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, 2018
or

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

For the transition period From To
Commission File Number: 001-38558

TRICIDA, INC.

(Exact name of registrant as specified in its charter)

Delaware		**46-3372526**
(State or other jurisdiction of incorporation or organization)		(I.R.S. Employer Identification Number)
7000 Shoreline Court Suite 201 South San Francisco, CA	**94080**	**(415) 429-7800**
(Address of principal executive offices)	(Zip code)	(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☒ (Do not check if a smaller reporting company)	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 in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

On August 1, 2018, the registrant had 42,095,927 shares of common stock, par value $0.001 per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “seek,” “should,” “target,” “will,” “would,” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- estimates of our expenses, capital requirements and our needs for additional financing;
- the prospects of TRC101, our only product candidate, which is still in development;
- our expectations regarding the timing of submitting a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, and our ability to obtain approval, for TRC101 under the FDA’s Accelerated Approval Program;
- our expectations regarding the timing of the completion of our nonclinical studies and drug-drug interaction studies;
- our expectations regarding the timing of the completion and reporting of our safety extension trial, TRCA-301E;
- the design of our confirmatory postmarketing trial, VALOR-CKD, including the sample size, trial duration, endpoint definition, event rate assumptions and eligibility criteria;
- our expectations regarding the timing of the enrollment, completion and reporting of our confirmatory postmarketing trial, VALOR-CKD;
- outcome and results of TRCA-301, TRCA-301E and VALOR-CKD trials;
- market acceptance or commercial success of TRC101 and the degree of acceptance among physicians, patients, patient advocacy groups, health care payors and the medical community;
- our expectations regarding competition, potential market size, the size of the patient populations for TRC101, if approved for commercial use, and market acceptance;
- our ability to maintain regulatory approval of TRC101, and any related restrictions, limitations and/or warnings in the label of TRC101;
- our sales, marketing or distribution capabilities and our ability to commercialize TRC101, if we obtain regulatory approval;
- current and future agreements with third parties in connection with the manufacturing, commercialization, packaging and distribution of TRC101;
- our expectations regarding the ability of our contract manufacturing partners to produce TRC101 in the quantities and timeframe that we will require;
- our expectations regarding our future costs of goods;
- our ability to attract, retain and motivate key personnel and increase the size of our organization;
- the scope of protection we are able to establish and maintain for intellectual property rights covering TRC101;
- potential claims relating to our intellectual property and third-party intellectual property;
- the duration of our intellectual property estate that will provide protection for TRC101;
- our ability to establish collaborations in lieu of obtaining additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our anticipated use of proceeds from our initial public offering; and
- our financial performance.

These forward-looking statements are based on management’s current expectations, estimates, forecasts, and projections about our business and the industry in which we operate and management’s beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in Quarterly Report on Form 10-Q may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. You are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Except as required by law, we assume no obligation to update or revise these

forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission after the date of this Quarterly Report on Form 10-Q.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
Tricida, Inc.

Condensed Balance Sheets
(Unaudited)
(In thousands, except share and per share amounts)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 5,788	$ 9,774
Short-term investments	49,518	57,740
Prepaid expenses and other current assets	1,550	1,910
Total current assets	56,856	69,424
Property and equipment, net	1,303	1,150
Deferred offering costs	6,468	—
Total assets	$ 64,627	$ 70,574
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 11,436	$ 3,861
Accrued expenses and other current liabilities	14,134	7,361
Total current liabilities	25,570	11,222
Term loan	23,317	—
Other long-term liabilities	483	323
Total liabilities	49,370	11,545
Commitments and contingencies (Note 8)		
Series A convertible preferred stock, $0.001 par value; 11,398,694 shares authorized as of June 30, 2018 and December 31, 2017; 11,398,694 and 11,302,758 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively; aggregate liquidation preference of $10,099 and $10,014 as of June 30, 2018 and December 31, 2017, respectively	10,258	9,800
Series B convertible preferred stock, $0.001 par value; 32,526,878 shares authorized as of June 30, 2018 and December 31, 2017; 32,526,878 shares issued and outstanding as of June 30, 2018 and December 31, 2017; aggregate liquidation preference of $30,250 as of June 30, 2018 and December 31, 2017	29,618	29,618
Series C convertible preferred stock, $0.001 par value; 35,806,451 shares authorized as of June 30, 2018 and December 31, 2017; 35,806,451 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively; aggregate liquidation preference of $55,500 as of June 30, 2018 and December 31, 2017	50,347	50,347
Series D convertible preferred stock, $0.001 par value; 24,500,000 shares authorized as of June 30, 2018 and December 31, 2017; 24,493,615 shares issued and outstanding as of June 30, 2018 and December 31, 2017; aggregate liquidation preference of $57,560 as of June 30, 2018 and December 31, 2017	57,305	57,305
Stockholders' deficit:		
Common stock, $0.001 par value; 134,000,000 shares authorized as of June 30, 2018 and December 31, 2017; 2,453,606 and 2,272,609 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	2	2
Additional paid-in capital	3,005	1,356
Accumulated other comprehensive loss	(26)	(13)
Accumulated deficit	(135,252)	(89,386)
Total stockholders' deficit	(132,271)	(88,041)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 64,627	$ 70,574

See accompanying notes to condensed financial statements (unaudited).

Tricida, Inc.

Condensed Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 21,034	$ 4,567	$ 37,667	$ 10,411
General and administrative	4,245	2,355	7,710	5,180
Total operating expenses	25,279	6,922	45,377	15,591
Loss from operations	(25,279)	(6,922)	(45,377)	(15,591)
Change in fair value—preferred stock tranche obligation	—	(813)	—	5,649
Other income (expense), net	827	11	740	11
Interest expense	(910)	(2)	(1,229)	(4)
Net loss	(25,362)	(7,726)	(45,866)	(9,935)
Other comprehensive loss:				
Net unrealized gain (loss) on marketable securities, net of tax	41	(9)	(13)	(10)
Comprehensive loss	$ (25,321)	$ (7,735)	$ (45,879)	$ (9,945)
Net loss per share, basic and diluted	$ (10.89)	$ (3.60)	$ (19.91)	$ (4.75)
Weighted-average number of shares outstanding, basic and diluted	2,329,085	2,145,965	2,304,087	2,092,993

See accompanying notes to condensed financial statements (unaudited).

Tricida, Inc.

Condensed Statements of Cash Flows
(Unaudited)
(In thousands)

	Six months ended June 30,	
	2018	**2017**
Operating activities:		
Net loss	$ (45,866)	$ (9,935)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	280	171
Amortization of term loan discount and issuance costs	504	—
Net amortization of premiums and discounts on marketable securities	(264)	(5)
Stock-based compensation	1,323	376
Changes in fair value of warrants and compound derivative liabilities	(236)	8
Changes in fair value of preferred stock tranche obligation	—	(5,649)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	229	387
Accounts payable	4,652	(562)
Accrued expenses and other liabilities	5,303	(945)
Net cash used in operating activities	(34,075)	(16,154)
Investing activities:		
Purchase of marketable securities	(20,002)	(31,217)
Maturities of marketable securities	28,475	22,265
Purchase of property and equipment	(542)	(31)
Net cash provided by (used in) investing activities	7,931	(8,983)
Financing activities:		
Loan proceeds (repayments) relating to tenant improvement loan	220	(22)
Proceeds from exercise of common stock options	236	6
Proceeds from issuance of convertible preferred stock for cash, net of issuance costs	85	25,160
Deferred offering costs	(2,017)	—
Net proceeds from issuance of term loan	23,634	—
Net cash provided by financing activities	22,158	25,144
Net increase (decrease) in cash and cash equivalents	(3,986)	7
Cash and cash equivalents at beginning of period	9,774	5,682
Cash and cash equivalents at end of period	$ 5,788	$ 5,689
Supplemental disclosures		
Cash paid for interest	$ 539	$ —
Supplemental disclosures of non-cash financing activities		
Deferred offering costs incurred but not paid	$ 4,320	$ —
Compound derivative and warrant related to the term loan	$ 810	$ —
Purchase of property and equipment included in accrued expenses and accounts payable	$ 90	$ —
Series C fair value of preferred stock obligation upon closing	$ —	$ 2,278

See accompanying notes to condensed financial statements (unaudited).

Tricida, Inc.

Notes to Condensed Financial Statements

(Unaudited)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization—Tricida, Inc., or the Company, was incorporated in the state of Delaware on May 22, 2013 and was granted its certification of qualification in the state of California on August 5, 2013 (inception). The Company is engaged in the development of TRC101, a non-absorbed, orally-administered polymer drug designed to treat metabolic acidosis in patients with chronic kidney disease (CKD).

As of June 30, 2018, the Company has devoted substantially all of its efforts to the formation and financing of the Company, as well as product development, and has not realized revenues from its planned principal operations. The Company has no manufacturing facilities and all manufacturing related activities are contracted out to third-party service providers.

On July 2, 2018, the Company completed its initial public offering (IPO) and issued 13,455,000 shares of common stock for net proceeds of approximately $237.7 million. Upon the closing of the IPO, all shares of preferred stock outstanding were automatically converted into 26,187,321 shares of common stock. See Note 9 to these condensed financial statements for additional details.

Basis of presentation—The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X.

Unaudited Interim Financial Statements—The condensed balance sheet as of June 30, 2018, the condensed statements of operations and comprehensive loss for the three and six months ended June 30, 2018 and 2017 and the condensed statements of cash flows for the six months ended June 30, 2018 and 2017 are unaudited. These unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's financial position as of June 30, 2018, its results of operations for the three and six months ended June 30, 2018 and 2017and the condensed statements of cash flows for the six months ended June 30, 2018 and 2017. The results of operations for the three and six months ended June 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other future annual or interim period. The condensed balance sheet as of December 31, 2017 included herein was derived from the audited financial statements as of that date.

Reverse Stock Split—On June 14, 2018 the Company's board of directors approved a 1-for-3.98 reverse split of shares of our common stock. The par values and the authorized shares of the common and convertible preferred stock were not adjusted as a result of the reverse stock split, nor were the outstanding shares of preferred stock. All issued and outstanding common stock and related per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented. The reverse stock split was effected on June 15, 2018.

Use of Estimates—The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents—The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents.

Short-term Investments—All highly liquid investments with original maturities of greater than three months from the date of purchase are classified as short-term investments. Management has classified the Company's short-term investments as available-for-sale securities in the accompanying financial statements. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a component of accumulated other comprehensive loss. Realized gains and losses on the sale of all such securities are reported in other income (expense), net and computed using the specific identification method. For the three and six months ended June 30, 2018, there were no realized gains or losses on these securities. The Company's investments are in commercial paper, asset-backed securities and corporate debt securities. Pursuant to the Company's investment policy, all purchased securities have a minimum short-term rating of A1 (Moody's) or P1 (Standard & Poor's) or equivalent. If

there is no short-term rating, a purchased security is required to have a long-term rating no lower than A3/A- or equivalent.

Concentration of Credit Risk—Financial instruments that potentially subject the Company to a concentration of credit risk, consist primarily of cash and cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that these financial institutions are financially sound, and, accordingly, minimal credit risk exists with respect to those financial institutions. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents and short-term investments and issuers of marketable securities to the extent recorded in the balance sheet.

Property and Equipment—Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is determined using the straight-line method over the estimated useful lives of the respective assets, which is three years. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or the estimated useful economic lives of the related assets.

Deferred Offering Costs—The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' deficit as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss. As of June 30, 2018, $6.5 million of deferred offering costs were capitalized on the balance sheet. The deferred offering costs were reclassified to additional paid-in capital upon the closing of the Company's initial public offering on July 2, 2018. See Note 9 to these condensed financial statements for additional details.

Impairment of Long-Lived Assets—Long-lived assets consist of property and equipment. The Company assesses potential impairment losses on long-lived assets used in operations when events and circumstances indicate that assets might be impaired. If such events or changes in circumstances arise, the Company compares the carrying amount of the long-lived assets to the estimated future undiscounted cash flows expected to be generated by the long-lived assets. If the estimated aggregate undiscounted cash flows are less than the carrying amount of the long-lived assets, an impairment charge, calculated as the amount by which the carrying amount of the assets exceeds the fair value of the assets, is recorded. The fair value of the long-lived assets is determined based on the estimated discounted cash flows expected to be generated from the long-lived assets. The Company has not recognized any impairment losses through the six months ended June 30, 2018 and 2017.

Clinical and Manufacturing Accruals—The Company records accruals for estimated costs of research, preclinical and clinical studies, and manufacturing development, which are a significant component of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers, including clinical research organizations (CROs) and contract manufacturing organizations (CMOs). The Company's contracts with CROs generally include pass-through fees such as regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fees to be paid for such services.

The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. As actual costs become known, the Company adjusts its accruals. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrual is dependent, in part, upon the receipt of timely and accurate reporting from information provided as part of its clinical and non-clinical studies and other third-party vendors. Through June 30, 2018, there have been no material differences from the Company's accrued estimated expenses to the actual clinical trial and manufacturing expenses. However, variations in the assumptions used to estimate accruals, including, but not limited to the number of patients enrolled, the rate of patient enrollment, the actual services performed, and the amount of manufactured drug substance and/or drug product, and related costs may vary from the Company's

estimates, resulting in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect its financial position and results of operations.

Convertible preferred stock—The Company records all shares of convertible preferred stock at their respective fair values, net of issuance costs, on the dates of issuance. In the event of a change of control of the Company, proceeds will be distributed in accordance with the liquidation preferences set forth in its Amended and Restated Certificate of Incorporation unless the holders of convertible preferred stock have converted their convertible preferred shares into common shares. Therefore, convertible preferred stock is classified outside of stockholders' deficit on the accompanying balance sheets as events triggering the liquidation preferences are not solely within the Company's control. The Company has elected not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such an event would occur. Upon the closing of the IPO on July 2, 2018, all shares of preferred stock outstanding were automatically converted into 26,187,321 shares of common stock. See Note 9 to these condensed financial statements for additional details.

Warrant Liability—The Company has issued freestanding warrants to purchase shares of its Series A convertible preferred stock. Freestanding warrants for shares of the Company's convertible preferred stock that are classified outside of permanent equity, and other similar instruments related to shares that are classified as liabilities, are recorded at fair value, and are subject to remeasurement at each balance sheet date until the earlier of the exercise of the warrants or the completion of a liquidation event, including the completion of an initial public offering. Upon exercise, the warrant liability would be reclassified to additional paid-in capital, with any change in fair value recognized as a component of other income (expense), net.

Preferred Stock Tranche Obligation—From time to time, the Company enters into convertible preferred stock financings where, in addition to the initial closing, investors agree to buy, and the Company agrees to sell, additional shares of that convertible preferred stock at a set price in the event that certain agreed milestones are achieved (a tranched financing). The Company evaluates this tranche obligation and assesses whether it meets the definition of a freestanding instrument, and if so, determines the fair value of this obligation and records it on the balance sheet with the residual of the proceeds raised being allocated to convertible preferred stock. The preferred stock tranche obligation is revalued each reporting period with changes in the fair value of the obligation recorded as a component of other income (expense), net in the statements of operations and comprehensive loss. The preferred stock tranche obligation is revalued at settlement and the resultant fair value is then reclassified to convertible preferred stock at that time.

Research and Development Costs—Research and development costs are charged to the statements of operations and comprehensive loss in the year in which they are incurred. Research and development expenses consist primarily of:

- salaries and related costs, including stock-based compensation expense, for personnel and consultants in our research and development functions;
- fees paid to clinical consultants, clinical trial sites and vendors, including CROs;
- costs related to pre-commercialization manufacturing activities including payments to CMOs and other vendors and consultants;
- costs related to regulatory activities;
- expenses related to lab supplies and services; and
- depreciation and other allocated facility-related and overhead expenses

Stock-Based Compensation—The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all share-based payments made to employees and directors based on estimated grant-date fair values. The Company uses the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period, and estimates the fair value of share-based awards to employees and directors using the Black-Scholes option-valuation model. The Black-Scholes model requires the input of subjective assumptions, including expected volatility, expected dividend yield, expected term, risk-free rate of return, and the estimated fair value of the underlying common stock on the date of grant. Stock-based compensation expense is recorded net of estimated forfeitures of unvested awards.

The Company records the expense attributed to nonemployee services paid with share-based awards based on the estimated fair value of the awards determined using the Black-Scholes option pricing model. The

measurement of stock-based compensation for nonemployees is subject to re-measurement as the options vest, and the expense is recognized over the period during which services are received.

Income Taxes—The Company accounts for income taxes using the liability method, whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance when it is more likely than not that some portion, or all of its deferred tax assets will not be realized.

The Company accounts for income tax contingencies using a benefit recognition model. If it considers that a tax position is more likely than not to be sustained upon audit, based solely on the technical merits of the position, it recognized the benefit. The Company measures the benefit by determining the amount that is greater than 50% likely of being realized upon settlement, presuming that the tax position is examined by the appropriate taxing authority that has full knowledge of all relevant information. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Comprehensive Loss—Comprehensive loss includes net loss and certain changes in stockholders' deficit that are excluded from net loss, primarily unrealized losses on the Company's short-term investments.

Segment reporting—The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. All of the Company's assets are maintained in the United States.

Net Loss per Share—Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

Recent Accounting Pronouncements

Adopted Standards

In May 2017, the FASB issued ASU No. 2017-09, *Compensation - Stock Compensation* (ASC Topic 718): *Scope of Modification Accounting*. This ASU specifies the modification accounting applicable to any entity which changes the terms or conditions of a share-based payment award. We elected to prospectively adopt this ASU as of the beginning of the first quarter of 2018. The adoption of this ASU did not have a material impact on the Company's condensed financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share; Distinguishing Liabilities from Equity; Derivatives and Hedging, (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. The guidance in ASU 2017-11 allows for the exclusion of a down round feature, when evaluating whether or not an instrument or embedded feature requires derivative classification. The Company early adopted this guidance beginning January 1, 2018. The adoption of this standard had no material impact on the Company's condensed financial statements.

Standards Not Yet Effective

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which for operating leases requires the lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The guidance also requires a lessee to recognize single lease costs, calculated so that the cost of the lease is allocated over the lease term, on a generally straight-line basis. The accounting standard is effective for fiscal years beginning after December 15, 2018 including interim periods within those fiscal years. Early adoption is permitted. The Company expects the implementation of ASC 842 to have an impact on its financial statements and related disclosures as it had aggregate future minimum lease payments of approximately $3.3 million as of June 30, 2018. The Company anticipates recognition of additional assets and corresponding liabilities related to these leases on its condensed balance sheet.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which amends ASC Topic 718, "Compensation—Stock Compensation". The ASU simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of

the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. ASU 2018-07 is effective for public business entities for annual reporting periods, and interim periods within those annual periods, beginning after December 15, 2018. Early adoption will be permitted in any interim or annual period, with any adjustments reflected as of the beginning of the fiscal year of adoption. The Company is currently evaluating the new guidance and has not determined the impact this standard may have on its condensed financial statements.

2. FAIR VALUE OF FINANCIAL INSTRUMENTS

The fair value of the Company's financial assets and liabilities are determined in accordance with the fair value hierarchy established in FASB, ASC, Topic 820, *Fair Value Measurements and Disclosures*. ASC Topic 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy of ASC Topic 820 requires an entity to maximize the use of observable inputs when measuring fair value and classifies those inputs into three levels:

Level 1—Observable inputs, such as quoted prices in active markets

Level 2—Inputs, other than the quoted prices in active markets, which are observable either directly or indirectly such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the instrument's anticipated life

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

The Company's financial assets and liabilities include cash equivalents, short-term investments, a warrant liability and prior to April 2017, a preferred stock tranche obligation. Cash equivalents in the form of money market funds are stated at cost, which approximates their fair values.

The Company issued a freestanding preferred stock tranche obligation in connection with the initial closing of the Series C financing in July 2016. The investors in the Series C financing committed to the purchase of 16,274,192 shares of Series C convertible preferred stock at $1.55 per share upon achievement of a specified milestone. This milestone was met and the Series C investors purchased the shares in April 2017.

On April 25, 2017, the tranche obligation was settled, and the obligation was valued at intrinsic value, using the fair value of the Series C preferred stock from the Option Pricing Model. The various assumptions used to determine the fair value of the Series C preferred stock in the option pricing model were time to liquidity of 2.4 years, volatility of 54.0%, risk-free interest rate of 1.4% and equity value of $118.5 million. Since the per share value was lower than the contractual purchase price, the fair value of the tranche obligation was determined to be an asset and recorded at $2.3 million at settlement on April 25, 2017.

The Company had detachable warrants and compound derivatives that were recorded as liabilities and adjusted to fair value on a recurring basis. The fair value of the warrant liabilities were determined using an option-pricing model, which utilizes a series of unobservable inputs, and accordingly, the liabilities were classified as Level 3 measurements. On April 10, 2018, the Company entered into amendments with Hercules to modify the outstanding common stock warrants. The Company re-evaluated the classification of the modified warrants and determined that the outstanding common stock warrants are considered to be indexed to the Company's own stock and are therefore reclassified the common stock warrants as equity under ASC 480. The fair value of the common stock warrants of $194,000 upon execution of the amendment is no longer subject to remeasurement. On June 16, 2018, Sibling Co-Investment LLC provided the Notice of Exercise to purchase 95,936 shares of Series A convertible preferred stock for cash of $85,000. Upon exercise, the Company reclassified the fair value of the warrants from warrant liability to Series A convertible preferred stock.

The following table sets forth the Company's financial assets and liabilities that are measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	As of June 30, 2018			
	Level 1	Level 2	Level 3	Fair Value
Financial assets:				
Cash equivalents				
Money market fund	$ 2,787	$ —	$ —	$ 2,787
Marketable securities				
Commercial paper	—	21,584	—	21,584
Corporate debt securities	—	22,936	—	22,936
Asset backed securities	—	4,998	—	4,998
Financial liabilities:				
Long term liabilities				
Compound derivative liability	—	—	113	113

	As of December 31, 2017			
	Level 1	Level 2	Level 3	Fair Value
Financial assets:				
Cash equivalents				
Money market fund	$ 6,758	$ —	$ —	$ 6,758
Corporate debt securities	—	2,930	—	2,930
Marketable securities				
Commercial paper	—	25,773	—	25,773
Corporate debt securities	—	17,613	—	17,613
Asset backed securities	—	14,354	—	14,354
Financial liabilities:				
Long term liabilities				
Warrant liability	—	—	106	106

The following tables are a reconciliation of all liabilities measured at fair value using Level 3 unobservable inputs (in thousands):

	Compound Derivative	Warrant Liability
Fair value at January 1, 2018	$ —	$ 106
Addition	654	156
Change in fair value	(541)	305
Reclassification to equity	—	(194)
Issuance of convertible preferred stock on exercise of warrant	$ —	(373)
Fair value at June 30, 2018	$ 113	$ —

Where quoted prices are available in an active market, securities are classified as Level 1. The Company classifies money market funds as Level 1. When quoted market prices are not available for the specific security, then the Company estimates fair value by using quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to benchmark yields, reported trades and broker/dealer quotes. Where applicable the market approach utilizes prices and information from market transactions for similar or identical assets. The Company classifies corporate debt securities, commercial paper and asset backed securities as Level 2. In certain cases where there is limited activity or less

transparency around inputs to valuation, securities are classified as Level 3. Level 3 liabilities that are measured at fair value on a recurring basis consist of the compound derivative liability.

There were no transfers of assets or liabilities between the fair value measurement levels during the six months ended June 30, 2018 and year ended December 31, 2017.

The carrying values of the Company's financial instruments, such as accounts payable and accrued expenses and other current liabilities, approximate fair value due to the short-term nature of these items.

All marketable securities were considered available-for-sale at June 30, 2018 and December 31, 2017. The amortized cost, unrealized holding gains or losses, and fair value of the Company's short-term investments by major security type at June 30, 2018 and December 31, 2017 are summarized in the table below (in thousands):

	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	Aggregate Fair Value at June 30, 2018
Commercial paper	$ 21,595	$ 1	$ (12)	$ 21,584
Corporate debt securities	22,950	—	(14)	22,936
Asset backed securities	4,999	—	(1)	4,998
Total	$ 49,544	$ 1	$ (27)	$ 49,518

	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	Aggregate Fair Value at December 31, 2017
Commercial paper	$ 25,780	$ —	$ (7)	$ 25,773
Corporate debt securities	17,615	3	(5)	17,613
Asset backed securities	14,358	—	(4)	14,354
Total	$ 57,753	$ 3	$ (16)	$ 57,740

All marketable securities as of June 30, 2018 have contractual maturities of one year or less.

As of June 30, 2018, unrealized losses on available-for-sale investments are not attributable to credit risk and are considered to be temporary. The Company believes that it is more-likely-than-not that investments in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value. All marketable securities with unrealized losses as of June 30, 2018 have been in a loss position for less than twelve months or the loss is not material.

The estimated fair value of the Term Loan was $23.0 million as of June 30, 2018, which approximates the carrying value and is classified as Level 3. The Company utilized a market yield analysis and income approach to estimate a range of value for the Term Loan. The discount rate ranged between 13.5% to 14.5%.

3. BALANCE SHEET COMPONENTS:

Property and Equipment, Net

	June 30, 2018	December 31, 2017
(In thousands)		
Furniture and fixtures	$ 214	$ 193
Computer and lab equipment	1,794	1,382
Leasehold improvements	878	878
	2,886	2,453
Less: accumulated depreciation and amortization	(1,583)	(1,303)
Total property and equipment, net	$ 1,303	$ 1,150

Depreciation and amortization expense was approximately $0.1 million and $0.1 million for the three months ended June 30, 2018 and 2017, respectively, and $0.3 million and $0.2 million for the six months ended June 30, 2018 and 2017, respectively.

Accrued Expenses and Other Current Liabilities

	June 30, 2018	December 31, 2017
(In thousands)		
Accrued clinical and nonclinical study costs	$ 3,003	$ 2,235
Accrued contract manufacturing	7,132	4,157
Accrued compensation	1,451	—
Accrued professional fees and other	2,548	969
Total accrued expenses and other current liabilities	$ 14,134	$ 7,361

4. TERM LOAN

On February 28, 2018, the Company entered into a Loan and Security Agreement, or the Term Loan, with Hercules Capital, Inc., or Hercules. The Term Loan provides for a loan in an aggregate principal amount of up to $100.0 million to be funded in five tranches subject to certain performance—based milestones. The first tranche, in the amount of $25.0 million, was funded on the closing date of the Term Loan. The second tranche of $25.0 million is now available as the Company achieved positive clinical data from the pivotal Phase 3 clinical trial, TRCA-301 and can be drawn down on or before December 31, 2018. A third tranche of $15.0 million will be available on or before December 31, 2019, on the condition that the Company submits a New Drug Application, or NDA, to the United States Food and Drug Administration, or FDA, which the FDA accepts for review, on or before December 31, 2019. A fourth tranche of $10.0 million will be available on or before December 15, 2020, provided that the Company obtains product approval from the FDA for the NDA for TRC101 on or before December 15, 2020. The fifth tranche of $25.0 million will be available on or before December 31, 2020, upon request by the Company and the approval of Hercules' investment committee.

The Term Loan bears interest at a floating per annum interest rate equal to the greater of either (i) 8.35% or (ii) the lesser of (x) 8.35% plus the prime rate as reported in The Wall Street Journal minus 5.00% and (y) 9.85%.

The Term Loan repayment schedule provides for interest only payments for the first 16 months, followed by consecutive equal monthly payments of principal and interest commencing on July 1, 2019 and continuing through the maturity date of March 1, 2022. The Term Loan also provides for a $650,000 facility fee that was paid at closing and an additional payment equal to 6.55% multiplied by the greater of (i) the aggregate term loans funded and (ii)(a) the aggregate term loans funded plus (b) one half of (x) $60.0 million minus (y) the aggregate term loans funded, which is due when the Term Loan becomes due or upon prepayment of the facility. If the Company elects to prepay

the Term Loan, there is also a prepayment fee of between 1% and 2% of the principal amount being prepaid depending on the timing and circumstances of prepayment.

In conjunction with the Term Loan, the Company issued warrants to purchase 53,458 shares of common stock with an exercise price of $9.35 per share. The estimated fair value of the warrants at the date of issuance was approximately $156,000. The fair value of the common stock warrant liability was determined using the probability weighted expected return method. It was recorded at its fair value at inception and was remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense), net in the accompanying condensed statement of operations and comprehensive loss.

On April 10, 2018, the Company entered into amendments with Hercules that resulted in the reclassification of the warrant liability to stockholders' deficit as the amended terms of the warrants qualified for them to be accounted for as equity instruments and as such are no longer subject to remeasurement. As of April 10, 2018, the various assumptions used in the option-pricing model were time to liquidity of 0.25 to 1.7 years, volatility of 72%, risk-free rate of 2.4% and equity value of $306 million to $420 million. The fair value of the common stock warrants of approximately $194,000 was reclassified to stockholders' deficit upon execution of the amendment.

In connection with any subsequent draw down under tranches two through five, the Company is obligated to issue additional common stock warrants equal to the quotient derived by dividing (a) 2.0% of the amount(s) funded under such tranche and (b) the lower of (x) $19.00 per share of common stock and (y) and the effective price at which the shares of the Company's Series D convertible preferred stock converted into common stock; provided however that in no event shall (x) or (y) be less than $0.80 per share.

The Term Loan is secured by substantially all of the Company’s assets, except the Company’s intellectual property, which is the subject of a negative pledge.

The Company determined that certain loan features were embedded derivatives requiring bifurcation and separate accounting. Those embedded derivatives were bundled together as a single, compound embedded derivative and then bifurcated and accounted for separately from the host contract. The Company initially recorded a compound derivative liability of $654,000, which is required to be marked to market in future periods. The Company calculated the fair values of the compound derivative by computing the difference between the fair value of the Term Loan with the compound derivative using the “with and without” method under the income approach, and the fair value of the Term Loan without the compound derivative. The Company calculated the fair values using a probability weighted discounted cash flow analysis. The key valuation assumptions used consist of the discount rate and the probability of the occurrence of certain events. The compound derivative liability is being remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense), net in the condensed statements of operations and comprehensive loss. As of June 30, 2018, the fair value of the compound derivative liability was approximately $113,000 and was classified as other long-term liabilities on the condensed balance sheet.

The facility fee, fair value of warrants at issuance, fair value of embedded derivatives which were bifurcated, and other debt issuance costs have been treated as debt discounts on the Company’s condensed balance sheet and together with the additional payment are being amortized to interest expense throughout the life of the Term Loan using the effective interest rate method.

As of June 30, 2018, there were unamortized issuance costs and debt discounts of $2.0 million, which were recorded as a direct deduction from the Term Loan on the condensed balance sheet.

Future payments of principal and interest (in thousands) as of June 30, 2018 are as follows:

Years ending December 31:	
2018 (remaining six months)	$ 1,061
2019	6,158
2020	10,206
2021	10,206
2022	5,393
	33,024
Less: amount representing interest	(8,024)
Present value of notes payable	25,000
Less: current portion	—
Long-term portion of notes payable	$ 25,000

5. CAPITAL STRUCTURE

Common Stock—Common stock reserved for future issuance, on an as if converted basis, consisted of the following:

	June 30, 2018	December 31, 2017
Preferred stock, issued and outstanding	26,187,321	26,163,217
Stock options issued and outstanding	4,470,054	3,588,663
Stock options authorized for future issuance	225,823	884,947
Total	30,883,198	30,636,827

Convertible Preferred Stock—As of June 30, 2018 and December 31, 2017, convertible preferred stock consisted of the following (in thousands, except share amounts):

	June 30, 2018			
	Authorized Shares	Shares Issued and Outstanding	Net Proceeds	Aggregate Liquidation Preference
Shares designated as:				
Series A convertible preferred stock	11,398,694	11,398,694	$ 9,885	$ 10,099
Series B convertible preferred stock	32,526,878	32,526,878	29,618	30,250
Series C convertible preferred stock	35,806,451	35,806,451	50,347	55,500
Series D convertible preferred stock	24,500,000	24,493,615	57,305	57,560
Total	104,232,023	104,225,638	$ 147,155	$ 153,409

	December 31, 2017			
	Authorized Shares	Shares Issued and Outstanding	Net Proceeds	Aggregate Liquidation Preference
Shares designated as:				
Series A convertible preferred stock	11,398,694	11,302,758	$ 9,800	$ 10,014
Series B convertible preferred stock	32,526,878	32,526,878	29,618	30,250
Series C convertible preferred stock	35,806,451	35,806,451	50,347	55,500
Series D convertible preferred stock	24,500,000	24,493,615	57,305	57,560
Total	104,232,023	104,129,702	$ 147,070	$ 153,324

6. PREFERRED STOCK WARRANT LIABILITY

The Company entered into a Note and Warrant Purchase Agreement with Sibling Co—Investment LLC, or Sibling, in 2013, the principal and interest of which was subsequently converted into the Company's Series A Preferred stock in the same year. In accordance with the agreement a warrant to purchase 95,936 shares of Series A Preferred stock was established in conjunction with the Series A financing round and remains outstanding as of June 30, 2018. The warrant has a contractual life of 7 years and an exercise price of $0.886. The fair value of the warrant liability was determined using the Option Pricing Method and was recorded at its fair value at inception and remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense), net in the accompanying statement of operations and comprehensive loss.

On June 16, 2018, Sibling provided the Notice of Exercise to purchase 95,936 shares of Series A Preferred stock. The fair value adjustment recognized upon exercise was determined using the intrinsic value which was calculated as the initial public offering ("IPO") price of $19.00 less the warrant exercise price, with the change in fair value being recognized as a component of other income (expense) in the accompanying statement of operations and comprehensive loss. As of June 30, 2018 and December 31, 2017, the fair value of the warrant is zero and approximately $106,000, respectively, and was classified as a long-term liability on the condensed balance sheet.

7. NET LOSS PER SHARE

The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except share and per share data):

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
(In thousands, except share and per share amounts)				
Numerator:				
Net loss	$ (25,362)	$ (7,726)	$ (45,866)	$ (9,935)
Denominator:				
Weighted average common shares outstanding	2,354,946	2,265,327	2,322,947	2,265,327
Less: weighted average shares subject to repurchase	(25,861)	(119,362)	(18,860)	(172,334)
Weighted average number of shares used in basic and diluted net loss per share	2,329,085	2,145,965	2,304,087	2,092,993
Net loss per share, basic and diluted	$ (10.89)	$ (3.60)	$ (19.91)	$ (4.75)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows, on an as converted basis:

	June 30,	
	2018	2017
Series A convertible preferred stock	2,863,990	2,839,886
Series B convertible preferred stock	8,172,579	8,172,579
Series C convertible preferred stock	8,996,586	8,996,586
Series D convertible preferred stock	6,154,166	—
Warrants to purchase preferred stock	53,458	24,104
Common stock subject to repurchase	38,976	77,670
Options issued and outstanding	4,470,054	2,884,434
Total	30,749,809	22,995,259

8. COMMITMENTS AND CONTINGENCIES

Operating lease obligations: In July 2014, the Company entered into a five-year noncancelable operating lease that expires in June 2019, with an option for the Company to extend the lease for an additional three years. In August 2017, the Company entered into an amendment which extended the existing operating lease to June 2021 and added 13,258 square feet of additional lease space resulting in a total of 26,897 square feet being leased in the aggregate under the amended lease. The total remaining minimum lease payments of $3.3 million payable over the lease term do not include any related common area maintenance charges or real estate taxes. In addition, associated with the operating lease, the Company has a tenant improvement loan with remaining payments totaling approximately $0.3 million, which is to be amortized at 8% interest over the life of the lease.

Purchase obligations: On May 8, 2018, the Company and Patheon Austria GmbH & Co KG, or Patheon, entered into a master development/validation services and clinical/launch supply agreement, or MDS, pursuant to which Patheon will manufacture and supply the Company drug substances. Statements of work under the MDS commit the Company to certain purchase obligations of approximately $43.0 million over the next 36 months with approximately one-third of this amount occurring in each of the three successive 12-month periods.

The Company also enters into other contracts in the normal course of business with CROs, contract development and manufacturing organizations and other service providers and vendors. These contracts generally provide for termination on short notice and are cancelable contracts and accordingly, are not included in the contractual obligations and disclosures summarized above.

9. SUBSEQUENT EVENTS

Initial Public Offering

Effective on July 2, 2018, the Company completed its IPO and issued a total of 13,455,000 shares of common stock, which includes the allotment-option of 1,755,000 shares exercised by the underwriters in the IPO, at an offering price of $19.00 per share. In aggregate, the Company received net proceeds of approximately $237.7 million, after deducting underwriting discounts and commissions of $17.9 million. In connection with the IPO, the following events occurred subsequent to June 30, 2018:

- On July 2, 2018, the 104,225,638 outstanding shares of Convertible Preferred Stock automatically converted into an aggregate of 26,187,321 shares of common stock;
- On July 2, 2018, total common shares outstanding were 42,095,927, which includes common shares outstanding as of June 30, 2018, shares issued in the IPO and Convertible Preferred Stock converted and reclassified; and
- On July 2, 2018, the Company's amended and restated certificate of incorporation became effective, authorizing 400,000,000 shares of common stock and 40,000,000 shares of undesignated preferred stock.

The table below shows, on a pro forma basis, the impact of the Company's IPO on certain condensed balance sheet items as if all of the transactions occurred on June 30, 2018:

	June 30, 2018	Pro forma June 30, 2018
Cash and cash equivalents and short-term investments	$ 55,306	$ 293,056
Deferred offering costs	6,468	—
Convertible preferred stock	147,528	—
Common stock	2	42
Additional paid-in capital	3,005	381,774
Total stockholders' (deficit) equity	$ (132,271)	$ 246,538

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. You should review "Risk Factors" for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Tricida, Inc. is a pharmaceutical company focused on the development and commercialization of its product candidate, TRC101, a non-absorbed, orally-administered polymer drug designed to treat metabolic acidosis in patients with chronic kidney disease (CKD). Metabolic acidosis is a condition commonly caused by CKD that is believed to accelerate the progression of kidney deterioration.

We have no products approved for marketing, and we have not generated any revenue from product sales or other arrangements. Through June 30, 2018, we have primarily funded our operations through the sale of $152.4 million of convertible preferred stock and borrowing of $23.6 million under the Term Loan facility. On July 2, 2018, we completed our initial public offering, raising net proceeds of $237.7 million. We have incurred losses in each year since our inception. Our net losses were $25.4 million and $7.7 million for the three months ended June 30, 2018 and 2017, respectively, and $45.9 million and $9.9 million for the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018 and December 31, 2017, we had an accumulated deficit of $135.3 million and $89.4 million, respectively. Substantially all of our operating losses resulted from expenses incurred in connection with advancing TRC101 through development activities and general and administrative costs associated with our operations.

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

- conduct clinical studies of TRC101;
- manufacture clinical study materials, and upon a successful validation campaign, commercial launch materials;
- increase our research and development efforts;
- hire additional personnel;
- create additional infrastructure to support our product development;
- seek regulatory approval for TRC101;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems to support ongoing operations, including operating as a public company.

We do not expect to generate any revenues from product sales until we successfully complete development and obtain regulatory approval for TRC101, which we expect will take a number of years. If we obtain regulatory approval for TRC101, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, 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 TRC101.

Components of Our Results of Operations

Research and Development Expenses

Research and development expenses consist primarily of costs associated with the development of our product candidate and include salaries, benefits, travel and other related costs, including equity-based compensation expenses, for personnel engaged in research and development functions; expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants that conduct our nonclinical and clinical studies; manufacturing development and scale-up expenses and the cost of acquiring and manufacturing clinical study materials and commercial materials, including manufacturing registration and validation batches; payments to consultants engaged in the development of TRC101, including equity-based compensation, travel and other expenses; costs related to compliance with quality and regulatory requirements; research and development facility-related expenses, which include direct and allocated expenses, and other related costs. Research and development expenses are charged to operations as incurred when these expenditures relate to our research and development efforts and have no alternative future uses. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

All of our research and development expenses to date have been incurred in connection with TRC101. We expect our research and development expenses to increase for the foreseeable future as we advance TRC101 through clinical development, including conducting our ongoing safety extension trial, TRCA-301E and our confirmatory post marketing trial, known as VALOR-CKD, or TRCA-303. The process of conducting clinical studies necessary to obtain regulatory approval is costly and time consuming and the successful development of TRC101 is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when, and to what extent, we will generate revenue from commercialization and sale of TRC101. Therefore, we are unable to estimate with any certainty the costs we will incur in the continued development of TRC101. The degree of success, timelines and cost of development can differ materially from expectations. We may never succeed in achieving regulatory approval for TRC101.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits, travel, equity-based compensation expense and facility-related expenses for personnel in finance and administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, accounting and audit services and other related costs.

We anticipate that our general and administrative expenses will increase in the future as we build our infrastructure to support our continued research and development of TRC101. We also anticipate increased expenses related to accounting, legal and regulatory-related services associated with maintaining compliance with exchange listing and the Securities and Exchange Commission, or the SEC, requirements, director and officer insurance premiums and other costs associated with being a public company.

Results of Operations and Comprehensive Loss

The following table summarizes our results of operations for the three and six months ended June 30, 2018 and 2017:

	Three months ended June 30,		Change		Six months ended June 30,		Change	
	2018	2017	$	%	2018	2017	$	%
(In thousands)								
Operating expenses:								
Research and development	$ 21,034	$ 4,567	$ 16,467	361 %	$ 37,667	$ 10,411	$ 27,256	262 %
General and administrative	4,245	2,355	1,890	80 %	7,710	5,180	2,530	49 %
Total operating expenses	25,279	6,922	18,357	265 %	45,377	15,591	29,786	191 %
Loss from operations	(25,279)	(6,922)	(18,357)	265 %	(45,377)	(15,591)	(29,786)	191 %
Change in fair value—preferred stock tranche obligation	—	(813)	813	(100)%	—	5,649	(5,649)	(100)%
Other income (expense), net	827	11	816	*N/M*	740	11	729	*N/M*
Interest expense	(910)	(2)	(908)	*N/M*	(1,229)	(4)	(1,225)	*N/M*
Net loss	(25,362)	(7,726)	(17,636)	228 %	(45,866)	(9,935)	(35,931)	362 %
Other comprehensive loss	41	(9)	50	(556)%	(13)	(10)	(3)	30 %
Comprehensive loss	$ (25,321)	$ (7,735)	$ (17,586)	227 %	$ (45,879)	$ (9,945)	$ (35,934)	361 %

N/M = Not meaningful

Research and Development Expense

The following table summarizes our research and development expense for the three months ended June 30, 2018 and 2017:

	Three months ended June 30,		Change	
	2018	2017	$	%
(In thousands)				
Clinical development costs	$ 17,252	$ 2,821	$ 14,431	512%
Personnel and related costs	2,455	1,209	1,246	103%
Equity-based compensation expense	527	82	445	543%
Other research and development costs	800	455	345	76%
Total research and development expense	$ 21,034	$ 4,567	$ 16,467	361%

Comparison of the three months ended June 30, 2018 and 2017

Research and development expense was $21.0 million and $4.6 million for the three months ended June 30, 2018 and 2017, respectively. The increase of $16.5 million was due to increased activities in connection with our TRC101 clinical development program, resulting in increased development costs of $14.4 million related to TRC-101, related to our safety extension trial, TRCA-301E, and preparation of our confirmatory postmarketing trial, known as VALOR-CKD, or TRCA-303, increased personnel and related costs of $1.2 million, increased equity-based compensation expense of $0.4 million related to increased headcount and increased fair value of award grants and increased other research and development costs of $0.3 million which primarily included increases in facilities and office expenses.

The following table summarizes our research and development expense for the six months ended June 30, 2018 and 2017:

	Six months ended June 30,		Change	
	2018	2017	$	%
(In thousands)				
Clinical development costs	$ 30,920	$ 7,490	$ 23,430	313%
Personnel and related costs	4,404	1,805	2,599	144%
Equity-based compensation expense	699	161	538	334%
Other research and development costs	1,644	955	689	72%
Total research and development expense	$ 37,667	$ 10,411	$ 27,256	262%

Comparison of the six months ended June 30, 2018 and 2017

Research and development expense was $37.7 million and $10.4 million for the six months ended June 30, 2018 and 2017, respectively. The increase of $27.3 million was due to increased activities in connection with our TRC101 clinical development program, resulting in increased development costs of $23.4 million related to TRC-101, related to our safety extension trial, TRCA-301E, and preparation of our confirmatory postmarketing trial, known as VALOR-CKD, or TRCA-303, increased personnel and related costs of $2.6 million, increased equity-based compensation expense of $0.5 million related to increased headcount and increased fair value of award grants and increased other research and development costs of $0.7 million which primarily included increases in facilities and office expenses.

General and Administrative Expense

The following table summarizes our general and administrative expense for the three months ended June 30, 2018 and 2017:

	Three months ended June 30,		Change	
	2018	2017	$	%
(In thousands)				
Personnel and related costs	$ 1,552	$ 1,368	$ 184	13%
Equity-based compensation expense	443	105	338	322%
Other general and administrative costs	2,250	882	1,368	155%
Total general and administration expense	$ 4,245	$ 2,355	$ 1,890	80%

Comparison of the three months ended June 30, 2018 and 2017

General and administrative expense was $4.2 million and $2.4 million for the three months ended June 30, 2018 and 2017, respectively. The increase of $1.9 million was due to increased administrative costs supporting the increased activities in connection with our TRC101 clinical development program, resulting in increased personnel and related costs of $0.2 million, increased equity-based compensation expense of $0.3 million due to increased headcount and increased fair value of award grants and increased other general and administrative expenses of $1.4 million, which included increases in audit and legal services of $0.6 million, commercialization, medical affairs and outside consultants of $0.4 million, and facilities, travel and entertainment and office expenses of $0.3 million.

The following table summarizes our general and administrative expense for the six months ended June 30, 2018 and 2017:

	Six months ended June 30,		Change	
	2018	2017	$	%
(In thousands)				
Personnel and related costs	$ 3,388	$ 3,087	$ 301	10%
Equity-based compensation expense	624	216	408	189%
Other general and administrative costs	3,698	1,877	1,821	97%
Total general and administration expense	$ 7,710	$ 5,180	$ 2,530	49%

Comparison of the six months ended June 30, 2018 and 2017

General and administrative expense was $7.7 million and $5.2 million for the six months ended June 30, 2018 and 2017, respectively. The increase of $2.5 million was due to increased administrative costs supporting the increased activities in connection with our TRC101 clinical development program, resulting in increased personnel and related costs of $0.3 million, increased equity-based compensation expense of $0.4 million due to increased headcount and increased fair value of award grants and increased other general and administrative expenses of $1.8 million, which included increases in audit and legal services of $1.1 million and facilities, travel and entertainment and office expenses of $0.5 million.

Change in Fair Value—Preferred Stock Tranche Obligation

The fair value of the Series C preferred stock tranche obligation was determined considering the terms of the preferred stock agreement and the fair value of the Series C stock relative to the contractual purchase price for the tranche. At issuance, the Series C preferred stock tranche obligation was considered to be a contingent obligation, where the investors had agreed to invest at a price of $1.55 per share upon achievement of a specified milestone.

The Series C preferred stock tranche obligation was modeled as a warrant within the Option Pricing Model framework as of December 2016. The various assumptions used to determine the fair value of the Series C preferred stock tranche obligation in the option pricing model were time to liquidity of 2.4 years, volatility of 54.0%, risk-free interest rate of 1.3% and equity value of $91.4 million. The fair value of the tranche obligation was determined to be a liability and recorded at $3.4 million as of December 31, 2016.

On April 25, 2017, the tranche obligation was settled, and the obligation was valued at intrinsic value, using the fair value of the Series C preferred stock from the Option Pricing Model. The various assumptions used to determine the fair value of the Series C preferred stock in the option pricing model were time to liquidity of 2.4 years, volatility of 54.0%, risk-free interest rate of 1.4% and equity value of $118.5 million. Since per share value was lower than the contractual purchase price, the fair value of the tranche obligation was determined to be an asset and recorded at $2.3 million at settlement on April 25, 2017, which resulted in a mark-to-market adjustment of $5.6 million for the six months ended June 30, 2017.

Liquidity and Capital Resources

Sources of Liquidity

From our inception through June 30, 2018, we have funded our operations primarily through the sale and issuance of our convertible preferred stock and a term loan. From our inception through June 30, 2018, we raised aggregate cash proceeds of $152.4 million from the issuance of our convertible preferred stock and $23.6 million from the issuance of a term loan. As of June 30, 2018, we had cash, cash equivalents and short-term investments of $55.3 million.

Hercules Loan and Security Agreement

On February 28, 2018, we entered into a loan and security agreement, or the Term Loan, with Hercules Capital, Inc., or Hercules. The Term Loan provides for a loan in an aggregate principal amount of up to $100.0 million to be advanced in five tranches subject to certain performance-based milestones. The first tranche, in the

amount of $25.0 million, was funded on the closing date of the Term Loan, or the Closing Date. The second tranche of $25.0 million is now available as we achieved positive clinical data from our pivotal Phase 3 clinical trial, TRCA-301 and can be drawn down on or before December 31, 2018. A third tranche of $15.0 million will be available on or before December 31, 2019, on the condition that we submit an NDA to the FDA, which the FDA accepts for review, on or before December 31, 2019. A fourth tranche of $10.0 million will be available on or before December 15, 2020, provided that we obtain final approval from the FDA for the NDA for TRC101 on or before December 15, 2020. We must also not have an event of default to be eligible for all performance-based tranches. Furthermore, tranches three and four are subject to Hercules' verification of the required milestones, and we must provide supporting documentation when requested by Hercules. The fifth tranche of $25.0 million will be available on or before December 31, 2020, solely upon the approval of Hercules' investment committee.

The outstanding principal balance of the Term Loan bears interest at a floating per annum interest rate (based on a year consisting of 360 days) equal to the greater of either (i) 8.35% or (ii) the lesser of (x) 8.35% plus the prime rate as reported in The Wall Street Journal minus 5.00% and (y) 9.85%. Interest on each Term Loan advance is due on the first day of each month, beginning the second month after the advance date. Furthermore, commencing on July 1, 2019, the Term Loan will begin to amortize in equal monthly installments of principal and interest, provided, that such commencement of amortization may be extended to April 1, 2021 if certain conditions are met. Any remaining obligations are due in full on the maturity date, which is March 1, 2022; however, if we obtain final approval from the FDA for the NDA for TRC101 on or before February 15, 2022, the maturity date will be September 1, 2022. Furthermore, on the earliest to occur of the maturity date, the date we prepay our outstanding obligations under the loan agreement in full or the date such obligations otherwise become due and payable, we must pay Hercules an additional charge equal to 6.55% multiplied by the greater of (i) the aggregate term loans funded and (ii)(a) the aggregate term loans funded plus (b) one half of (x) $60,000,000 minus (y) the aggregate term loans funded. In addition, during an event of default, all obligations, including principal, interest, compounded interest, and professional fees will bear interest at the stated interest rate plus 3.00% per annum. If we prepay the Term Loan during any of the first twelve months following the Closing Date, we will be required to pay a prepayment charge equal to 2.00% of the amount being prepaid; if we prepay the Term Loan after the first 12 months but before 24 months have elapsed from the Closing Date, we must pay a prepayment charge of 1.50% of the amount being prepaid; if we prepay the Term Loan after 24 months but before thirty-six months have elapsed from the Closing Date, we must pay a prepayment charge of 1.00% of the amount being prepaid; and if we prepay the Term Loan on any date thereafter, we will not have to pay a prepayment charge. Notwithstanding the foregoing prepayment obligations, the agent and lender under this Term Loan can waive the prepayment charge (i) if both parties agree in writing to refinance the amounts prior to the maturity date, and (ii) with respect to a prepayment that is made, such waiver of the prepayment charge only applies to the principal amount prepaid. The Term Loan includes customary events of default for a failure to pay principal and interest when due, breach of covenants, bankruptcy/insolvency proceedings, and the occurrence of any event having a material adverse effect.

The Term Loan is secured by substantially all of our assets, except our intellectual property, which is the subject of a negative pledge; however, the collateral does consist of rights to payments and proceeds from the sale, licensing or disposition of all or any part of, or rights in, our intellectual property. Under the Term Loan, we are subject to certain customary covenants that require us to deliver financial reports at designated times of the year and maintain a minimum level of cash. These covenants also limit or restrict our ability to incur additional indebtedness or liens, acquire, own or make any investments, pay cash dividends, repurchase stock or enter into certain corporate transactions, including mergers and changes of control.

In connection with the Term Loan, we have agreed to issue warrants to each of Hercules and Hercules Technology III, L.P. upon each advance under the Term Loan. In connection with the draw down of the first tranche, we issued warrants for the right to purchase an aggregate number of shares of our common stock equal to the quotient derived by dividing (a) $500,000 by (b) the lower of (x) $19.00 per share of common stock and (y) and the effective price at which the shares of our Series D convertible preferred stock converted into common stock; provided however that in no event shall (x) or (y) be less than $0.20 per share, or the Floor Price.

In connection with any subsequent draw down under tranches two through five of the Term Loan, we will issue additional warrants to each of Hercules and Hercules Technology III, L.P. for the right to purchase an aggregate number of shares of our common stock equal to the quotient derived by dividing (a) 2.0% of the amount(s) funded under such tranche of the Term Loan with Hercules, by (b) the lower of (x) $19.00 per share of common stock and (y) and the effective price at which the shares of our Series D convertible preferred stock converted into common stock; provided however that in no event shall (x) or (y) be less than the Floor Price.

Funding Requirements

We have incurred losses and negative cash flows from operations since inception and anticipate that we will continue to incur net losses for the foreseeable future. As of June 30, 2018, we had an accumulated deficit of $135.3 million. Management expects to incur additional losses in the future to conduct product research and development and to conduct pre-commercialization activities and recognizes the need to raise additional capital to fully implement its business plan.

Such 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 studies of TRC101;
- the timing and outcome of regulatory reviews of TRC101;
- the revenue, if any, received from commercial sales of TRC101 for which we may receive regulatory approval;
- our ability to maintain and enforce our intellectual property rights and defend any intellectual property-related claims;
- the costs, timing and success of future commercialization activities, including product manufacturing, marketing, sales and distribution, for TRC101 if we receive regulatory approval and do not partner for commercialization; and
- the extent to which we acquire or in-license other products and technologies.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic partnerships and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. If we raise additional funds through collaborations, strategic partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to TRC101, associated intellectual property, our other technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us.

However, there can be no assurance that we will be successful in securing additional funding at levels sufficient to fund its operations or on terms acceptable to us. If we are unsuccessful in its efforts to raise additional financing, we could be required to significantly reduce operating expenses and delay, reduce the scope of or eliminate some of its development programs or its future commercialization efforts, out-license intellectual property rights to its product candidates and sell unsecured assets, or a combination of the above, any of which may have a material adverse effect on our business, results of operations, financial condition and/or its ability to fund its scheduled obligations on a timely basis or at all. The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if we are unable to continue as a going concern.

In July 2018, we completed our IPO pursuant to a registration statement on Form S-1. In the IPO, we issued and sold an aggregate of 13,455,000 shares of common stock, including the underwriters' exercise in full of their over-allotment option, under the registration statement at a public offering price of $19.00 per share. Net proceeds were approximately $237.7 million, after deducting underwriting discounts and commissions.

Cash Flows

The following table sets forth a summary of the net cash flow activity for each of the periods set forth below:

	Six months ended June 30,	
	2018	2017
(In thousands)		
Net cash provided by (used in):		
Operating activities	$ (34,075)	$ (16,154)
Investing activities	7,931	(8,983)
Financing activities	22,158	25,144
Net increase (decrease) in cash and cash equivalents	$ (3,986)	$ 7

Cash Used in Operating Activities

During the six months ended June 30, 2018, cash used in operating activities was $34.1 million, which consisted of a net loss of $45.9 million, adjusted by cash provided by changes in our operating assets and liabilities of $10.2 million and non-cash charges of $1.6 million. The changes in our operating assets and liabilities were primarily due to increases in accrued expenses and other current liabilities of $5.3 million and accounts payable of $4.7 million and a decrease in prepaid and other assets of $0.2 million. The non-cash charges consisted primarily of stock-based compensation of $1.3 million, amortization of term loan discounts and issuance costs of $0.5 million and depreciation and amortization of $0.3 million, partially offset by net amortization of premiums and discounts on marketable securities of $0.3 million and net changes in the fair value of the warrants and compound derivative liabilities of $0.2 million.

During the six months ended June 30, 2017, cash used in operating activities was $16.2 million, which consisted of a net loss of $9.9 million, adjusted by non-cash charges of $5.1 million and changes in cash used in our operating assets and liabilities of $1.1 million. The non-cash charges consisted primarily of changes in the fair value of our preferred stock trance financing obligation of $5.6 million, partially offset by stock-based compensation of $0.4 million and depreciation and amortization of $0.2 million. The changes in our operating assets and liabilities of $1.1 million are mostly due to decreases in accrued expenses and other liabilities of $0.9 million and accounts payable of $0.6 million, partially offset by an increase in prepaid and other assets of $0.4 million.

Cash Used in Investing Activities

Net cash provided by (used in) investing activities was $7.9 million and $(9.0) million for the six months ended June 30, 2018 and 2017, respectively. The net cash provided by investing activities during the six months ended June 30, 2018 was primarily due to maturities of marketable securities of $28.5 million, partially offset by purchases of marketable securities of $20.0 million and purchases of property and equipment of $0.5 million. The net cash used in investing activities during the six months ended June 30, 2017 was primarily due to purchases of marketable securities of $31.2 million, partially offset by maturities of marketable securities of $22.3 million.

Cash Used in Financing Activities

Net cash provided by financing activities was $22.2 million and $25.1 million for the six months ended June 30, 2018 and 2017, respectively. The net cash provided by financing activities during the six months ended June 30, 2018 was primarily the result of net proceeds from the Hercules loan of $23.6 million, partially offset by deferred initial public offering costs of $2.0 million. The net cash provided by financing activities during the six months ended June 30, 2017 was primarily the result of net proceeds of $25.2 million from our sale of Series C convertible preferred stock, net of issuance costs of $65,000.

Contractual Obligations and Commitments

For additional details regarding our contractual obligations, see Note 8 “Commitments and Contingencies” to our condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

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 rules of the SEC.

Jumpstart Our Business Startups Act

We are an emerging growth company, as defined in the JOBS Act. Under this act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act 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. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended.

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 financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported 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 historical experience and on various other factors that we believe are 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 significantly from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 1 to our condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. We consider all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. We do maintain significant amounts of cash at one or more financial institutions that are in excess of federally insured limits and have highly liquid marketable securities.

The primary objective of our investment activities is to preserve capital to fund our operations. We classify our marketable securities as available-for-sale securities in our financial statements. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a component of accumulated other comprehensive loss. Realized gains and losses on the sale of all such securities are reported in other income (expense) and other, net and computed using the specific identification method. For the six months ended June 30, 2018 and 2017, there were no realized gains or losses on these securities. The Company's investments are in commercial paper, asset-backed securities and corporate debt securities. Pursuant to the company's investment policy, all purchased securities have a minimum short-term rating of A1 (Moody's) or P1 (Standard & Poor's) or equivalent. If there is no short-term rating, a purchased security is required to have a long-term rating no lower than A3/A- or equivalent.

Our investments are subject to interest rate risk and could fall in value if market interest rates increase. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Foreign Currency Sensitivity

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions with CROs and contract manufacturing organizations, or CMOs, that are denominated in currencies other than the U.S. dollar, primarily the Euro, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against the Euro affects the reported amounts of expenses, assets and liabilities associated with a limited number of nonclinical and clinical activities. We do not engage in any hedging activity to reduce our potential exposure to currency fluctuations. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our condensed financial statements.

Effects of Inflation

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is our principal executive officer and our Chief Financial Officer, who is the principal financial officer, to allow timely decisions regarding required disclosure.

As of June 30, 2018, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of June 30, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the period covered by this report 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. We may, however, in the ordinary course of business face various claims brought by third parties and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business.

ITEM IA. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as our other filings with the Securities and Exchange Commission before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

We have a limited operating history, have incurred significant losses in each year since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We have only one product candidate, TRC101, which is in clinical trials and has no commercial sales, which, together with our limited operating history, makes it difficult to assess our future viability.

We are a late-stage pharmaceutical company focused on the development and commercialization of our drug candidate, TRC101, a non-absorbed polymer designed to treat metabolic acidosis by binding and removing acid from the gastrointestinal tract. We have only a limited operating history upon which you can evaluate our business and prospects. We are not profitable and have incurred significant losses in each year since our inception in May 2013. Our net losses were $45.9 million for the six months ended June 30, 2018, $41.3 million for the year ended December 31, 2017 and $28.7 million for the year ended December 31, 2016. As of June 30, 2018, we had an accumulated deficit of $135.3 million. Pharmaceutical product development is a highly speculative undertaking, entails substantial upfront capital expenditures and involves a substantial degree of risk, including the risk that a potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical industry. To date, we have focused principally on developing our product candidate TRC101. We have no products approved for commercial sale and have not generated any revenue from product sales or other arrangements to date and neither will we for the foreseeable future. We continue to incur significant research and development and other expenses related to our ongoing operations. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, and seek regulatory approval for, TRC101, prepare for potential commercialization of TRC101 and continue to operate as a public company and comply with legal, accounting and other regulatory requirements.

If TRC101 is not successfully developed or commercialized, including because of a lack of capital, or if we do not generate enough revenue following marketing approval, we will not achieve profitability and our business may fail. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that

may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts of TRC101.

We are currently advancing TRC101 through clinical development. As of June 30, 2018 we had working capital of $31.3 million and cash, cash equivalents and marketable securities of $55.3 million. We believe that we will continue to expend substantial resources for the foreseeable future as we continue clinical development, seek regulatory approval, and prepare for the commercialization of TRC101 and develop any other product candidates we may choose to pursue in the future. These expenditures will include costs associated with research and development, sales and marketing, conducting nonclinical and clinical studies and trials, obtaining regulatory approvals, and manufacturing and supply. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial and the regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of TRC101.

We believe that the net proceeds from our initial public offering of $237.7 million, proceeds of $23.6 million from our Loan and Security Agreement, or Term Loan, with Hercules Capital, Inc., or Hercules, together with our existing cash, cash equivalents and marketable securities of $55.3 million, will allow us to fund our operating plan through at least the next 12 months. However, we have based these estimates on assumptions that may prove to be wrong, and we could spend our available capital resources much faster than we currently expect or require more capital to fund our operations than we currently expect. Moreover, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity, debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the time and cost necessary to obtain regulatory approvals for TRC101 and any future product candidates that we develop, in-license or acquire;
- our ability to obtain approval for TRC101 under the Accelerated Approval Program;
- the costs of confirmatory postmarketing studies or trials for TRC101 that could be required by regulatory agencies or that we might otherwise choose to conduct;
- the costs of obtaining commercial supplies of TRC101;
- our ability to successfully commercialize TRC101;
- the manufacturing, selling and marketing costs associated with TRC101, including the cost and timing of expanding our sales and marketing capabilities;
- the amount of sales and other revenues from TRC101, including the sales price and the availability of adequate third-party reimbursement;
- the timing, receipt and amount of sales of, or royalties on, TRC101, if any;
- the costs of operating as a public company;
- the costs associated with any product recall that could occur;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;
- the cash requirements of any future acquisitions or discovery of future product candidates, if any;
- the progress, timing, scope and costs of our nonclinical and clinical studies and trials, including the ability to enroll patients in a timely manner for potential future clinical trials;
- the time and cost necessary to respond to technological and market developments; and
- the costs of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation.

We cannot assure you that anticipated additional financing will be available to us on favorable terms, or at all. Our current Term Loan contains negative covenants that restrict our ability to obtain additional debt financing. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Although we have been successful in obtaining financing through the issuance of our equity securities, we cannot assure you that we will be able to do so in the future. If we are unable to raise additional capital to fund our clinical development and commercialization of TRC101, if approved, and other business activities, we could be forced to significantly delay, scale back or abandon one or more clinical development programs or commercialization efforts and curtail or cease our operations. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

We and our auditors have substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2017 with respect to this uncertainty. Our 2017 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. Our ability to continue as a going concern will require us to obtain additional funding. We believe that the net proceeds from our initial public offering of $237.7 million, additional borrowings under our Term Loan with Hercules of $23.6 million, together with our existing cash, cash equivalents and marketable securities, will allow us to fund our operating plan through at least the next 12 months. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect and need to raise additional funds sooner than we anticipate. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs and commercialization efforts.

Risks Related to Our Business

We are dependent on the success of TRC101, our only product candidate. If we are unable to successfully develop, obtain regulatory approval for and commercialize TRC101, or experience significant delays in doing so, our business will be materially harmed.

To date, we have invested all of our efforts and financial resources in the research and development of TRC101, which is our only product candidate, and our business and future success depends on our ability to successfully develop, obtain regulatory approval for and commercialize TRC101. We recently completed a randomized, double-blind, placebo-controlled, multicenter pivotal Phase 3 clinical trial for TRC101, known as TRCA-301. The TRCA-301 trial enrolled 217 CKD patients with metabolic acidosis. Eligible subjects who completed the 12-week treatment period in our pivotal Phase 3 trial were invited to continue in our 40-week safety extension trial, TRCA-301E. We expect to complete our TRCA-301E trial in the first half of 2019 and then seek approval for TRC101 through the Accelerated Approval Program. While we believe that the TRCA-301 trial successfully met its primary and secondary endpoints, we cannot assure you that the FDA or any foreign regulatory agency will approve TRC101 for marketing. Furthermore, even if we obtain regulatory approval for TRC101, we will still need to develop a commercial organization, or collaborate with a third party for the commercialization of TRC101, establish commercially viable pricing and obtain approval for coverage and adequate reimbursement from third parties, including government payors. If we are unable to successfully commercialize TRC101, we may not be able to generate sufficient revenues to continue our business.

Our near-term prospects, including our ability to finance our operations and generate revenue, will depend heavily on the successful development and commercialization of TRC101 in the United States. Though we plan to engage in marketing approval discussions with foreign regulatory agencies in the future, we have not yet begun marketing approval discussions with any regulatory agency other than the FDA, and we are not currently seeking regulatory approval for TRC101 outside the United States. The clinical and commercial success of TRC101 will depend on a number of factors, including the following:

- our ability to demonstrate TRC101’s safety and efficacy to the satisfaction of the FDA and/or foreign regulatory agencies;

- the timely completion and reporting of our safety extension trial, TRCA-301E, and our confirmatory postmarketing trial, known as the VALOR-CKD trial, or TRCA-303;
- whether we are required by the FDA and/or foreign regulatory agencies to conduct additional clinical trials prior to approval to market TRC101;
- the prevalence and severity of adverse side effects of TRC101 in our ongoing and future clinical trials and commercial use, if approved;
- the timely receipt of necessary regulatory and marketing approvals from the FDA and foreign regulatory agencies for TRC101;
- our ability to obtain U.S. marketing approval for TRC101 under the Accelerated Approval Program;
- our ability to successfully conduct our confirmatory postmarketing trial, VALOR-CKD, and confirm renal benefit of TRC101, assuming TRC101 is initially approved under the FDA's Accelerated Approval Program;
- our ability to successfully commercialize TRC101, if approved for marketing and sale by the FDA and/or foreign regulatory agencies;
- our ability to manufacture clinical trial and commercial quantities of TRC101 drug substance and drug product and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP, at a scale sufficient to meet anticipated demand and over time enable us to reduce our cost of manufacturing;
- achieving and maintaining compliance with all regulatory requirements applicable to TRC101;
- our success in educating physicians and patients about the benefits, administration and use of TRC101;
- acceptance of TRC101 as safe and effective by patients and the medical community;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- our ability to obtain and sustain an adequate level of reimbursement for TRC101 by third-party payors;
- the effectiveness of our own or any future strategic collaborators' marketing, sales and distribution strategy and operations;
- our ability to continue to obtain protection for and to enforce our intellectual property rights in and to TRC101; and
- our ability to avoid and defend against third-party patent interference or patent infringement claims or similar proceedings with respect to our patent rights and patent infringement claims.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of TRC101. If we are not successful in commercializing TRC101, or are significantly delayed in doing so, our business will be materially harmed.

We will attempt to secure approval of TRC101 from the FDA through the use of the Accelerated Approval Program, but such mechanism may not actually lead to a faster development or regulatory review or approval process. If we are unable to obtain approval of TRC101 through the Accelerated Approval Program in the United States, we may be required to conduct additional nonclinical and clinical studies and trials beyond those that we currently contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, necessary marketing approval. Even if we receive approval from the FDA under the Accelerated Approval Program, if our confirmatory postmarketing trial does not verify clinical benefit, or if we do not comply with rigorous postmarketing requirements, the FDA may seek to withdraw the approval.

We currently plan to seek U.S. approval for our sole product candidate, TRC101, through the FDA's Accelerated Approval Program based on the results of our Phase 1/2 trial, TRCA-101, our pivotal Phase 3 clinical trial, TRCA-301, and our safety extension trial, TRCA-301E. For any approval to market a drug product, we must provide the FDA and foreign regulatory agencies with clinical data that adequately demonstrate the safety and efficacy of the product for the indication applied for in the New Drug Application, or NDA, or other respective regulatory filings. As described in the "Government Regulation" section, the Accelerated Approval Program is one of several approaches used by the FDA to make prescription drugs more rapidly available for the treatment of serious or life-threatening diseases. Section 506(c) of the Federal Food, Drug and Cosmetic Act, or FFDCA, provides that the FDA may grant accelerated approval to "a product for a serious or life-threatening condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is

reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments." Approval under the Accelerated Approval Program is subject, however, to the requirement that the applicant conduct additional postmarketing clinical trials to verify and describe the drug's clinical benefit, where there is uncertainty as to the relationship of the surrogate endpoint to the clinical benefit, or of the observed clinical endpoint to ultimate outcome. Typically, clinical benefit is verified when postmarketing clinical trials show that the drug provides a clinically meaningful positive therapeutic effect, that is, an effect on how a patient feels, functions, or survives. The FDA may require that any confirmatory postmarketing trial be initiated or substantially underway prior to the submission of an application under the Accelerated Approval Program. And, if such confirmatory postmarketing trial fails to confirm the drug's clinical profile or risks and benefits, the FDA may withdraw its approval of the drug.

The FDA has broad discretion with regard to approval under the Accelerated Approval Program, and even if we believe that the Accelerated Approval Program is appropriate for TRC101, we cannot assure you that the FDA will ultimately agree. Furthermore, even if we do obtain approval under the Accelerated Approval Program, we may not experience a faster development process, review or approval compared to conventional FDA procedures.

We have sought feedback from the FDA on our ability to seek and receive approval for TRC101 under the Accelerated Approval Program, but there can be no assurance that the FDA will ultimately agree that the results of our pivotal Phase 3 clinical trial, TRCA-301, and our safety extension trial, TRCA-301E and the design of our confirmatory postmarketing trial, VALOR-CKD, will be sufficient to support such approval. There also can be no assurance that after subsequent FDA feedback that we will continue to pursue approval under the Accelerated Approval Program. Furthermore, if we submit an application for approval through the Accelerated Approval Program, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. For example, the FDA could require us to conduct further studies or trials prior to considering our application or granting approval of any type, including by determining that approval under the Accelerated Approval Program is not appropriate and that our pivotal Phase 3 clinical trial, TRCA-301, may not be used to support approval under the conventional pathway. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. A failure to obtain approval under the Accelerated Approval Program could result in a longer time period to commercialize TRC101, could increase the cost of development of it and could significantly harm our financial position and competitive position in the marketplace.

Even if we receive approval for TRC101 under the Accelerated Approval Program, we will be subject to rigorous postmarketing requirements, including the completion of our confirmatory postmarketing trial, VALOR-CKD, or such other confirmatory postmarketing trials as the FDA may require, to verify the clinical benefit of the product, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw the approval for multiple reasons, including if we fail to conduct any required confirmatory postmarketing trial with due diligence, a confirmatory postmarketing trial does not confirm the predicted clinical benefit, other evidence shows that the product is not safe or effective under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading.

Any delay in obtaining, or inability to obtain, approval under the Accelerated Approval Program would delay or prevent commercialization of TRC101 and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

We may be unable to obtain regulatory approval for TRC101 under applicable regulatory requirements.

To gain approval to market a drug product, regardless of whether it is through Accelerated Approval or the conventional pathway, we must provide the FDA and foreign regulatory agencies with clinical data that adequately demonstrates the safety and efficacy of the product for the intended indication applied for in the NDA or other respective regulatory filing. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials even after promising results in earlier nonclinical or clinical studies and trials. These setbacks have been caused by, among other things, nonclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

Our business currently depends entirely on the successful development, regulatory approval and

commercialization of our sole product candidate, TRC101. Based on the results of our pivotal Phase 3 clinical trial, TRCA-301, we plan to prepare and submit an NDA seeking approval under the FDA's Accelerated Approval Program to market TRC101. We currently have efficacy and safety data from our TRCA-101 trial, and topline efficacy and safety data from our pivotal Phase 3 clinical trial, TRCA-301. In addition to our TRCA-101 and TRCA-301 clinical results, our NDA submission will include data from our safety extension trial, TRCA-301E, and such additional data may be less favorable than the information we have currently.

Furthermore, TRC101 may not receive marketing approval even though we believe we achieved the primary and secondary endpoints in our pivotal Phase 3 clinical trial, TRCA-301. The FDA and other foreign regulatory agencies have substantial discretion in evaluating the results of our pivotal Phase 3 clinical trial, TRCA-301, and our earlier Phase 1/2 trial, TRCA-101. For example, notwithstanding our view to the contrary, the FDA may determine that the efficacy data and/or safety data from our Phase 1/2 trial, TRCA-101, our pivotal Phase 3 clinical trial, TRCA-301, and our safety extension trial, TRCA-301E, do not support approval of an NDA for TRC101. Clinical data often is susceptible to varying interpretations and many companies that have believed that their products performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. The FDA or foreign regulatory agencies may disagree with our trial design and our interpretation of data from our Phase 1/2 trial, TRCA-101, our pivotal Phase 3 clinical trial, TRCA-301, our safety extension trial, TRCA-301E, or our nonclinical studies. Upon the FDA's review of the data from our pivotal Phase 3 clinical trial, TRCA-301, and our safety extension trial, TRCA-301E, it may request that we conduct additional analyses of the data and, if it believes that the data are not satisfactory, could advise us to delay our submission of an NDA. Accordingly, we may not submit our NDA for TRC101 within our anticipated time frame and, even after we make the submission, the FDA may not accept it for filing, may request additional information from us, including data from additional clinical trials, and, ultimately, may not grant marketing approval for TRC101.

While there are comparable approval pathways outside the United States that are similar to the Accelerated Approval Program, we have not yet explored whether TRC101 might qualify for such a program. Foreign regulatory authorities may determine that the results of our pivotal Phase 3 clinical trial, TRCA-301, and our safety extension trial, TRCA-301E, and our earlier Phase 1/2 trial, TRCA-101, are not sufficient to support regulatory approval and may require us to complete additional clinical trials or other studies prior to submitting an application for approval.

The denial of regulatory approval for TRC101 could mean that we need to cease operations, and a delay in obtaining such approval could delay commercialization of TRC101 and adversely impact our ability to generate revenue, our business and our results of operations.

If we are not successful in commercializing TRC101, or are significantly delayed in doing so, our business will be materially harmed, and we may need to curtail or cease operations. We currently have no drug products approved for sale, and we may never obtain regulatory approval to commercialize TRC101, either under FDA's Accelerated Program or the conventional pathway. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory agencies in the United States and other countries, and such regulations differ from country to country. We are not permitted to market TRC101 in the United States until we receive approval of an NDA from the FDA.

The FDA or any foreign regulatory agency can delay, limit or deny approval to market TRC101 for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency that TRC101 is safe and effective for the requested indication;
- our inability to gain agreement from the FDA that TRC101 is appropriate for approval under FDA's Accelerated Approval Program;
- our inability to gain agreement from applicable foreign regulatory authorities that TRC101 is appropriate for approval under applicable regulatory pathways;
- the FDA's or the applicable foreign regulatory agency's disagreement with the interpretation of data from nonclinical and clinical studies and trials;
- our inability to demonstrate that the clinical and other benefits of TRC101 outweigh any safety or other perceived risks;
- our ability to enroll an adequate number of patients in our confirmatory postmarketing trial, VALOR-CKD;
- the FDA's or the applicable foreign regulatory agency's requirement for additional nonclinical or clinical studies or trials;

- the FDA's or the applicable foreign regulatory agency's having differing requirements for the trial protocols used in our clinical trials;
- the FDA's or the applicable foreign regulatory agency's non-approval of the formulation, labeling and/or the specifications of TRC101;
- the FDA's or the applicable foreign regulatory agency's failure to accept the manufacturing processes or third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

Even if we eventually complete clinical testing and receive approval of an NDA or foreign marketing authorization for TRC101, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials, which may be required after approval. The FDA or the applicable foreign regulatory agency may also approve TRC101 for a more limited indication and/or a narrower patient population than we originally request, and the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of TRC101. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of TRC101 and would materially adversely impact our business and prospects.

Clinical drug development involves 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. We have not submitted an NDA for TRC101, or similar drug approval filings, to the FDA or to comparable foreign authorities.

Clinical testing 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. The results of nonclinical and clinical studies and trials of our product candidate may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in our Phase 1/2 trial, TRCA-101, and our pivotal Phase 3 trial, TRCA-301, for TRC101 do not ensure that our late-stage clinical program, including our ongoing safety extension trial, TRCA-301E, will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical and clinical studies and trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies and trials, and we cannot be certain that we will not face similar setbacks. Based upon negative or inconclusive results, we or any potential future collaborator may decide, or regulators may require us, to conduct additional nonclinical and clinical studies and trials. 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. Furthermore, we rely on contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance. Even though we completed our pivotal Phase 3 clinical trial, TRCA-301, and even if our safety extension trial, TRCA-301E, and any future clinical trials are completed, the results may not be sufficient to obtain regulatory approval, regardless of whether it is through the Accelerated Approval Program or the conventional pathway, for TRC101 in the time frame we anticipate, or at all.

For approval of TRC101 through the Accelerated Approval Program, the FDA has specifically requested that a confirmatory postmarketing clinical trial be completely or nearly completely enrolled prior to submission of our NDA. We may experience delays in starting our confirmatory postmarketing trial, VALOR-CKD, as a result of various factors including reaching agreement with the FDA on the final clinical trial protocol for the trial and timely enrollment of an adequate number of patients. In addition, our confirmatory postmarketing trial, VALOR-CKD, may have a large dropout rate of participants, which could add time, expense and risk to the completion of the trial and could affect the results of the trial.

In addition, we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence a trial, if applicable;

- reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain ethics committee or institutional review board, or IRB, approval at each site;
- recruit suitable patients to participate in a trial and have such patients complete the clinical trial or return for post-treatment follow-up;
- ensure that clinical sites follow the trial protocol, comply with good clinical practices, or GCPs, and continue to participate in a clinical trial;
- address any patient safety concerns that arise during the course of a clinical trial;
- ensure that patients comply with and complete clinical trial protocol;
- achieve a sufficient level of endpoint events in the placebo group, if applicable;
- initiate or add a sufficient number of clinical trial sites;
- ensure that trial sites do not deviate from clinical trial protocol or drop out of a clinical trial;
- address any conflicts with new or existing laws or regulations;
- manufacture sufficient quantities of product candidate for use in clinical trials and ensure clinical trial material is provided to clinical sites in a timely manner; and
- obtain the statistical analysis plan to be used to evaluate the clinical trial data.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the ethics committees or IRBs of the institutions in which such trials are being conducted, by an independent Safety Review Board, or SRB, for such trial or by the FDA or other regulatory agencies. Such parties may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory agencies resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries presents additional risks that may delay completion of our clinical trials. These risks include the failure of physicians or enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. In addition, the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States.

If we experience delays in the start or completion of, or termination of, any clinical trial of our sole product candidate, TRC101, the commercial prospects of TRC101 may be harmed, and our ability to generate product revenues from TRC101 will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our TRC101 development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of TRC101.

Results from completed human clinical trials may not be representative of the results that are obtained after approval, if obtained, and product launch.

Human clinical trials are very complicated undertakings and working with subjects with CKD is particularly difficult because of the serious nature of the disease and the comorbidities experienced by the subjects. If we obtain FDA approval under the Accelerated Approval Program, safety risks not identified in our prior clinical trials may first appear after we obtain approval and commercialize TRC101. Any new postmarketing adverse events may significantly impact our ability to market TRC101 and may require that we recall and discontinue commercialization of the product. Furthermore, if the confirmatory postmarketing trial, VALOR-CKD, fails to confirm TRC101's clinical

profile or clinical benefits, the FDA may withdraw its approval of TRC101. Any of these events would materially harm our business.

We have relied and continue to rely on third parties, particularly CROs, to conduct and complete our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize TRC101, if approved.

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs, to conduct clinical trials for TRC101. We rely on these third parties to conduct and complete our clinical trials according to GCPs and the study protocol, statistical analysis plan and other study-specific documents (for example, monitoring and blinding plans). Responsibilities of these third parties include, but are not limited to, monitoring of the study sites and ensuring that the study is conducted in compliance with International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines and GCPs, the informed consent process, protocol-specified requirements, safety reporting requirements, data collection guidelines and all study-specific blinding procedures.

Our safety extension trial, TRCA-301E, is being conducted at 29 sites in the United States and Europe. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and, except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our program. Although we rely on these third parties to conduct all of our clinical trials in accordance with a transfer of obligations, we remain responsible for ensuring that each of our clinical trials is conducted and its data analyzed in accordance with its protocol and statistical analysis plan. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, including ICH guidelines and GCPs for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials.

In addition, the execution of clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. These third parties may terminate their agreements with us upon as little as 30 days' prior written notice. Some of these agreements may also be terminated by such third parties under certain other circumstances, including our insolvency. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the intentional or inadvertent failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. The third parties upon whom we rely may be inspected by FDA or other regulatory authorities in relation to our, or to other, studies or trials. Such inspections may result in FDA or other regulatory authorities not accepting the data produced by the third party.

If any of the foregoing were to occur, we may not be able to obtain regulatory approval for or commercialize TRC101, which would have a material adverse effect on our business, results of operations and financial condition.

We rely completely on third-party suppliers to manufacture our clinical drug supply of TRC101 drug substance and drug product, and we intend to rely on third parties to produce commercial supply of TRC101 drug substance and drug product, if approved.

We do not currently have, nor do we plan to acquire, the infrastructure or internal capability to manufacture TRC101 on a clinical or commercial scale. As such, we contract with third-party service providers to manufacture TRC101 drug substance and drug product and to perform analytical testing services under cGMPs. Pharmaceutical manufacturing facilities are subject to inspection by the FDA and foreign regulatory agencies on a regular basis, before and after product approval.

We do not directly control, and are completely dependent on, our contract manufacturers for compliance with, applicable requirements including cGMP, for manufacture of both TRC101 drug substance and drug product. If

our contract manufacturers cannot successfully manufacture material that conforms to our specifications or they are unable to comply with the strict regulatory requirements of the FDA or foreign regulatory agencies, we will not be able to secure and/or maintain adequate supply of TRC101 drug substance and drug product. In addition, we have no direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such other materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory clearance of our contract manufacturers' facilities. If our contract manufacturers' facilities fail to comply with the FDA or a comparable foreign regulatory agency requirements, we may need to find alternative manufacturing facilities for TRC101 drug substance or drug product, which would negatively impact our ability to develop, obtain regulatory approval for, or market TRC101, if approved, and materially adversely affect our financial condition.

We currently depend on a single third-party supplier for the manufacture of TRC101 drug substance, and any performance failure on the part of our supplier could delay the development and potential commercialization of TRC101.

We cannot be certain that our drug substance supplier will continue to provide us with sufficient quantities of TRC101 drug substance, or that our manufacturers will be able to produce sufficient quantities of drug product incorporating such drug substance, to satisfy our anticipated specifications and quality requirements, or that such quantities can be obtained at pricing necessary to sustain acceptable pharmaceutical margins. We believe that there are a limited number of experienced contract manufacturers in the world capable of manufacturing a polymeric drug substance such as TRC101. Our current dependence on a single supplier for our drug substance and the challenges we may face in obtaining adequate supply of TRC101 drug substance involves several risks, including limited control over pricing, availability, quality and delivery schedules. Any supply interruption in TRC101 drug substance or drug product could materially harm our ability to complete our development program or satisfy commercial demand, if approved, until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of TRC101, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

Moreover, our current supplier of drug substance may not have the capacity to manufacture TRC101 drug substance in the quantities that we believe will be sufficient to meet anticipated market demand or to enable us to achieve the economies of scale necessary to reduce the manufacturing cost of TRC101 drug substance. Our business plan assumes that we are able to develop a supply chain with multiple suppliers and significantly decrease our cost of goods within the first several years of commercialization of TRC101, if approved, enabling us to achieve gross margins similar to those achieved by other companies with polymer based drugs. If we are unable to reduce the manufacturing cost of TRC101 drug substance, our financial results will suffer and our ability to achieve profitability will be significantly jeopardized. Outside of our current supplier, we currently do not have any agreements for the commercial production of TRC101 drug substance. If our contract manufacturer for drug substance is unable to source, or we are unable to purchase, sufficient quantities of materials necessary for the production of TRC101 drug substance, the ability of TRC101 to reach its market potential to be launched, would be delayed or suffer from a shortage in supply, which would impair our ability to generate revenues from the sale of TRC101. If there is a disruption to our contract manufacturers' or suppliers' relevant operations, we will have no other means of producing TRC101 drug substance until they restore the affected facilities or we or they procure alternative manufacturing facilities. Additionally, any damage to or destruction of our contract manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture TRC101 on a timely basis.

We are in the process of scaling our two-step manufacturing process to commercial scale with our third-party supplier. Any performance failure or time delay in scaling our two-step drug substance manufacturing process could materially adversely affect or delay validation of our manufacturing process or delay the start or interrupt the execution of our confirmatory postmarketing trial, VALOR-CKD, and potentially impact the commercialization of TRC101, if approved.

While we believe we have sufficient drug substance to supply the anticipated demand for at least the first four months of our confirmatory postmarketing trial, VALOR-CKD, we are in the process of scaling our two-step manufacturing process to commercial scale with our third-party supplier. The scale of the first step in our drug

substance manufacturing process, step one, (currently at approximately 340 kg/batch) is being increased two-fold, and the scale of the second step in our manufacturing process, step two, (currently at approximately 65 kg/batch) is being increased ten-fold, to provide targeted commercial batch sizes for each of the steps in the range of 500 to 700 kg. As compared to soluble, small organic molecule pharmaceuticals, insoluble, non-absorbed polymers are manufactured in larger batches to satisfy greater doses, e.g., gram quantities versus milligram or even microgram quantities per dose, which presents unique requirements both in terms of scale-up and process controls. We are in the process of scaling the current production methods to meet our anticipated commercial needs without introducing changes to key TRC101 properties, including binding capacity, selectivity for hydrochloric acid and non-absorption. We use acid binding, competitive anion binding and particle size measurement assays to confirm these properties. Any difficulties experienced in the ongoing scale-up of our drug substance manufacturing processes to commercial scale could materially adversely affect or delay our ability to (i) meet regulatory process validation requirements to demonstrate that our manufacturing process is capable of consistently delivering quality product, or (ii) have sufficient quantities of TRC101 drug product manufactured to timely initiate and successfully conduct our confirmatory postmarketing trial, VALOR-CKD, or (iii) have sufficient quantities of TRC101 drug substance and drug product to supply commercial supply of TRC101, if approved, all of which would have a material adverse effect on our business and our prospects.

If we fail to establish an effective distribution process for TRC101 drug product, if approved, our business may be adversely affected.

We do not currently have the infrastructure necessary for distributing pharmaceutical products to patients. We intend to contract with a third-party logistics company to warehouse TRC101 and distribute it. This distribution network will require significant coordination with our sales and marketing and finance teams. Failure to secure contracts with a logistics company could negatively impact the distribution of TRC101, if approved, and failure to coordinate financial systems could negatively impact our ability to accurately report product revenue. If we are unable to effectively establish and manage the distribution process, the commercial launch and sales of TRC101 will be delayed or severely compromised and our results of operations may be harmed.

Even if TRC101 obtains regulatory approval, it may never achieve market acceptance or commercial success, which will depend, in part, upon the degree of acceptance among physicians, patients, patient advocacy groups, health care payors and the medical community.

Even if we obtain FDA or other regulatory approvals, TRC101 may not achieve market acceptance among physicians, patients, patient advocacy groups, health care payors or the medical community, and may not be commercially successful. If approved, market acceptance of TRC101 depends on a number of factors, including:

- the efficacy of the product as demonstrated in clinical trials;
- the prevalence and severity of any side effects and overall safety profile of the product;
- the clinical indications for which the product is approved;
- the potential and perceived advantages of TRC101 over current options or future alternative treatments;
- the strength of our marketing organization and distribution channels;
- the quality of our relationships with patient advocacy groups;
- the availability and sufficiency of third-party coverage and adequate reimbursement;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective chronic daily treatment and willingness of physicians to prescribe TRC101;
- the cost of treatment in relation to alternative treatments and willingness to pay for TRC101, if approved, on the part of patients;
- relative convenience and ease of administration of TRC101; and
- the availability of the product and our ability to meet market demand, including providing a reliable supply for long-term daily treatment.

Any failure by our product candidate, if it obtains regulatory approval, to achieve market acceptance or commercial success would adversely affect our results of operations.

The incidence and prevalence of the target patient population for TRC101 are based on estimates and third-party sources. If the market opportunity for TRC101 is smaller than we estimate or if any approval that we

obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations based on various third-party sources and internally generated analysis. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity for TRC101 will depend on, among other things, acceptance of TRC101 by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with TRC101, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects.

TRC101, if approved, may face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration.

While we are not aware of any therapies approved by the FDA for the chronic treatment of metabolic acidosis and are not aware of any active clinical development programs other than ours for such a treatment in the United States, the pharmaceutical market is highly competitive and dynamic, and is characterized by rapid and substantial technological development and product innovations. Our TRC101 development program may serve as a template for a fast follower to develop a competing product candidate. Furthermore, we expect TRC101 to compete against non-approved options for increasing blood bicarbonate levels, including oral alkali supplementation such as sodium bicarbonate, sodium citrate or potassium citrate. TRC101 may not be able to compete effectively with existing non-approved options for increasing blood bicarbonate levels or new drugs that may be developed by competitors. The risk of competition is specifically important to us because TRC101 is our only product candidate.

Our competitors may have materially greater financial, manufacturing, marketing, research and drug development resources than we do. Large pharmaceutical companies in particular, may have extensive expertise in nonclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

Failure to compete effectively against available options for raising blood bicarbonate levels or in the future with new products would materially harm our business, financial condition and results of our operations.

We currently have limited sales or marketing capabilities. If we are unable to establish effective sales and marketing capabilities or if we are unable to enter into agreements with third parties to commercialize TRC101, we may not be able to effectively generate product revenues.

We currently have limited sales or marketing capabilities. In order to commercialize TRC101, if approved, we must build marketing and sales capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If TRC101 is approved by the FDA, we plan to initially commercialize it in the United States by deploying an 80- to 100-person specialty sales force targeting that subset of nephrologists most focused on treating CKD patients. Building the requisite sales, marketing or distribution capabilities will be expensive and time-consuming and will require significant attention of our leadership team to manage. Any failure or delay in the development of our sales, marketing or distribution capabilities would adversely impact the commercialization of our product. The competition for talented individuals experienced in selling and marketing pharmaceutical products is intense, and we cannot assure you that we can assemble an effective team. Additionally, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties on the commercialization of TRC101. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize TRC101 if and when it receives regulatory approval or any such commercialization may experience delays or limitations.

We may be subject to additional risks related to operating in foreign countries either ourselves or through a third-party, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other 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 revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as 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.

Our clinical development program may not uncover all possible adverse events that patients who take TRC101 may experience. The number of subjects exposed to TRC101 treatment and the average exposure time in the clinical development program may be inadequate to detect adverse events, or chance findings, that may only be detected once TRC101 is administered to more patients and for greater periods of time.

Clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, we cannot be fully assured that TRC101 has no serious or severe side effects, and any such side effects may only be uncovered with a significantly larger number of patients exposed to the drug candidate. It is possible that ongoing and future clinical trials, as well as reports received from TRC101 use commercially, if approved, may identify safety concerns.

Although we have monitored the subjects in our trials for certain safety concerns and we have not seen evidence of significant safety concerns in our clinical trials to date, patients treated with TRC101 may experience adverse reactions. The most commonly reported adverse effect of TRC101 in the TRCA-101 trial was mild-to-moderate GI events, such as diarrhea and constipation. The most commonly reported treatment-related adverse events in the TRCA-301 trial were mild to moderate GI disorders, which included diarrhea, flatulence, nausea and constipation. It is possible that the FDA may ask for additional data regarding such matters. In addition, CKD patients often experience significant and frequent comorbidities and are being treated with other medications. Although in vitro studies and human drug-drug interaction, or DDI, studies available to date indicate that TRC101 does not interact with medications commonly used by CKD patients, if significant DDIs occur in the future, TRC101 may no longer be compatible with some of the medications used to treat CKD patients. If safety problems occur or are identified after TRC101 reaches the market, the FDA may require that we amend the labeling of TRC101, recall TRC101, or even withdraw approval for TRC101.

The FDA may not agree that the safety of TRC101 has been sufficiently characterized by the amount and quality of data provided from our clinical development program.

The NDA safety database for new drugs intended for chronic use in non-life-threatening conditions typically includes at least 1500 individuals, with at least 100 patients exposed to the drug for a minimum of one year (Guideline for Industry ICH-E1A: *The Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions*). At the time of filing our NDA, we anticipate that the TRC101 safety database will be significantly smaller than the guidance suggests. Given the toxicology study results and clinical safety profile observed to date for TRC101, as well as the non-absorbed nature of the drug, we believe our proposed safety database will be adequate for the filing of the TRC101 NDA and its review through the Accelerated Approval Program. However, we cannot assure you that the FDA will agree with our proposal. If they require additional safety data in the initial NDA filing, this could have a material adverse effect on our expected clinical and regulatory timelines, business, prospects, financial condition and results of operations.

Our product candidate, TRC101, may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, reduce the commercial attractiveness of a prescribing label or result in significant negative consequences following regulatory approval, if approved.

Clinical studies of TRC101 could reveal a high and unacceptable incidence and severity of undesirable and currently unknown side effects. Undesirable side effects could adversely affect patient enrollment in clinical studies, cause us or regulatory authorities to interrupt, delay or halt clinical studies or result in the delay, denial or withdrawal of regulatory approval by the FDA, the European Medicines Agency, or EMA, or other global regulatory authorities. Undesirable side effects also could result in regulatory authorities mandating additional clinical testing prior to approval, postmarketing testing following approval, or a more restrictive prescribing label for a product, which, in turn, could limit the market acceptance of the product by physicians and consumers.

Drug-related side effects could result in potential product liability claims, especially if they were not included in the consent forms for clinical trial patients or included in the warnings of any FDA-approved labeling. We currently carry product liability insurance covering use in our clinical trials in the amount of $10 million in the aggregate; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts if liability and legal costs exceed the threshold limited. 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, business and financial condition, and commercial reputation. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, increased costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators or other governmental entities, monetary awards to patients or other claimants, the inability to commercialize TRC101 and decreased demand for our product, if approved for marketing.

Additionally, if TRC101 receives regulatory approval, and we or others later identify undesirable side effects or unanticipated adverse events caused by such product, a number of potentially significant negative consequences could result, including but not limited to:

- the requirement of additional warnings on the prescribing label;
- the withdrawal of approvals by regulatory authorities;
- the requirement of a risk evaluation and mitigation strategy plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- litigation and the potential to be held liable for harm caused to patients; and
- an adverse effect on our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of TRC101 and could significantly harm our business, results of operations, financial condition and prospects.

We will need to significantly increase the size of our organization, and we may experience difficulties in managing growth.

As of June 30, 2018, we had 62 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations, regulatory filings, manufacturing and supply activities, clinical trials, marketing and commercialization activities for TRC101. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- expand our general and administrative and sales and marketing organizations;
- identify, recruit, retain, incentivize and integrate additional employees;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, legal, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and commercialize TRC101 will depend, in part, on our ability to effectively manage any future growth. Our management will have to dedicate a significant amount of its attention to managing these growth activities. In addition, we expect to incur additional costs in hiring, training and retaining such additional personnel.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully execute the tasks necessary to further develop

and commercialize our product candidate and, accordingly, may not achieve our research, development and commercialization goals.

If we fail to attract and keep senior management, we may be unable to successfully develop TRC101, conduct our clinical trials and commercialize TRC101, if approved.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified personnel. In particular, we are highly dependent upon our experienced senior management. The loss of services of any of these individuals or our inability to attract and retain additional qualified personnel could delay or prevent the successful development of our product, completion of our planned clinical trials or the commercialization of TRC101. Although we have entered into employment agreements with our senior management team, these agreements do not provide for a fixed term of service. Any of our employees could leave our employment at any time, with or without notice.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

We may hire part-time employees or use consultants. As a result, certain of our employees, officers, directors or consultants may not devote all of their time to our business, and may from time to time serve as employees, officers, directors and consultants of other companies.

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

We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. In connection with our initial public offering, we adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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 misconduct or other failure to be in compliance with applicable laws or regulations.

Misconduct by our employees, independent contractors, consultants, commercial partners and vendors could include intentional failures to comply with FDA or international regulations, provide accurate information to the FDA or other international regulatory bodies, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data timely, completely and accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by third parties could also involve the improper use of information obtained in the course of clinical trials.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from government-funded healthcare programs, such as Medicare and Medicaid, additional integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we seek and obtain approval to commercialize TRC101 outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If TRC101 is approved for commercialization outside the United States, we may enter into agreements with third parties to market TRC101 outside the United States. We expect that we will be subject to additional risks related to entering into these international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing U.S. and foreign drug import and export rules;
- reduced protection for intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems, and different competitive drugs indicated to treat metabolic acidosis;
- 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 revenues, 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;
- potential liability resulting from development work conducted by these distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

Our Term Loan contains restrictions that limit our flexibility in operating our business.

Our Term Loan with Hercules contains various covenants that limit our ability to engage in specified types of transactions without obtaining prior consent from our lenders. These covenants limit our ability to, among other things:

- use all of our cash;
- create, incur, assume, guarantee or be or remain liable with respect to any indebtedness;
- prepay any indebtedness;
- subject our assets that serve as collateral under the loan agreement, our intellectual property and all other property and assets used in our business to any lien or legal process;
- acquire, own or make investments;
- repurchase or redeem shares of our capital stock;
- declare or pay any cash dividends or make any other cash distributions;
- lend money to our employees, officers or directors, or guarantee such loans;
- waive, release or forgive indebtedness owed by our employees, officers or directors;
- voluntarily or involuntarily transfer, sell, lease, license, lend or convey our assets;
- merge or consolidate with another business organization;
- change our corporate name, legal form or jurisdiction of formation;
- suffer a change in control;
- relocate our chief executive office or principal place of business; and
- maintain deposit accounts or securities accounts without account control agreements in place.

The covenants in our Term Loan may limit our ability to take certain actions and, in the event that we breach one or more covenants, the agent may, and at the direction of the lenders will, declare an event of default and require that we immediately repay all amounts outstanding, plus penalties and interest, terminate their commitments to extend further credit and foreclose on the collateral granted to them to secure such indebtedness. The exercise of remedies by the lenders would have a material adverse effect on our business, operating results and financial condition.

Our debt obligations expose us to risks that could adversely affect our business, operating results, overall financial condition and may result in further dilution to our stockholders.

Our Term Loan with Hercules obligates us to make certain interest and principal payments. Our ability to make payments on this indebtedness depends on our ability to generate cash in the future. We expect to experience negative cash flow for the foreseeable future as we fund our operations and capital expenditures. There can be no assurance we will be in a position to repay this indebtedness when due or obtain extensions to the maturity date. We anticipate that we will need to secure additional funding to repay these obligations when due. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If that additional funding involves the sale of equity securities or convertible securities, it would the issuance of additional shares of our capital stock, which would result in dilution to our stockholders.

This level of debt could have an adverse impact on our business or operations. For example, it could:

- limit our flexibility in planning for the development, clinical testing, approval and marketing of TRC101;
- place us at a competitive disadvantage compared to any of our competitors that are less leveraged than we are;
- increase our vulnerability to both general and industry-specific adverse economic conditions; and
- limit our ability to obtain additional funds.

We will incur significant costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.

We will incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Global Select Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

In addition, we implemented an enterprise resource planning, or ERP, system for our company. An ERP system is intended to combine and streamline the management of our financial, accounting, human resources, sales and marketing and other functions, enabling us to manage operations and track performance more effectively. However, an ERP system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Additionally, in the future, we may be limited in our ability to convert any business that we acquire to the ERP. Any disruptions or difficulties in using an ERP system could adversely affect our controls and harm our business, including our ability to forecast or make sales and collect our receivables. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

We will be subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the Securities and Exchange Commission, or SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. 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 an aggregate of $1.0 billion in non-convertible debt during the prior three-year period.

We have identified material weaknesses in our internal control over financial reporting, and if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely effected.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by the Sarbanes-Oxley Act. During our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. We and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting, related to (i) the lack of sufficient qualified accounting personnel and controls with respect to the review of third-party valuations used to determine the fair value of our preferred stock tranche obligations and the recording of the corresponding fair value, and (ii) a lack of effective communication and coordination between the accounting and operations personnel with respect to estimation of progress to completion on work orders with contract manufacturers, which resulted in a number of adjustments in contract manufacturing accruals. Following identification of the material weaknesses, we have undertaken specific remediation actions to address the control deficiencies in our financial reporting. During the first quarter of 2018, we have undertaken specific remediation actions to address the control deficiencies in our financial reporting. These remediation actions included hiring a Chief Accounting Officer who has extensive experience in developing and executing plans to remediate control deficiencies. In addition, we hired a Director of Financial Planning & Analysis who has extensive experience in developing and implementing internal controls specific to research and development and manufacturing operations. We added new control activities, modified existing controls, and enhanced the documentation that evidences that controls are performed. We concluded that the control deficiencies have been remediated as of March 31, 2018, as the applicable controls have operated for a sufficient period and we have concluded that these controls are operating effectively.

Furthermore, if in the future, we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Select Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize TRC101.

We may seek to establish collaboration or similar agreements with one or more established biotechnology, pharmaceutical or specialty pharmaceutical companies to support the development, regulatory approval and commercialization of TRC101 outside of the United States and we may seek similar arrangements for the development or commercialization of TRC101. We may enter into these arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for TRC101, both in the United States and internationally. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. If we were to enter into any collaboration agreements, any such termination or expiration would adversely affect us financially and could harm our business reputation.

If we engage in acquisitions, we will incur a variety of costs and we may never realize the anticipated benefits of such acquisitions.

Although we currently have no intent to do so, we may attempt to acquire businesses, technologies, services, products or product candidates that we believe are a strategic fit with our business. If we do undertake any acquisitions, the process of integrating an acquired business, technology, service, products or product candidates into our business may result in unforeseen operating difficulties and expenditures, including diversion of resources and management's attention from our core business. In addition, we may fail to retain key executives and employees of the companies we acquire, which may reduce the value of the acquisition or give rise to additional integration costs. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results. In addition, we may fail to realize the anticipated benefits of any acquisition.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of TRC101 and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable agencies may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. It may also harm our ability to attract and retain collaboration partners or customers. Additionally,

currency fluctuations may affect our ability to successfully market and sell TRC101 in markets outside of the United States. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current or future economic climate and financial market conditions could adversely impact our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain may operate from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in material disruptions to our drug development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, cyber attacks, industrial espionage, other unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur, it could cause interruptions to our operations and result in material disruptions to our drug development programs. For example, the loss or theft of clinical trial data from completed or ongoing clinical trials for our product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss or theft of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be adversely affected, our reputation could be harmed and the further development of our product candidate could be delayed.

We are subject to European data protection laws, including the new EU General Data Protection Regulation 2016/679, or GDPR. If we fail to comply with existing or future data protection regulations, our business, financial condition, results of operations and prospects may be materially adversely affected.

By virtue of our clinical trial activities in Europe, we are subject to European data protection laws, including GDPR. The GDPR which came into effect on May 25, 2018, establishes new requirements applicable to the processing of personal data (i.e., data which identifies an individual or from which an individual is identifiable), affords new data protection rights to individuals (e.g., the right to erasure of personal data) and imposes penalties for serious breaches of up to 4% annual worldwide turnover or €20 million, whichever is greater. Individuals (e.g., study subjects) also have a right to compensation for financial or non-financial losses (e.g., distress). There may be circumstances under which a failure to comply with GDPR, or the exercise of individual rights under the GDPR, would limit our ability to utilize clinical trial data collected on certain subjects. The GDPR will likely impose additional responsibility and liability in relation to our processing of personal data. This may be onerous and materially adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

The regulatory approval process is highly uncertain and we may not obtain approval under the Accelerated Approval Program or the conventional pathway, as required for the commercialization of TRC101.

The research, testing, manufacturing, labeling, approval, selling, import, export, pricing and reimbursement marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory agencies in the United States and other countries, which regulations differ from country to country. Neither we nor any future collaboration partner is permitted to market TRC101 in the United States until we receive approval of an NDA from the FDA. We have not submitted an application or obtained marketing approval for TRC101 anywhere in the world. Obtaining regulatory approval of an NDA, even under the Accelerated Approval Program, can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

- warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of regulatory approval of products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Prior to obtaining approval to commercialize a drug candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such drug candidates are safe and effective for their intended uses. The number of nonclinical and clinical studies and trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. We will seek approval for TRC101 under the FDA's Accelerated Approval Program, which would allow us to demonstrate an effect on a surrogate endpoint that is reasonably likely to predict TRC101's clinical benefit, but we will be subject to rigorous postmarketing requirements, including the completion of one or more confirmatory postmarketing trials to verify the clinical benefit of TRC101. If unable to obtain approval under the Accelerated Approval Program, we will have to pursue a conventional approval pathway for TRC101. In addition, in such case, the FDA could determine that our pivotal Phase 3 clinical trial, TRCA-301, may not be sufficient to support approval under the conventional pathway**.** Results from nonclinical and clinical trials and studies can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our drug candidate is promising, such data may not be sufficient to support approval by the FDA and other regulatory agencies. Administering drug candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory agencies denying approval of a drug candidate for any or all targeted indications.

Both accelerated and conventional regulatory approval pathways of an NDA or NDA supplement are not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process and we may encounter matters with the FDA that require us to expend additional time and resources and delay or prevent the approval of our product candidate. For example, the FDA may require us to conduct additional studies or trials for TRC101 either prior to approval or postmarketing, such as additional drug-drug interaction studies or safety or efficacy studies or trials, or it may object to elements of our clinical development program such as the number of subjects enrolled in our current clinical trials from the United States. Despite the time and expense exerted, failure can occur at any stage. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to, the following:

- a drug candidate may not be deemed safe or effective;
- the FDA might not approve our trial design and analysis plan;
- the FDA may not find the data from nonclinical and clinical studies and trials sufficient;
- clinical inspection(s) by the FDA or other regulatory authorities may result in unacceptable findings that could negatively impact approval of TRC101;
- the FDA might not accept or deem acceptable a third-party manufacturers' processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

If TRC101 fails to demonstrate safety and efficacy in clinical trials or does not gain regulatory approval, our business and results of operations will be materially and adversely harmed. Additionally, if the FDA requires that we conduct additional clinical trials, places limitations on TRC101 in our label, delays approval to market TRC101 or limits the use of TRC101, our business and results of operations may be harmed.

We have not yet finalized the design of the confirmatory postmarketing trial, VALOR-CKD, including the sample size, trial duration, endpoint definition, event rate assumptions and eligibility criteria. The FDA and/or comparable foreign regulators may not agree with our proposed confirmatory postmarketing trial design, in which case we may be required to modify our planned clinical trials, or conduct additional clinical trials, before we can submit the NDA or comparable foreign applications.

We are in discussions with the FDA to finalize the design of our confirmatory postmarketing trial, VALOR-CKD, for TRC101's approval under the Accelerated Approval Program. There can be no assurance that we will reach agreement with the FDA on the VALOR-CKD trial design. For example, we anticipate a sample size of 1,400 to 1,600 subjects, but agreement with the FDA on the sample size and the design of the VALOR-CKD trial is needed to support FDA's acceptance of the NDA submission for review under the Accelerated Approval Program; this is still an outstanding topic in our ongoing discussions with the FDA. The FDA has noted that a quantitative understanding of the relationship between changes in blood bicarbonate caused by TRC101 in our pivotal, Phase 3 study, TRCA-301, and the kidney disease progression endpoint planned for the VALOR-CKD trial is a key factor in finalizing the VALOR-CKD trial design. To address this factor and justify our methodology for establishing the sample size for our confirmatory postmarketing trial, VALOR-CKD, we are currently using a quantitative predictive model developed by Navdeep Tangri, M.D., Ph.D., of the University of Manitoba, in which he modeled the relationship between the change in blood bicarbonate and the risk of kidney disease progression. We have submitted that model to the FDA. However, if we are unable to reach consensus with the FDA on the sample size for our confirmatory postmarketing trial, VALOR-CKD, we may be required to find other approaches to justify the sample size, thereby requiring an increase or decrease of our proposed sample size. Moreover, the FDA may require us to make other changes to our proposed design of our confirmatory postmarketing trial, VALOR-CKD, including changes related to trial duration, endpoint definition, event rate assumptions and eligibility criteria. In general, a sponsor planning to use the Accelerated Approval Program should discuss with the FDA the possibility of accelerated approval and design of any necessary confirmatory postmarketing trials during development and any confirmatory postmarketing trials should be in progress at the time of NDA approval. The FDA has specifically requested that our confirmatory postmarketing trial, VALOR-CKD, be completely enrolled or nearly completely enrolled prior to submission of our NDA for TRC101. Therefore, we must obtain the FDA's agreement and finalize the design of our confirmatory postmarketing trial, VALOR-CKD, and completely enroll or nearly completely enroll our confirmatory postmarketing trial, VALOR-CKD, prior to the submission of an NDA. Our NDA submission may be delayed if the FDA does not accept the design of our proposed confirmatory postmarketing trial, we are unable to completely, or nearly completely, enroll our confirmatory postmarketing trial, VALOR-CKD, or the FDA imposes any additional requirements prior to NDA submission, any of which could have a material adverse effect on our expected clinical and regulatory timelines, business, prospects, financial condition and results of operations.

Because we are developing a product candidate for the treatment of a disease or condition on the basis of an unvalidated surrogate endpoint, there are increased risks that the FDA or other regulatory authorities may find that our clinical program provides insufficient evidence of clinical benefit, may have difficulty analyzing and interpreting the results of our clinical program, and may delay or refuse to approve TRC101.

There are no FDA-approved therapies for the chronic treatment of metabolic acidosis in CKD patients. In addition, we are not aware of any chronic therapeutic agent that has previously been approved by the FDA on the basis of a clinical trial that used blood bicarbonate level as the primary endpoint. We have engaged in discussions with the FDA regarding the design of our pivotal Phase 3 clinical trial, TRCA-301, and whether the use of blood bicarbonate as a surrogate endpoint is reasonably likely to predict clinical benefit. However, the FDA has discretion at any time, including during the NDA review, to determine whether there is support for the use of blood bicarbonate as a surrogate endpoint.

Key issues with our endpoint include uncertainty about the degree of change from baseline blood bicarbonate that will translate into improved clinical outcomes, the population in which such change is expected to translate into improved clinical outcomes, and the need for data supporting a causal relationship between blood bicarbonate concentration and clinical outcomes. As a result, we cannot be certain that FDA will ultimately conclude that the design and results of our pivotal Phase 3 clinical trial, TRCA-301, which uses changes from baseline in

blood bicarbonate level as the primary endpoint, will be sufficient for approval of TRC101.

Moreover, even if the FDA does find that changes from baseline in blood bicarbonate are sufficiently likely to predict clinical benefit for patients, the FDA may not agree that we have achieved the primary endpoint in our pivotal Phase 3 clinical trial, TRCA-301, to the magnitude or to the degree of statistical significance required by the FDA. Further, even if those requirements are satisfied, the FDA also could give overriding weight to inconsistent or otherwise confounding results on other efficacy endpoints or other results of the trial, including results on secondary and exploratory endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Regulatory authorities in other countries may take similar positions.

We are conducting and may in the future conduct clinical trials for our product candidate, TRC101, outside the United States and the FDA may not accept data from such trials.

Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.

We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

Even if we receive regulatory approval for TRC101, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, TRC101, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with TRC101.

Even if a drug is approved by the FDA and/or foreign regulatory agencies, regulatory agencies may still impose significant restrictions on a product's indicated uses or marketing or impose various ongoing requirements. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs to assure compliance. In addition, if a drug receives approval under the FDA's Accelerated Approval Program, it will be subject to special postmarketing requirements, including the completion of confirmatory postmarketing clinical trials to verify the clinical benefit of the product, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw the approval for multiple reasons, including if we fail to conduct any required confirmatory postmarketing trial with due diligence, a confirmatory postmarketing trial does not confirm the predicted clinical benefit, other evidence shows that the product is not safe or effective under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading.

If TRC101 receives approval under the Accelerated Approval Program, it will be subject to ongoing regulatory requirements for conducting postmarketing clinical studies and trials, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information, including both federal and state requirements in the United States. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMP. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we must conduct the confirmatory postmarketing trial in a diligent manner and we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for TRC101. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the

information in the product's approved label. As such, we may not promote TRC101 for indications or uses for which it does not have FDA approval.

If TRC101 receives approval under the Accelerated Approval Program but we fail to conduct the required confirmatory postmarketing trials with due diligence or such postmarketing trials fail to confirm TRC101's clinical profile or risks and benefits, the FDA may withdraw its approval. If a regulatory agency discovers previously unknown problems with TRC101, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing, or labeling of a product, the regulatory agency may impose restrictions on the product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from TRC101. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from the sale of TRC101 our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

The regulatory requirements and policies may change, and additional government regulations may be enacted for which we may also be required to comply. 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 in other countries. If we or any future collaboration partner are not able to maintain regulatory compliance, we or such collaboration partner, as applicable, may face government enforcement action and our business will suffer.

Currently we plan to seek regulatory approval to market TRC101 for the treatment of metabolic acidosis and slowing of kidney disease progression in patients with metabolic acidosis associated with CKD and, unless we seek regulatory approval for additional indications, we will be prohibited from marketing TRC101 for other indications.

We intend to seek FDA approval to market TRC101 for the treatment of metabolic acidosis and slowing of kidney disease progression in patients with metabolic acidosis, but we cannot be certain what indication and what labeling language will be approved for TRC101 until the NDA review and potentially as late as approval. If TRC101 is approved under the Accelerated Approval Program, the indications and usage section of the label is likely to include a statement that clinical benefit of TRC101 has not yet been established and that continued approval may be contingent upon demonstration of clinical benefit in a confirmatory postmarketing trial. The FDA strictly regulates the promotional claims that may be made about prescription products, and TRC101 may not be promoted for uses that are not approved by the FDA as reflected in its approved labeling. Under applicable regulations, promoting uses that are not reflected in the FDA-approved labeling, referred to as "off-label" marketing, is prohibited. If we are found to have promoted such off-label uses, we may become subject to significant liability.

If we fail to comply or are found to have failed to comply with FDA and other regulations related to the promotion of TRC101 for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. If we receive marketing approval for TRC101, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing

practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of TRC101 for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FFDCA, the federal civil False Claims Act, or FCA, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "qui tam" actions under the FCA. Under the FCA, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, or other applicable prohibitions we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

If approved, TRC101 may cause or contribute to adverse medical events that we are required to report to regulatory agencies and if we fail to do so we could be subject to sanctions that would materially harm our business.

Some participants in our Phase 1/2 trial, TRCA-101, and our pivotal Phase 3 clinical trial, TRCA-301, reported mild to moderate adverse effects after being treated with TRC101, most commonly mild-to-moderate GI events, such as diarrhea, flatulence, nausea and constipation. If we are successful in commercializing TRC101, FDA and most foreign regulatory agency regulations require that we report certain information about adverse medical events if the product may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of TRC101. If we fail to comply with our reporting obligations, the FDA or a foreign regulatory agency could take action, including criminal prosecution, the imposition of civil monetary penalties, and seizure of our products.

If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.

Before commercial distribution of TRC101, contract manufacturers may be inspected to determine acceptability by FDA or foreign regulatory agencies for their manufacturing facilities, processes and quality systems, as part of the NDA approval. In addition, pharmaceutical manufacturing facilities are subject to inspection by the FDA and foreign regulatory agencies on a regular basis, before and after product approval. Due to the complexity of the processes used to manufacture pharmaceutical products and product candidates, any potential third-party manufacturer may be unable to continue to pass or initially pass federal, state or international regulatory inspections in a cost-effective manner.

If a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, TRC101 may not be approved, or we may be subject to fines, unanticipated compliance expenses, recall or seizure of our products, total or partial suspension of production and/or enforcement actions, including injunctions, and

criminal or civil prosecution. These possible sanctions would adversely affect our financial results and financial condition.

We are currently only seeking regulatory approval to market TRC101 in the United States. If we want to expand the geographies in which we may market TRC101, we will need to obtain additional regulatory approvals.

We currently plan to seek regulatory approval for TRC101 in the United States. In the future, we may attempt to develop and seek regulatory approval to promote and commercialize TRC101 outside of the United States. In order to obtain such approvals, we may be required to conduct additional clinical trials or studies to support our applications, which would be time consuming and expensive, and may produce results that do not result in regulatory approvals. Further, we will have to expend substantial time and resources in order to establish the commercial infrastructure or pursue a collaboration arrangement that would be necessary to promote and commercialize TRC101 outside of the United States. If we do not obtain regulatory approvals for TRC101 in foreign jurisdictions, our ability to expand our business outside the United States will be severely limited.

Our failure to obtain regulatory approvals in foreign jurisdictions for TRC101 would prevent us from marketing our products internationally.

In order to market any product in the European Economic Area, or EEA (which is composed of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), and many other foreign jurisdictions, separate regulatory approvals are required. In the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization. Before granting a Marketing Authorization, the EMA, or the competent agencies of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. It is unclear how the United Kingdom's pending exit of the European Union may affect our ability to seek marketing authorization for the United Kingdom market.

The approval procedures vary among countries and can involve additional nonclinical and clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory agencies in other countries. Approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one or more foreign regulatory agencies does not ensure approval by regulatory agencies in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not be able to file for regulatory approvals or to do so on a timely basis, and even if we do file we may not receive necessary approvals to commercialize TRC101 in any market. If we do not obtain regulatory approvals for TRC101 in foreign jurisdictions, our ability to expand our business outside the United States will be severely limited.

We may be subject to healthcare laws, regulation and enforcement; our failure to comply with these laws could have a material adverse effect on our results of operations and financial conditions.

Although we do not currently have any products on the market, we are subject to a variety of regulatory requirements, and from time to time, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments of the countries in which we conduct our business. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights may be applicable to our business. The laws that affect our current and future operations include:

- the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and

formulary managers on the other the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product. In addition, 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 FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product, providing consulting fees and other benefits to physicians to induce them to prescribe products, engaging in promotion for "off-label" uses, and submitting inflated best price information to the Medicaid Rebate Program;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, or collectively, HIPAA, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- state law equivalents of each of the above federal laws, such as Anti-Kickback Statute and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers;
- U.S. and European reporting requirements detailing interactions with and payments to healthcare providers, such as the U.S. the federal transparency requirements under the Physician Payments Sunshine Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Department of Health and Human Services information related to payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members. Failure to submit required information may result in civil monetary penalties; and
- state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers, and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

In addition, the approval and commercialization of TRC101 outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Further, the Patient Protection and Affordable Care Act, or PPACA, among other things, amends the intent requirement of the federal

Anti-Kickback Statute and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. 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.

In addition, there has been a recent trend of increased federal and state regulation related to payments made to physicians. Some states mandate implementation of compliance programs and/or the tracking and reporting of gifts, compensation, and other remuneration to physicians. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil, administrative and criminal penalties, damages, fines, the curtailment or restructuring of our operations, contractual damages, disgorgement, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, the exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to market TRC101, if approved, and adversely impact our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the applicable regulatory agencies or the courts, and their provisions are open to a variety of interpretations.

Legislative or regulatory FDA reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of TRC101 and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of TRC101. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recall, replacement, or discontinuance of TRC101; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals would harm our business, financial condition and results of operations.

Further, the United States and some foreign jurisdictions have enacted or are considering a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products, if approved, and profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access.

In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including the PPACA, which contains provisions that may potentially reduce the profitability of products, including, for example, increased rebates for products sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. There have been judicial and Congressional challenges to the PPACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of

certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law, including the repeal, effective January 1, 2019, of the tax-based shared responsibility payment imposed by the PPACA 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." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the PPACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Moreover, the Bipartisan Budget Act of 2018, among other things, amends the PPACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount to eligible beneficiaries during their coverage gap period that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In the future, there may be additional challenges and amendments to the PPACA. It remains to be seen precisely what new legislation will provide, when it will be enacted, and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare, including the cost of pharmaceutical products.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to end Medicare Part B coverage of medications and to shift those medication costs to Medicare Part D, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump 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 are increasingly passing legislation and implementing 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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize TRC101 and those for which we may receive regulatory approval in the future.

If we fail to obtain and sustain an adequate level of coverage and reimbursement for TRC101 by third-party payors, sales would be adversely affected.

We expect patients who have metabolic acidosis to need chronic treatment but we anticipate that most patients will rely on coverage and reimbursement by a third-party payor, such as Medicare, Medicaid or a private health insurer, to pay for such treatment. There will be no commercially viable market for TRC101 without coverage and reimbursement from third-party payors. Additionally, even if we obtain third-party payor coverage and reimbursement for TRC101, if the level of coverage and reimbursement is below our expectations, our revenue and gross margins will be adversely affected.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor can be an expensive and time-consuming process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. We cannot be certain if and when we will obtain formulary approval to allow us to sell TRC101, if approved, into our target markets. Even if we do obtain formulary approval, third-party payors, carefully review and increasingly question the coverage of, and challenge the prices charged for, drugs. Reimbursement rates from third-party payors vary depending on the payor, the insurance plan and other factors. A current trend in the United States health care industry is toward cost containment. Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, are questioning the coverage of, and challenging the prices charged for medical products and services, and many third-party payors limit coverage of, or reimbursement for, newly approved health care products.

In addition, there may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses.

Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including 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.

We cannot be sure that reimbursement will be available for TRC101 and, if coverage and reimbursement are available, what the level of reimbursement will be. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, TRC101, if approved. Assuming we obtain coverage for TRC101 by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use TRC101 unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of TRC101. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

We expect to experience pricing pressures in connection with the sale of our product candidate due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for TRC101, if approved.

These cost-control initiatives could decrease the price we might establish for TRC101, which could result in product revenues being lower than anticipated. The pricing, coverage and reimbursement of TRC101, if approved, must be adequate to support a commercial infrastructure. If the price for TRC101 decreases or if governmental and other third-party payors do not provide adequate coverage and reimbursement levels, our revenue and prospects for profitability will suffer. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis.

Outside the United States, international operations are generally subject to extensive governmental price controls and market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, China and other countries will put pressure on the pricing and usage of TRC101. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medicinal products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are

able to charge for TRC101, if approved. Accordingly, in markets outside the United States, the reimbursement for TRC101 compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the United States domestic bribery statute contained in 18 U.S.C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell TRC101 abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Risks Related to Intellectual Property

We may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development and commercialization of TRC101.

Our success depends in part on our ability to develop, manufacture, market and sell TRC101, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and other intellectual property rights of third parties. There have been many lawsuits and other proceedings asserting patents and other intellectual property rights in the pharmaceutical and biotechnology industries. We cannot assure you that TRC101 will not infringe existing or future third-party patents. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be applications now pending of which we are unaware and which may later result in issued patents that we may infringe by commercializing TRC101. There may also be issued patents or pending patent applications that we are aware of, but that we think are irrelevant to TRC101, which may ultimately be found to be infringed by the manufacture, sale, or use of TRC101. Moreover, we may face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. In addition, TRC101 has a complex structure that makes it difficult to conduct a thorough search and review of all potentially relevant third-party patents. We may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of TRC101.

We may be subject to third-party claims in the future against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third-party's patents. Furthermore, because of the potential for significant damage awards, which are not necessarily predictable, it is not unusual to find even arguably unmeritorious claims resulting in large settlements. We may be required to indemnify future collaborators against such claims. If a patent infringement suit were brought against us or our collaborators, we or they 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. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which

would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. Even if we are successful in defending against such claims, such litigation can be expensive and time consuming to litigate and would divert management's attention from our core business. Moreover, some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. Any of these events could harm our business significantly.

In addition to infringement claims against us, if third parties prepare and file patent applications in the United States that also claim technology similar or identical to ours, we may have to participate in interference or derivation proceedings in the U.S. Patent and Trademark Office, or the USPTO, to determine which party is entitled to a patent on the disputed invention. Recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. This reform adds uncertainty to the possibility of challenge to our patents in the future. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to TRC101 and our technology. Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidate.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights or other intellectual property, or those of our licensors. To counter infringement, misappropriation, unauthorized use or other violations, we may be required to file legal claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

We may not be able to prevent, alone or with our licensees or any future licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from exploiting the claimed subject matter at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from exploiting its technology on the grounds that our patents do not cover such technology. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making, using, importing and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement, misappropriation or other intellectual property litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

If our intellectual property related to TRC101 is not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection, employment and confidentiality agreements to protect the intellectual property related to TRC101. Any disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in foreign countries, and even if issued, the patents may not meaningfully protect TRC101, effectively prevent competitors and third parties from commercializing competitive products or otherwise provide us with any competitive advantage. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. Even if patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in some jurisdictions third parties can raise questions of validity with a patent office even before a patent has granted. 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. For example, a third party may develop a competitive product that provides therapeutic benefits similar to TRC101 but has a sufficiently different composition to fall outside the scope of our patent protection. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to TRC101 is successfully challenged, then our ability to commercialize TRC101 could be negatively affected, and we may face unexpected competition that could have a material adverse impact on our business. Further, if we encounter delays in our clinical trials, the period of time during which we could market TRC101 under patent protection would be reduced.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or one of our future collaborators were to initiate legal proceedings against a third party to enforce a patent covering TRC101, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability against our intellectual property related to TRC101, we would lose at least part, and perhaps all, of the patent protection on TRC101. Such a loss of patent protection would have a material adverse impact on our business. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from exploiting its technology on the grounds that our patents do not cover that technology. Moreover, our competitors could counterclaim that we infringe their intellectual property, and some of our competitors have substantially greater intellectual property portfolios than we do.

We also rely on trade secret protection, employment and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain and/or enforce and any other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and endeavor to execute confidentiality agreements with all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or who had access to our proprietary information, nor can we be certain that our agreements will not be breached. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they

communicate such technology or information, from using that technology or information to compete with us. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors or third parties such as contract manufacturers will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, we and our third-party suppliers continue to refine and improve the manufacturing process, certain aspects of which are complex and unique, and we may encounter difficulties with new or existing processes, particularly as we seek to significantly increase our capacity to commercialize TRC101. Our reliance on contract manufacturers exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidate, TRC101.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but 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 such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to TRC101 or (ii) invent any of the subject matter claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Obtaining and maintaining our 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.

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. Noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We have not yet registered trademarks for a commercial trade name for TRC101 in the United States or elsewhere and failure to secure such registrations could adversely affect our business.

We have not yet registered trademarks for a commercial trade name for TRC101 in the United States or elsewhere. During trademark registration proceedings, our trademark application may be rejected. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties can oppose pending trademark applications and seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, approval may be delayed or we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. For example, the requirements for patentability may differ in certain countries, particularly developing countries, and we may be unable to obtain issued patents that contain claims that adequately cover or protect TRC101 or any future product candidates. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market TRC101. Consequently, we may not be able to prevent third parties from practicing our technology in all countries outside the United States, or from selling or importing products made using our technology in and into those other jurisdictions where we do not have intellectual property rights. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export 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 product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

We may be subject to claims that we or our employees, consultants, contractors or advisors have infringed, misappropriated or otherwise violated the intellectual property of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the intellectual property and other proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. To the extent that we fail to obtain such assignments, such assignments do not contain a self-executing assignment of intellectual property rights or such assignments are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Patent terms may be inadequate to protect our competitive position on our product candidate, TRC101, for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering TRC101 are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of our product candidate, TRC101, patents protecting TRC101 might expire before or shortly after TRC101 is commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Intellectual property rights do not necessarily address all potential threats to our business.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative:

- others may be able to make products that are similar to TRC101 but that are not covered by the claims of our patent rights;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we may own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section of this Quarterly Report on Form 10-Q and others such as:

- announcements of regulatory approval or a complete response letter to TRC101, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- adverse events experienced by the patient population taking TRC101, whether or not related to our product candidate;
- changes or developments in laws or regulations applicable to TRC101;
- changes in existing tax laws, treaties or regulations or the interpretations or enforcement thereof, or the enactment or adoption of new tax laws, regulations or policies;
- any adverse changes to our relationship with any manufacturers or suppliers;
- the success of our testing and clinical trials;
- the success of our efforts to acquire or license or discover additional product candidates, if any;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- general economic and market conditions and overall fluctuations in the United States equity markets; and
- the loss of any of our key scientific or management personnel.

In addition, the stock markets in general, and the markets for pharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the public offering price.

Prior to our initial public offering, there has been no public market for shares of our common stock, and an active public market for our shares may not develop or be sustained after our initial public offering. We and the representatives of the underwriters of our initial public offering determined the offering price of our common stock through negotiation. This price does not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following our initial public offering. In addition, an active trading market may not develop following the completion of our initial public offering or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications or technologies using our shares as consideration.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and an extended transition period for complying with new or revised accounting standards. We cannot predict if investors will find our common stock less attractive because we will 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. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. 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 $1.0 billion in non-convertible debt during the prior three-year period.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to "opt out" of such extended transition period, and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

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.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. If stockholders who held shares of our common stock prior to our initial public offering sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale lapse, the trading price of our common stock could decline.

We have outstanding a total of 42,095,927 shares. Of these shares, only the shares of common stock sold in our initial public offering by us (other than the Company directed shares purchased in our initial public offering by an officer or director of the Company) are currently freely tradable without restriction in the public market. Goldman Sachs & Co. LLC, J.P. Morgan Securities LLC and Cowen and Company, LLC, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

We expect that the lock-up agreements pertaining to our initial public offering will expire 180 days from June 27, 2018. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2018 Equity Incentive Plan or our Employee Stock Purchase Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. The number of shares of our common stock reserved for issuance under our 2018 Equity Incentive Plan will automatically increase on the first day of each fiscal year by the lesser of 4% of the number of shares of common stock outstanding on the first day of such fiscal year, 3,200,000 shares of our common stock or such lesser amount as is determined by our board of directors.

The number of shares of our common stock reserved for issuance under our ESPP will automatically increase on the first day of each fiscal year by the lesser of 1% of the number of shares of common stock outstanding on the first day of such fiscal year, 800,000 shares of our common stock or such lesser amount as is determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Holders of an aggregate of approximately 26.3 million shares of our common stock are entitled, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 67% of our outstanding voting stock.

Therefore, even after the completion of our initial public offering these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders 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 feel are in your best interest as one of our stockholders.

We have broad discretion to determine how to use the funds raised in our initial public offering and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management will have broad discretion over the use of proceeds from our initial public offering, and we could spend the proceeds from our initial public offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently intend to use substantially all of the net proceeds of our initial public offering for supporting our activities for our NDA submission and approval process for TRC101, manufacturing activities related to TRC101, conducting our safety extension trial, TRCA-301E, and commencing our confirmatory postmarketing trial, VALOR-CKD, commercial expenses related to TRC101, interest payments under our Term Loan with Hercules, and the remainder for working capital and general corporate purposes. However, our use of these proceeds may differ substantially from our current plans. If we do not invest or apply the proceeds of our initial public offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws that is in effect since the completion of our initial public offering contains provisions that could significantly reduce the value of our shares to a potential acquirer or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents includes the following:

- a classified board of directors with 3-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors, unless the board of directors determines by resolution that any such vacancy shall be filled by the affirmative vote of the stockholders;
- the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66⅔% of the shares entitled to vote at an election of directors to adopt, amend or repeal certain provisions of our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the General Corporation Law of the State of Delaware, or the DGCL. Under Section 203 of the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated certificate of incorporation to be effective immediately prior to the completion of our initial public offering and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated certificate of incorporation provisions to reduce our indemnification obligations to directors and officers.

Our amended and restated certificate of incorporation and our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our current or former directors, officers or employees.

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders, any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, any action asserting a claim against us or any of our directors, officers or other employees that is governed by the internal affairs doctrine, or any other action asserting an "internal corporate claim," as defined in Section 115 of the DGCL. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation and amended and restated bylaws described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our current or former directors, officers or other employees, which may discourage such lawsuits against us and our current or former directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate and our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be required to pay severance benefits to our executive officers who are terminated in connection with a change in control, which could harm our financial condition or results.

Certain of our executive officers are parties to severance arrangements that contain change in control and severance provisions providing for aggregate cash payments of up to approximately $4.7 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately $49.8 million (as of June 30, 2018, based on the closing price of $29.90 per share) in the event of a termination of employment in connection with a change in control of our company. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Additionally, the terms of our Term Loan restrict our ability to pay dividends. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

Our ability to use our net operating losses to reduce our tax liability may be limited.

As of December 31, 2017, we had net operating loss carryforwards of approximately $89.6 million for U.S. federal income tax purposes, which begin to expire in 2033. However, our ability to utilize these net operating loss carryforwards is subject to the rules of Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. Section 382 generally restricts the use of net operating loss carryforwards after an "ownership change." If we have experienced or experience in the future an "ownership change" for purposes Section 382, we may be subject to annual limits on our ability to utilize net operating loss carryforwards. An ownership change is, as a general matter, triggered by sales or acquisitions of our stock in excess of 50% on a cumulative basis during a three-year period by persons or groups of persons owning 5% or more of our total equity value. We have not performed any analysis under Section 382 of the Code. As a result, uncertainty exists as to whether we may have undergone an ownership change in the past, whether as a result of our initial public offering or otherwise, or will undergo one as a result of a future transaction, if any. We cannot provide any assurance that our net operating losses will be available. Accordingly, we could pay taxes earlier and/or in larger amounts than would be the case if the net operating losses were available to reduce federal income taxes without restriction.

As noted above under "Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements," we anticipate that we will continue to incur losses for the foreseeable future. Our ability to utilize any future net operating losses may also be limited by the recently enacted legislation commonly known as the Tax Cuts and Jobs Act, or the Tax Act. Under the Tax Act, the amount of post-2017 net operating losses that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the net operating loss deduction itself. In addition, the Tax Act generally eliminates the ability to carry back any net operating loss to prior taxable years, while allowing post-2017 unused net operating losses to be carried forward indefinitely. Due to these changes under the Tax Act, or potential future ownership changes under Section 382 of the Code, we may not be able to realize a tax benefit from the use of our net operating losses, whether or not we attain profitability in future years.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered sales of equity securities

The following list sets forth information as to all securities we have sold during the quarter ended June 30, 2018, which were not registered under the Securities Act.

1. We issued and sold an aggregate of 95,936 shares of Series A Preferred Stock at an exercise price of $0.886 upon exercise of a warrant.
2. We granted stock options to purchase an aggregate of 303,751 shares of our common stock at a weighted-average exercise price of $10.78 per share to certain employees, consultants and directors.
3. We granted RSUs of 21,792 shares of our common stock to certain directors.
4. We issued and sold an aggregate of 151,478 shares of common stock to certain employees, directors and consultants for cash consideration in the aggregate amount of $158,987 upon the exercise of stock options.

We deemed the sales and issuances of the securities described in paragraph (1) above to be exempt from registration under the Securities Act, in reliance on Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, regarding transactions by an issuer not involving a public offering. All purchasers of securities in transactions exempt from registration pursuant to Regulation D represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

We deemed the grants and exercises of stock options described in paragraphs (2), (3), and (4) as exempt pursuant to Section 4(a)(2) of the Securities Act or to be exempt from registration under the Securities Act in reliance on Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

All certificates representing the securities issued in the transactions described above in this Item 2 included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth above in this Item 2.

Use of proceeds from Initial Public Offering of Common Stock

On July 2, 2018, we closed the sale of 13,455,000 shares of common stock, which includes the additional-allotment of 1,755,000 shares exercised by the underwriters in the IPO, to the public at an initial public offering price of $19.00 per share. The offer and sale of the shares in the IPO was registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333-225420), which was filed with the SEC on June 4, 2018 and amended subsequently and declared effective on June 27, 2018, and Form S-1MEF, which was filed with the SEC on June 27, 2018 and became effective on June 27, 2018. The underwriters of the offering were Goldman Sachs & Co. LLC, J.P. Morgan Securities LLC and Cowen and Company, LLC.

We raised approximately $237.7 million in net proceeds after deducting underwriting discounts and commissions of approximately $17.9 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

To date, we have not yet used the net proceeds from our IPO. We invested the funds received in short-term marketable securities in accordance with our investment policy. None of such payments were direct or indirect payments to any of our directors or officers (or their associates), to persons owning ten percent or more of our common stock or to any other affiliates. As described in our final prospectus filed with the SEC on June 29, 2018 pursuant to Rule 424(b) under the Securities Act, we expect to use the net proceeds from our IPO for supporting our activities for our NDA submission and approval process for TRC101, manufacturing activities related to TRC101, conducting our safety extension trial, TRCA-301E, and commencing our confirmatory postmarketing trial,

known as the VALOR-CKD trial, or TRCA-303, commercial expenses related to TRC101, interest payments under our Loan and Security Agreement with Hercules Capital, Inc., and the remainder for working capital and general corporate purposes.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
3.1^	Amended and Restated Certificate of Incorporation of Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on July 2, 2018).
3.2^	Bylaws of Registrant, as currently in effect (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed on July 2, 2018).
10.1+^	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 (333-225420), Amendment No. 2 filed on June 25, 2018).
10.2+^	2013 Equity Incentive Plan, as amended, and form of agreements thereunder (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1 (333-225420), Amendment No. 2 filed on June 25, 2018).
10.3+^	2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 (333-225420), Amendment No. 2 filed on June 25, 2018).
10.4+^	Form of Director Restricted Stock Unit Award Agreement (annual grant) (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 (333-225420), Amendment No. 2 filed on June 25, 2018).
10.5+^	Form of Director Stock Option Agreement (annual grant) (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 (333-225420), Amendment No. 2 filed on June 25, 2018).
10.6+^	2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (333-225420), Amendment No. 2 filed on June 25, 2018).
10.7+^	Form of Tricida, Inc. Executive Severance Benefit Plan, as amended (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 (333-225420), Amendment No. 2 filed on June 25, 2018).
10.8^	Loan and Security Agreement, dated February 28, 2018, among the Registrant, Hercules Capital, Inc. and the several banks and other financial institutions or entities from time to time parties thereto (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (333-225420) filed on June 4, 2018).
10.9^	First Amendment to Loan and Security Agreement and First Amendment to Warrants, dated as of April 10, 2018, among the Registrant, Hercules Capital, Inc. and the several banks and other financial institutions or entities from time to time parties thereto (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 (333-225420) filed on June 4, 2018).
10.10^	Lease Agreement, dated April 4, 2014, between the Registrant and ARE-San Francisco No. 17, LLC (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 (333-225420) filed on June 4, 2018).
10.11^	First Amendment to Lease, dated August 2, 2017, between the Registrant and ARE-San Francisco No. 17, LLC (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 (333-225420) filed on June 4, 2018).
10.12#^	Master Development/Validation Services and Clinical/Launch Supply Agreement (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1 (333-225420) filed on June 4, 2018).
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a) or 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act.
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a) or 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Taxonomy
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 Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

^	Previously filed.
+	Indicates a management contract or compensatory plan.
#	Portions of this exhibit have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: August 9, 2018

TRICIDA, INC.

By: /s/ Gerrit Klaerner, Ph.D.
Gerrit Klaerner, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Geoffrey M. Parker
Geoffrey M. Parker
Chief Financial Officer and Senior Vice President
(Principal Financial Officer)

By: /s/ Steffen Pietzke
Steffen Pietzke
Vice President of Finance and Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION

I, Gerrit Klaerner, Ph.D., certify that:

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

Date: August 9, 2018

/s/ Gerrit Klaerner, Ph.D.

Gerrit Klaerner, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Geoffrey M. Parker, certify that:

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

Date: August 9, 2018

/s/ Geoffrey M. Parker

Geoffrey M. Parker
Chief Financial Officer and Senior Vice President
(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

In connection with the Quarterly Report of Tricida, Inc. (the "Company"), on Form 10-Q for the fiscal quarter ended June 30, 2018, as filed with the Securities and Exchange Commission (the "Report"), each of Gerrit Klaerner, Ph.D., President and Chief Executive Officer of the Company, and Geoffrey M. Parker, Chief Financial Officer and Senior Vice President of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Dated: August 9, 2018

/s/ Gerrit Klaerner, Ph.D.

Gerrit Klaerner, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Geoffrey M. Parker

Geoffrey M. Parker
Chief Financial Officer and Senior Vice President
(Principal Financial Officer)