
**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 SEPTEMBER 30, 2017

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)

**4350 La Jolla Village Drive, Suite 800,
San Diego CA**
(Address of principal executive offices)

34-2037594
(IRS Employer
Identification No.)

92122
(Zip Code)

(858) 550-0780
(Registrant's telephone number, including area code)

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, a smaller reporting company or an emerging growth company.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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 November 3, 2017 was 17,511,928.

TRACON Pharmaceuticals, Inc.

FORM 10-Q

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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)

	September 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,864	\$ 35,710
Short-term investments	3,000	8,703
Prepaid and other assets	1,441	1,235
Total current assets	37,305	45,648
Property and equipment, net	71	82
Total assets	<u>\$ 37,376</u>	<u>\$ 45,730</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,505	\$ 6,213
Accrued compensation and related expenses	1,325	1,588
Current portion of deferred revenue	—	1,259
Long-term debt, current portion	1,994	333
Final payment due bank	—	850
Total current liabilities	9,824	10,243
Other long-term liabilities	407	21
Long-term debt, less current portion	5,329	7,130
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, authorized shares — 10,000,000 at September 30, 2017 and December 31, 2016; issued and outstanding shares — none	—	—
Common stock, \$0.001 par value; authorized shares — 200,000,000 at September 30, 2017 and December 31, 2016; issued and outstanding shares — 17,393,056 and 16,084,721 at September 30, 2017 and December 31, 2016, respectively	17	16
Additional paid-in capital	119,940	113,918
Accumulated deficit	(98,141)	(85,598)
Total stockholders' equity	21,816	28,336
Total liabilities and stockholders' equity	<u>\$ 37,376</u>	<u>\$ 45,730</u>

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Collaboration revenue	\$ 7,498	\$ 815	\$ 8,755	\$ 2,832
Operating expenses:				
Research and development	4,257	4,531	14,732	16,799
General and administrative	1,847	1,881	5,879	5,934
Total operating expenses	6,104	6,412	20,611	22,733
Income (loss) from operations	1,394	(5,597)	(11,856)	(19,901)
Other income (expense):				
Interest expense, net	(223)	(287)	(681)	(871)
Other income (expense), net	(1)	13	(6)	78
Total other income (expense)	(224)	(274)	(687)	(793)
Net income (loss)	<u>\$ 1,170</u>	<u>\$ (5,871)</u>	<u>\$ (12,543)</u>	<u>\$ (20,694)</u>
Net income (loss) per share, basic and diluted	<u>\$ 0.07</u>	<u>\$ (0.48)</u>	<u>\$ (0.76)</u>	<u>\$ (1.70)</u>
Weighted-average shares outstanding, basic	<u>16,828,801</u>	<u>12,227,081</u>	<u>16,550,730</u>	<u>12,200,628</u>
Weighted-average shares outstanding, diluted	<u>17,137,311</u>	<u>12,227,081</u>	<u>16,550,730</u>	<u>12,200,628</u>

See accompanying notes.

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

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities		
Net loss	\$ (12,543)	\$ (20,694)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,398	2,339
Common stock issued for services	29	—
Depreciation and amortization	41	70
Amortization of debt discount	86	77
Amortization of premium/discount on short-term investments	(6)	4
Noncash interest	267	403
Deferred rent	54	(38)
Deferred revenue	(1,259)	(1,604)
Changes in assets and liabilities:		
Prepaid expenses and other assets	(206)	(128)
Accounts payable and accrued expenses	468	(1,619)
Accrued compensation and related expenses	(263)	25
Net cash used in operating activities	(10,934)	(21,165)
Cash flows from investing activities		
Purchase of property and equipment	(30)	(3)
Purchases of available-for-sale short-term investments	(8,994)	(8,802)
Proceeds from the maturity of available-for-sale short-term investments	14,705	14,117
Net cash provided by investing activities	5,681	5,312
Cash flows from financing activities		
Proceeds from long-term debt	8,000	—
Repayment of long-term debt	(8,850)	(1,000)
Proceeds from sale of common stock	3,610	5,000
Costs paid in connection with sales of common stock	(339)	—
Proceeds from issuance of common stock under equity plans	123	128
Payment of tax withholdings related to net share settlements of vested restricted stock awards	(137)	—
Net cash provided by financing activities	2,407	4,128
Decrease in cash and cash equivalents	(2,846)	(11,725)
Cash and cash equivalents at beginning of period	35,710	41,373
Cash and cash equivalents at end of period	<u>\$ 32,864</u>	<u>\$ 29,648</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 lead product candidate is an antibody that binds 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 and is currently inactive. All significant intercompany accounts and transactions have been eliminated.

Basis of Presentation and Going Concern

As of September 30, 2017, 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 September 30, 2017, the Company had an accumulated deficit of \$98.1 million. The Company anticipates that it will continue to incur net losses into the foreseeable future as it continues the development and commercialization of its product candidates and works to develop additional product candidates through research and development programs. At September 30, 2017, the Company had cash, cash equivalents and short-term investments of \$35.9 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 through mid-2018. The Company's ability to execute its operating plan beyond mid-2018 depends on its ability to obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements. The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. However, the Company's current working capital, anticipated operating expenses and net losses and the uncertainties surrounding its ability to raise additional capital as needed, as discussed below, raise substantial doubt about its ability to continue as a going concern for a period of one year following the date that these financial statements are issued. The condensed consolidated financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company plans to continue to fund its losses from operations through cash, cash equivalents and investments on hand, as well as through future equity offerings, debt financings, other third party funding, and potential licensing or collaboration arrangements, including equity financing through the common stock purchase agreement the Company entered into with Aspire Capital Fund, LLC in March 2017 for the purchase of up to \$21.0 million of the Company's stock over a 30 month period and/or the at-the-market equity offering sales agreement the Company entered into with Stifel, Nicolaus & Company, Incorporated in February 2016 for the sale of up to \$25.0 million of the Company's stock. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to the Company. Even if the Company raises additional capital, it may also be required to modify, delay or abandon some of its plans which could have a material adverse effect on the Company's business, operating results and financial condition and the Company's ability to achieve its intended business objectives. 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 September 30, 2017, and for the three and nine months ended September 30, 2017 and 2016, 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, 2016, included in its Annual Report on Form 10-K filed with the SEC on March 1, 2017.

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 it 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, expenses incurred for clinical trials 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. The carrying amounts approximate fair value due to the short maturities of these investments. 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.

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.

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 consolidated statements of operations.

Milestones

The Company uses the milestone method of accounting and revenue is recognized when earned, as evidenced by written acknowledgment 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, clinical sites, contract research organizations (CROs), and consultants 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.

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 clinical trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through discussion with the clinical sites and applicable personnel and outside service providers as to the progress or state of consummation 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 clinical sites, 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 and nine months ended September 30, 2017 and 2016, 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 (RSUs) 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. The Company estimates the fair value of stock option grants and ESPP rights using the Black-Scholes option pricing model. The fair value of RSUs is based on the stock price on the date of grant.

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 Income (Loss)

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

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average shares of common stock outstanding for the period, as adjusted for the weighted-average number of common shares outstanding that are subject to repurchase. The Company has excluded 3,368 and 6,980 weighted-average shares subject to repurchase or forfeiture from the weighted-average number of common shares outstanding for the three and nine months ended September 30, 2017, respectively, and 7,013 and 5,663 weighted-average shares subject to repurchase for the three and nine months ended September 30, 2016, respectively. Diluted net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of common shares outstanding and the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method.

The following table sets forth a reconciliation of basic and diluted net income (loss) per share (in thousands, except share and per share amount):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Numerator:				
Net income (loss)	\$ 1,170	\$ (5,871)	\$ (12,543)	\$ (20,694)
Denominator:				
Weighted average common shares outstanding for basic	16,828,801	12,227,081	16,550,730	12,200,628
Dilutive potential common stock outstanding:				
Stock options	308,510	—	—	—
Weighted average common shares outstanding for diluted	17,137,311	12,227,081	16,550,730	12,200,628
Basic and diluted net income (loss) per share	\$ 0.07	\$ (0.48)	\$ (0.76)	\$ (1.70)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Warrants to purchase common stock	103,865	57,173	103,865	57,173
Common stock options and RSUs	1,993,207	1,977,988	2,506,246	1,977,988
ESPP shares	—	—	4,871	3,079
	2,097,072	2,035,161	2,614,982	2,038,240

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 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 plans on adopting this ASU using the modified retrospective approach and is continuing to evaluate the potential impact that this standard will have on its financial position and results of operations.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which outlines a comprehensive lease accounting model and supersedes the current lease guidance. The new accounting standard requires lessees to recognize lease liabilities and corresponding right-of-use assets for all leases with lease terms of greater than twelve months. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The new accounting standard must be adopted using the modified retrospective approach and is effective for public entities for annual reporting periods beginning after December 15, 2018 with early adoption permitted. The Company does not expect the adoption of ASU 2016-02 to have a material impact on its financial statements and related disclosures.

Recently Adopted Accounting Standards

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 was effective for public entities for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. The Company adopted the standard in the first quarter of 2017, and has made an accounting policy change to record forfeitures as they occur, which resulted in no change to its financial statements and related disclosures.

2. Short-Term Investments, Cash Equivalents and Fair Value Measurements

At September 30, 2017, short-term investments consisted of U.S. treasury securities. 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. 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 September 30, 2017, the remaining contractual maturities of all available-for-sale investments were less than one year.

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.

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 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.

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

Cash equivalents and short-term investments, all of which are classified as available-for-sale securities, consisted of the following (in thousands):

	September 30, 2017				December 31, 2016			
	Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value	Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	\$ 7,463	\$ —	\$ —	\$ 7,463	\$ 3,188	\$ —	\$ —	\$ 3,188
Certificates of deposit	—	—	—	—	3,655	—	—	3,655
U.S. treasury securities	3,000	—	—	3,000	16,503	—	—	16,503
	<u>\$ 10,463</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10,463</u>	<u>\$ 23,346</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 23,346</u>
Classified as:								
Cash equivalents				\$ 7,463				\$ 14,643
Short-term investments				3,000				8,703
Total cash equivalents and short-term investments				<u>\$ 10,463</u>				<u>\$ 23,346</u>

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)
At September 30, 2017				
U.S. treasury securities and money market funds, included in cash equivalents and short-term investments	<u>\$ 10,463</u>	<u>\$ —</u>	<u>\$ 10,463</u>	<u>\$ —</u>
At December 31, 2016				
Certificates of deposit, U.S. treasury securities and money market funds, included in cash equivalents and short-term investments	<u>\$ 23,346</u>	<u>\$ —</u>	<u>\$ 23,346</u>	<u>\$ —</u>

3. Property and Equipment

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

	September 30, 2017	December 31, 2016
Computer and office equipment	\$ 124	\$ 115
Furniture and fixtures	19	19
Leasehold improvements	21	124
	164	258
Less accumulated depreciation and amortization	(93)	(176)
	<u>\$ 71</u>	<u>\$ 82</u>

Depreciation expense related to property and equipment totaled approximately \$7,000 and \$23,000 for the three months ended September 30, 2017 and 2016, respectively, and \$41,000 and \$70,000 for the nine months ended September 30, 2017 and 2016, respectively.

4. Long-Term Debt

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

	September 30, 2017	December 31, 2016
Long-term debt	\$ 8,000	\$ 8,000
Less debt discount, net of current portion	(271)	(537)
Long-term debt, net of debt discount	7,729	7,463
Less current portion of long-term debt	(2,400)	(333)
Long-term debt, net of current portion	\$ 5,329	\$ 7,130
Current portion of long-term debt	\$ 2,400	\$ 333
Current portion of debt discount	(406)	—
Current portion of long-term debt, net	\$ 1,994	\$ 333

In January 2017, the Company entered into a second amendment to its Amended and Restated Loan and Security Agreement with Silicon Valley Bank (the 2017 Amended SVB Loan) under which the Company borrowed \$8.0 million, all of which was immediately used to repay the Company's existing loan with SVB (the 2015 Amended SVB Loan). In accordance with the terms of the 2015 Amended SVB Loan, the Company paid a final payment of \$0.9 million associated with the pay off of the 2015 Amended SVB Loan. The transaction was accounted for as a debt modification.

The 2017 Amended SVB Loan provides for interest to be paid at a rate of 8.55% per annum. Interest-only payments are due monthly through December 2017, which will be extended through June 2018 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 December 31, 2017 (or June 30, 2018, as applicable) divided by 30 months. At maturity (or earlier prepayment), the Company is also required to make a final payment equal to 4.0% of the original principal amount borrowed.

The 2017 Amended SVB Loan provides for prepayment fees of 3.0% of the outstanding balance of the loan if the loan is repaid prior to January 26, 2018, 2.0% of the amount prepaid if the prepayment occurs after January 25, 2018 but prior to January 25, 2019 and 1.0% of the amount prepaid if the prepayment occurs thereafter.

Except as described above, the 2017 Amended SVB Loan is subject to the same material terms set forth in the 2015 Amended SVB Loan agreement. Consistent with the terms of the 2015 Amended SVB Loan agreements, the 2017 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 2017 Amended SVB Loan.

In connection with the 2017 Amended SVB Loan, the Company issued SVB a warrant to purchase 46,692 shares of its common stock at an exercise price of \$5.14 per share. The warrant is fully exercisable and expires on January 25, 2024. The fair value of the warrant and the final payment related to the 2017 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 2015 Amended SVB Loan.

At September 30, 2017, the Company had the following exercisable outstanding warrants for the purchase of common stock issued in connection with the Company's loan agreements with SVB:

Expiration	Number of shares	Exercise price
November 14, 2023 through June 4, 2024	38,758	\$ 7.74
May 13, 2022	18,415	\$ 10.86
January 25, 2024	46,692	\$ 5.14
	<u>103,865</u>	

Future minimum principal and interest payments under the 2017 Amended SVB Loan, including the final payment, as of September 30, 2017 are as follows (in thousands):

Remaining 2017	\$	172
2018		3,766
2019		3,489
2020		1,961
		<u>9,388</u>
Less interest and final payment		<u>(1,388)</u>
Long-term debt	\$	<u>8,000</u>

5. Commitments and Contingencies

Lonza Biologics Tuas Pte Ltd (Lonza)

On February 22, 2017, the Company entered into a long-term manufacturing agreement, or the Manufacturing Agreement, with Lonza for the long term manufacture and supply of registration and commercial batches of TRC105, the Company's lead drug product candidate. Under the Manufacturing Agreement, Lonza has agreed to manufacture TRC105 pursuant to purchase orders and in accordance with the manufacturing specifications agreed upon between the Company and Lonza. The Company is required to purchase certain batches of TRC105 prior to regulatory approval with a total estimated cost of approximately \$15.0 million. Following regulatory approval, the Company will be required to purchase a specified minimum number of batches annually with a total annual estimated cost of approximately \$22.0 million. If the Company cancels any purchase orders, the Company may be obligated to pay certain cancellation fees. In addition, the Company will be obligated to pay a milestone fee to Lonza upon the earlier of the first approval of TRC105 by the U.S Food and Drug Administration (FDA) or European Medicines Agency (EMA) or the Company's receipt of a complete response letter or non-approvability letter (or equivalent communication) indicating that the rejection of the marketing application was not due to a deficiency in Lonza's facility, the manufacturing process or services performed by Lonza.

The Manufacturing Agreement has an initial term beginning on the effective date and ending on the seventh anniversary of the date of first regulatory approval of TRC105 by the FDA or EMA. The Manufacturing Agreement may be renewed for an additional three years upon the written agreement of both parties no later than the fifth anniversary of the date of first approval of TRC105 by the FDA or EMA.

Either party may terminate the Manufacturing Agreement due to a material breach of the Manufacturing Agreement by the other party, subject to prior written notice and a cure period, due to the insolvency or bankruptcy of the other party, or due to a force majeure event that prevents performance under the Manufacturing Agreement for at least six months. The Company may terminate the Manufacturing Agreement, subject to 60 days' written notice, if the Company discontinues the TRC105 program, whether due to a notice of non-approval or withdrawal of marketing approval by a regulatory agency or otherwise. In the event of a termination by the Company due to discontinuation of the TRC105 program or a termination by Lonza due to the Company's material breach or insolvency or bankruptcy, the Company would be obligated to pay to Lonza certain batch cancellation and/or early termination fees.

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/or sublicensing fees. Each of the license agreements is generally cancelable by the Company, given appropriate prior written notice. At September 30, 2017, potential future milestone payments under these agreements, including future milestone payments associated with assets acquired from Janssen Pharmaceutica N.V. should they not exercise their option to regain their rights to certain assets as discussed in Note 7, totaled an aggregate of approximately \$126.0 million.

6. Stockholders' Equity

Sales of Common Stock

In March 2017, the Company entered into a Common Stock Purchase Agreement (the Purchase Agreement) with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations, Aspire Capital is committed to purchase up to an aggregate of \$21.0 million of shares of the Company's common stock. Under the terms of the Purchase Agreement, the Company sold 222,222 shares of the Company's common stock to Aspire Capital at \$4.50 per share for net

proceeds of approximately \$0.9 million upon execution of the Purchase Agreement and Aspire Capital is committed to purchase up to \$20.0 million of additional shares of its common stock solely at TRACON's request from time to time during a 30 month period beginning on May 1, 2017 and at prices based on the market price at the time of each sale, subject to certain conditions. In consideration for entering into the Purchase Agreement and concurrently with the execution of the Purchase Agreement, the Company issued 195,726 shares of its common stock to Aspire Capital.

In February 2016, the Company entered into an At-the-Market Equity Offering Sales Agreement (Sales Agreement) with Stifel, Nicolaus & Company, Incorporated (Stifel), pursuant to which it may sell from time to time, at its option, up to an aggregate of \$25.0 million of the Company's shares of its common stock through Stifel, as sales agent. The Company is required to pay Stifel 2.5% of gross proceeds for the common stock sold through the Sales Agreement. During the three and nine months ended September 30, 2017, the Company sold approximately 737,000 shares of common stock through the Sales Agreement with Stifel for gross proceeds of approximately \$2.6 million, and approximately \$22.4 million of common stock remains available for sale under the Sales Agreement, subject to limitations on the amount of securities the Company may sell under its effective registration statement on Form S-3 within any 12 month period.

During the nine months ended September 30, 2017, the Company issued 53,756 shares of common stock upon the exercise of outstanding stock options and 74,044 shares of common stock upon the vesting of restricted stock units. The Company withheld shares of common stock on the vesting date of certain restricted stock units to settle the employees' minimum statutory tax obligations for income and other related employment taxes, the payment of which is reported as a financing activity in the unaudited Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2017. During the year ended December 31, 2016, the Company issued 9,300 shares of common stock upon the exercise of outstanding stock options.

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Risk-free interest rate	—%	—%	2.1%	1.6%
Expected volatility	—%	—%	83%	78%
Expected term (in years)	—	—	6.2	6.3
Expected dividend yield	—%	—%	—%	—%

No stock options were granted to employees during the three months ended September 30, 2017 and 2016. Stock compensation expense for the ESPP was immaterial for the three and nine months ended September 30, 2017.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	\$ 379	\$ 85	\$ 1,104	\$ 795
General and administrative	418	453	1,294	1,544
	<u>\$ 797</u>	<u>\$ 538</u>	<u>\$ 2,398</u>	<u>\$ 2,339</u>

7. Collaborations

Santen

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 also 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 were delivered during the 41-month period over which the Company provided technical and regulatory support to Santen. At inception and through September 30, 2017, 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 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 recognized revenue for the fixed or determinable collaboration consideration on a straight-line basis over the 41-month period over which it delivered its technical and regulatory support.

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. During the nine months ended September 30, 2017 and the year ended December 31, 2015, development milestones that were deemed substantive milestones at the inception of the arrangement were achieved, and accordingly, the milestone payments of \$7.0 million and \$3.0 million, respectively, were recognized as revenue. 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 \$7.5 million and \$0.8 million for the three months ended September 30, 2017 and 2016, respectively, and \$8.8 million and \$2.8 million for the nine months ended September 30, 2017 and 2016, respectively.

Janssen Pharmaceutica N.V. (Janssen)

In September 2016, the Company entered into a license and option agreement with Janssen (the License and Option Agreement) under which Janssen granted the Company a license to technology and intellectual property to develop, manufacture and commercialize two compounds: a small molecule inhibitor of androgen receptor and androgen receptor mutations (the AR Mutant

Program or TRC253) which is intended for the treatment of men with prostate cancer, and an inhibitor of NF-kB inducing kinase (the NIK Program or TRC694, and, together with the AR Mutant Program, the Programs).

With respect to the AR Mutant Program, Janssen maintains an option, which is exercisable until 90 days after the Company demonstrates clinical proof of concept, to regain the rights to the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the AR Mutant Program. If Janssen exercises the option, Janssen will be obligated to pay the Company (i) a one-time option exercise fee of \$45.0 million; (ii) regulatory and commercial based milestone payments totaling up to \$137.5 million upon achievement of specified events; and (iii) royalties in the low single digits on annual net sales of AR Mutant Program products. If Janssen does not exercise the option, the Company would then have the right to retain worldwide development and commercialization rights to the AR Mutant Program, in which case, the Company would be obligated to pay to Janssen (x) development and regulatory based milestone payments totaling up to \$45.0 million upon achievement of specified events, and (y) royalties in the low single digits based on annual net sales of AR Mutant Program products, subject to certain specified reductions.

With respect to the NIK Program, Janssen maintains a right, which is exercisable within 90 days following the date on which the Company demonstrates clinical proof of concept with respect to the NIK Program, to negotiate exclusively for a period of six months for a reversion of the related rights in the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the NIK Program. If Janssen does not exercise its right of first negotiation, or, if after exercise of such right, the Company and Janssen are unable to reach an agreement on the terms of a reversion and exclusive license, and, in either case, the Company continues the development of the NIK Program, then the Company would be obligated to pay Janssen (i) development and regulatory based milestone payments totaling up to \$60.0 million upon achievement of specified events, and (ii) royalties in the low single digits based on annual net sales of NIK Program products, subject to certain specified reductions.

No consideration was exchanged for these assets on the acquisition date. Given the early preclinical stage of development of these assets and the low likelihood of success of development through regulatory approval on the acquisition date, no value was assigned to these assets in the accompanying consolidated balance sheet.

The Company is obligated to use diligent efforts to develop the Programs according to agreed upon development plans, timelines and budgets. For each Program that the Company retains, the Company is further obligated to use commercially reasonable efforts to develop, obtain marketing approval for, and commercialize licensed products. Until the expiration or earlier termination of the development term of the AR Mutant Program or the NIK Program, as applicable, under the License and Option Agreement, subject to specified exceptions, the Company has agreed not to research, develop or commercialize any compounds or products related to the AR Mutant Program or the NIK Program, as applicable, other than pursuant to the collaboration with Janssen.

The License and Option Agreement may be terminated for uncured breach, bankruptcy, or the failure or inability to demonstrate clinical proof of concept with respect to a particular Program during specified timeframes. In addition, the License and Option Agreement will automatically terminate (a) with respect to the AR Mutant Program, upon Janssen exercising its option in respect of the AR Mutant Program and making payment of the option exercise fee to the Company or, if Janssen does not exercise the option, upon the expiration of all payment obligations of the Company to Janssen with respect of the AR Mutant Program, and (b) with respect to the NIK Program, upon the Company and Janssen entering into an exclusive license agreement following Janssen's exercise of its right of first negotiation or, if Janssen's right of first negotiation with respect to the NIK Program expires and the Company and Janssen have not entered into an exclusive license agreement, upon the expiration of all payment obligations of the Company to Janssen with respect of the NIK Program. The Company may also terminate a Program or the License and Option Agreement in its entirety without cause, subject to specified conditions.

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

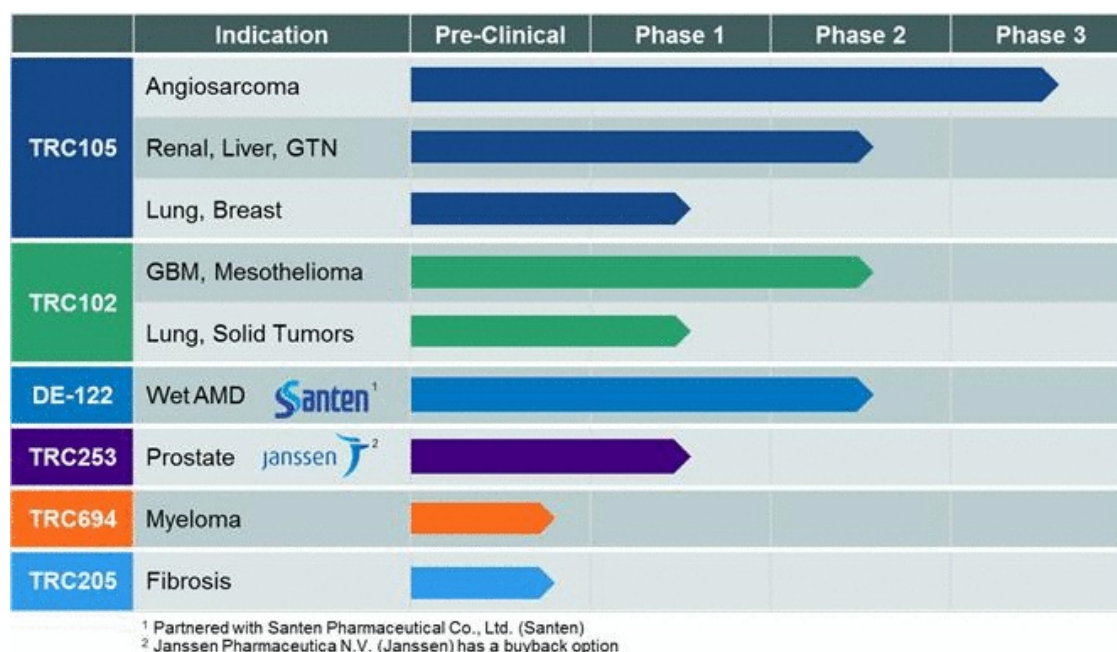
We are a biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration, or wet AMD, and fibrotic diseases. We are a leader in the field of endoglin biology and are using our expertise to develop antibodies that bind to the endoglin receptor. Endoglin is essential to angiogenesis, the process of new blood vessel formation required for solid cancer growth and wet AMD, and a key contributor to the development of fibrosis, or tissue scarring. We are developing our lead product candidate, TRC105 (carotuximab), an endoglin antibody, 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. We believe treatment with TRC105 in combination with VEGF inhibitors may improve survival in cancer patients when compared to treatment with a VEGF inhibitor alone. TRC105 has been studied in eight completed Phase 2 clinical trials and three completed Phase 1 clinical trials, and is currently being dosed in one Phase 3 clinical trial, three Phase 2 clinical trials and three Phase 1 clinical trials. Our TRC105 oncology clinical development plan is broad and involves a tiered approach. We are initially focused on angiosarcoma which is a tumor that highly expresses endoglin, the target of TRC105, and therefore may be more responsive to treatment with TRC105. We have seen complete ongoing responses in this tumor type and have initiated dosing in an international multicenter Phase 3 trial in angiosarcoma. We obtained Special Protocol Assessment (SPA) agreement from the US Food and Drug Administration (FDA) on our clinical trial design for the Phase 3 trial in angiosarcoma and also incorporated scientific advice from the European Medicines Agency (EMA) regarding the adequacy of the trial design. We also received orphan drug designation from the FDA and the EMA for TRC105 for the treatment of soft tissue sarcoma, including angiosarcoma, in 2016.

Our other product candidates are TRC205, a preclinical endoglin antibody for the treatment of fibrotic diseases, TRC102, which is a small molecule that is in Phase 2 clinical development for the treatment of mesothelioma and glioblastoma, and two compounds that we licensed from Janssen Pharmaceutica N.V. (Janssen) in September 2016: TRC253, which is a small molecule for which we initiated a Phase 1/2 clinical trial for the treatment of metastatic castration-resistant prostate cancer in March 2017, and TRC694, a small molecule in pre-clinical development for the treatment of myeloma. In March 2014, Santen Pharmaceutical Co. Ltd. (Santen) licensed from us exclusive worldwide rights to develop and commercialize our endoglin antibodies for ophthalmology indications, and in July 2017 Santen initiated dosing in a Phase 2 clinical trial of DE-122 in wet AMD.

TRC102 is a small molecule in clinical development to reverse resistance to specific chemotherapeutics by inhibiting base-excision repair, or BER. In initial clinical trials of more than 100 patients, TRC102 has shown good tolerability and promising anti-tumor activity, in combination with alkylating and antimetabolite chemotherapy in the treatment of lung cancer and glioblastoma. TRC102 began Phase 2 testing in mesothelioma in combination with the approved chemotherapeutic Alimta in 2015 and began Phase 2 testing in glioblastoma in combination with the approved chemotherapeutic Temodar in 2016. TRC102 is also being studied in three Phase 1 or Phase 1/2 clinical trials: in combination with Alimta and cisplatin in mesothelioma patients, in combination with chemoradiation in lung cancer patients, and in combination with Temodar in ovarian, lung and colorectal cancer patients. All current TRC102 trials are sponsored and funded by the National Cancer Institute, or NCI. We retain global rights to develop and commercialize TRC102 in all indications.

We have collaborated with the NCI, which selected TRC105 and TRC102 for federal funding of clinical development, as well as Case Western Cancer Center (Case Western) and the University of Alabama – Birmingham. Under these collaborations, NCI sponsored or is sponsoring ten completed or ongoing clinical trials of TRC105 and TRC102, Case Western sponsored two clinical trials of TRC102 and the University of Alabama – Birmingham is sponsoring one clinical trial of TRC105. All TRC105 NCI sponsored trials have been completed. If merited by Phase 2 data, we expect to fund additional 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 our pipeline of product candidates:



The following table summarizes key information regarding ongoing and planned development of our product candidates:

	Phase	Data Expected
TRC105		
Ongoing trials:		
Angiosarcoma	Phase 3	Interim analysis second half 2018
Renal Cell Carcinoma	Randomized Phase 2	First half 2018
Soft Tissue Sarcoma (including angiosarcoma)	Phase 2	Second half 2017
Gestational Trophoblastic Neoplasia (GTN)	Phase 2	2018
Hepatocellular Carcinoma	Phase 1/2	2018
Lung Cancer (with Opdivo)	Phase 1	2018
Breast Cancer	Phase 1/2	2018
Lung Cancer	Phase 1	2018
Wet AMD (Santen) (DE-122)	Phase 1/2	First half 2018
Wet AMD (Santen) (DE-122)	Phase 2	2019
TRC102		
Ongoing trials:		
Mesothelioma	Phase 2	2018
Glioblastoma	Phase 2	2018
Solid tumors	Phase 1	2018
Solid tumors (Oral) and Lymphomas	Phase 1/2	2018
Lung Cancer	Phase 1	2018
TRC253		
Ongoing trials:		
Prostate Cancer	Phase 1/2	2018

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. To date, we have not generated any revenue from product sales and instead, have funded our operations from the sales of capital stock, payments received in connection with our collaboration with Santen and commercial bank debt under our credit facilities with Silicon Valley Bank (SVB). At September 30, 2017, we had cash, cash equivalents and short-term investments totaling \$35.9 million.

We have incurred losses from operations in each year since our inception. Our net losses were \$27.0 million and \$24.4 million for the years ended December 31, 2016 and 2015, respectively. At September 30, 2017, we had an accumulated deficit of \$98.1 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;
- manufacture preclinical study and clinical trial materials and prepare for potential commercial manufacture of TRC105;
- continue our research and development efforts;
- maintain, expand and protect our intellectual property portfolio; and
- seek regulatory approvals for our product candidates that successfully complete clinical trials.

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.

2017 Developments

In October, two posters highlighting TRC105 were presented at the 18th World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer (IASLC) in Yokohama, Japan. Initial data from patients in the ongoing Phase 1b study of TRC105 in combination with Avastin® (bevacizumab) and chemotherapy for the treatment of non-squamous cell lung cancer were presented. Three of eight (37%) evaluable patients had partial responses by Response Evaluation Criteria in Solid Tumors (RECIST) 1.1, including one patient who achieved an 81% reduction in tumor volume. The study's complete enrollment of approximately 18 patients is expected by the end of 2018. In addition, investigators at the University of Alabama-Birmingham presented a "trials in progress" poster which detailed the study design of the Phase 1b dose-escalation trial of TRC105 and Opdivo® (nivolumab) in patients with metastatic non-small cell lung cancer that is open for accrual.

In October, we initiated a Phase 1 trial of TRC105 in combination with Opdivo (nivolumab) in patients with non-small cell lung cancer. The primary outcome of the trial is to determine the safety and tolerability of TRC105 in combination with Opdivo in order to determine a dose for a Phase 2 trial. Endoglin is expressed on activated myeloid derived suppressor cells, and we have observed encouraging activity of TRC105, or its preclinical surrogate antibody, in combination with programmed cell death protein 1 (PD-1) inhibitors in preclinical syngeneic mouse tumor models. We expect that these preclinical data will be presented at a scientific conference in 2018.

In September, we announced the completion of enrollment in the randomized Phase 2b TRC105 and Axitinib in Advanced Renal cell carcinoma (TRAXAR) study that compares treatment with TRC105 and Inlyta® (axitinib) to treatment with single agent Inlyta in patients with clear cell renal cell cancer. Our current tracking of total combined events across both treatment arms indicates we will not achieve the projected 115 events of progression or death by central radiographic review, which will decrease the statistical power of the trial. A planned futility analysis was cancelled by the study's Independent Data Monitoring Committee given we had completed enrollment. We will continue to monitor total events confirmed by central review in order to continue assessing the

expected timing of the data release and we currently expect to report top line progression free survival (PFS) data from the study in the first half of 2018.

In July, Santen initiated a Phase 2a clinical study of DE-122, the ophthalmic formulation of our TRC105 antibody, for the treatment of patients with wet AMD. The Phase 2a AVANTE study is a randomized controlled trial assessing the efficacy and safety of repeated intravitreal injections of DE-122 in combination with Lucentis® (ranibizumab) compared to Lucentis monotherapy in patients with wet AMD. The initiation of the Phase 2a study triggered Santen's obligation to pay a \$7.0 million milestone payment to us which we received in the third quarter. We expect Santen to report data showing the assessment of safety and bioactivity of DE-122 in refractory wet-AMD patients from the Phase 1/2 PAVE study in the first half of 2018.

In June, we reported the following positive clinical results from multiple studies with TRC105 and TRC102 at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting in Chicago, Illinois:

- In our Phase 1b trial of TRC105 with Votrient® (pazopanib) in patients with soft tissue sarcoma, it was observed that patients who had greater than a 10% reduction in tumor volume following treatment with TRC105 and Votrient were significantly more likely to have lower baseline levels of soluble intracellular adhesion molecule-1 (ICAM-1) ($p=0.018$) and thrombospondin-2 ($p=0.041$). We plan to separately assess these biomarkers as part of the completed 63 patient Phase 2 trial of TRC105 and Votrient in soft tissue sarcoma and in our ongoing randomized Phase 3 trial of TRC105 and Pazopanib versus Pazopanib alone in patients with advanced AngioSarcoma (TAPPAS).
- In our Phase 1b trial of TRC105 with Inlyta in patients with renal cell carcinoma, it was observed that patients with a partial response by RECIST 1.1 following treatment with TRC105 and Inlyta were more likely to have lower levels of soluble osteopontin ($p=0.026$) and higher levels of soluble transforming growth factor- β receptor III ($p=0.0028$). We plan to assess these biomarkers as part of the ongoing randomized Phase 2 TRAXAR study of TRC105 and Inlyta in patients with renal cell carcinoma.
- The NCI reported data from a Phase 1 trial of TRC102 in combination with Temodar in patients with refractory solid tumors. Based on partial responses in patients with ovarian cancer, non-small cell lung cancer, and KRAS-positive colorectal cancer, the NCI decided to enroll expansion cohorts in each of these tumor types at the recommended Phase 2 oral dose of TRC102. The authors concluded that the combination of Temodar and TRC102 is active, and DNA damage response markers (Rad51, γ -H2AX and/or pNbs1) were induced in four of five paired colonic biopsies, indicating DNA damage following treatment.

In May, we initiated dosing in our Phase 1/2 clinical trial of TRC253 in patients with metastatic castration-resistant prostate cancer. TRC253 is a novel, orally bioavailable small molecule high affinity competitive inhibitor of the androgen receptor (AR) and AR mutations.

In May, the NCI published the results of its completed Phase 1/2 trial of TRC105 and Nexavar® (sorafenib) in patients with hepatocellular cancer (HCC) online in the journal Clinical Cancer Research, which was subsequently published in the September 2018 hard copy edition. These data assessed the overall response rate (ORR) by RECIST across four dose groups. All observed responses occurred in the two highest dose groups, in which 5 of 15 (33%) patients demonstrated a response. Four patients had confirmed stable disease, one of whom was treated for 22 months. Median PFS was 3.8 months (95% CI: 3.2-5.6 months) and median overall survival (OS) was 15.5 months (95% CI: 8.5-26.3 months). Nexavar was approved for the treatment of patients with advanced HCC based on median OS of 10.7 months (95% CI: 9.4-13.3 months) versus 7.9 months (95% CI: 6.8-9.1 months) with placebo in the multicenter SHARP trial. The ORR for Nexavar treatment by RECIST in the SHARP trial was 2%.

In April, Dr. Rita Perlingeiro, Professor of Medicine at the University of Minnesota, and colleagues published preclinical data online in the journal Blood, that was subsequently published in the May 4, 2017 hard copy edition. These data demonstrated endoglin expression in the majority of blasts from patients with acute myeloid leukemia (AML) and B-cell acute lymphoblastic leukemia (B-cell ALL), and that endoglin expressing blasts had superior leukemogenic activity. The researchers further demonstrated that TRC105 prevented the engraftment of primary AML blasts and inhibited leukemic progression following disease establishment. In both AML and B-cell ALL, TRC105 showed synergy with reduced intensity myeloablative chemotherapy to inhibit leukemogenesis.

In April, preclinical data for TRC694, our small molecule inhibitor of NF- κ B inducing kinase (NIK), were presented at the annual meeting of the American Association for Cancer Research. The data demonstrated that TRC694 potently inhibits NIK in vitro and potently inhibits human myeloma and lymphoma cell lines in vivo. We expect to file an Investigational New Drug application, or IND, for TRC694 in 2018.

In March, we entered into a Common Stock Purchase Agreement with Aspire Capital Fund, LLC (Aspire Capital) providing for the sale of up to \$21.0 million of shares of our common stock. Under the terms of the Agreement, Aspire Capital made an initial

purchase of \$1.0 million of our common stock at \$4.50 per share. In addition, Aspire Capital has committed to purchase up to \$20.0 million of additional shares of our common stock at our request from time to time during a 30-month period beginning on May 1, 2017 and at prices based on the market price of our common stock at the time of each sale.

In February, we initiated dosing in the TAPPAS trial. In January 2017, we announced that it received a SPA agreement from the FDA. The SPA covers the protocol design, clinical endpoints and statistical analysis approach used for the TAPPAS trial. The TAPPAS trial was awarded “Most Innovative Trial Design” for Phase 3 at the 2017 Clinical and Research Excellence Awards. The trial is designed to enroll 124 patients to provide greater than 80% power to determine an improvement in median progression free survival, or PFS, from 4.0 to 7.3 months using a two-tailed alpha of 0.05, and includes an adaptive design, whereby the conditional power determined at the time of interim analysis may dictate an increase in the sample size to a total of 200 patients or the enrollment of 100 additional patients with cutaneous disease only. Specifically, we expect to conduct an interim analysis when 40 events have occurred in approximately 70 patients. At that time, the result will be categorized as belonging to either favorable, promising, enrichment or unfavorable zones, based on conditional power. The sample size and PFS events needed to complete the trial will be left unchanged in the favorable and unfavorable zones, but will be increased to a total of 200 patients in the promising zone. This will allow more than 80% power to detect a less robust, but still clinically meaningful improvement in PFS between the two arms. In the enrichment zone, the trial would enroll an additional 100 patients with cutaneous disease only, resulting in a total of 170 patients, which would preserve the power to detect the original treatment effect between the two arms in patients with cutaneous disease. We expect the interim analysis to be completed in the second half of 2018.

With respect to our international multicenter Phase 2 trial in GTN, given the limited commercial opportunity in this very rare indication that is cured with chemotherapy in the majority of cases, we have reduced planned enrollment in the trial from 30 patients to five patients and will no longer pursue a registration path in GTN at this time. We will continue to enroll patients in separate compassionate use investigator sponsored protocols. We expect to present data from these patients in 2018.

Collaboration and License Agreements

Janssen Pharmaceutica N.V.

During September 2016, we entered into a strategic licensing collaboration with Janssen for two novel oncology assets from Janssen’s early oncology development portfolio. The agreement grants us the rights to develop TRC253 (formerly JNJ-63576253), a novel small molecule high affinity competitive inhibitor of wild type androgen receptor (AR Mutant Program) and multiple AR mutant receptors which display drug resistance to approved treatments, which is intended for the treatment of men with prostate cancer, and TRC694 (formerly JNJ-6420694), a novel, potent, orally bioavailable inhibitor of NF-κB inducing kinase (the NIK Program and, together with the AR Mutant Program, the Programs), which is intended for the treatment of patients with hematologic malignancies, including myeloma.

Janssen maintains an option, which is exercisable until 90 days after we demonstrate clinical proof of concept with respect to the AR Mutant Program, to regain the rights to the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the AR Mutant Program. If Janssen exercises the option, Janssen will be obligated to pay us (i) a one-time option exercise fee of \$45.0 million; (ii) regulatory and commercial based milestone payments totaling up to \$137.5 million upon achievement of specified events; and (iii) royalties in the low single digits on annual net sales of AR Mutant Program products. If Janssen does not exercise the option, we would then have the right to retain worldwide development and commercialization rights to the AR Mutant Program, in which case, we would be obligated to pay to Janssen (x) development and regulatory based milestone payments totaling up to \$45.0 million upon achievement of specified events, and (y) royalties in the low single digits based on annual net sales of AR Mutant Program products, subject to certain specified reductions.

With respect to the NIK Program, Janssen maintains a right, which is exercisable within 90 days following the date on which we demonstrate clinical proof of concept with respect to the NIK Program, to negotiate for a period of six months for a reversion of the related rights in the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the NIK Program. If Janssen does not exercise its right of first negotiation, or, if after exercise of such right, Janssen and we are unable to reach an agreement on the terms of a reversion and exclusive license, and, in either case, we continue the development of the NIK Program, then we would be obligated to pay Janssen (i) development and regulatory based milestone payments totaling up to \$60.0 million upon achievement of specified events, and (ii) royalties in the low single digits based on annual net sales of NIK Program products, subject to certain specified reductions.

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 (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 September 30, 2017, we had received \$10.0 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 recognized 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, whether and when Janssen reacquires rights to the AR Mutant Program and/or NIK Program 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:

- salaries and employee-related expenses, including stock-based compensation and benefits for personnel in research and development functions;
- costs incurred under clinical trial agreements with investigative sites;
- costs to acquire, develop and manufacture preclinical study and clinical trial materials;
- 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;
- payments related to licensed products and technologies; and
- facilities, depreciation and other expenses, including allocated expenses for rent and maintenance of facilities.

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(in thousands)			
Third-party research and development expenses:				
TRC105	\$ 2,390	\$ 2,944	\$ 8,423	\$ 11,487
TRC253	305	102	750	102
TRC102	22	97	65	395
TRC694	48	95	342	95
TRC205	—	29	15	71
Total third-party research and development expenses	2,765	3,267	9,595	12,150
Unallocated expenses	1,492	1,264	5,137	4,649
Total research and development expenses	<u>\$ 4,257</u>	<u>\$ 4,531</u>	<u>\$ 14,732</u>	<u>\$ 16,799</u>

Unallocated expenses consist primarily of our internal personnel related and facility costs.

We expect our current level of research and development expenses to continue to increase for the foreseeable future as we continue development of TRC105, including our Phase 3 clinical trial in angiosarcoma, continue development activities for our licensed compounds, TRC253 and TRC694, including our Phase 1/2 clinical trial in TRC253 castration-resistant prostate cancer, and initiate manufacturing activities required for regulatory approval for TRC105.

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;
- the extent to which costs for comparator drug are borne by third parties;
- 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 legal services, including those associated with obtaining and maintaining patents, insurance, occupancy costs, accounting services, and the cost of various consultants.

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, 2016.

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the Financial Accounting Standard Board (FASB) issued Accounting Standards Update (ASU) 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 plan on adopting ASU 2014-09 using the modified retrospective approach and are continuing to evaluate the potential impact that this standard will have on our financial position and results of operations.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which outlines a comprehensive lease accounting model and supersedes the current lease guidance. The new accounting standard requires lessees to recognize lease liabilities and corresponding right-of-use assets for all leases with lease terms of greater than twelve months. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The new accounting standard must be adopted using the modified retrospective approach and is effective for public entities for annual reporting periods beginning after December 15, 2018 with early adoption permitted. We do not expect the adoption of ASU 2016-02 to have a material impact on our financial statements and related disclosures.

Recently Adopted Accounting Standards

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. We adopted ASU 2016-09 in the first quarter of 2017 and made an accounting policy change to record forfeitures as they occur, which resulted in no change to our financial statements and related disclosures.

Results of Operations

Comparison of the Three Months Ended September 30, 2017 and 2016

The following table summarizes our results of operations for the three months ended September 30, 2017 and 2016:

	Three Months Ended September 30,		Change
	2017	2016 (in thousands)	
Collaboration revenue	\$ 7,498	\$ 815	\$ 6,683
Research and development expenses	4,257	4,531	(274)
General and administrative expenses	1,847	1,881	(34)
Other income (expense)	(224)	(274)	50

Collaboration revenue. Collaboration revenue was \$7.5 million and \$0.8 million for the three months ended September 30, 2017 and 2016, respectively. The increase of \$6.7 million was primarily due to the achievement of a development milestone by Santen in July 2017 in connection with our collaboration, which triggered a \$7.0 million milestone payment.

Research and development expenses. Research and development expenses were \$4.3 million and \$4.5 million for the three months ended September 30, 2017 and 2016, respectively.

General and administrative expenses. General and administrative expenses were \$1.8 million and \$1.9 million for the three months ended September 30, 2017 and 2016, respectively.

Other income (expense). Other expense was \$0.2 million and \$0.3 million for the three months ended September 30, 2017 and 2016, respectively.

Comparison of the Nine Months Ended September 30, 2017 and 2016

The following table summarizes our results of operations for the nine months ended September 30, 2017 and 2016:

	Nine Months Ended September 30,		Change
	2017	2016 (in thousands)	
Collaboration revenue	\$ 8,755	\$ 2,832	\$ 5,923
Research and development expenses	14,732	16,799	(2,067)
General and administrative expenses	5,879	5,934	(55)
Other income (expense)	(687)	(793)	106

Collaboration revenue. Collaboration revenue was \$8.8 million and \$2.8 million for the nine months ended September 30, 2017 and 2016, respectively. The increase of \$5.9 million was primarily due to the achievement of a development milestone by Santen in July 2017 in connection with our collaboration, which triggered a \$7.0 million milestone payment.

Research and development expenses. Research and development expenses were \$14.7 million and \$16.8 million for the nine months ended September 30, 2017 and 2016, respectively. The decrease of \$2.1 million was due primarily to decreased TRC105 drug manufacturing expenses in 2017, offset by increased direct clinical trial expenses due to the initiation of the Phase 3 in angiosarcoma.

General and administrative expenses. General and administrative expenses were \$5.9 million for the nine months ended September 30, 2017 and 2016.

Other income (expense). Other expense was \$0.7 million and \$0.8 million for the nine months ended September 30, 2017 and 2016, respectively.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception. As of September 30, 2017, we had an accumulated deficit of \$98.1 million, and we expect to continue to incur net losses for the foreseeable future. We expect that our research and development 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.

Common Stock Purchase Agreement with Aspire Capital Fund, LLC

In March 2017, we entered into a common stock purchase agreement (the Purchase Agreement) with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations of the Purchase Agreement, Aspire Capital is committed to purchase up to an aggregate of \$21.0 million of shares of our common stock. Upon execution of the Purchase Agreement, we sold to Aspire Capital 222,222 shares of common stock at \$4.50 per share for proceeds of \$1.0 million and Aspire Capital is committed to purchase up to \$20.0 million of additional shares of our common stock at our request from time to time during a 30 month period beginning on May 1, 2017 and at prices based on the market price of our common stock at the time of each sale, subject to certain conditions. In consideration for entering into the Purchase Agreement and concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 195,726 shares of our common stock. As of September 30, 2017, we had issued 417,948 shares of common stock to Aspire Capital under the Purchase Agreement for net proceeds of approximately \$0.9 million after offering expenses.

Credit Facility with SVB

In January 2017, we entered into a second amendment to our Amended and Restated Loan and Security Agreement with SVB (the 2017 Amended SVB Loan) under which we borrowed \$8.0 million, all of which was used to refinance previously outstanding amounts under the loan and security agreement. In connection with the 2017 Amended SVB Loan, we issued warrants to purchase up to 46,692 shares of common stock at an exercise price of \$5.14 per share. The warrants are fully exercisable and expire on January 25, 2024.

The 2017 Amended SVB Loan provides for interest to be paid at a rate of 8.55% per annum, with interest-only payments due monthly through December 31, 2017 which will be extended through June 30, 2018 in the event certain funding and clinical development conditions are met. Thereafter, in addition to interest accrued during such period, the monthly payments include an amount equal to the outstanding principal at December 31, 2017 or June 30, 2018, as applicable, divided by 30 months. At maturity (or earlier prepayment), we are also required to make a final payment equal to 4.0% of the original principal amounts borrowed. The 2017 Amended SVB Loan provides for prepayment fees of 3.0% of the amount prepaid if the prepayment occurs prior to January 26, 2018, 2.0% of the amount prepaid if the prepayment occurs after January 26, 2018 but prior to January 25, 2019, and 1.0% of the amount prepaid if the prepayment occurs thereafter.

The 2017 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 all obligations under the 2017 Amended SVB Loan.

ATM Facility with Stifel, Nicolaus & Company, Incorporated

In February 2016, we entered into a Sales Agreement with Stifel pursuant to which we may sell from time to time, at our option, up to an aggregate of \$25.0 million of 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 2.5% of the gross proceeds of the sales price for common stock sold under the Sales Agreement. As of September 30, 2017, approximately 737,000 shares of our common stock have been sold under the Sales Agreement and approximately \$22.4 million of common stock remains available to be sold, subject to limitations on the amount of securities we may sell under our effective registration statement on Form S-3 within any 12 month period.

Cash Flows

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

	Nine Months Ended September 30,	
	2017	2016
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (10,934)	\$ (21,165)
Investing activities	5,681	5,312
Financing activities	2,407	4,128
Decrease in cash and cash equivalents	<u>\$ (2,846)</u>	<u>\$ (11,725)</u>

Operating activities. Net cash used in operating activities was \$10.9 million and \$21.2 million for the nine months ended September 30, 2017 and 2016, respectively, and was primarily due to our net loss and changes in our working capital, offset by non-cash charges including stock-based compensation.

Investing activities. Net cash provided by investing activities was \$5.7 million and \$5.3 million for the nine months ended September 30, 2017 and 2016, respectively, and was primarily due to maturities of short-term investments, offset by purchases of these investments.

Financing activities. Net cash provided by financing activities was \$2.4 million during the nine months ended September 30, 2017 and primarily resulted from \$3.3 million in net proceeds received from the issuance of common stock offset by \$0.9 million in net repayments on borrowings under our SVB loan agreement. Net cash provided by financing activities was \$4.1 million during the nine months ended September 30, 2016 and primarily resulted from \$5.0 million in proceeds received from the sale of our common stock to Johnson & Johnson Innovation-JJDC, Inc, offset in part by \$1.0 million in repayments under our SVB loan agreement.

Funding Requirements

At September 30, 2017, we had cash, cash equivalents and short-term investments totaling \$35.9 million. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our anticipated cash requirements through mid-2018. We will need additional funding to complete the development and commercialization of our product candidates, specifically our lead product candidate, TRC105, including to complete our ongoing Phase 3 trial in angiosarcoma. In addition, we may evaluate in-licensing and acquisition opportunities to gain access to new product candidates that fit with our strategy. Any such transaction will likely increase our future funding requirements. We may not be successful in raising sufficient additional capital to continue to operate our business. These uncertainties raise substantial doubt about our ability to continue as a going concern for a period of one year following the date that the accompanying financial statements were issued.

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;
- Santen's ability and willingness to continue clinical development of DE-122;
- our ability to enter into and maintain our collaborations, including our collaborations with Santen and Janssen;
- 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;
- whether and when Janssen reacquires the rights to the AR Mutant Program and/or the NIK Program;
- 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. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. Even if we raise additional capital, we may also be required to modify, delay or abandon some of our plans which could have a material adverse effect on our business, operating results and financial condition and our ability to achieve our intended business objectives. Any of these actions could materially harm our business, results of operations and future prospects.

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

At September 30, 2017, our cash and cash equivalents consist of cash, money market funds and U.S. treasury obligations. 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 2017 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 September 30, 2017, 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 September 30, 2017, 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, 2016. 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 \$27.0 million and \$24.4 million for the years ended December 31, 2016 and 2015, respectively. At September 30, 2017, we had an accumulated deficit of \$98.1 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.

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. There is substantial doubt as to our ability to continue as a going concern.*

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 and TRC253, and conduct manufacturing activities for TRC105.

At September 30, 2017, we had cash, cash equivalents and short-term investments totaling \$35.9 million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital requirements through mid-2018. We will need additional funding to complete the development and commercialization of our product candidates, specifically our lead product candidate, TRC105, including for the completion of our Phase 3 trial in angiosarcoma. In addition, in 2016 we licensed two early-stage oncology programs from Janssen Pharmaceutica N.V. (Janssen) and are subject to obligations to develop the programs through clinical proof of concept. While we concurrently received a \$5.0 million equity investment from an affiliate of Janssen that will help fund the costs of the development activities, we anticipate that we will need additional funds to complete clinical proof of concept for the programs and, to the extent we retain the programs

afterwards, to advance the programs through later stages of development. As more fully discussed in Note 1 to the condensed consolidated financial statements included in this report, the uncertainties around our ability to obtain additional funding raise substantial doubt regarding our ability to continue as a going concern for a period of one year following the date that these financial statements were issued.

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.

In February 2016, we entered into an At-the-Market Equity Offering Sales Agreement, or the Stifel 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, subject to limitations on the amount of securities we may sell under our effective registration statement on Form S-3 within any 12 month period. In March 2017, we entered into a Common Stock Purchase agreement, or the Aspire Agreement, with Aspire Capital Fund, LLC, or Aspire, pursuant to which, upon the terms and subject to the conditions and limitations set forth in the Aspire Agreement, Aspire committed to purchase up to an aggregate of \$21.0 million of shares of our common stock at our request from time to time. While the Stifel and Aspire agreements provide us with additional options to raise capital through sales of our common stock, there can be no guarantee that we will be able to sell shares under either agreement in the future, or that any sales will generate sufficient proceeds to meet our capital requirements. In particular, Stifel is under no obligation to sell any shares of our common stock that we may request to be sold under the Stifel Agreement from time to time, and while Aspire is obligated to purchase shares of our common stock under the Aspire Agreement, the obligation is subject to our satisfaction of various conditions which we may not be able to meet in the future. If sales are made under either the Stifel Agreement or Aspire Agreement, our existing stockholders may experience dilution and such sales, or the perception that such sales are or will be occurring, may cause the trading price of our common stock to decline.

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 January 2017, we entered into an amended loan and security agreement with SVB to borrow up to \$8.0 million, all 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 3 and Phase 2 development 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. We obtained Special Protocol Assessment (SPA) agreement from the FDA on our clinical trial design for the Phase 3 trial of TRC105 in angiosarcoma, but that agreement may not ensure that the FDA approves TRC105 for angiosarcoma, even if the trial is successful. In addition, while we have the right to terminate our long-term manufacturing agreement with Lonza Sales AG, or Lonza, if we were to cease the TRC105 program, we may still be required to pay batch cancellation fees that could harm our financial position and ability to continue development of our other drug candidates. Even if TRC105 is approved, if it is not approved in indications that justify the minimum number of batches we are required to purchase from Lonza following regulatory approval, our ability to commercialize TRC105 profitably would be harmed.

*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. For example, we recently determined that we will not achieve the projected 115 events of progression or death by central radiographic review, which will decrease the statistical power of our ongoing randomized Phase 2 clinical trial of TRC105 and Inlyta in renal cell carcinoma, which will decrease the power of the trial to detect a statistically significant improvement in efficacy versus Inlyta alone. 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 clinical trials of TRC105 demonstrate unexpected safety issues, do not achieve the primary efficacy endpoints or are terminated prior to completion due to analysis of interim results, 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 enrollment caused by the availability of alternative treatments;
- 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 in our ability to acquire 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. TRC253 has not previously been tested in humans, and it is possible that we could observe AEs in our Phase 1 study of TRC253 that would preclude further development or cause Janssen to not exercise its option to regain rights to the program.

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, which expresses high levels of endoglin. We previously analyzed endoglin expression on archival tumor tissue across various sarcoma subtypes and did not find a correlation between endoglin expression and response to TRC105 treatment in sarcoma subtypes other than angiosarcoma. We believe that this analysis may have limited utility due to tumor heterogeneity, the long period of time between sampling and treatment, and the effects of tumor evolution resulting from prior treatment. If we are unable to establish a correlation between endoglin expression and response to TRC105 treatment in subsequent analyses or to identify additional tumor types that express endoglin, our ability to successfully identify target patient populations for future clinical development or to expand TRC105's market potential may be limited.

We also expect to target specific patient populations with TR253 and TRC694 and expect to continue to develop companion diagnostic tests in prostate cancer and myeloma, respectively, to improve selection of susceptible patients. If we are unable to establish a companion diagnostic for either of these treatments, our ability to successfully identify target patient populations for future clinical development may 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 2016 in the US and EU and we intend to seek orphan drug designation for our eligible product candidates in other indications. 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. For example, we have withdrawn our previously filed application for orphan drug designation in GTN. However, we may refile the

application in the future. 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 hampered.

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 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 with drug substance for preclinical and clinical trials. Moreover, the market for contract manufacturing services for drug products, including biologics such as TRC105 and small molecules such as TRC253 and TRC694, 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.

For TRC105, we have relied on Lonza for drug substance clinical supply manufacture. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including filling into vials, shipping and storage. For our clinical stage pipeline programs, while we believe that our existing supplies of drug product and our contract manufacturing relationships will be sufficient to accommodate clinical trials through Phase 3 for TRC105, Phase 2 for TRC102, and to proof of concept for TRC253, there can be no guarantee that lack of clinical supplies will not force us to delay or terminate any of our ongoing or planned clinical trials.

We also expect to continue to rely on third party manufacturers for any drug required for commercial supply, and do not intend to build our own manufacturing capability. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is costly, time consuming and subject to potential difficulties and delays. For example, we rely on Lonza to manufacture TRC105 drug substance 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 under specified conditions, 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. In February 2017 we entered into a long-term manufacturing agreement with an affiliate of Lonza for the manufacture of TRC105 drug substance intended for registration batches and future commercial supply if TRC105 receives regulatory approval. As part of the manufacturing agreement, we and Lonza will need to transfer the TRC105 manufacturing process to a separate Lonza facility. This transfer may result in setbacks in replicating the current manufacturing process at a new facility that has not previously manufactured TRC105. In particular, for biologics, it is not uncommon to experience setbacks and delays in process transfer, which may delay our ability to obtain regulatory approval or may result in higher costs to manufacture commercial drug product than we currently expect.

Other than our TRC105 manufacturing agreement with Lonza, 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. In addition, our manufacturing agreement with Lonza may be terminated early by Lonza if we are in material breach of the agreement, subject to prior written notice and a cure period, due to our insolvency or bankruptcy, or due to a force majeure event that prevents performance under the agreement for at least six months.

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, we may experience delays in initiating planned clinical trials and we may 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.

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 four clinical trials involving TRC102. The University of Alabama, Birmingham Cancer Center, or UAB, is also funding trials with TRC105 in breast cancer and lung cancer. In addition, Case Western has sponsored and funded two separate clinical trials involving TRC102. 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, execution 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 or there are errors in the reported data, 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 discloses such information or permits 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. For example, if Janssen exercises its option to reacquire rights to TRC253, we would be entitled to receive a pre-negotiated up-front fee from Janssen, but we would be dependent on Janssen to further develop the program in order to receive any further value in the form of milestone payments or royalties.

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 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. We will compete with many other companies for the resources of these third party contractors, laboratories, investigators, collaborators, and the initiation and completion of our preclinical studies and 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.

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 September 30, 2017, we are the exclusive licensee of six issued U.S. patents, one pending U.S. patent application, and ten issued non-U.S. patents and two 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.” We are also the exclusive licensee of pending applications, which have not yet published, related to TRC253 and TRC694.

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. TRC105 is protected by patents exclusively in-licensed from Roswell Park Cancer Institute. TRC102 is protected by patents exclusively licensed from Case Western. TRC253 and TRC694 and associated intellectual property have been licensed from Janssen.

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 or diligence obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our and our partners' 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. For example, the recent approval of Opdivo (nivolumab) and Cabometyx (cabozantinib) have decreased the use of Inlyta as a second line treatment in renal cell carcinoma.

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 or ACA, was enacted. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. The Trump administration has also announced that it will discontinue the payment of cost-sharing reduction (CSR) payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans

under the ACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain. Further, each chamber of Congress has put forth multiple bills this year designed to repeal or repeal and replace portions of the ACA, although none of these measures has been enacted by Congress to date. The Trump administration and Congress will likely continue to seek legislative and regulatory changes, including repeal and replacement of certain provisions of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

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 2025 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. Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products. 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 our product candidates 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. With respect to TRC253, Janssen has an option to reacquire the intellectual property rights to the program on pre-negotiated terms until a certain period of time following the completion of clinical proof of concept. If Janssen exercises this right, while we would be entitled to receive an up-front payment and would have the opportunity to receive future milestone and royalty payments from Janssen, we would have no further rights to develop, commercialize or realize value from TRC253. In addition, Janssen has an option to negotiate with us to reacquire rights to TRC694 following the completion of clinical proof of concept, which may or may not result in an out-license of the product candidate back to Janssen. If we are unable to retain existing product candidates and 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, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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, 2016, we had federal and California net operating loss carryforwards, or NOLs, of approximately \$69.1 million and \$44.0 million, respectively, which expire in various years beginning in 2030, if not utilized. As of December 31, 2016, we had federal and California research and development and Orphan Drug tax credit carryforwards of approximately \$3.6 million and \$1.1 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;
- 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 September 30, 2017, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially owned over 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.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1(1)	<u>Amended and Restated Certificate of Incorporation, as currently in effect.</u>
3.2(1)	<u>Amended and Restated Bylaws, as currently in effect.</u>
4.1(2)	<u>Form of Common Stock Certificate of the Registrant.</u>
4.2(2)	<u>Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated September 19, 2014.</u>
4.3(3)	<u>Investor Agreement by and between Johnson & Johnson Innovation-JJDC, Inc. and TRACON Pharmaceuticals, Inc., dated September 27, 2016.</u>
4.4(4)	<u>Registration Rights Agreement, dated March 14, 2017, by and between the Registrant and Aspire Capital Fund, LLC.</u>
4.5(4)	<u>Common Stock Purchase Agreement, dated March 14, 2017 by and between TRACON Pharmaceuticals, Inc. and Aspire Capital Fund, LLC.</u>
31.1	<u>Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.</u>
31.2	<u>Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.</u>
32.1	<u>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.</u>
32.2	<u>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.</u>
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

- (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.
- (3) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 9, 2016.
- (4) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on March 14, 2017.

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: November 7, 2017

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

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

Date: November 7, 2017

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

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

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2017

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

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2017

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

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: November 7, 2017

/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.

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: November 7, 2017

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

