsequent drug is safer, more effective or makes a major contribution to patient care, and orphan exclusivity can be lost if the orphan drug manufacturer is unable to assure that a sufficient quantity of the orphan drug is available to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective. In addition, orphan drug exclusivity does not prevent the FDA from approving competing drugs for the same or similar indication containing a different active ingredient. If orphan drug exclusivity is lost and we were unable to successfully enforce any remaining patents covering our eligible product candidates, we could be subject to generic competition earlier than we anticipate. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as any of our product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others.

For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as studies or trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we would intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

Any of our product candidates for which we receive regulatory approvals will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing, as well as continued compliance with regulatory requirements for current good manufacturing practices, or cGMPs, and current good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of existing approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

## **Risks Related to Our Reliance on Third Parties**

### ***We depend in part on NCI and other third party sponsors to advance clinical development of TRC105 and TRC102.\****

NCI is currently sponsoring and funding two ongoing clinical trials involving TRC105 and four clinical trials involving TRC102. In addition, Case Western has sponsored and funded two separate clinical trials involving TRC102 and we are planning a clinical trial of TRC105 sponsored by the University of Alabama, Birmingham Cancer Center, or UAB. The advancement of our product candidates depends in part on the continued sponsorship and funding of clinical trials by these organizations, as our resources and capital would not be sufficient to conduct these trials on our own. None of these third party sponsors are obligated to continue sponsorship or funding of any clinical trials involving our product candidates and could stop their support at any time. If these third party sponsors ceased their support for our product candidates, our ability to advance clinical development of our product candidates could be limited and we may not be able to pursue the number of different indications for our product candidates that are currently being pursued.

Even if these third party sponsors continue to sponsor and fund clinical trials of our product candidates, our reliance on their support subjects us to numerous risks. For example, we have limited control over the design or timing of their clinical trials and limited visibility into their day-to-day activities, including with respect to how they are providing and administering our product candidates. If there is a failure in a clinical trial sponsored by a third party sponsor due to poor design of the trial, errors in the way the clinical trial is executed or any other reason, or if the sponsor fails to comply with applicable regulatory requirements, it could represent a major set-back for the development and approval of our product candidates, even if we were not directly involved in the trial and even if the clinical trial failure was not related to the underlying safety or efficacy of the product candidate. In addition, these third party sponsors could decide to de-prioritize clinical development of our product candidates in relation to other projects, which could adversely affect the timing of further clinical development. We are also subject to various confidentiality obligations with respect to the clinical trials sponsored by third party sponsors, which could prevent us from disclosing current information about the progress or results from these trials until the applicable sponsor publicly disclose such information or permit us to do so. This may make it more difficult to evaluate our business and prospects at any given point in time and could also impair our ability to raise capital on our desired timelines.

### ***We are dependent on our license agreement with Santen to develop and commercialize our endoglin antibodies, including DE-122, in the field of ophthalmology. The failure to maintain our agreement with Santen or the failure of Santen to perform its obligations under the agreement, could negatively impact our business.***

Pursuant to the terms of our license agreement with Santen, we granted Santen an exclusive, worldwide license to certain patents, information and know-how related to our endoglin antibodies, including TRC105, which is referred to by Santen as DE-122, for development and commercialization in ophthalmology indications, excluding systemic treatment of ocular tumors. Consequently, our ability to realize value or generate any revenues from our endoglin antibodies in the field of ophthalmology depends on Santen's willingness and ability to develop and obtain regulatory approvals for and successfully commercialize product candidates using our technology for these indications. We have limited control over the amount and timing of resources that Santen will dedicate to these efforts. In particular, we will not be entitled to receive additional milestone or royalty payments from Santen absent further development and eventual commercialization of endoglin antibodies in ophthalmology indications.

We are subject to a number of other risks associated with our dependence on our license agreement with Santen, including:

- Santen may not comply with applicable regulatory requirements with respect to developing or commercializing products under the license agreement, which could adversely impact development, regulatory approval and eventual commercialization of such products;
- we and Santen could disagree as to future development plans and Santen may delay initiation of clinical trials or stop a future clinical trial;

- there may be disputes between us and Santen, including disagreements regarding the terms of the license agreement, that may result in the delay of or failure to achieve development, regulatory and commercial objectives that would result in milestone or royalty payments to us, the delay or termination of any future development or commercialization of endoglin antibodies using our technology in the field of ophthalmology, and/or costly litigation or arbitration that diverts our management's attention and resources;
- Santen may not provide us with timely and accurate information regarding development progress and activities under the license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our endoglin antibodies, including TRC105, in non-ophthalmology indications;
- business combinations or significant changes in Santen's business strategy may adversely affect Santen's ability or willingness to perform its obligations under the license agreement;
- Santen may not properly maintain or defend our intellectual property rights in the field of ophthalmology or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation; and
- the royalties we are eligible to receive from Santen may be reduced or eliminated based upon Santen's and our ability to maintain or defend our intellectual property rights.

The license agreement is subject to early termination, including through Santen's right to terminate without cause upon advance notice to us. If the agreement is terminated early, we may not be able to find another collaborator for the commercialization and further development of our endoglin antibodies for ophthalmology indications on acceptable terms, or at all, and we may otherwise be unable to pursue continued development on our own for these indications.

To the extent we enter into additional agreements for the development and commercialization of our product candidates we would likely be similarly dependent on the performance of those third parties and subject to similar risks.

***We may not be successful in establishing and maintaining additional collaborations, which could adversely affect our ability to develop and commercialize our product candidates.***

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into additional out-licensing and collaboration agreements, including potentially with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as having the requisite potential to demonstrate safety and efficacy and as being economically valuable in light of the terms that we are seeking and other available products for licensing by other companies. Due to our existing license agreement with Santen, we may find it more difficult to secure additional collaborations for our endoglin antibodies if major biotechnology or pharmaceutical companies would prefer to have exclusive control over development for all indications. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any inability or delay in entering into new collaboration agreements related to our product candidates, in particular in foreign countries where we do not have and do not intend to establish significant capabilities, could delay the development and commercialization of our product candidates and reduce their market potential.

***We rely on third parties to conduct preclinical studies and clinical trials of our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.***

We do not have our own capabilities to perform preclinical testing of our product candidates, and therefore rely entirely on third party contractors and laboratories to conduct these studies for us. In addition, while we intend to

continue designing, monitoring and managing our domestic Phase 1 and Phase 2 clinical trials of our product candidates using our clinical operations and regulatory team, we still depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials at their sites under agreements with us. In addition, we expect that we will need to rely on third party contract research organizations, or CROs, to assist in monitoring, managing and otherwise carrying out any portion of our Phase 2 clinical trials, or any future Phase 3 clinical trials, that we sponsor at sites outside the United States. We will compete with many other companies for the resources of these third party contractors, laboratories, investigators, collaborators and CROs, and the initiation and completion of our preclinical studies and Phase 2 or future Phase 3 clinical trials may be delayed if we encounter difficulties in engaging these third parties or need to change service providers during a study or trial.

We control only certain aspects of the activities conducted for us by the third parties on which we currently rely and on which we will rely in the future for our preclinical studies and clinical trials. Nevertheless, we are responsible for ensuring that each of our clinical trials and certain of our preclinical studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. With respect to clinical trials, we and these third parties are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with product candidates produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state health care laws, including, among others, fraud and abuse, false claims, privacy and security, and physician payment transparency laws. Any third parties conducting our preclinical studies and clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical development programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our preclinical studies and clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines.

***We rely on third party manufacturers to make our product candidates, and any failure by a third party manufacturer may delay or impair our ability to complete clinical trials or commercialize our product candidates.***

Manufacturing drugs and biologics is complicated and is tightly regulated by regulatory authorities, including the FDA and foreign equivalents. We currently rely on third party manufacturers to supply us, as well as other parties conducting studies and trials of our product candidates, such as NCI, Case Western and Santen, with drug substance for preclinical and clinical trials. We also expect to continue to rely on third party manufacturers for any drug substance required for commercial supply, and do not intend to build our own manufacturing capability. Moreover, the market for contract manufacturing services for drug products, especially biologics such as TRC105, is highly cyclical, with periods of relatively abundant capacity alternating with periods in which there is little available capacity. If any need we have for

contract manufacturing services increases during a period of industry-wide tight capacity, we may not be able to access the required capacity on a timely basis or on commercially viable terms, which could result in delays in initiating or completing clinical trials or our ability to apply for or receive regulatory approvals. In addition, we contract with fill and finishing providers with the appropriate expertise, facilities and scale to meet our needs.

Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is time consuming and subject to potential difficulties and delays. For example, we rely on Lonza Sales AG, or Lonza, to manufacture TRC105 drug substance for our on-going and planned clinical trials and separately license from Lonza its proprietary cell line and other methods of producing TRC105 drug substance. While we have the right to transfer the manufacture of TRC105 drug substance to additional or alternate suppliers and to sublicense Lonza's TRC105 manufacturing technology to such other suppliers, we may encounter delays in any such transfer due to the time and effort required for another party to understand and successfully implement Lonza's proprietary process. We are currently optimizing the process and transferring the manufacturing of TRC105 drug substance to a separate Lonza facility in order to meet cGMP regulatory requirements and scale production for commercial quantities. This new process and transfer may result in setbacks in replicating the current manufacturing process at a new facility and in scaling up production. In particular, for biologics, it is not uncommon to experience setbacks and delays in scaling up production in a reliable and contamination-free manner, which may delay our ability to obtain regulatory approval or may result in higher costs to manufacture commercial drug product than we currently expect. In addition, we do not have any long-term supply agreements for the manufacture of our product candidates and cannot guarantee that Lonza or any other third party manufacturer would be willing to continue supplying drug product for clinical trials or commercial sale at a reasonable cost or at all.

The facilities used by our current or future third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA or an NDA to the FDA. While we work closely with our third party manufacturers on the manufacturing process for our product candidates, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our third party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both drug substances and finished drug products. If our third party manufacturers cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or other third party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates.

#### **Risks Related to Our Intellectual Property**

***If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively.***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies which could do harm to our business and affect our ability to be profitable. In particular, our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. Additionally, we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Any disclosure or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in our market.

The patent position of biotechnology companies is generally uncertain because it involves complex legal and factual considerations in a legal framework that is constantly evolving. The standards applied by the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. There is a substantial amount of prior art in the biotechnology and pharmaceutical fields, including scientific publications, patents and patent applications. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If patent applications we hold or have in-licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us. Several patent applications covering our product candidates have been filed recently. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidate that we may develop. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate.

For applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the claims of our applications and patents. As of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear, what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. Furthermore, due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all our product candidates or methods involving these product candidates in the parent patent application.

In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords is limited. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic and biosimilar products.

Any loss of patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products.

***We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely impact our business and operations.\****

As of March 31, 2016, we are the exclusive licensee of ten issued U.S. patents and four pending U.S. patent applications and eight issued non-U.S. patents and six pending non-U.S. patent applications relating to “Anti-Endoglin Monoclonal Antibodies and their use in Antiangiogenic Therapy,” “Method For Increasing the Efficacy of Anti-Tumor Agents by Anti-Endoglin Antibody,” “Methoxyamine Potentiation of Temozolomide Anti-Cancer Activity,” “Methoxyamine Combinations in the Treatment of Cancer,” “Alkylating Agent Combinations in the Treatment of Cancer” and “Combination Therapy of Cancer with Anti-Endoglin Antibodies and Anti-VEGF Agents.”

As a licensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

***Third party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts.***

Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination and review proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we and our partners are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates, that we failed to identify. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our product candidates or methods of use of our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use or manufacture of our product candidates.

The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity requires a

showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also, in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

If any third party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we or our partner obtain a license. These licenses may not be available on acceptable terms, if at all. Even if we or our partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we or our partner could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our partner are unable to enter into licenses on acceptable terms.

Parties making claims against us or our partner may obtain injunctive or other equitable relief, which could effectively block our or our partner's ability to further develop and commercialize one or more of our product candidates. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Third parties may submit applications for patent term extensions in the United States and/or supplementary protection certificates in the European Union member states seeking to extend certain patent protection which, if approved, may interfere with or delay the launch of one or more of our products.

We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages.

During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

***We may become involved in lawsuits to protect or enforce our inventions, patents or other intellectual property or the patent of our licensors, which could be expensive and time consuming.***

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. In addition, one or more of our third party collaborators may have submitted, or may in the future submit, a patent application to the USPTO without naming a lawful inventor that developed the subject matter in whole or in part while under an obligation to execute an assignment of rights to us. As a result, we may be required to file infringement or inventorship claims to stop third party infringement, unauthorized use, or to correct inventorship. This can be expensive, particularly for a company of our size, and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation or other proceedings brought at the USPTO or any foreign patent authority may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or collaborators, to prevent misappropriation of our trade secrets, confidential information or proprietary 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 or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

***We have in-licensed a portion of our intellectual property, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.***

We are a party to a number of license agreements that are important to our business, and we may enter into additional license agreements in the future. Our product candidate TRC105 is protected by patents exclusively in-licensed from Roswell Park Cancer Institute. Our product candidate TRC102 is protected by patents exclusively licensed from Case Western.

Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our and our partner's ability to utilize the affected intellectual property in our drug development efforts, and our ability to enter into collaboration or marketing agreements for a product candidate, may be adversely affected.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the

enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

***Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.***

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our development processes that involve proprietary know-how or information that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business.

#### **Risks Related to Commercialization of Our Product Candidates**

***Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors and others in the medical community.***

The use of endoglin antibodies as a means of inhibiting angiogenesis, including in combination with VEGF inhibitors for the treatment of cancer, is a recent clinical development and may not become broadly accepted by

physicians, patients, hospitals, cancer treatment centers, third party payors and others in the medical community. Factors that will influence whether our product candidates are accepted in the market include:

- the clinical indications for which our product candidates are approved, if any;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by governmental and commercial third party payors;
- the willingness of patients to pay out-of-pocket in the absence of coverage by governmental and commercial third party payors;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, we expect that in oncology indications, TRC105 will be most effective as a combination treatment with VEGF inhibitors. If VEGF inhibitors become associated with presently unknown safety concerns, are withdrawn from the market or otherwise fall out of favor as cancer treatments among physicians, patients, hospitals, cancer treatment centers or others in the medical community, the market potential for TRC105 would likely be significantly harmed.

If, for any of these or other reasons, our product candidates fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

***We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.***

We face competition both in the United States and internationally, including from major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, other pharmaceutical and biotechnology companies, including Pfizer, Inc. and Acceleron Pharma Inc., have active programs to develop therapies targeting proteins in the endoglin pathway that would compete directly with certain of our product candidates, including TRC105. Many other companies are developing other cancer therapies that, if successful, could change the standard of care for cancer patients and relegate anti-angiogenesis therapy to a last-line or niche role or make it obsolete.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

Under the terms of our license agreement with Case Western, we obtained an exclusive, worldwide license to certain patents, know-how and other intellectual property controlled by Case Western related to TRC102. Despite our exclusive license, Case Western retained the right to grant non-exclusive licenses to third parties in the same field of use as our exclusive license as a means to settle any intellectual property disputes Case Western may have in the future with such third parties. While Case Western has not made us aware of any present intent to exercise this right, there can be no guarantee that Case Western will not do so in the future or that it would not grant such a non-exclusive license to a competitor of ours seeking to develop and commercialize a product that is identical to TRC102 in the same field of use that we are pursuing. If this were to occur, and we did not have other intellectual property outside of the Case Western license agreement to prevent competitive products for the same indications, we may face competition much earlier than we currently anticipate and the value of TRC102 may decline substantially.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from “biosimilars” due to the changing regulatory environment. In the United States, the Biologics Price Competition and Innovation Act created an abbreviated approval pathway for biological products that are demonstrated to be “highly similar,” or “biosimilar,” to or “interchangeable” with an FDA-approved biological product. This new pathway could allow competitors to reference data from biological products already approved after 12 years from the time of approval. Future FDA standards or criteria for determining biosimilarity and interchangeability, and FDA discretion to determine the nature and extent of product characterization, non-clinical testing and clinical testing on a product-by-product basis, may further facilitate the approval of biosimilar products and their ability to compete with our product candidates. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Any such event or further changes in the law could decrease the period for which we have exclusivity and consequently negatively impact our business and competitive position. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired.

Finally, as a result of the expiration or successful challenge of our patent rights, we could face litigation with respect to the validity and/or scope of patents relating to our competitors’ products. The availability of our competitors’ products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

***Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.***

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third party payors. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and other third party payors, such as commercial health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third party payor may depend upon a number of factors, including, but not limited to, the third party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Obtaining coverage and reimbursement approval of a product from a government or other third party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data to each payor separately for the use of our products, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of coverage and adequate reimbursement from third party payors for our product candidates.

***Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.***

Third party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, was enacted. The Affordable Care Act and its implementing regulations, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, including our product candidates, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit

reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain market acceptance in the medical community;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.***

Although we intend to establish a specialty sales and marketing organization to promote or co-promote TRC105 and/or TRC102 in North America, if approved in oncology indications, we currently have no such organization or capabilities, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, we must build sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services.

In addition, we do not intend to establish our own sales and marketing organizations outside the United States and will therefore depend on third parties to commercialize our product candidates outside of the United States. Any third parties upon which we rely for commercializing our product candidates may not dedicate sufficient resources to the commercialization effort or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective third party arrangements to enable the sale of our product candidates in territories outside of the United States, or if our potential future partners do not successfully commercialize our product candidates in these territories, our ability to generate revenue from product sales will be adversely affected.

If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all, when we are otherwise ready and able to commercially launch a product candidate. If we do not have sufficient funds, we will not be able to bring any product candidates to market or generate product revenue, including in the United States.

We and any partners that we may engage will be competing with many companies that currently have extensive and well-funded marketing and sales operations to commercialize alternative therapies. If we, alone or with

commercialization partners, are unable to compete successfully against these established companies, the commercial success of any approved products will be limited.

***If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.***

If TRC105 or other product candidates are approved for commercialization, we expect that we or our partners will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If we or our partners outside of the United States are unable to successfully manage these risks associated with international operations, the market potential for our product candidates outside the United States will be limited and our results of operations may be harmed.

#### **Risks Related to Our Business and Industry**

***If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.***

We do not have internal new drug discovery capabilities or a technology platform with which to develop novel product candidates. Unless we develop or acquire these capabilities or a technology platform, our only means of expanding our product pipeline will be to acquire or in-license product candidates that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring or licensing promising product candidates requires substantial technical, financial and human resources. Efforts to do so may not result in the actual development, acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

***If we fail to attract and keep senior management and key clinical operations and regulatory personnel, we may be unable to successfully develop our product candidates and execute our business strategy.***

We are highly dependent on members of our senior management, including Charles Theuer, M.D., Ph.D., our President and Chief Executive Officer. Our clinical development strategy and ability to directly manage or oversee our on-going and planned clinical trials are also dependent on the members of our clinical operations and regulatory team. The loss of the services of any of these persons could impede the development of our product candidates and our ability to execute our business strategy. We may be particularly impacted by the unexpected loss of employees due to our small employee base and limited ability to quickly shift responsibilities to other employees in our organization. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining other qualified employees for our business, including scientific, quality assurance and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense, particularly in the San Diego, California area, and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our development and strategic objectives.

***Our employees, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate:

- FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA;
- manufacturing standards;
- federal and state fraud and abuse laws and other healthcare laws;
- laws governing the conduct of business abroad; or
- laws that require the reporting of true and accurate financial information or data.

Additionally, these parties may fail to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***We may encounter difficulties in managing our growth and expanding our operations successfully.***

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with additional third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with partners, consultants, suppliers and other third parties. Future growth will impose significant added responsibilities on members of our management, including having to divert a disproportionate amount of its attention away from day-to-day operating activities to implement and manage future growth. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

***We are subject to extensive federal and state regulation, and our failure to comply with these laws could harm our business.***

Although we do not currently have any products on the market, we are subject to healthcare regulation and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal anti-kickback statute, which applies to our business activities, including our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or in return for the purchase or recommendation of any good, facility item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other governmental healthcare programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which created federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes certain regulatory and contractual requirements on covered entities and their business associates regarding the privacy, security and transmission of individually identifiable health information;
- federal “sunshine” requirements imposed by the Affordable Care Act, on certain drug manufacturers regarding any transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by such physicians and their immediate family members; and
- state or foreign law equivalents of each of the above federal laws that may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare

providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

It is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened certain of these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them to have committed a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, administrative, civil and/or criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

***We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.***

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We currently carry product liability insurance covering our clinical trials with limits we believe are customary for other companies in our field and stage of development. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

***If our third party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States and abroad governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability, including through obligations to indemnify our third party manufacturers, or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our development and production efforts or those of our third party manufacturers, which could harm our business, prospects, financial condition or results of operations.

***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

As of December 31, 2015, we had federal and California net operating loss carryforwards, or NOLs, of approximately \$42.9 million and \$22.9 million, respectively, which expire in various years beginning in 2030, if not utilized. As of December 31, 2015, we had federal and California research and development tax credit carryforwards of approximately \$1.7 million and \$0.7 million, respectively. The federal research and development tax credit carryforwards expire in various years beginning in 2031, if not utilized. The California research and development credit will carry forward indefinitely under current law. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We believe we have experienced certain ownership changes in the past and have reduced our deferred tax assets related to NOLs and research and development tax credit carryforwards accordingly. In the event that it is determined that we have in the past experienced additional ownership changes, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability.

***Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.***

Despite the implementation of security measures, our internal computer systems and those of our current or future contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, third parties that are also sponsoring clinical trials involving our product candidates, such as NCI and Case Western, could experience similar events relating to their computer systems, which could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

***Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.***

Our operations, and those of our contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. In addition, NCI may be affected by government shutdowns or withdrawn funding, which may lead to suspension or termination of ongoing NCI-sponsored clinical development of our product candidates. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. In addition, our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of our third party manufacturers, including Lonza, are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters are located in San Diego, California near major earthquake faults and fire zones. The ultimate impact on us and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

**Risks Related to Our Common Stock**

***The market price of our common stock may be highly volatile, and our stockholders may not be able to resell their shares at a desired market price and could lose all or part of their investment.***

Prior to our initial public offering which was completed in 2015, there was no public market for our common stock. We cannot assure you that an active, liquid trading market for our shares will develop or persist. Our stockholders may not be able to sell their shares quickly or at a recently reported market price if trading in our common stock is not active. The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in clinical trials;
- inability to obtain additional funding;
- any delay in filing a BLA or an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that BLA or NDA;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our product candidates;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, collaborations, joint ventures or capital commitments by us or our competitors;

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- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future, in particular any sales by significant stockholders or our affiliates; and
- trading volume of our common stock.

In addition, the stock market in general, and the Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.\****

As of March 31, 2016, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially owned approximately 50% of our voting stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

***We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.\****

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this Quarterly Report and our other periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least \$1 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

***We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

We completed our initial public offering on February 4, 2015. As a newly public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. For example, as a public company, we are now subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. We have incurred and will continue to incur costs associated with the preparation and filing of these reports. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC, and the Nasdaq Global Market have imposed various other requirements on public companies, and we have incurred and will continue to incur costs associated with compliance with such requirements. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in areas such as “say on pay” and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we incur substantial costs to maintain our current levels of such coverage.

***Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

***We are at risk of securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

***We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.***

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Additionally, our credit agreement with SVB contains covenants that restrict our ability to pay dividends. Any return to stockholders will therefore be limited to the appreciation of their stock.

***Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.***

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES**

**Recent Sales of Unregistered Securities**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1(1)	Amended and Restated Certificate of Incorporation, as currently in effect.
3.2(1)	Amended and Restated Bylaws, as currently in effect.
4.1(2)	Form of Common Stock Certificate of the Registrant.
4.2(2)	Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated September 19, 2014.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on February 4, 2015.

(2) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-201280), as amended.

**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.

**TRACON Pharmaceuticals, Inc.**

Date: May 11, 2016

\_\_\_\_\_  
*/s/ Charles P. Theuer, M.D., Ph.D.*

Charles P. Theuer, M.D., Ph.D.  
*President and Chief Executive Officer*  
*(principal executive officer)*

Date: May 11, 2016

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*/s/ Patricia L. Bitar, C.P.A.*

Patricia L. Bitar, C.P.A.  
*Chief Financial Officer*  
*(principal financial and accounting officer)*

**Exhibit Index**

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CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles P. Theuer, M.D., Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TRACON Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2016

/s/ Charles P. Theuer, M.D., Ph.D.  
Charles P. Theuer, M.D., Ph.D.  
President and Chief Executive Officer

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CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Patricia L. Bitar, CPA, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TRACON Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2016

/s/ Patricia L. Bitar, CPA  
Patricia L. Bitar, CPA  
Chief Financial Officer  
(Principal Financial Officer)

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

I, Charles P. Theuer, M.D., Ph.D., President and Chief Executive Officer of TRACON Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) this Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (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 Registrant.

Date: May 11, 2016

/s/ Charles P. Theuer, M.D., Ph.D.

Charles P. Theuer, M.D., Ph.D.  
President and Chief Executive Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

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

I, Patricia L. Bitar, CPA, Chief Financial Officer of TRACON Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) this Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (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 Registrant.

Date: May 11, 2016

/s/ Patricia L. Bitar, CPA  
Patricia L. Bitar, CPA  
Chief Financial Officer

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The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

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