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 JUNE 30, 2019

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	**34-2037594**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
4350 La Jolla Village Drive, Suite 800, San Diego CA	**92122**
(Address of principal executive offices)	**(Zip Code)**

(858) 550-0780

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	TCON	The NASDAQ Stock Market LLC

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

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 13(a) of the Exchange 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 August 2, 2019 was 29,937,457.

TRACON Pharmaceuticals, Inc.

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PART I FINANCIAL INFORMATION
Item 1. Financial Statements

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

	June 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 26,336	$ 25,136
Short-term investments	—	13,968
Prepaid and other assets	594	1,499
Total current assets	26,930	40,603
Property and equipment, net	32	45
Other assets	989	—
Total assets	$ 27,951	$ 40,648
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,466	$ 10,947
Accrued compensation and related expenses	937	1,464
Long-term debt, current portion	2,536	1,084
Total current liabilities	13,939	13,495
Other long-term liabilities	1,036	368
Long-term debt, less current portion	4,057	5,343
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.001 par value, authorized shares — 10,000,000 at June 30, 2019 and December 31, 2018; issued and outstanding shares — none	—	—
Common stock, $0.001 par value; authorized shares — 200,000,000 at June 30, 2019 and December 31, 2018; issued and outstanding shares — 29,937,457 and 29,871,327 at June 30, 2019 and December 31, 2018, respectively	30	30
Additional paid-in capital	162,088	161,072
Accumulated deficit	(153,199)	(139,660)
Total stockholders' equity	8,919	21,442
Total liabilities and stockholders' equity	$ 27,951	$ 40,648

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenue	$ —	$ —	$ —	$ 3,000
Operating expenses:				
Research and development	4,347	8,115	9,561	17,553
General and administrative	1,893	1,622	3,842	3,373
Total operating expenses	6,240	9,737	13,403	20,926
Loss from operations	(6,240)	(9,737)	(13,403)	(17,926)
Other income (expense):				
Interest expense, net	(87)	(23)	(133)	(192)
Other income (expense), net	1	6	(3)	—
Total other expense	(86)	(17)	(136)	(192)
Net loss	$ (6,326)	$ (9,754)	$ (13,539)	$ (18,118)
Net loss per share, basic and diluted	$ (0.21)	$ (0.33)	$ (0.45)	$ (0.76)
Weighted-average shares outstanding, basic and diluted	29,929,364	29,706,717	29,910,789	23,992,497

See accompanying notes.

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

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (13,539)	$ (18,118)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,012	1,370
Depreciation and amortization	13	14
Noncash interest	123	146
Amortization of debt discount	43	51
Amortization of premium/discount on short-term investments	(52)	(11)
Deferred rent	—	9
Deferred revenue	—	(3,000)
Changes in assets and liabilities:		
Prepaid expenses and other assets	905	97
Accounts payable and accrued expenses	(802)	3,683
Accrued compensation and related expenses	(527)	(673)
Net cash used in operating activities	(12,824)	(16,432)
Cash flows from investing activities		
Purchases of available-for-sale short-term investments	(4,980)	(18,923)
Proceeds from the maturity of available-for-sale short-term investments	19,000	5,000
Net cash provided by (used in) investing activities	14,020	(13,923)
Cash flows from financing activities		
Proceeds from long-term debt	—	7,000
Repayment of long-term debt	—	(8,320)
Proceeds from sale of common stock and warrants, net of offering costs	—	36,507
Proceeds from issuance of common stock under equity plans	24	213
Payment of tax withholdings related to net share settlements of vested restricted stock awards	(20)	(78)
Net cash provided by financing activities	4	35,322
Increase in cash and cash equivalents	1,200	4,967
Cash and cash equivalents at beginning of period	25,136	29,467
Cash and cash equivalents at end of period	$ 26,336	$ 34,434

See accompanying notes.

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 and, through its license to Santen Pharmaceutical Co. Ltd. (Santen), wet age-related macular degeneration, or wet AMD. The Company's product development platform, which emphasizes capital efficiency, also provides to ex-U.S. companies a rapid and capital-efficient U.S. drug development solution that includes U.S. and European Union (EU) clinical development expertise and U.S. commercialization expertise.

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, TRACON Pharma Limited and TRACON Pharma International Limited, which were formed in September 2015 and January 2019, respectively, and are currently inactive. All significant intercompany accounts and transactions have been eliminated.

Basis of Presentation

As of June 30, 2019, 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 June 30, 2019, the Company had an accumulated deficit of $153.2 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 June 30, 2019, the Company had cash and cash equivalents of $26.3 million. Based on the Company's current business plan, management believes that there is substantial doubt as to whether existing cash and cash equivalents will be sufficient to meet its obligations as they become due within one year from the date these financial statements are issued. The Company's ability to execute its operating plan through 2020 and beyond depends on its ability to obtain additional funding through equity offerings, debt financings, or potential licensing and collaboration arrangements. The accompanying unaudited 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 unaudited 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 and cash equivalents 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 common stock over a 30 month period, which expires in September 2019, and/or the Capital on Demand™ Sales Agreement (the Sales Agreement) the Company entered into with JonesTrading Institutional Services LLC (JonesTrading) in September 2018, as amended in February 2019, pursuant to which the Company could sell, at its option, up to an aggregate of $8.0 million of the Company's common stock, all of which remains available for sale. 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 June 30, 2019, and for the three and six months ended June 30, 2019 and 2018, 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. These unaudited condensed consolidated financial

statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2018, included in its Annual Report on Form 10-K filed with the SEC on March 1, 2019.

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. The most significant estimates in the Company's financial statements relate to revenue recognition and expenses incurred for clinical trials. 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.

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

To date, substantially all of the Company's revenue has been derived from its license agreements with Santen and Ambrx, Inc. (Ambrx) as described in Note 6. The terms of these arrangements include payments to the Company for the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. In accordance with ASU 2014-09, the Company performs the following five steps in determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of these agreements: (i) identification of the contract(s) with a customer; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including any constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as, the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services transferred to the customer. Once a contract is determined to be within the scope of Accounting Standards Codification 606, Revenue from Contracts with Customers, at contract inception, the Company assesses the goods or services promised within the contract to determine those that are performance obligations and assesses whether each promised good is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied.

As part of the accounting for these arrangements, the Company develops assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promised goods or services, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, the Company evaluates whether the achievement of the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. Performance milestone payments represent a form of variable consideration. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Achievement of milestones that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable until the approvals are achieved. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis and the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achieving such milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the outset of the arrangement.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its out-licensing arrangements.

The Company receives payments from its collaborators based on billing schedules established in each contract. Up-front and other payments may require deferral of revenue recognition to a future period until the Company performs its obligations under its collaboration arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

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 six months ended June 30, 2019 and 2018, 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 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. Equity award forfeitures are recorded as they occur.

Comprehensive Loss

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

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average shares of common stock outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted average number of common shares outstanding that are subject to repurchase. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

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

	June 30,	
	2019	2018
Warrants to purchase common stock	15,619,113	15,619,113
Common stock options and restricted stock units	4,368,911	3,125,753
ESPP shares	3,825	4,289
	19,991,849	18,749,155

Leases

The Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, operating leases are included in Other assets, Accounts payable and accrued expenses, and Other long-term liabilities within the consolidated balance sheet. The Company currently does not have any finance leases.

Operating lease right-of-use (ROU) assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. Lease terms may include options to extend or terminate when the Company is reasonably certain that the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term.

Recently Adopted Accounting Standards

In February 2016, the FASB issued ASU 2016-02, *Leases*, which outlines a comprehensive lease accounting model and supersedes the then current lease guidance. The new accounting standard requires lessees to recognize lease liabilities and corresponding ROU 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 adopted ASU 2016-02 on January 1, 2019, using the alternative modified transition method. Under this approach, financial information and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. The Company elected the 'package of practical expedients' upon adoption, which permits it to not reassess under the new standard prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect the use of hindsight or the practical expedient pertaining to land easements, the latter of which not being applicable. Upon adoption, the Company (i) recognized a ROU asset and lease liability on its balance sheet for its corporate office operating lease and (ii) derecognized the deferred rent balance as of December 31, 2018 under the superseded lease guidance. The ROU asset has been recorded within Other assets and the short-term and long-term lease liability has been recorded within Accounts payable and accrued expenses and Other long-term liabilities, respectively, of the condensed consolidated balance sheet. There was no impact on retained earnings or other components of equity, nor was there any impact on the statement of operations, upon adoption.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Accounting Standards Codification 718, *Compensation-Stock Compensation*, to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. The new accounting standard is effective for public entities for annual reporting periods beginning after December 15, 2018 with early adoption permitted. The

Company adopted ASU 2018-07 on January 1, 2019, which did not have a material impact on the condensed consolidated financial statements and related disclosures.

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

The Company classifies all investments as available-for-sale securities, 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 June 30, 2019, the Company had no short-term investments.

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

	June 30, 2019				December 31, 2018			
	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Money market funds	$ 5,001	$ —	$ —	$ 5,001	$ 5,832	$ —	$ —	$ 5,832
U.S. treasury securities	—	—	—	—	13,968	—	—	13,968
	$ 5,001	$ —	$ —	$ 5,001	$ 19,800	$ —	$ —	$ 19,800
Classified as:								
Cash equivalents				$ 5,001				$ 5,832
Short-term investments				—				13,968
Total Cash equivalents and Short-term investments				$ 5,001				$ 19,800

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 June 30, 2019				
Money market funds included in Cash equivalents	$ 5,001	$ —	$ 5,001	$ —
At December 31, 2018				
Money market funds and U.S. treasury securities, included in Cash equivalents and Short-term investments	$ 19,800	$ —	$ 19,800	$ —

3. Long-Term Debt

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

	June 30, 2019	December 31, 2018
Long-term debt	$ 7,000	$ 7,000
Less debt discount, net of current portion	(143)	(257)
Long-term debt, net of debt discount	6,857	6,743
Less current portion of long-term debt	(2,800)	(1,400)
Long-term debt, net of current portion	$ 4,057	$ 5,343
Current portion of long-term debt	$ 2,800	$ 1,400
Current portion of debt discount	(264)	(316)
Current portion of long-term debt, net	$ 2,536	$ 1,084

In May 2018, the Company entered into a third amendment to its Amended and Restated Loan and Security Agreement with Silicon Valley Bank (the 2018 Amended SVB Loan) under which the Company borrowed $7.0 million, all of which was immediately used to repay the Company's existing loan with SVB (the 2017 Amended SVB Loan). In accordance with the terms of the 2017 Amended SVB Loan, the Company paid a final payment of $0.3 million associated with the payoff of the 2017 Amended SVB Loan. The transaction was accounted for as a debt modification.

The 2018 Amended SVB Loan provides for interest to be paid at a rate of 9.0% per annum. Interest-only payments were due monthly through June 30, 2019. Thereafter, in addition to interest accrued during such period, the monthly payments include an amount equal to the outstanding principal at June 30, 2019 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 2018 Amended SVB Loan provides for prepayment fees of 2.0% of the amount prepaid if the prepayment occurs after May 3, 2019 but prior to May 3, 2020 and 1.0% of the amount prepaid if the prepayment occurs thereafter.

The 2018 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 2018 Amended SVB Loan. As of June 30, 2019, the Company was in compliance with all covenants and conditions of the 2018 Amended SVB Loan.

In connection with the 2018 Amended SVB Loan, the Company issued SVB a warrant to purchase 53,639 shares of its common stock at an exercise price of $2.61 per share. The warrant is fully exercisable and expires on May 3, 2025. The fair value of the warrant and the final payment related to the 2018 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 2017 Amended SVB Loan.

At June 30, 2019, 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
May 13, 2022	18,415	$ 10.86
November 14, 2023 through June 4, 2024	38,758	$ 7.74
January 25, 2024	46,692	$ 5.14
May 3, 2025	53,639	$ 2.61
	157,504	

Future minimum principal and interest payments under the 2018 Amended SVB Loan, including the final payment, are as follows (in thousands):

Remaining 2019	1,694
2020	3,195
2021	3,218
	8,107
Less interest and final payment	(1,107)
Long-term debt	$ 7,000

4. Commitments and Contingencies

Lonza Biologics Tuas Pte Ltd (Lonza)

On February 22, 2017, the Company entered into a long-term manufacturing agreement (Manufacturing Agreement) with Lonza for the long term manufacture and supply of registration and commercial batches of TRC105. Under the Manufacturing Agreement, Lonza agreed to manufacture TRC105 pursuant to purchase orders and in accordance with the manufacturing specifications agreed upon between the Company and Lonza. Following the announcement of the TAPPAS interim unblinded safety and efficacy data in April 2019, the Company exercised its right to terminate the Manufacturing Agreement as a result of its decision to terminate further TRC105 development in oncology. As a result of the discontinuation of TRC105, costs associated with certain batches prior to regulatory approval and batches following regulatory approval will not be incurred, however the Company will be obligated to pay for any costs incurred associated with work completed prior to the termination.

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 June 30, 2019, potential future milestone payments under these agreements, including future milestone payments associated with TRC253 acquired from Janssen Pharmaceutica N.V. (Janssen) should they not exercise their option to regain their rights to certain assets as discussed in Note 6, totaled an aggregate of approximately $66.0 million.

5. Stockholders' Equity

Stockholders' Equity

The following tables present the changes in stockholders' equity (in thousands, except share data):

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2018	29,871,327	$ 30	$ 161,072	$ (139,660)	$ 21,442
Issuance of common stock under equity plans	27,371	—	(20)	—	(20)
Stock-based compensation expense	—	—	596	—	596
Net loss	—	—	—	(7,213)	(7,213)
Balance at March 31, 2019	29,898,698	$ 30	$ 161,648	$ (146,873)	$ 14,805
Issuance of common stock under equity plans	38,759	—	24	—	24
Stock-based compensation expense	—	—	416	—	416
Net loss	—	—	—	(6,326)	(6,326)
Balance at June 30, 2019	29,937,457	$ 30	$ 162,088	$ (153,199)	$ 8,919

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2017	17,711,928	$ 18	$ 121,670	$ (104,701)	$ 16,987
Issuance of common stock under equity plans	38,019	—	(78)	—	(78)
Stock-based compensation expense	—	—	706	—	706
Vested shares related to repurchase liability	—	—	3	—	3
Issuances of common stock and warrants, net of offering costs	10,691,588	10	33,225	—	33,235
Net loss	—	—	—	(8,364)	(8,364)
Balance at March 31, 2018	28,441,535	$ 28	$ 155,526	$ (113,065)	$ 42,489
Issuance of common stock under equity plans	149,126	—	213	—	213
Stock-based compensation expense	—	—	664	—	664
Vested shares related to repurchase liability	—	—	3	—	3
Issuances of common stock and warrants, net of offering costs	1,238,937	2	3,341	—	3,343
Net loss	—	—	—	(9,754)	(9,754)
Balance at June 30, 2018	29,829,598	$ 30	$ 159,747	$ (122,819)	$ 36,958

Sales of Common Stock

In March and April 2018, the Company sold 11,930,525 shares of its common stock at a purchase price of $2.70 per share, warrants to purchase 1,765,542 shares of its common stock at a purchase price of $2.69 per share and an exercise price of $0.01 per share (the Pre-Funded Warrants) and warrants to purchase 13,696,067 shares of its common stock at a purchase price of $0.125 per share and an exercise price of $2.70 per share (the Common Warrants) for net proceeds of approximately $36.5 million in a private placement to new and certain existing accredited investors. In accordance with their terms, the Pre-Funded Warrants and the Common Warrants may not be exercised if the holder's ownership of the Company's common stock would exceed 9.99% or 19.99% of the Company's total shares outstanding following such exercise, depending on the investor. Both the Pre-Funded Warrants and the Common Warrants were recorded as a component of stockholders' equity within additional paid-in capital. In April 2018, in connection with this transaction, the Company paid Angel Pond Capital, an affiliate of a holder of more than 5% of the Company's common stock and an affiliate of a member of the Company's Board of the Directors at that time, a fee totaling approximately $1.9 million as consideration for acting as a nonexclusive placement agent for this financing.

At-The-Market Issuance Sales Agreement

In September 2018, the Company entered into the Sales Agreement, as amended in February 2019, with JonesTrading, pursuant to which it may sell from time to time, at its option, up to an aggregate of $8.0 million of the Company's shares of its common stock through JonesTrading, as sales agent. The Company is required to pay JonesTrading 2.5% of gross proceeds for the common stock sold through the Sales Agreement. During the three and six months ended June 30, 2019 and the year ended December 31, 2018, the Company sold no shares of common stock through the Sales Agreement with JonesTrading and $8.0 million of common stock remains available for sale under the Sales Agreement.

In September 2018, the Company terminated its At-the-Market Equity Offering Sales Agreement (Stifel Sales Agreement) with Stifel, Nicolaus & Company, Incorporated (Stifel). The Company had sold an aggregate of approximately $3.5 million of common stock through Stifel pursuant to the Stifel Sales Agreement prior to termination.

Equity Plan Activity

During the three and six months ended June 30, 2019, the Company issued no shares of common stock upon the exercise of outstanding stock options. During the three and six months ended June 30, 2019, the Company issued no shares and 27,371 shares, respectively, of common stock upon the vesting of restricted stock units. The Company withheld 18,934 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 six months ended June 30, 2019. During the three and six months ended June 30, 2019, the Company issued 38,759 shares of common stock in connection with the employee stock purchase plan. During the year ended December 31, 2018, the Company issued 136,720 shares of common stock upon the exercise of outstanding stock options, 38,019 shares of common stock upon the vesting of restricted stock units, and 54,135 shares of common stock in connection with the employee stock purchase plan.

Common Stock Warrants

As of June 30, 2019, the Company had the following outstanding warrants for the purchase of common stock:

Expiration	Number of shares		Exercise price
May 13, 2022	18,415	$	10.86
November 14, 2023 through June 4, 2024	38,758	$	7.74
January 25, 2024	46,692	$	5.14
March 27, 2024	13,696,067	$	2.70
March 27, 2025	1,765,542	$	0.01
May 3, 2025	53,639	$	2.61
	15,619,113		

During the three and six months ended June 30, 2019 and the year ended December 31, 2018, no warrants were exercised.

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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Risk-free interest rate	1.9%	2.7%	2.6%	2.8%
Expected volatility	87%	80%	81%	80%
Expected term (in years)	5.5	6.1	6.2	6.2
Expected dividend yield	—%	—%	—%	—%

Stock compensation expense for the ESPP was immaterial for the three and six months ended June 30, 2019 and 2018.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	$ 205	$ 375	$ 521	$ 739
General and administrative	211	289	491	631
	$ 416	$ 664	$ 1,012	$ 1,370

6. Collaborations

I-Mab

In November 2018, the Company and I-Mab Biopharma (I-Mab) entered into separate strategic collaboration and clinical trial agreements (the Collaboration Agreements) for the development of programs for multiple immuno-oncology product candidates, including I-Mab's proprietary CD73 antibody TJ004309 (the TJ004309 Agreement) as well as up to five proprietary bispecific antibodies currently under development by I-Mab (the Bispecific Agreement).

No consideration was exchanged in the Collaboration Agreements. Given the early preclinical stage of development of these assets as of the agreement date, no value was assigned to the Collaboration Agreements in the accompanying consolidated balance sheet.

TJ004309 Agreement

Pursuant to the TJ004309 Agreement, the Company and I-Mab will collaborate on developing the TJ004309 antibody, with the Company bearing the costs of filing an IND and for Phase 1 clinical trials, with the parties sharing costs equally for Phase 2 clinical trials, and with the Company and I-Mab bearing 40% and 60%, respectively, of the costs for pivotal clinical trials. I-Mab will be responsible for the cost of certain non-clinical activities, the drug supply of TJ004309, and any reference drugs used in the clinical trials. Each of the parties also agreed for a specified period of time to not develop or license to or from a third party any monoclonal antibody targeting CD73 or any other biologic for certain indications that a joint steering committee (JSC), as set up under the TJ004309 Agreement, selects for TJ004309 development.

In the event that I-Mab out-licenses the rights to TJ004309 to a third party, the Company would be entitled to receive escalating portions of royalty and non-royalty consideration received by I-Mab with respect to certain territories outside of Greater China. In the event that I-Mab commercializes TJ004309, the Company would be entitled to receive a royalty percentage on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the EU and Japan in the mid-single digits. The portions of certain third party royalty and non-royalty consideration and the royalty from net sales by I-Mab to which the Company would be entitled will escalate based on the phase of development and relevant clinical trial obligations the Company completes under the TJ004309 Agreement, ranging from a high-single digit to a mid-teen percentage of non-royalty consideration as well as a double digit percentage of royalty consideration.

The TJ004309 Agreement may be terminated by either party in the event of an uncured material breach by the other party, bankruptcy of the other party, or for safety reasons related to TJ004309. I-Mab may also terminate the TJ004309Agreement if the Company causes certain delays in completing a Phase 1 clinical trial. In addition, I-Mab may terminate the TJ004309 Agreement for any reason within 90 days following the completion of the first Phase 1 clinical study, in which case the Company would be entitled to a minimum termination fee of $9.0 million, or following the completion of the first Phase 2 clinical study, in which case the Company would be entitled to a pre-specified termination fee of $15.0 million and either a low double-digit percentage of non-royalty consideration up to $35.0 million that I-Mab may receive as part of a license to a third party, or an additional payment of $35.0 million if TJ004309 is approved for marketing outside Greater China before a third party license is executed, in addition to a double digit percentage of royalty consideration.

Bispecific Agreement

Pursuant to the Bispecific Agreement, the Company and I-Mab may mutually select through a JSC up to five of I-Mab's bispecific antibody product candidates within a five-year period for development and commercialization in North America.

For each product candidate selected by the JSC for development under the Bispecific Agreement, I-Mab will be responsible and bear the costs for IND-enabling studies and establishing manufacturing for the product candidate, while the Company will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical studies, and the Company will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical studies, in each case within North America. Subject to I-Mab's right to co-promote an approved product candidate, the Company will be responsible for commercializing any approved product candidates in North America and will share profits and losses equally with I-Mab in North America. The Company would also be entitled to tiered low single digit royalties on net sales of product candidates in the EU and Japan.

At any time prior to completing the first pivotal clinical study for a product candidate or if I-Mab ceases to support development costs or pay its portion of Phase 3 clinical study costs for a product candidate or the JSC decides to cease development over the Company's objections after initiating Phase 3 clinical studies, the Company will have an option to obtain an exclusive license to such product candidate in all territories except Greater China and Korea, and any other territories in which I-Mab previously licensed rights to a third party subject to the Company's right of first refusal for any licenses I-Mab may grant to third-parties.

If the Company exercises the option, it would assume sole responsibility for developing and commercializing the product candidate in the licensed territory, and in lieu of profit or loss sharing with I-Mab with respect to such product candidate, the Company would owe I-Mab pre-specified upfront and milestone payments and royalties on net sales, with the payments and royalties escalating depending on the phase of development the product candidate reached at the time the Company obtained the exclusive license as follows: (i) if before IND-enabling studies and the preparation of the CMC activities of the collaborative product, the Company would owe I-Mab a one-time upfront payment of $10.0 million, development and regulatory based milestone payments totaling up to $90.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the mid-single digits on annual net sales; (ii) if after IND submission but before completion of a Phase 1a study of the collaborative product, the Company would owe I-Mab a one-time upfront payment of $25.0 million, development and regulatory based milestone payments totaling up to $125.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the high single digits on annual net sales; (iii) if after completion of a Phase 1a study but before completion of Phase 2 proof of concept study for the collaborative product, the Company would owe I-Mab a one-time upfront payment of $50.0 million, development and regulatory based milestone payments totaling up to $250.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the low double digits on annual net sales; and (iv) if after completion of Phase 2 proof of concept study and before completion of pivotal study for the collaborative product, the Company would owe I-Mab a one-time upfront payment of $80.0 million, development and regulatory based milestone payments totaling up to $420.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the high-teen double digits on annual net sales.

Each party agreed that for a specified period of time, it would not develop or license to or from any third party any bispecific monoclonal antibody targeting the same two biological targets as those of any selected product candidates under the Bispecific Agreement.

If development of any selected product candidates is terminated by a decision of the JSC, all rights to the product candidate will revert to I-Mab, subject to the Company's right to obtain an exclusive license in certain circumstances. If development is terminated after submission of an IND and prior to initiating Phase 3 clinical studies or after initiating Phase 3 clinical studies and with the Company's concurrence, the Company would be entitled to tiered low single digit royalties on net sales of the product candidate in North America, the EU, and Japan.

The Bispecific Agreement may be terminated by either party in the event of an uncured material breach by the other party, bankruptcy of the other party, or with respect to any selected product candidate, for safety reasons related to that product candidate.

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 carotuximab. Under the agreement, Santen is permitted to use, develop, manufacture and commercialize carotuximab 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 carotuximab 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 carotuximab 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. 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. As of June 30, 2019 and December 31, 2018, two development milestones had been received totaling $10.0 million. If carotuximab 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 carotuximab 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 carotuximab products in a given country or 12 years after the first commercial sale of the first carotuximab 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.

Upon the adoption of ASU 2014-09 on January 1, 2018, the Company assessed this agreement and identified multiple promised goods and services, which include at inception: (1) a license to patents, information and know-how related to carotuximab, (2) a technology transfer, and (3) a collaboration, including technical and regulatory support provided by the Company. In addition, customer options were identified that include manufacturing and supply obligations and shared chemistry, manufacturing and controls (CMC) development activities. All performance obligations were satisfied by the year ended December 31, 2017, which completed the Company's obligations.

As of June 30, 2019, the transaction price includes the $10.0 million upfront payment and the two development milestones received totaling $10.0 million, all of which had been fully recognized as revenue at December 31, 2017. The remaining $62.5 million of potential development and regulatory milestone payments are fully constrained as the achievement of the milestones is not considered probable, and therefore no amounts have been included in the transaction price for these remaining milestones. In addition, in accordance with ASU 2014-09, any consideration related to the commercialization and sales-based milestones (including royalties) will be recognized when the related sales occur and have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Revenue recognized related to this agreement totaled $0 for the three and six months ended June 30, 2019 and 2018.

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). Following completion of the pre-clinical development of TRC694, the Company determined the compound did not warrant further development and, in February 2019, issued written notice to terminate the License and Option Agreement with respect to the NIK Program and returned TRC694 and all rights thereto to Janssen.

With respect to the AR Mutant Program, the License and Option Agreement, as amended, provides Janssen with an option, which is exercisable until 90 days after the Company demonstrates clinical proof of concept of TRC253, 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.

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 AR Mutant Program according to agreed upon development plans, timelines and budgets. If the Company retains the AR Mutant Program, 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, 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, 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 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. The Company may also terminate the License and Option Agreement in its entirety without cause, subject to specified conditions.

Ambrx, Inc.

In December 2017, the Company entered into a license agreement with Ambrx for the development and commercialization of the Company's endoglin antibodies, including TRC105, in Greater China. The license granted Ambrx the exclusive rights to use, develop, manufacture and commercialize the Company's endoglin antibodies in all indications (excluding ophthalmology which are held by Santen) in Greater China.

In February 2019, following discussions between the Company and Ambrx regarding Ambrx's progress towards initiating a Phase 1 clinical trial of TRC105 in China, Ambrx notified the Company that it had elected to terminate the license agreement, resulting in all rights to TRC105 in Greater China reverting to the Company.

In consideration of the rights granted to Ambrx under the agreement, the Company received a one-time upfront fee of $3.0 million. At December 31, 2017, the $3.0 million upfront payment had been received and was recorded as deferred revenue in the consolidated balance sheet. The license and know-how related to TRC105 was delivered to Ambrx in the first quarter of 2018, and accordingly, the $3.0 million was recognized as revenue in the first quarter of 2018. No further revenue will be recognized associated with this agreement given Ambrx's decision to terminate the license agreement, resulting in all rights to TRC105 in Greater China reverting to the Company.

7. Leases

The Company leases its office space under a non-cancelable operating lease that expires in April 2022 and may be extended for an additional term of 60 months. The option to extend this lease has been excluded from the lease term as the Company is not reasonably certain that the option will be exercised. The lease is subject to base lease payments and additional charges for common area maintenance and other costs and includes certain lease incentives and tenant improvement allowances. Operating lease expense was $0.1 million and $0.2 million for the three and six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, the Company does not have any finance leases, nor any other operating leases.

Supplemental cash flow information, as of June 30, 2019, related to operating leases was as follows (in thousands):

Cash paid within operating cash flows	$	208
Right-of-use assets recognized in exchange for new lease obligations	$	1,143

Supplemental balance sheet information, as of June 30, 2019, related to operating leases was as follows (in thousands, except lease term and discount rate):

Reported as:		
Other assets (ROU asset)	$	989
Accounts payable and accrued expenses (lease liability)	$	327
Other long-term liabilities (lease liability)		756
Total lease liabilities	$	1,083
Weighted average remaining lease term		2.80
Weighted average discount rate		11.30%

As of June 30, 2019, the maturities of the Company's operating lease liabilities are as follows (in thousands):

Remaining 2019	$	215
2020		442
2021		461
2022		156
Total lease payments		1,274
Less imputed interest		(191)
Total operating lease liabilities	$	1,083

Under the terms of the lease agreement, the Company provided the lessor with an irrevocable letter of credit in the amount of $175,000. The lessor is entitled to draw on the letter of credit in the event of any default by the Company under the terms of the lease.

ASC 840 Disclosures

The Company elected the alternative modified transition method and previously disclosed the following:

Future minimum payments under the non-cancelable operating lease as of December 31, 2018 were as follows (in thousands):

2019	$	423
2020		442
2021		461
2022		156
	$	1,482

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 Quarterly 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 degermation, or wet AMD, through our license to Santen Pharmaceutical Co. Ltd. (Santen), and utilizing our product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the United States. In April, we announced the termination of enrollment in trials of TRC105 (carotuximab) in oncology following the Independent Data Monitoring Committee (IDMC) recommendation that the Phase 3 TAPPAS trial be terminated for futility. We continue to terminate activities, including manufacturing, related to TRC105 development in oncology and are working with investigators to appropriately conclude the clinical studies in a manner consistent with the best interest of patients.

We continue to support Santen's development of the ophthalmic formulation of carotuximab, called DE-122, for the treatment of wet AMD, the leading cause of blindness in the Western world. In March 2014, 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 the randomized Phase 2a AVANTE study of DE-122, which 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 single agent therapy in patients with wet AMD. Santen completed enrollment in the randomized Phase 2a AVANTE study and we expect top-line data in the first half of 2020.

Other clinical stage product candidates include TRC102, which is a small molecule that is in Phase 1 and Phase 2 clinical development for the treatment of mesothelioma, lung cancer and solid tumors, TRC253, which is a small molecule that is in a Phase 1/2 clinical trial for the treatment of metastatic castration-resistant prostate cancer, that we licensed from Janssen Pharmaceutica N.V. (Janssen) in September 2016, and TJ004309, which is a CD73 antibody in Phase 1 clinical development for the treatment of solid tumors, that we licensed from I-Mab Biopharma (I-Mab) in November 2018.

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 cancer patients. TRC102 began Phase 2 testing in mesothelioma in combination with the approved chemotherapeutic Alimta in 2015. TRC102 is also being studied in three Phase 1 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 (NCI). We retain global rights to develop and commercialize TRC102 in all indications.

TRC253 is being developed for the treatment of men with prostate cancer and is a novel small molecule high affinity competitive inhibitor of wild type androgen receptor (AR) and multiple AR mutant receptors containing point mutations that cause drug resistance to currently approved treatments. We expect top-line data from the Phase 2 portion of the study by the end of 2020. Until 90 days after we complete the initial Phase 1/2 study, Janssen has an exclusive option to reacquire full rights to TRC253 for an upfront payment of $45.0 million to us, and obligations to make regulatory and commercialization milestone payments totaling up to $137.5 million upon achievement of specified events and a low single-digit royalty. If Janssen does not exercise its exclusive option to reacquire the program, we would then retain worldwide development and commercialization rights, in which case we would be obligated to pay Janssen a total of up to $45.0 million in development and regulatory milestones upon achievement of specified events, in addition to a low single digit royalty.

TJ004309, also known as TJD5, is a novel humanized antibody against CD73 expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to highly immunosuppressive adenosine. We are developing TJ004309 in collaboration with I-Mab under a strategic collaboration and clinical trial agreement that we entered into in November 2018 (the TJ004309 Agreement). In July 2019, we began enrollment in a Phase 1 clinical study to assess safety and preliminary efficacy of

TJ004309 as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq® (atezolizumab) in patients with advanced solid tumors. We also entered into a separate strategic collaboration and clinical trial agreement (the Bispecific Agreement) which allows for the development of up to five of I-Mab's proprietary bispecific antibody product candidates to be nominated within a five-year period for development and commercialization in North America, with the option to opt-in and acquire product rights outside of Greater China and Korea prior to completing the first pivotal clinical study for a product candidate.

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

	Phase	Data Expected
DE-122 (Santen)		
Wet AMD	Randomized Phase 2	2020
TRC253		
Prostate Cancer	Phase 2	2020
TJ004309 (I-Mab)		
Solid Tumors	Phase 1	2020
TRC102		
Mesothelioma	Phase 2	2020
Solid tumors	Phase 1	2020
Solid tumors and Lymphomas	Phase 1/2	2020
Lung Cancer	Phase 1	2020

We utilize a product development platform that emphasizes capital efficiency. Our experienced clinical operations, data management, quality assurance, product development and regulatory affairs groups manage significant aspects of our clinical trials with internal resources. We use these internal resources to minimize the costs associated with utilizing contract research organizations, or CROs. In our experience, this model has resulted in capital efficiencies and improved communication with clinical trial sites, which expedites patient enrollment and improves the quality of patient data as compared to a CRO-managed model. We have leveraged this platform in all of our ongoing clinical trials. We have also leveraged our product development platform to diversify our product pipeline without payment of upfront license fees through license agreements with Janssen and I-Mab. We continue to evaluate ex-U.S. companies who are in need of a rapid and capital-efficient U.S. drug development solution that includes U.S. and European Union (EU) clinical development expertise. We believe we can become a preferred U.S. clinical development partner through a cost- and risk-sharing partnership structure which may include U.S. commercialization.

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 equity securities, payments received in connection with our collaboration agreements, and commercial bank debt under our credit facilities with Silicon Valley Bank (SVB). At June 30, 2019, we had cash and cash equivalents totaling $26.3 million.

We have incurred losses from operations in each year since our inception. Our net losses were $35.0 million and $19.1 million for the years ended December 31, 2018 and 2017, respectively. At June 30, 2019, we had an accumulated deficit of $153.2 million.

We expect to continue to incur significant expenses and 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 to decrease due to the termination of TRC105 development in oncology, but remain relatively constant in connection with our other ongoing activities as we:

- manufacture preclinical study and clinical trial materials;
- continue to conduct clinical trials of product candidates;
- continue our research and development efforts;
- maintain, expand and protect our intellectual property portfolio; and
- seek regulatory approvals for 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 product candidates, which we expect will take a number of years. If we obtain regulatory approval for any 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 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 product candidates.

2019 Developments

In July, we initiated dosing of the first patient in a Phase 1 study of TJ004309 (CD73 antibody), which doses TJ004309 as a single agent and in combination with Tecentriq in patients with advanced solid tumors. We expect to report top-line data from this study in the second half of 2020.

In July, Phase 1 data from the ongoing Phase 1/2 clinical trial of TRC253 in patients with metastatic castrate resistant prostate cancer was published in the 2019 ASCO Proceedings. We enrolled 22 patients with metastatic castrate resistant prostate cancer who had progressed on prior Xtandi® (enzalutamide) or Erleada™ (apalutamide) treatment into one of six cohorts of escalating doses of TRC253 in the Phase 1 portion of the trial. Target PK exposures were achieved consistently with the 280 mg daily oral dose, which was selected as the recommended Phase 2 dose. The single patient with a F877L androgen receptor (AR) point mutation at baseline remained on treatment for 49 weeks with a partial response by RECIST. The remaining 21 patients did not have a F877L AR point mutation at baseline, and 48% (10) remained on study for at least six months and one patient had a greater than 50% decrease in prostate specific antigen (PSA). TRC253 was well-tolerated and no drug-related serious adverse events were reported. Drug-related adverse events included QTcF prolongation, elevated lipase, fatigue, arthralgia, diarrhea, and platelet count decrease, with QTcF prolongation being the most frequently observed adverse event. Based on evidence of potential efficacy in the data from the completed Phase 1 portion of the study, an additional cohort of patients was added to the ongoing Phase 2 study. Enrollment is ongoing in the new cohort with a defined point mutation, as well as the two existing cohorts, the first including patients with a F877L AR mutation and the second consisting of patients with another basis for resistance to Xtandi or Erleada.

In April, we announced the termination of enrollment in trials of TRC105 (carotuximab) in oncology following the Independent Data Monitoring Committee (IDMC) recommendation that the Phase 3 TAPPAS trial be terminated for futility. We continue to terminate activities, including manufacturing, related to TRC105 development in oncology and are working with investigators to appropriately conclude the clinical studies in a manner consistent with the best interest of patients.

In April, the National Cancer Institute reported top-line data from the Phase 2 trial of TRC102 and Temodar in patients with relapsed metastatic colorectal cancer at the American Association for Cancer Research annual meeting. The combination of TRC102 and Temodar was tolerable, but the overall response rate of 6% did not meet the primary efficacy endpoint.

Collaboration and License Agreements

Collaboration Agreements with I-Mab Biopharma

In November 2018, we entered into separate strategic collaboration and clinical trial agreements (the Collaboration Agreements) with I-Mab for the development of multiple immuno-oncology programs, including I-Mab's proprietary CD73 antibody TJ004309 as well as up to five proprietary bispecific antibodies currently under development by I-Mab.

In the TJ004309 Agreement, we are collaborating with I-Mab on developing TJ004309, also known as TJD5, and will bear the costs of filing an IND and for Phase 1 clinical trials, share costs equally for Phase 2 clinical trials, and we will bear 40% and I-Mab 60% of the costs for pivotal clinical trials. I-Mab will also be responsible for the cost of certain non-clinical activities and the supply of TJ004309 and any reference drugs used in the development activities.

In the event that I-Mab licenses rights to TJ004309 to a third party, we would be entitled to receive escalating portions of royalty and non-royalty consideration received by I-Mab with respect to territories outside of Greater China. In the event that I-Mab commercializes TJ004309, we would be entitled to receive a royalty on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the EU and Japan in the mid-single digits. The portions of certain third party royalty and non-royalty consideration and the royalty from net sales by I-Mab to which we would be entitled escalate based on the phase of development and relevant clinical trial obligations we complete under the TJ004309 Agreement, ranging from a high-single digit to a mid-teen percentage of non-royalty consideration as well as a double digit percentage of royalty consideration.

The TJ004309 Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to TJ004309. I-Mab may also terminate the TJ004309 Agreement if we

cause certain delays in completing a Phase 1 clinical trial. In addition, I-Mab may terminate the TJ004309 Agreement for any reason within 90 days following the completion of the first Phase 1 clinical study, in which case we would be entitled to a minimum termination fee of $9.0 million, or following the completion of the first Phase 2 clinical study, in which case we would be entitled to a pre-specified termination fee of $15.0 million and either a percentage of non-royalty consideration I-Mab may receive as part of a license to a third party or an additional payment if TJ004309 is approved for marketing outside Greater China before a third party license is executed, in addition to a double digit percentage of royalty consideration.

Pursuant to the Bispecific Agreement, we and I-Mab may mutually select through a joint steering committee (JSC) up to five of I-Mab's bispecific antibody product candidates within a five-year period for development and commercialization in North America.

For each product candidate selected by the JSC for development under the Bispecific Agreement, I-Mab will be responsible and bear the costs for IND-enabling studies and establishing manufacturing for the product candidate, we will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical studies, and we will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical studies, in each case within North America. Subject to I-Mab's right to co-promote an approved product candidate, we will be responsible for commercializing any approved product candidates in North America, and we will share profits and losses equally with I-Mab in North America. We would also be entitled to tiered low single digit royalties on net sales of product candidates in the EU and Japan.

At any time prior to completing the first pivotal clinical study for a product candidate or if I-Mab ceases to support development costs or pay its portion of Phase 3 clinical study costs for a product candidate or the JSC decides to cease development over our objections after initiating Phase 3 clinical studies, we will have an option to obtain an exclusive license to such product candidate in all territories except Greater China and Korea and any other territories in which I-Mab previously licensed rights to a third party subject to our right of first refusal for any licenses I-Mab may grant to third-parties.

If we exercise the option, we would assume sole responsibility for developing and commercializing the product candidate in the licensed territory, and in lieu of profit or loss sharing with I-Mab with respect to such product candidate, we would owe I-Mab pre-specified upfront and milestone payments and royalties on net sales, with the payments and royalties escalating depending on the phase of development the product candidate reached at the time we obtained the exclusive license as follows: (i) if before IND-enabling studies and the preparation of the chemistry-manufacturing-controls activities of the collaborative product, we would owe I-Mab a one-time upfront payment of $10.0 million, development and regulatory based milestone payments totaling up to $90.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the mid-single digits on annual net sales; (ii) if after IND submission but before completion of P1a study of the collaborative product, we would owe I-Mab a one-time upfront payment of $25.0 million, development and regulatory based milestone payments totaling up to $125.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the high single digits on annual net sales; (iii) if after completion of P1a study but before completion of Phase 2 proof of concept study for the collaborative product, we would owe I-Mab a one-time upfront payment of $50.0 million, development and regulatory based milestone payments totaling up to $250.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the low double digits on annual net sales; and (iv) if after completion of Phase 2 proof of concept study and before completion of pivotal study for the collaborative product, we would owe I-Mab a one-time upfront payment of $80.0 million, development and regulatory based milestone payments totaling up to $420.0 million that begin upon completion of a pivotal study, sales milestones totaling up to $250.0 million, and royalties in the high-teens on annual net sales.

License Agreement with Janssen Pharmaceutica N.V.

In 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, as amended, 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-kB inducing kinase intended for the treatment of patients with hematologic malignancies, including myeloma (the NIK Program and, together with the AR Mutant Program, the Programs). Following completion of the pre-clinical development of TRC694, we determined the compound did not warrant further development and in February 2019 we issued written notice to terminate the agreement with respect to the NIK Program and returned TRC694 and all rights thereto to Janssen.

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.

License Agreement with Santen

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 carotuximab, or the Carotuximab Technology. Under the agreement, as amended, Santen is permitted to use, develop, manufacture and commercialize carotuximab 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. In the event Santen sublicenses any of its rights under the agreement relating to the Carotuximab Technology, Santen will be obligated to pay us 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 carotuximab products in the field of ophthalmology. In the event that Santen fails to meet certain commercial diligence obligations, we will have the option to co-promote carotuximab products in the field of ophthalmology in the United States with Santen. If we exercise this option, we will pay Santen a percentage of certain development expenses, and we 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, 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. If carotuximab 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 carotuximab 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 carotuximab products in a given country or 12 years after the first commercial sale of the first carotuximab product commercially launched in such country. As of June 30, 2019, $10.0 million of the development milestones have been achieved and received in accordance with the agreement.

Financial Operations Overview

Revenue

Our revenue to date has been derived from our March 2014 collaboration with Santen and our December 2017 collaboration with Ambrx. In February 2019, Ambrx notified us that it had elected to terminate the agreement, which became effective 90 days after the notice. The terms of these arrangements contain multiple promised goods and services. The license agreements provide for the receipt of multiple types of payments, including a non-refundable upfront payment, payment for various technical and regulatory support, payments for delivery of drug substance and drug product, reimbursement of certain development costs, milestone payments, and royalties on net product sales. In accordance with our revenue recognition policy, we have identified one performance obligation for all the promised goods or services under the agreements and recognized revenue for the fixed or determinable collaboration consideration on a straight-line basis over the estimated development period for the Santen license, and at a point in time for the Ambrx license.

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, the timing of any additional collaboration agreements and recognition of associated upfront and milestone payments, such as from our license with Santen, whether and when Janssen reacquires rights to the AR Mutant Program, and the extent to which any of our products are approved and successfully commercialized by us or our partners. If we or our partners 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 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 and I-Mab 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)			
Third-party research and development expenses:				
TRC105	$ 1,942	$ 5,402	$ 4,006	$ 12,151
TRC253	863	929	2,082	1,863
TRC102	21	22	43	46
TRC694	10	122	141	197
TJ004309	50	—	114	—
Total third-party research and development expenses	2,886	6,475	6,386	14,257
Unallocated expenses	1,461	1,640	3,175	3,296
Total research and development expenses	$ 4,347	$ 8,115	$ 9,561	$ 17,553

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

We expect our current level of research and development expenses to decrease with the termination of further enrollment in company sponsored trials of 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 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 the NCI;
- the extent to which costs for comparator drugs 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 participation in the trials and 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 in part 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 (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, 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, 2018 other than the following:

Leases

We determine if an arrangement contains a lease at inception. For arrangements where we are the lessee, operating leases are included in Other assets, Accounts payable and accrued expenses, and Other long-term liabilities within the consolidated balance sheet. We currently do not have any finance leases.

Operating lease right-of-use (ROU) assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. We use our incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as our leases generally do not provide an implicit rate. Lease terms may include options to extend or terminate when we are reasonably certain that the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		
	2019	2018	Change
	(in thousands)		
Collaboration revenue	$ —	$ —	$ —
Research and development expenses	4,347	8,115	(3,768)
General and administrative expenses	1,893	1,622	271
Other expense	(86)	(17)	(69)

Collaboration revenue. Collaboration revenue was $0 for the three months ended June 30, 2019 and 2018.

Research and development expenses. Research and development expenses were $4.3 million and $8.1 million for the three months ended June 30, 2019 and 2018, respectively. The decrease of $3.8 million was primarily due to lower drug manufacturing expenses and direct clinical trial expenses following the termination of further enrollment in company sponsored trials of TRC105.

General and administrative expenses. General and administrative expenses were $1.9 million and $1.6 million for the three months ended June 30, 2019 and 2018, respectively. The increase of $0.3 million was primarily due to corporate related expenses, partially offset by lower stock-based compensation expenses.

Other expense. Other expense was $0.1 million and $0 for the three months ended June 30, 2019 and 2018, respectively.

Comparison of the Six Months Ended June 30, 2019 and 2018

The following table summarizes our results of operations for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,		
	2019	2018	Change
	(in thousands)		
Collaboration revenue	$ —	$ 3,000	$ (3,000)
Research and development expenses	9,561	17,553	(7,992)
General and administrative expenses	3,842	3,373	469
Other expense	(136)	(192)	56

Collaboration revenue. Collaboration revenue was $0 and $3.0 million for the six months ended June 30, 2019 and 2018, respectively. The decrease of $3.0 million was due to revenue recognized under the Ambrx license agreement in the six months ended June 30, 2018 with no corresponding revenue in the comparable period in 2019.

Research and development expenses. Research and development expenses were $9.6 million and $17.6 million for the six months ended June 30, 2019 and 2018, respectively. The decrease of $8.0 million was primarily due to lower drug manufacturing expenses and direct clinical trial expenses following the termination of further enrollment in company sponsored trials of TRC105.

General and administrative expenses. General and administrative expenses were $3.8 million and $3.4 million for the six months ended June 30, 2019 and 2018, respectively. The increase of $0.5 million was primarily due to corporate related expenses, partially offset by lower stock-based compensation expenses.

Other expense. Other expense was $0.1 and $0.2 million for the six months ended June 30, 2019 and 2018, respectively.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception. As of June 30, 2019, we had an accumulated deficit of $153.2 million, and we expect to continue to incur net losses for the foreseeable future. We expect our current level of research and development expenses to decrease with the termination of further enrollment in company sponsored trials of TRC105. Given we do not anticipate any revenues from product sales in the foreseeable future, we will need additional capital to fund our operations, which we may seek to obtain through one or more equity offerings, debt financings, government or other third party funding, and licensing or collaboration arrangements.

On February 4, 2015, we completed our initial public offering and a concurrent private placement of our common stock, which resulted in net proceeds to us of approximately $35.0 million. In September 2016, we sold shares of our common stock in a private placement for net proceeds of approximately $5.0 million and in November 2016, we completed an underwritten public offering which resulted in net proceeds of approximately $16.1 million. In March 2017, we sold shares of our common stock to Aspire Capital Fund, LLC (Aspire) for net proceeds of approximately $0.9 million, and throughout 2017, we sold shares through our previous At-the-market (ATM) facility with Stifel, Nicolaus & Company, Incorporated (Stifel) for net proceeds of approximately $3.4 million. In March and April 2018, we sold shares of our common stock and common warrants in a private placement for net proceeds of approximately $36.5 million. We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements into the third quarter of 2020. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to capital preservation.

Credit Facility with SVB

In May 2018, we entered into a third amendment to our Amended and Restated Loan and Security Agreement with SVB (the 2018 Amended SVB Loan) under which we borrowed $7.0 million, all of which was used to refinance previously outstanding amounts under the loan and security agreement. In connection with the 2018 Amended SVB Loan, we issued warrants to purchase up to 53,639 shares of common stock at an exercise price of $2.61 per share. The warrants are fully exercisable and expire on May 3, 2025.

The 2018 Amended SVB Loan provides for interest to be paid at a rate of 9.0% per annum, with interest-only payments due monthly through June 30, 2019. Thereafter, in addition to interest accrued during such period, the monthly payments include an amount equal to the outstanding principal at June 30, 2019 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 amount of the amounts borrowed. The 2018 Amended SVB Loan provides for prepayment fees of 2.0% of the amount prepaid if the prepayment occurs after May 3, 2019 but prior to May 3, 2020 and 1.0% of the amount prepaid if the prepayment occurs thereafter.

The 2018 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 2018 Amended SVB Loan. As of June 30, 2019, we were in compliance with all covenants and conditions of the 2018 Amended SVB Loan.

Private Placement of Common Shares and Warrants

In March 2018, we entered into a securities purchase agreement with new and certain existing investors for the purchase of $38.7 million of our common stock and warrants. We sold approximately 11.9 million shares of common stock at a purchase price of $2.70 per share, pre-funded warrants to purchase approximately 1.8 million shares of common stock at a purchase price of $2.69 per share and an exercise price of $0.01 per share, and warrants to purchase approximately 13.7 million shares of common stock at a purchase price of $0.125 per share and an exercise price of $2.70 per share.

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 that began 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 June 30, 2019 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.

ATM Facility

In September 2018, as amended in February 2019, we entered into a Sales Agreement with JonesTrading pursuant to which we may sell from time to time, at our option, up to an aggregate of $8.0 million of shares of our common stock through JonesTrading, 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 JonesTrading, on the Nasdaq Global Market or otherwise, at negotiated prices or at prices related to the prevailing market price. JonesTrading 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 required to pay JonesTrading 2.5% of gross proceeds from the common stock sold through the Sales Agreement. As of June 30, 2019, we had not sold any shares of common stock through the Sales Agreement with JonesTrading and $8.0 million of common stock remained available for sale under the Sales Agreement.

In September 2018, we terminated a similar at-the-market sales agreement we had entered into with Stifel, Nicolaus & Company, Incorporated. We had sold approximately 1,037,000 shares of common stock for aggregate proceeds of approximately $3.5 million under the Stifel agreement prior to it being terminated.

Cash Flows

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

	Six Months Ended June 30,	
	2019	2018
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (12,824)	$ (16,432)
Investing activities	14,020	(13,923)
Financing activities	4	35,322
Decrease in cash and cash equivalents	$ 1,200	$ 4,967

Operating activities. Net cash used in operating activities was $12.8 million and $16.4 million for the six months ended June 30, 2019 and 2018, respectively, and was primarily due to our net loss and changes in our working capital, partially offset by non-cash charges including stock-based compensation.

Investing activities. Net cash provided by investing activities was $14.0 million for the six months ended June 30, 2019 and was due to maturities of short-term investments partially offset by purchases of these investments. Net cash used in investing activities was $13.9 million for the six months ended June 30, 2018 and was due to purchases of short-term investments partially offset by maturities of these investments.

Financing activities. Net cash provided by financing activities was $4,000 during the six months ended June 30, 2019. Net cash provided by financing activities was $35.3 million during the six months ended June 30, 2018 and primarily resulted from $36.5 million in net proceeds received from the issuance of common stock and warrants, offset by $1.3 million in net repayments on borrowings under our SVB loan agreement.

Funding Requirements

At June 30, 2019, we had cash and cash equivalents totaling $26.3 million. We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements into the third quarter of 2020, presuming our payment obligations under the 2018 Amended SVB Loan continue to follow the contractual maturity schedule. We will need additional funding to complete the development and commercialization of our product candidates or those of our partners. 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. 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;
- the ability and willingness of our collaboration partners and licensees to continue clinical development of product candidates;
- our ability to enter into and maintain our collaborations, including our collaborations with Santen, Janssen, and I-Mab;
- 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 product candidates for clinical trials and regulatory submissions;
- the scope, progress, results and costs of preclinical development, and clinical trials of product candidates;
- whether and when Janssen reacquires the rights to the AR Mutant Program;
- the costs, timing and outcome of regulatory review of product candidates;
- the revenue, if any, received from commercial sales of product candidates for which we or any of our partners, including Santen or I-Mab, 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 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.

Contractual Obligations and Commitments

Our contractual obligations and commitments were reported in our Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the SEC on March 1, 2019.

As described more fully in Note 4, “Commitments and Contingencies,” following the announcement of the TAPPAS interim unblinded safety and efficacy data in April 2019, the Company exercised its right to terminate the long-term manufacturing agreement with Lonza Biologics Tuas Pte Ltd as a result of its decision to terminate further TRC105 development in oncology. As a result of the discontinuation of TRC105, costs associated with certain batches prior to regulatory approval and batches following regulatory approval will not be incurred, however the Company will be obligated to pay for any costs incurred associated with work completed prior to the termination, which have been accrued for within the consolidated balance sheet.

There have been no other material changes from the contractual obligations and commitments previously disclosed in our Annual Report on Form 10-K.

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 (SEC).

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

At June 30, 2019, our cash and cash equivalents consist of cash and money market funds. 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 expenses for patients enrolled in our clinical studies and for the manufacture of clinical trial materials outside the United States based on contractual obligations denominated in currencies other than the U.S. dollar, primarily Pounds Sterling and Euros. 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 2019 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 President and Chief Executive Officer ("Principal Executive Officer and Principal Financial Officer"), as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our President and Chief Executive Officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our President and Chief Executive Officer has concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of June 30, 2019, 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 June 30, 2019, 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 with the SEC. 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, 2018. 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 the product candidates we are developing will require substantial additional development time and resources before we or our partners 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 $35.0 million and $19.1 million for the years ended December 31, 2018 and 2017, respectively. At June 30, 2019, we had an accumulated deficit of $153.2 million.

We expect to continue to incur substantial expenses as we expand our development activities and advance our clinical programs. To become and remain profitable, we or our partners must succeed in developing 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 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 current level of research and development expenses to decrease with the termination of further enrollment in company sponsored trials of TRC105.

At June 30, 2019, we had cash and cash equivalents totaling $26.3 million. Based upon our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital requirements into the third quarter of 2020. We will need additional funding to complete the development and commercialization of product candidates. In addition, in 2016 we licensed TRC253 from Janssen Pharmaceutica N.V., or Janssen, and are subject to obligations to develop the program through clinical proof of concept. We will need additional funds to complete clinical proof of concept for the TRC253 program and, to the extent we retain the program afterwards, to advance the program through later stages of development. In November 2018, we entered into separate collaboration and clinical trial agreements with I-Mab for the development of multiple immuno-oncology programs. Under the agreements, we are responsible for various portions of the costs to conduct clinical trials, among other development obligations. We will need additional funds to advance the development of these programs and meet our cost-sharing obligations, and these requirements may be substantial depending on how many programs are selected for development

and the stage of development each program reaches. As more fully discussed in Note 1 to the 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 clinical development, filing for regulatory approval, or commercializing any product candidates.

In September 2018, we entered into a Capital on Demand™ Sales Agreement, or the JonesTrading Agreement, as amended in February 2019, with JonesTrading Institutional Services LLC, or JonesTrading, pursuant to which we could sell from time to time, at our option, up to an aggregate of $8.0 million of shares of our common stock through JonesTrading, as sales agent. 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. As of the date of this report, we have not sold any shares of our common stock under the JonesTrading Agreement and have sold $1.0 million of shares of our common stock under the Aspire Agreement. While the JonesTrading Agreement and Aspire Agreement 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, JonesTrading is under no obligation to sell any shares of our common stock that we may request to be sold under the JonesTrading 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 JonesTrading 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 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 product candidates or otherwise significantly curtail, or cease, operations. If we are unable to pursue or are 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 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 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.

On May 3, 2018, we entered into an amended loan and security agreement with SVB to borrow $7.0 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 Product Candidates

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, we announced in April 2019 that the Phase 3 TAPPAS trial evaluating TRC105 in combination with Votrient (pazopanib) in patients with advanced or metastatic angiosarcoma was terminated for futility based on the recommendation of the Independent Data Monitoring Committee (IDMC) following its review of interim unblinded safety and efficacy data from more than 120 patients enrolled in the trial at the time of the analysis. Given these data, we terminated further enrollment in trials of TRC105 in oncology and are working with investigators to appropriately conclude the clinical studies in a manner consistent with the best interest of patients. It is possible that the failure of TRC105 to show efficacy in late-stage oncology clinical trials makes it less likely that it will be effective in wet AMD due to the same mechanism of action and strategy to combine it with VEGF inhibitors. In addition, favorable results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of subsequent clinical trials.

Even if 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 potential lack of safety or efficacy of 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, or differences in determination of progression events by investigators compared to central radiographic reviewers. 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 any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and 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 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 product candidates could be materially harmed, which could have a material adverse effect on our business. For example, we have experienced slower than anticipated enrollment in our on-going Phase 2 clinical trial of TRC253 resulting from a lower than expected frequency of a specific tumor mutation targeted by TRC253 among metastatic prostate cancer patients.

Our product candidates or those of our partners 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 product candidates or other potentially harmful characteristics of product candidates could cause us, our partners, including the National Cancer Institute, or 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 TRC102 conducted to date have generated AEs related to the study drug, some of which have been serious. The most common AE identified in our clinical trials of TRC102 has been anemia. TRC253 is currently being tested in a Phase 2 clinical trial and the most common AE identified has been QTcF prolongation. It is possible that the AE profile in our Phase 2 study of TRC253 could preclude further development or cause Janssen to not exercise its option to regain rights to the program. There can be no assurance that adverse events associated with product candidates will not be observed. As is typical in drug development, we have a program of ongoing toxicology studies in animals for clinical stage product candidates and cannot provide assurance that the findings from such studies or any ongoing or future clinical trials will not adversely affect our clinical development activities.

Further, if any 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 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 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.

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 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; 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 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 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 or those of our partners.

We also expect to target specific patient populations with TRC253 and expect to continue to develop companion diagnostic tests in prostate cancer to improve selection of patients that would respond to treatment. If we are unable to establish a companion diagnostic for TRC253, our ability to successfully identify target patient populations for future clinical development may be limited. In addition, as the actual patient population with the specific genetic mutation targeted by TRC253 is lower than originally expected, the commercial opportunity for TRC253 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 product candidates will be successful in clinical trials or receive regulatory approval. Further, product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more 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.*

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. 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 product candidates or may not ultimately realize the potential benefits of orphan drug designation.*

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. We cannot guarantee that we will be able to receive orphan drug status from the FDA for any product candidates or indications. If we are unable to secure orphan drug designation for additional product candidates or indications, our regulatory and commercial prospects may be negatively impacted.

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

Obtaining and maintaining regulatory approval of 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 or those of our partners will be harmed.

Even if we receive regulatory approval of 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 product candidates.

Any 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 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 product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for 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. Moreover, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses of approved pharmaceutical products. Later discovery of previously unknown problems with 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 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 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 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 and our partners rely on third party manufacturers to make 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 small molecules such as TRC253, is highly cyclical, with periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need 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.

We rely on other third parties for drug substance and to perform additional steps in the manufacturing process, including filling into vials, shipping and storage. For our clinical stage pipeline programs, there can be no guarantee that lack of clinical supplies will not force us or our partners to delay or terminate any ongoing or planned clinical trials. For example, DE-122 had been supplied to us from Lonza, which we then provided to Santen under our collaboration. In April 2019, we exercised our right to terminate the supply and manufacturing agreement with Lonza following our decision to stop further development of TRC105 in oncology, and cannot be certain that Santen will be able to procure additional supplies of DE-122 from Lonza or any other third party.

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.

We do not have any long-term supply agreements for the manufacture of product candidates and cannot guarantee that any 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, manufacturing agreements are often subject to early termination by the third party manufacturer under certain circumstances.

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 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 or those of our collaborators 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 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 product candidates.

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

NCI is currently sponsoring and funding multiple clinical trials involving TRC102. In addition, Case Western has sponsored and funded two separate clinical trials involving TRC102. The advancement of TRC102 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 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 a clinical trial sponsored by a third party has a failure due to poor design of the trial, errors in the way the clinical trial is executed or for any other reason, or if the sponsor fails to comply with applicable regulatory requirements or if 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 and may enter into additional license agreements with third parties. The failure to maintain our license agreements or the failure of our licensees to perform their obligations under the agreements, 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 carotuximab, 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 or any other licensees will dedicate to their respective 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 and will be subject to similar risks with respect to any other license agreement, including:

- our licensees may not comply with applicable regulatory requirements with respect to developing or commercializing products under the license agreements, which could adversely impact development, regulatory approval and eventual commercialization of such products;
- we and our licensees could disagree as to future development plans and our licensees may delay initiation of clinical trials or stop a future clinical trial;
- there may be disputes between us and our licensees, 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 licensed products using our technology, and/or costly litigation or arbitration that diverts our management's attention and resources;
- our licensees 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;
- our licensees may fail to meet expected timelines, which could result in the delay of or failure to achieve development, regulatory and commercial objectives;
- business combinations or significant changes in a licensee's business strategy may adversely affect the licensee's ability or willingness to perform its obligations under the applicable license agreement;
- our license partners and potential license partners may not properly maintain or defend our intellectual property rights in their licensed fields or territories 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 or other licensees may be reduced or eliminated based upon their and our ability to maintain or defend our intellectual property rights.

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

Our ability to realize value from any product candidates developed under our agreements with I-Mab will depend in part on I-Mab's activities and willingness to fund future development.

Pursuant to the terms of our strategic collaboration and clinical trial agreements with I-Mab, we are largely responsible for clinical development activities and I-Mab is responsible for pre-clinical development and manufacturing activities. Consequently, our ability to realize value or generate any revenues from the development of product candidates in collaboration with I-Mab will depend in part of I-Mab's willingness and ability to successfully complete pre-clinical development and manufacturing activities, in addition to funding agreed-upon portions of the costs of clinical development. We have limited control over the amount and timing of resources that I-Mab will dedicate to its respective efforts, and have limited rights in the event that I-Mab determines to cease development or manufacturing activities or funding for any product candidate under the collaboration. We could also encounter disagreements with I-Mab over the timing and scope of development or manufacturing of any product candidates under the collaboration or which, if any, bispecific antibody product candidates are selected for development.

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

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into additional licensing and collaboration agreements, including potentially with major biotechnology or pharmaceutical companies. In particular, we are actively seeking additional corporate partnerships in which we would share in the cost and risk of clinical development and commercialization of innovative product candidates of third parties. We face significant competition in seeking appropriate partners, 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. With respect to additional partnerships whereby we would develop third party product candidates, we will need to identify promising product candidates where the owner of the development and commercial rights could benefit from our clinical development capabilities. 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 and in all territories. In addition, under our collaboration and clinical trial agreement with I-Mab for TJ004309, we are prohibited from developing other biologic product candidates targeting the same indications for which TJ004309 is being developed, which increases our reliance on the success of I-Mab's activities with respect to TJ004309 and could limit our ability to collaborate with others with respect to biologic product candidates in certain 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. If we are unable to enter into additional collaborations that leverage our clinical development capabilities, we may be forced to reduce these capabilities, which could lower the value of our company and make it less likely that third parties will seek to collaborate with us to develop their product candidates.

We rely on third parties to conduct preclinical studies and clinical trials of 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 product candidates.

We do not have our own capabilities to perform preclinical testing of 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 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 and 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 product candidates. As a result, our financial results and the commercial prospects for our product candidates or those of our partners 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 June 30, 2019, we are the exclusive licensee of six issued U.S. patents, two pending U.S. patent applications, sixteen 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 two issued U.S. patents, three issued non-U.S. patents, one pending U.S. patent application, and forty pending non-U.S. applications related to TRC253.

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. Carotuximab is protected, in part, by patents exclusively in-licensed from Roswell Park Cancer Institute. TRC102 is protected, in part, by patents exclusively licensed from Case Western. TRC253 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 Product Candidates

Even if we obtain regulatory approval of 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.*

Factors that will influence whether product candidates are accepted in the market include:

- the clinical indications for which product candidates are approved, if any;
- physicians, hospitals, cancer treatment centers and patients considering product candidates as a safe and effective treatment;
- the potential and perceived advantages of 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 product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement 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.

If, for any of these or other reasons, 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 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.

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 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 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 or those of our partners. 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 product candidates, which could make it difficult for us to sell product candidates profitably.

Successful sales of product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third party payors. In addition, because our product candidates and those of our partners represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from these 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 product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of product candidates.

We intend to seek approval to market product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for 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 product candidates will depend significantly on the availability of coverage and adequate reimbursement from third party payors for 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 in the United States. 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, the current U.S. President has signed two Executive Orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA. For example, the Tax Cuts and Jobs Act of 2017 (Tax Act) includes a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the District Court Judge, as well as the current U.S presidential administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact 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 ACA 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, due to subsequent legislative changes to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, the former U.S. President 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 pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the current U.S. President's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the current U.S. President's administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services (HHS) has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare

Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, HHS through CMS proposed a rule that would require drug manufacturers to disclose drug prices in television advertisements. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although a number of these and other potential proposals may require authorization through additional legislation to become effective, Congress and the current U.S. President's administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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. 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 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Right to Try Act) was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a prescription drug or biologic manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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 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 any 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;
- different payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- 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 Unites States are unable to successfully manage these risks associated with international operations, the market potential for our product candidates or those of our partners outside the Unites 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. In addition, part of our corporate strategy is to leverage our existing internal clinical development and regulatory capabilities by entering into collaborations where we conduct development activities related to third party product candidates in exchange for commercialization and payment rights, such as our collaboration with Janssen with respect to TRC253 and our collaboration with I-Mab with respect to I-Mab's proprietary CD73 antibody, TJ004309, and potential bispecific antibody candidates. 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. With respect to TJ004309, if I-Mab licenses rights to TJ004309 to a third party, while we would be entitled to receive varying portions of royalty and non-royalty payments from I-Mab, we would have no further rights to develop, commercialize or realize value from TJ004309. If we are unable to retain existing product candidates and add additional product candidates to our pipeline, we may not be able to execute on an important part of our business strategy and 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 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 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, imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages, integrity oversight and reporting obligations, 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 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 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, 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, and its implementing regulations, 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 ACA 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; state laws that require the reporting of information relating to drug

and biologic pricing; state and local laws that require the registration of pharmaceutical sales representatives; 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, amended 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 federal False Claims Act.

We are also subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. There are foreign and state law versions of these laws and regulations to which we are currently and/or may in the future, be subject. For example, the collection and use of personal health data in the European Union is governed by the General Data Protection Regulation, or the GDPR. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The GDPR requirements apply not only to third party transactions, but also to transfers of information within our company, including employee information. The GDPR and similar data privacy laws of other jurisdictions place significant responsibilities on us and create potential liability in relation to personal data that we or our third party vendors process, including in clinical trials conducted in the United States and European Union. In addition, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

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 criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, imprisonment, exclusion from governmental health care programs, 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, 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 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 or those of our partners. 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 product candidates; and
- decreased demand for 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 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, 2018 we had federal and California net operating loss carryforwards, or NOLs, of approximately $114.6 million and $117.8 million, respectively, which expire in various years beginning in 2030, if not utilized. Under the Tax Act, federal NOLs generated in 2018 and in future years may be carried forward indefinitely, but the deductibility of such NOLs is limited. It is uncertain if and to what extent various states will conform to the Tax Act. As of December 31, 2018, we had federal and California research and development and Orphan Drug tax credit carryforwards of approximately $9.2 million and $2.0 million, respectively. The federal research and development and Orphan Drug 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 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, the current U.S. President signed into law the Tax Act which significantly revises the Code. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for NOLs to 80% of current year taxable income and elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

We are dependent upon our own or third party information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems may make them vulnerable to service interruption or destruction, malicious intrusion, or random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our clinical trial data, intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Third party sites that take part in clinical trials we sponsor or third parties that are also sponsoring clinical trials involving our product candidates or those of our partners, such as NCI and Case Western, face similar risks and any security breach of their systems could adversely affect us. A security breach or privacy violation that leads to disclosure or modification of, or prevents access to, patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to litigation or other liability under laws and regulations that protect personal data, any of which could disrupt our business and/or result in increased costs or loss of revenue. Any of these events could be particularly harmful to our business due to our reliance on internal clinical development functions and systems to conduct our clinical trials. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

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 and the ability of our partners to obtain clinical supplies of product candidates could be disrupted if the operations of our third party manufacturers 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.

Even though our common stock trades on the Nasdaq Global Market, 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 has been, and is likely to continue 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 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 product candidates;
- changes in laws or regulations applicable to product candidates;
- changes in the structure of healthcare payment systems;

- inability to obtain adequate product supply for 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.

If we fail to continue to meet all applicable listing requirements, our common stock may be delisted from the Nasdaq Global Market, which could have an adverse impact on the liquidity and market price of our common stock.*

Our common stock is currently listed on the Nasdaq Global Market, which has qualitative and quantitative listing criteria. If we are unable to meet any of the Nasdaq listing requirements in the future, including, for example, if the closing bid price for our common stock falls below $1.00 per share for 30 consecutive trading days, Nasdaq could determine to delist our common stock. On May 28, 2019, we received a notification from the Nasdaq Stock Market that for the preceding 30 consecutive business days, the closing bid price of our common stock was below $1.00 per share. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days from the notice date, or until November 25, 2019, to regain compliance. To regain compliance, the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days. If we do not regain compliance by November 25, 2019, we may submit a transfer application to the Nasdaq Capital Market in order to receive an additional 180-day compliance period to comply. In order to be eligible for the transfer and additional compliance period, we will be required to meet the continued listing requirement for market value of publicly held shares and all of the initial listing requirements for the Nasdaq Capital Market, other than the minimum bid price requirement, and must notify Nasdaq in writing of our intention to cure the deficiency during the additional compliance period. As of August 2, 2019, the closing price of our common stock on the Nasdaq Global Market was $0.461 per share. A delisting of our common stock could adversely affect the market liquidity of our common stock, decrease the market price of our common stock, adversely affect our ability to obtain financing for the continuation of our operations and result in the loss of confidence in our company.

In the event that our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

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 June 30, 2019, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially owned over 45% 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 $1.07 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)	Amended and Restated Certificate of Incorporation, as currently in effect.
3.2(1)	Amended and Restated Bylaws, as currently in effect.
4.1(2)	Form of Common Stock Certificate of the Registrant.
4.2(2)	Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated September 19, 2014.
4.3(3)	Investor Agreement by and between Johnson & Johnson Innovation-JJDC, Inc. and TRACON Pharmaceuticals, Inc., dated September 27, 2016.
4.4(4)	Registration Rights Agreement, dated March 14, 2017, by and between the Registrant and Aspire Capital Fund, LLC.
4.5(4)	Common Stock Purchase Agreement, dated March 14, 2017 by and between TRACON Pharmaceuticals, Inc. and Aspire Capital Fund, LLC.
4.6(5)	Securities Purchase Agreement, dated March 22, 2018, among TRACON Pharmaceuticals, Inc. and the purchasers listed on Exhibit A thereto.
31.1	Certification of the Principal Executive and Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Principal Executive and Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(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.

(5) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on March 23, 2018.

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: August 7, 2019

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

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my conclusion 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. I have disclosed, based on my 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: August 7, 2019

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

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

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: August 7, 2019

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