UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

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

For the quarterly period ended March 31, 2019
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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☒ Smaller reporting company ☐

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common stock, par value $0.001 per share	TCDA	The Nasdaq Global Select Market

On May 6, 2019, the registrant had 49,140,257 shares of common stock, par value $0.001 per share, outstanding.

TABLE OF CONTENTS

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. Forward-looking statements generally can be identified by words 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 veverimer (TRC101), our only product candidate, which is still in development;
- our expectations regarding the timing of submitting the New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, and our ability to obtain approval for veverimer under the Accelerated Approval Program;
- our expectations regarding the timing of the completion of our nonclinical studies;
- 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 our VALOR-CKD trial;
- market acceptance or commercial success of veverimer, if approved, and the degree of acceptance among physicians, patients, patient advocacy groups, health care payers and the medical community;
- our expectations regarding competition, potential market size and the size of the patient population for veverimer, if approved for commercial use;
- our expectations regarding our ability to draw under our credit facility with Hercules Capital, Inc.;
- our expectations regarding the safety, efficacy and clinical benefit of veverimer;
- our ability to achieve and maintain regulatory approval of veverimer, and any related restrictions, limitations and/or warnings in the label of veverimer;
- our sales, marketing or distribution capabilities and our ability to commercialize veverimer, if we obtain regulatory approval;
- current and future agreements with third parties in connection with the manufacturing, commercialization, packaging and distribution of veverimer;
- our expectations regarding the ability of our contract manufacturing partners to produce veverimer 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 veverimer;
- potential claims relating to our intellectual property and third-party intellectual property;
- the duration of our intellectual property estate that will provide protection for veverimer;

- 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 Jumpstart Our Business Startups Act, or JOBS Act; 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 this 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 in Item 1A. "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Investors in our securities 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. Investors in our securities 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)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 21,928	$ 37,172
Short-term investments	197,040	203,906
Prepaid expenses and other current assets	3,018	3,269
Total current assets	221,986	244,347
Long-term investments	—	2,287
Property and equipment, net	1,209	1,215
Operating lease right-of-use assets	2,052	—
Deferred offering costs	717	—
Total assets	$ 225,964	$ 247,849
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,045	$ 8,460
Current operating lease liabilities	1,038	—
Accrued expenses and other current liabilities	20,663	6,344
Total current liabilities	26,746	14,804
Term Loan	36,940	38,071
Non-current operating lease liabilities	1,223	—
Other long-term liabilities	446	449
Total liabilities	65,355	53,324
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 40,000,000 shares authorized, no shares issued or outstanding as of March 31, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized as of March 31, 2019 and December 31, 2018; 42,676,106 and 42,148,247 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	43	42
Additional paid-in capital	390,508	386,830
Accumulated other comprehensive income (loss)	149	(153)
Accumulated deficit	(230,091)	(192,194)
Total stockholders' equity	160,609	194,525
Total liabilities and stockholders' equity	$ 225,964	$ 247,849

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 March 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 31,423	$ 16,633
General and administrative	6,352	3,465
Total operating expenses	37,775	20,098
Loss from operations	(37,775)	(20,098)
Other income (expense), net	1,267	(87)
Interest expense	(1,389)	(319)
Net loss	(37,897)	(20,504)
Other comprehensive income (loss):		
Net unrealized gain (loss) on available-for-sale securities	302	(54)
Total comprehensive loss	$ (37,595)	$ (20,558)
Net loss per share, basic and diluted	$ (0.90)	$ (9.00)
Weighted-average number of shares outstanding, basic and diluted	42,268,062	2,278,266

See accompanying notes to condensed financial statements (unaudited).

TRICIDA, INC.

CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share amounts)

Three Months Ended March 31, 2019	Stockholders' Equity (Deficit)							
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	—	$ —	42,148,247	$ 42	$ 386,830	$ (153)	$ (192,194)	$ 194,525
Issuance of warrants in connection with Term Loan	—	—	—	—	284	—	—	284
Issuance of common stock upon exercise of stock options	—	—	527,859	1	736	—	—	737
Stock-based compensation	—	—	—	—	2,658	—	—	2,658
Unrealized gain on available-for-sale investments	—	—	—	—	—	302	—	302
Net loss	—	—	—	—	—	—	(37,897)	(37,897)
Balance at March 31, 2019	—	$ —	42,676,106	$ 43	$ 390,508	$ 149	$ (230,091)	$ 160,609

Three Months Ended March 31, 2018	Convertible Preferred Stock		Stockholders' Equity (Deficit)					
			Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2017	104,129,702	$ 147,070	2,272,609	$ 2	$ 1,356	$ (13)	$ (89,386)	$ (88,041)
Issuance of common stock upon exercise of stock options	—	—	29,519	—	24	—	—	24
Stock-based compensation	—	—	—	—	353	—	—	353
Unrealized loss on available-for-sales securities	—	—	—	—	—	(54)	—	(54)
Net loss	—	—	—	—	—	—	(20,504)	(20,504)
Balance at March 31, 2018	104,129,702	$ 147,070	2,302,128	$ 2	$ 1,733	$ (67)	$ (109,890)	$ (108,222)

See accompanying notes to condensed financial statements (unaudited).

TRICIDA, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2019	**2018**
Operating activities:		
Net loss	$ (37,897)	$ (20,504)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	172	138
Amortization of operating lease right-of-use assets	204	—
Amortization of Term Loan discount and issuance costs	488	128
Accretion (amortization) of premiums and discounts on investments	(756)	(123)
Stock-based compensation	2,658	353
Changes in fair value of compound derivative liabilities and warrants	174	136
Changes in operating assets and liabilities:	—	—
Prepaid expenses and other assets	243	1,110
Accounts payable	(3,390)	4,699
Accrued expenses and other liabilities	14,479	(1,033)
Operating lease liabilities	(217)	—
Net cash used in operating activities	(23,842)	(15,096)
Investing activities:		
Purchase of investments	(44,769)	(16,802)
Maturities of investments	54,981	11,865
Purchase of property and equipment	(193)	(494)
Net cash provided by (used in) investing activities	10,019	(5,431)
Financing activities:		
Payments of equity offering costs	(321)	(726)
Proceeds from exercise of common stock under equity award plans	251	77
Proceeds from leasehold improvement loan	—	250
Repayment of leasehold improvement loan	(32)	—
Proceeds (payments) under Term Loan, net	(1,319)	23,634
Net cash provided by (used in) financing activities	(1,421)	23,235
Net increase (decrease) in cash and cash equivalents	(15,244)	2,708
Cash and cash equivalents at beginning of period	37,172	9,774
Cash and cash equivalents at end of period	$ 21,928	$ 12,482
Supplemental disclosures		
Cash paid for interest	$ 782	$ —
Supplemental disclosures of non-cash financing activities		
Deferred offering costs incurred but not paid	$ 396	$ 1,452
Warrants and compound derivative related to Term Loan	$ 284	$ 810
Purchase of property and equipment in accounts payable and accrued expenses	$ —	$ 51

See accompanying notes to condensed financial statements (unaudited).

TRICIDA, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1. ORGANIZATION AND BASIS OF PRESENTATION

Organization—Tricida, Inc. (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, or inception. The Company is focused on the development and commercialization of its drug candidate, veverimer (TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis by binding and removing acid from the gastrointestinal, or GI, tract. In May 2018, the Company completed its pivotal Phase 3 clinical trial, TRCA-301, that met both its primary and secondary endpoints in a highly statistically significant manner. In March 2019, the Company completed its extension trial, TRCA-301E. Based on the initial topline data analyses, the TRCA-301E trial met all of its primary and secondary endpoints. The Company plans to submit a New Drug Application, or NDA, in the second half of 2019, pursuant to the U.S. Food and Drug Administration's, or FDA's, Accelerated Approval Program. As part of the Accelerated Approval Program, the Company has committed to conduct a confirmatory postmarketing trial, VALOR-CKD (also known as TRCA-303), to evaluate the efficacy and safety of veverimer in delaying CKD progression in subjects with metabolic acidosis. The VALOR-CKD trial has been initiated, and the Company has committed to completely enrolling, or nearly completely enrolling, subjects in the trial prior to the Company's NDA submission.

The Company has sustained operating losses and expects such annual losses to continue over the next several years. The Company's ultimate success depends on the outcome of its research and development and commercialization activities for veverimer, for which it expects to incur additional losses in the future. The Company recognizes the need to raise additional capital to fully implement its business plan. Through March 31, 2019, the Company has relied primarily on the proceeds from equity offerings and debt financing to finance its operations.

The Company intends to raise additional capital through the issuance of equity, borrowings, or strategic alliances with partner companies. However, if such financing is not available at adequate levels or on reasonable terms, the Company will need to reevaluate its operating plans.

Basis of Presentation—The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The condensed balance sheet as of March 31, 2019, the condensed statements of operations and comprehensive loss for the three months ended March 31, 2019 and 2018, the condensed statements of convertible preferred stock and stockholders' equity (deficit) for the three months ended March 31, 2019 and 2018 and the condensed statements of cash flows for the three months ended March 31, 2019 and 2018 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company consider necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The condensed balance sheet at December 31, 2018 has been derived from audited financial statements.

Although the Company believes that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

With the exception of the change for the accounting of leases as a result of the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842), or Topic 842, there have been no new or material changes to the significant accounting policies discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, that are of significance, or potential significance, to the Company.

Leases—The Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, operating leases are included in operating lease right-of-use (ROU) assets; current

operating lease liabilities; and non-current operating lease liabilities on its condensed balance sheets. The Company currently does not have any finance leases.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. ROU assets also include any initial direct costs incurred and any lease payments made on or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. The Company considered information available at the adoption date of Topic 842 to determine the incremental borrowing rate for leases in existence as of this date. Lease terms may include options to extend or terminate the lease when the Company is reasonably certain that the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term.

The Company elected to apply each of the practical expedients described in Accounting Standards Codification Topic 842-10-65-1(f) which allow companies not to reassess: (i) whether any expired or existing agreements contain leases, (ii) the classification of any expired or existing leases, and (iii) the capitalization of initial direct costs for any existing leases. The Company also elected to apply the short-term lease measurement and recognition exemption in which ROU assets and lease liabilities are not recognized for short-term operating leases. A short-term is a lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

Recent Accounting Pronouncements

Adopted Standards

In February 2016, the Financial Accounting Standards Board (FASB) issued Topic 842, which amended prior accounting standards for leases. The Company adopted Topic 842 on January 1, 2019, using the alternative modified transition method, which applies the standard as of the effective date and therefore, the Company has not applied the standard to the comparative periods presented on the Company's condensed financial statements.

The Company elected the following practical expedients when assessing the transition impact available to lessees: (i) not to reassess whether any expired or existing contracts as of January 1, 2019, are or contain leases; (ii) not to reassess the lease classification for any expired or existing leases as of January 1, 2019; and (iii) not to reassess initial direct costs for any existing leases as of January 1, 2019.

As a lessee, the primary impact for the Company was the recognition of operating lease ROU assets of $2.3 million and operating lease liabilities of $2.5 million on its condensed balance sheet as of January 1, 2019. See Note 4 "Leases" for additional details.

Standards Not Yet Effective

In September 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which amends ASC Topic 820, *Fair Value Measurement*. The FASB issued final guidance that eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. Under the ASU, entities will no longer be required to disclose the amount of transfers between Level 1 and Level 2 of the fair value hierarchy. Public companies will be required to disclose changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. ASU No. 2018-13 is effective for public business entities for annual reporting periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption will be permitted in any interim or annual period. The Company plans to adopt this guidance on January 1, 2020. The new guidance only affects disclosures in the notes to the financial statements and will not affect the Company's financial statements.

NOTE 3. FAIR VALUE MEASUREMENTS AND 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; and

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 policy is to recognize transfers in and out of Level 1, 2 and 3 as of the end of the reporting period. There were no transfers of assets or liabilities between the fair value measurement levels during the three months ended March 31, 2019.

The Company's financial instruments consist primarily of cash, cash equivalents, short-term and long-term investments, accounts payable and the Term Loan with Hercules.

Cash, cash equivalents and investments are reported at their respective fair values on the Company's condensed balance sheets. 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 commercial paper, corporate debt securities and asset-backed securities as Level 2.

The Company's short-term and long-term investments are classified as available-for-sale. The following tables summarize the Company's cash, cash equivalents and available-for-sale investments' amortized cost, gross unrealized gains, gross unrealized losses and estimated fair value by significant investment category reported as cash and cash equivalents, short-term investments or long-term investments as of March 31, 2019 and December 31, 2018.

	March 31, 2019						
					Reported as:		
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Short-Term Investments	Long-Term Investments
Cash	$ 636	$ —	$ —	$ 636	$ 636	$ —	$ —
Level 1:							
Money market fund	21,292	—	—	21,292	21,292	—	—
Level 2:							
Commercial paper	76,665	40	(1)	76,704	—	76,704	—
Corporate debt securities	68,114	59	(4)	68,169	—	68,169	—
Asset-backed securities	52,112	55	—	52,167	—	52,167	—
Subtotal	196,891	154	(5)	197,040	—	197,040	—
Total assets measured at fair value	$ 218,819	$ 154	$ (5)	$ 218,968	$ 21,928	$ 197,040	$ —

	December 31, 2018						
					Reported as:		
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Short-Term Investments	Long-Term Investments
Cash	$ 3,021	$ —	$ —	$ 3,021	$ 3,021	$ —	$ —
Level 1:							
Money market fund	33,154	—	—	33,154	33,154	—	—
Level 2:							
Commercial paper	68,467	—	(63)	68,404	997	67,407	—
Corporate debt securities	89,038	4	(63)	88,979	—	86,692	2,287
Asset-backed securities	49,838	3	(34)	49,807	—	49,807	—
Subtotal	207,343	7	(160)	207,190	997	203,906	2,287
Total assets measured at fair value	$ 243,518	$ 7	$ (160)	$ 243,365	$ 37,172	$ 203,906	$ 2,287

Interest income related to the Company's cash, cash equivalents and available-for-sale investments included in other income (expense), net was approximately $1.6 million and $0.3 million for the three months ended March 31, 2019 and 2018, respectively. There were no gross realized gains and gross realized losses for the three months ended March 31, 2019 and 2018.

The following table summarizes the Company's available-for-sale investments that were in a continuous unrealized loss position but were not deemed to be other-than-temporarily impaired, as of March 31, 2019 and December 31, 2018.

	March 31, 2019		December 31, 2018	
(in thousands)	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Commercial paper	$ 7,935	$ (1)	$ 67,407	$ (63)
Corporate debt securities	27,552	(4)	85,699	(63)
Asset-backed securities	—	—	36,730	(34)
Total	$ 35,487	$ (5)	$ 189,836	$ (160)

The Company held a total of 10 and 48 positions which were in an unrealized loss position as of March 31, 2019 and December 31, 2018, respectively. All available-for-sale investments in an unrealized loss position were in a continuous loss position for less than 12 months. As of March 31, 2019, unrealized losses on available-for-sale investments were not attributable to credit risk. The Company determined that there were no other-than-temporary impairments as of March 31, 2019 because the Company does not intend to sell these securities nor does the Company believes that the Company will be required to sell these securities before the recovery of their amortized cost basis.

The following table presents a reconciliation of financial liabilities measured at fair value on a recurring basis using Level 3 unobservable inputs for the three months ended March 31, 2019 and 2018.

	Three Months Ended March 31,		
	2019	2018	
(in thousands)	Compound Derivative Liability	Compound Derivative Liability	Warrant Liability
Fair value at beginning of period	$ 161	$ —	$ 106
Additions	—	654	156
Change in fair value	174	35	101
Fair value at end of period	$ 335	$ 689	$ 363

The following table presents information about significant unobservable inputs related to the Company's significant Level 3 financial liabilities as of March 31, 2019.

	March 31, 2019			
(in thousands)	Fair Value	Valuation Technique	Significant Unobservable Input	Range of Inputs
Compound derivative liability	$ 335	Discounted cash flow	Discount rate	11.0% - 11.2%
			Probability of the occurrence of certain events	10.0%

Term Loan

The estimated fair value of the Term Loan was $39.7 million as of March 31, 2019 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 values for the Term Loan. The discount rate ranged between 11.0% and 11.2%.

NOTE 4. LEASES

The Company has an operating lease for its office and laboratory space in South San Francisco, California. Operating lease expense was $0.3 million for the three months ended March 31, 2019. Cash paid within operating cash flows for operating leases was $0.3 million for the three months ended March 31, 2019. Short-term lease expense for the months ended March 31, 2019 was not material.

The following table presents supplemental balance sheet information related to operating leases as of March 31, 2019.

(in thousands, except lease term and discount rate)	March 31, 2019
Operating lease right-of-use assets	$ 2,052
Operating lease liabilities:	
Current operating lease liabilities	1,038
Non-current operating lease liabilities	1,223
Total operating lease liabilities	$ 2,261
Weighted average remaining lease term	2.25 years
Weighted average discount rate	8.0%

The following table presents the maturities of the Company's operating lease liabilities as of March 31, 2019.

(in thousands)	March 31, 2019
2019 (remaining nine months)	$ 811
2020	1,108
2021	562
Total lease payments	2,481
Less: imputed interest	(220)
Total operating lease liabilities	$ 2,261

ASC Topic 840 Disclosures

The Company elected the alternative modified transition method. The following table presents the future minimum lease commitments under the Company’s operating leases as of December 31, 2018, as previously disclosed.

(in thousands)	December 31, 2018
2019	$ 1,076
2020	1,108
2021	562
2022 and thereafter	—
Total future minimum lease payments	$ 2,746

NOTE 5. OTHER BALANCE SHEET COMPONENTS

Property and Equipment, Net

The following table presents the components of property and equipment, net as of March 31, 2019 and December 31, 2018.

(in thousands)	March 31, 2019	December 31, 2018
Furniture and fixtures	$ 193	$ 193
Computer and lab equipment	2,051	1,888
Leasehold improvements	1,058	1,055
	3,302	3,136
Less: accumulated depreciation and amortization	(2,093)	(1,921)
Total property and equipment, net	$ 1,209	$ 1,215

Depreciation and amortization expense was approximately $0.2 million and $0.1 million for the three months ended March 31, 2019 and 2018, respectively.

Accrued Expenses and Other Current Liabilities

The following table presents the components of accrued expenses and other current liabilities as of March 31, 2019 and December 31, 2018.

(in thousands)	March 31, 2019	December 31, 2018
Accrued clinical and nonclinical study costs	$ 6,112	$ 2,168
Accrued contract manufacturing	10,694	1,676
Accrued compensation	2,077	1,565
Accrued professional fees and other	1,780	935
Total accrued expenses and other current liabilities	$ 20,663	$ 6,344

NOTE 6. BORROWINGS

Term Loan

On February 28, 2018, the Company entered into the Term Loan with Hercules. The Term Loan provided 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.

On October 15, 2018, the Company entered into the second amendment to the Term Loan with Hercules, which amended certain terms of the Term Loan. After giving effect to the second amendment, the Term Loan continued to provide 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 second tranche was reduced from $25.0 million to $15.0 million and was funded on December 28, 2018. The Company accounted for the second amendment as a modification to the existing Term Loan.

On March 27, 2019, the Company modified the Term Loan with Hercules by entering into the third amendment to the Term Loan. After giving effect to the third amendment, the amount available under the Term Loan is increased from up to $100.0 million to up to $200.0 million to be funded in tranches, subject to certain performance-based milestones, and the maturity of the Term Loan is extended. Under the terms of the Term Loan, as amended by the third amendment, the $40.0 million principal outstanding remains outstanding, and additional tranches of $20.0 million and $15.0 million will be available for draw down prior to December 15, 2019 and December 15, 2020, respectively. An additional tranche of $75.0 million will be available for draw down between January 1, 2020 and December 15, 2020, on the condition that the Company obtains final approval from the FDA for the NDA for veverimer. A final tranche of $50.0 million will be available for draw down on or prior to December 15, 2021, upon request by the Company and the approval of Hercules' investment committee. The Company accounted for the third amendment as a modification to the existing Term Loan.

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 6.00% and (y) 9.85%. The maturity date is extended to April 1, 2023 and may be extended to April 1, 2024 if the tranche of $75.0 million described above is drawn. The Company will initially be making interest-only payments until April 1, 2021. If the Company achieves certain performance milestones and financial covenants, the interest-only period could be extended for up to an additional 24 months. Upon expiration of the interest-only period, the Company will repay the Term Loan in equal monthly installments comprised of principal and interest, based on a 30-month amortization schedule, through maturity. The Company will pay an additional amount of (a) $2.6 million due on March 1, 2022 and (b) the product of 7.55% and the aggregate loans funded under the Term Loan due at maturity or on any earlier date on which the loans become due. If the Company prepays the Term Loan, the Company will be required to pay a prepayment charge equal to (i) 2.00% of the amount being prepaid at any time during the first 12 months following the effective date of the third amendment (ii) 1.50% of the amount being prepaid after 12 months but prior to 24 months following the effective date of the third amendment (iii) 1.00% of the amount being prepaid after 24 months but prior to 36 months following the effective date of the third amendment and (iv) zero if prepaid any time after 36 months following the effective date of the third amendment but prior to the maturity.

The Term Loan is secured by substantially all of the Company's assets, except its 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, its intellectual property. Under the Term Loan, the Company is subject to certain covenants, including but not limited to requirements to deliver financial reports at designated times of the year and maintain a minimum level of cash. These covenants also limit or restrict the Company's 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.

Warrants

In conjunction with the Term Loan entered into on February 28, 2018, the Company issued warrants to Hercules to purchase 53,458 shares of its 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 $0.2 million. 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 statements 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' equity (deficit) as the amended terms of the warrants qualified for them to be accounted for as equity instruments and, as such, were no longer subject to remeasurement. The fair value of the common stock warrants of approximately $0.2 million was reclassified to stockholders' equity upon execution of the amendment.

In connection with the funding of the second tranche on December 28, 2018, the Company issued to Hercules a warrant to purchase 53,458 shares of its common stock with an exercise price of $9.35 per share. The common stock warrant was recorded in stockholders' equity (deficit) at its fair value of approximately $0.9 million on December 28, 2018.

In conjunction with the third amendment, the Company issued warrants to Hercules to purchase 16,721 shares of its common stock with an exercise price of $23.92 per share. The common stock warrants were recorded in stockholders' equity (deficit) at its fair value of approximately $0.3 million on March 27, 2019. The fair value of the

common stock warrants were determined using an option-pricing model with the following assumptions: time to liquidity of 7.0 years, volatility of 75.0%, risk-free rate of 2.3% and stock price based on the March 27, 2019 closing price of the Company's common stock reported by The Nasdaq Global Select Market.

In connection with each subsequent draw down under the tranches described above, the Company is obligated to issue additional warrants to purchase a number of shares of the Company's common stock determined by dividing (x) an amount equal to 1.0% of the principal amount of the applicable tranche by (y) a volume weighted average price.

Embedded Derivatives and Other Debt Issuance Costs

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 $0.7 million, which is required to be marked to market in future periods.

As of March 31, 2019, 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 of 11.2% and the probability of the occurrence of certain events of 10.0%. 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. The fair value of the compound derivative liability was approximately $0.3 million as of March 31, 2019 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 sheets 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 March 31, 2019 and December 31, 2018 there were unamortized issuance costs and debt discounts of $4.1 million and $2.7 million, respectively, which were recorded as a direct deduction from the Term Loan on the condensed balance sheets.

The following table presents future payments of principal and interest on the Term Loan as of March 31, 2019.

(in thousands)	March 31, 2019
2019 (remaining nine months)	$ 2,566
2020	3,396
2021	14,173
2022	20,403
2023	16,282
	56,820
Less: amount representing interest	(16,820)
Present value of Term Loan	40,000
Less: current portion	—
Long-term portion of Term Loan	$ 40,000

Convertible 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 convertible preferred stock in the same year. In accordance with the agreement a warrant to purchase 95,936 shares of Series A convertible preferred stock was established in conjunction with the Series A financing round. The warrant had a contractual life of 7 years and an exercise price of $0.886. The fair value of the warrant liability was determined using a Black-Scholes option pricing model 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 and purchased 95,936 shares of Series A convertible preferred stock. The fair value adjustment recognized upon exercise was determined using the intrinsic value which was calculated as the initial public offering, or 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), net in the condensed statements of operations and comprehensive loss. The resultant fair value was reclassified to Series A convertible preferred stock on June 16, 2018.

NOTE 7. COMMITMENTS AND CONTINGENCIES

Facilities

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 26,987 square feet being leased in the aggregate under the amended lease. See Note 4 "Leases" for details of related commitments. In addition, associated with the operating lease, the Company has a tenant improvement loan with remaining payments totaling approximately $0.2 million as of March 31, 2019.

Other Commitments

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 $54.3 million, of which $12.6 million was paid through March 31, 2019 and $41.7 million will be paid over the next 36 months, with the majority of this amount occurring in the first successive 12-month period. The Company expects to incur additional purchase obligations relating to future statements of work under such MDS.

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.

Contingencies

While there are no legal proceedings the Company is aware of, the Company may become party to various claims and complaints arising in the ordinary course of business. The Company does not believe that any ultimate liability resulting from any of these claims will have a material adverse effect on its results of operations, financial position, or liquidity. However, the Company cannot give any assurance regarding the ultimate outcome of these claims, and their resolution could be material to operating results for any particular period, depending upon the level of income for the period.

Guarantees and Indemnifications

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director is or was serving at the Company’s request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director liability insurance. This insurance allows the transfer of risk associated with the Company’s exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, it has not recognized any liabilities relating to these obligations for any period presented.

NOTE 8. STOCKHOLDERS' EQUITY

On July 2, 2018, the Company's amended and restated certificate of incorporation became effective, authorizing the Company to issue a total of 440,000,000 shares of all classes of capital stock, consisting of 400,000,000 shares of common stock, par value $0.001 per share, and 40,000,000 shares of preferred stock, par value $0.001 per share. As of March 31, 2019 and December 31, 2018, the Company had 42,676,106 and 42,148,247 shares of common stock outstanding, respectively. As of March 31, 2019 and December 31, 2018, the Company had no shares of preferred stock outstanding.

Common Stock

On July 2, 2018, the Company completed its IPO and issued 13,455,000 shares of common stock at an offering price of $19.00 per share for net proceeds of approximately $237.7 million, after deducting underwriting discounts and commissions of $17.9 million. Upon the closing of the IPO, all of the 104,225,638 shares of convertible preferred stock outstanding were automatically converted on a 1:3.98 basis into 26,187,321 shares of common stock.

On April 8, 2019, the Company consummated an underwritten public offering and issued 6,440,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 840,000 additional shares of common stock at an offering price of $36.00 per share for net proceeds of approximately $217.9 million, after deducting underwriting discounts and commissions of $13.9 million. See Note 10 "Subsequent Events" for additional information about the underwritten public offering.

Common stock reserved for future issuance as of March 31, 2019 and December 31, 2018, consisted of the following.

	March 31, 2019	December 31, 2018
Stock options and RSUs issued and outstanding	5,798,844	4,599,307
Stock options, RSUs and ESPP shares authorized for future issuance	4,914,799	4,534,784
Total	10,713,643	9,134,091

NOTE 9. NET LOSS PER SHARE

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders for the three months ended March 31, 2019 and 2018.

	Three Months Ended March 31,	
(In thousands, except share and per share amounts)	2019	2018
Numerator:		
Net loss	$ (37,897)	$ (20,504)
Denominator:		
Weighted average common shares outstanding	42,283,526	2,290,598
Less: weighted average shares subject to repurchase	(15,464)	(12,332)
Weighted average number of shares used in basic and diluted net loss per share	42,268,062	2,278,266
Net loss per share, basic and diluted	$ (0.90)	$ (9.00)

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.

The following weighted-average outstanding common stock equivalents were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive.

	March 31,	
	2019	2018
Series A convertible preferred stock	—	2,839,886
Series B convertible preferred stock	—	8,172,579
Series C convertible preferred stock	—	8,996,586
Series D convertible preferred stock	—	6,154,166
Warrants to purchase preferred or common stock	123,637	77,562
Common stock subject to repurchase	12,621	16,959
Options and RSUs issued and outstanding	5,798,844	4,383,674
Total potential common shares excluded from the computation of diluted net loss per share	5,935,102	30,641,412

NOTE 10. SUBSEQUENT EVENTS

On April 8, 2019, the Company consummated an underwritten public offering and issued 6,440,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 840,000 additional shares of common stock at an offering price of $36.00 per share for net proceeds of approximately $217.9 million, after deducting underwriting discounts and commissions of $13.9 million.

The table below shows, on a pro forma basis, the impact of the Company's underwritten public offering on certain condensed balance sheet items as if all of the transactions occurred on March 31, 2019.

		Pro Forma (unaudited)
(in thousands)	March 31, 2019	March 31, 2019
Cash, cash equivalents and investments	$ 218,968	$ 436,898
Deferred offering costs	717	—
Common stock	43	49
Additional paid-in capital	390,508	607,715
Total stockholders' equity	160,609	377,822

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. Investors in our securities should review Item 1A. "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

We are a pharmaceutical company focused on the development and commercialization of our drug candidate, veverimer (TRC101), a non-absorbed, orally administered polymer designed to treat metabolic acidosis by binding and removing acid from the gastrointestinal tract. Our goal is to slow the progression of chronic kidney disease, or CKD, through the treatment of metabolic acidosis. In May 2018, we completed our randomized, double-blind, placebo controlled, pivotal Phase 3 clinical trial, TRCA-301, in 217 CKD patients with metabolic acidosis. The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner ($p < 0.0001$ for both the primary and secondary endpoints). One hundred ninety-six of the 208 subjects who completed the 12-week treatment period in our pivotal Phase 3 trial, TRCA-301, agreed and were eligible to continue in our extension trial, TRCA-301E, which we completed in March 2019. Based on the initial topline data analyses, the TRCA-301E trial met its primary and all secondary endpoints. We plan to submit a New Drug Application, or NDA, in the second half of 2019, seeking approval of veverimer through the U.S. Food and Drug Administration's, or FDA's, Accelerated Approval Program. As part of the Accelerated Approval Program, we have committed to conduct a confirmatory postmarketing trial, VALOR-CKD (also known as TRCA-303), to evaluate the efficacy and safety of veverimer in delaying CKD progression in subjects with metabolic acidosis. The VALOR-CKD trial has been initiated, and we have committed to completely enrolling, or nearly completely enrolling, subjects in the trial prior to our NDA submission.

Metabolic acidosis is a chronic condition commonly caused by CKD and is believed to accelerate the progression of kidney deterioration. Today, there are no FDA-approved chronic therapies for treating metabolic acidosis. Veverimer is an in-house discovered, new chemical entity, that we believe may effectively treat metabolic acidosis and slow the progression of kidney disease in CKD patients with metabolic acidosis.

We estimate that metabolic acidosis affects approximately 3 million CKD patients in the United States, and we believe that slowing the progression of CKD in patients with metabolic acidosis represents a significant medical need and market opportunity. If approved, we plan to commercialize veverimer in the United States initially using a nephrologist-focused sales force. To address markets outside of the United States, we plan to seek one or more partners with international sales expertise who can sell veverimer in target markets. We have an intellectual property estate that we believe will provide patent protection for veverimer until at least 2034 in the United States, the European Union, Japan, China, India and certain other markets. Tricida is led by a seasoned management team that includes a founder of Ilypsa, Inc. and Relypsa, Inc. Our management team has extensive experience in the development and commercialization of therapeutics, with deep expertise in developing polymers for the treatment of kidney-related diseases.

We have no products approved for marketing, and we have not generated any revenue from product sales or other arrangements. Through March 31, 2019, we have primarily funded our operations through the net proceeds from our initial public offering, or IPO, of $237.7 million, the sale of $152.4 million of convertible preferred stock and net borrowing of $37.3 million after fees of $2.7 million under the Loan and Security Agreement, or Term Loan, entered into with Hercules Capital Inc., or Hercules, on February 28, 2018. On April 8, 2019, we consummated an underwritten public offering, raising net proceeds of approximately $217.9 million. We have incurred losses in each year since our inception in 2013. Our net losses were $37.9 million and $20.5 million for the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019, we had an accumulated deficit of $230.1 million. Substantially all of our operating losses resulted from expenses incurred in connection with advancing veverimer 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 veverimer;
- optimize the scale-up of the manufacturing process and increase drug substance manufacturing for veverimer for planned 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 veverimer;
- engage in commercial launch activities;
- conduct confirmatory postmarketing trial, VALOR-CKD
- 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 revenue from product sales until we successfully complete development and obtain regulatory approval for veverimer, which we expect will take a number of years. If we obtain regulatory approval for veverimer, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will seek to fund our operations through available cash from our prior offerings and financing under the Hercules facility, and, as necessary, through additional 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 veverimer.

Components of Our Results of Operations

Research and Development Expense

Research and development expense consists primarily of costs associated with the development of veverimer and include salaries, benefits, travel and other related costs, including stock-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, optimization and scale-up expenses and the cost of acquiring and manufacturing clinical study materials and commercial materials; payments to consultants engaged in the development of veverimer, including stock-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 expense is 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 expense to date has been incurred in connection with veverimer. We expect our research and development expense to increase for the foreseeable future as we optimize our manufacturing processes and advance veverimer through clinical development, including our confirmatory post marketing trial, known as VALOR-CKD. The process of conducting clinical studies necessary to obtain regulatory approval is costly and time consuming and the successful development of veverimer 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 veverimer, if approved. Therefore, we are unable to estimate with any certainty the costs we will incur in the continued development of veverimer. The degree of success, timelines and cost of development can differ materially from expectations. We may never succeed in achieving regulatory approval for veverimer.

General and Administrative Expense

General and administrative expense consists primarily of salaries, related benefits, travel, stock-based compensation expense and facility-related expenses for personnel in finance and administrative functions. General and administrative expense also includes professional fees for legal, patent, consulting, accounting and audit services, pre-commercial preparation for the potential launch of veverimer and other related costs.

We anticipate that our general and administrative expense will increase in the future as we continue to build our infrastructure to support our continued research and development of veverimer. 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 SEC, requirements, director and officer insurance premiums and other costs associated with being a public company.

Results of Operations

The following table presents our results of operations for the three months ended March 31, 2019 and 2018.

	Three Months Ended March 31,		Change	
(in thousands)	2019	2018	$	%
Operating expenses:				
Research and development	$ 31,423	$ 16,633	$ 14,790	89%
General and administrative	6,352	3,465	2,887	83%
Total operating expenses	37,775	20,098	17,677	88%
Loss from operations	(37,775)	(20,098)	(17,677)	88%
Other income (expense), net	1,267	(87)	1,354	*N/M*
Interest expense	(1,389)	(319)	(1,070)	335%
Net loss	$ (37,897)	$ (20,504)	$ (17,393)	85%

N/M = Not meaningful

Research and Development Expense

The following table presents our research and development expense for the three months ended March 31, 2019 and 2018.

	Three months ended March 31,		Change	
(in thousands)	2019	2018	$	%
Clinical development costs	$ 25,617	$ 13,668	$ 11,949	87%
Personnel and related costs	3,529	1,949	1,580	81%
Stock-based compensation expense	1,380	172	1,208	*N/M*
Other research and development costs	897	844	53	6%
Total research and development expense	$ 31,423	$ 16,633	$ 14,790	89%

N/M = Not meaningful

Comparison of the three months ended March 31, 2019 and 2018

Research and development expense was $31.4 million and $16.6 million for the three months ended March 31, 2019 and 2018, respectively. The increase of $14.8 million was due to increased activities in connection with our veverimer clinical development program, resulting in increased clinical development costs of $11.9 million related to our confirmatory postmarketing trial, VALOR-CKD, and scale-up costs related to the optimization of our manufacturing process and drug substance manufacturing; increased personnel and related costs of $1.6 million related to headcount growth; and increased stock-based compensation expense of $1.2 million related to headcount growth and higher fair value of award grants.

General and Administrative Expense

The following table presents our general and administrative expense for the three months ended March 31, 2019 and 2018.

	Three Months Ended March 31,		Change	
(in thousands)	2019	2018	$	%
Personnel and related costs	$ 2,078	$ 1,836	$ 242	13%
Stock-based compensation expense	1,278	181	1,097	*N/M*
Other general and administrative costs	2,996	1,448	1,548	107%
Total general and administration expense	$ 6,352	$ 3,465	$ 2,887	83%

Comparison of the three months ended March 31, 2019 and 2018

General and administrative expense was $6.4 million and $3.5 million for the three months ended March 31, 2019 and 2018, respectively. The increase of $2.9 million was due to activities in connection with our veverimer clinical development program, resulting in increased stock-based compensation expense of $1.1 million due to headcount growth and higher fair value of award grants and additional other general and administrative costs of $1.5 million, which primarily related to legal services, facilities and office expenses.

Liquidity and Capital Resources

Sources of Liquidity

From our inception in 2013 through March 31, 2019, we have funded our operations primarily through the net proceeds from our IPO, the sale and issuance of our convertible preferred stock and the Term Loan. From our inception in 2013 through March 31, 2019, we raised aggregate cash proceeds of $237.7 million from our IPO, $152.4 million from the issuance of our convertible preferred stock and net borrowings of $37.3 million under the Term Loan. As of March 31, 2019, we had cash, cash equivalents and investments of $219.0 million. On April 8, 2019, we consummated an underwritten public offering, raising net proceeds of approximately $217.9 million.

Hercules Loan and Security Agreement

On February 28, 2018, we entered into the Term Loan with Hercules. The Term Loan provided 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.

On October 15, 2018, we entered into the second amendment to the Term Loan with Hercules, which amended certain terms of the Term Loan. After giving effect to the second amendment, the Term Loan continued to provide 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 second tranche was reduced from $25.0 million to $15.0 million and was funded on December 31, 2018.

On March 27, 2019, we modified the Term Loan with Hercules by entering into the third amendment to the Term Loan. After giving effect to the third amendment, the amount available under the Term Loan was increased from up to $100.0 million to up to $200.0 million to be funded in tranches, subject to certain performance-based milestones, and the maturity of the Term Loan was extended. Under the terms of the Term Loan, as amended by the third amendment, the $40.0 million of principal outstanding remains outstanding, and additional tranches of $20.0 million and $15.0 million will be available for draw down prior to December 15, 2019 and December 15, 2020, respectively. An additional tranche of $75.0 million will be available for draw down between January 1, 2020 and December 15, 2020, on the condition that we obtain final approval from the FDA for the NDA for veverimer. A final tranche of $50.0 million will be available for draw down on or prior to December 15, 2021, upon our request 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 6.00% and (y) 9.85%. The maturity date is extended to April 1, 2023 and may be extended to April 1, 2024 if the tranche of $75.0 million

described above is drawn. We will initially be making interest-only payments until April 1, 2021. If we achieve certain performance milestones and financial covenants, the interest-only period could be extended for up to an additional 24 months. Upon expiration of the interest-only period, we will repay the Term Loan in equal monthly installments comprised of principal and interest, based on a 30-month amortization schedule, through maturity. We will pay an additional amount of (a) $2.6 million due on March 1, 2022 and (b) the product of 7.55% and the aggregate loans funded under the Term Loan due at maturity or on any earlier date on which the loans become due. If we prepay the Term Loan, we will be required to pay a prepayment charge equal to (i) 2.00% of the amount being prepaid at any time during the first 12 months following the effective date of the third amendment (ii) 1.50% of the amount being prepaid after 12 months but prior to 24 months following the effective date of the third amendment (iii) 1.00% of the amount being prepaid after 24 months but prior to 36 months following the effective date of the third amendment and (iv) zero if prepaid any time after 36 months following the effective date of the third amendment but prior to the maturity.

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 covenants, including but not limited to requirements 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.

Funding Requirements

We have incurred losses and negative cash flows from operations since our inception and anticipate that we will continue to incur net losses for the foreseeable future. As of March 31, 2019, we had an accumulated deficit of $230.1 million. We expect to incur additional losses in the future to conduct research and development and to conduct pre-commercialization activities and recognizes the need to raise additional capital to fully implement our 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 veverimer;
- the timing and outcome of regulatory reviews of veverimer;
- the costs, timing and success of the scale-up and optimization of the process for manufacturing veverimer;
- the revenue, if any, received from commercial sales of veverimer 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 veverimer 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 veverimer, 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 our operations or on terms acceptable to us. If we are unsuccessful in our efforts to raise additional financing, we could be required to significantly reduce operating expenses and delay, reduce the scope of or

eliminate some of our development programs or our future commercialization efforts, out-license intellectual property rights to our 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 our ability to fund our scheduled obligations on a timely basis or at all.

On July 2, 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.

On April 8, 2019, we consummated an underwritten public offering and issued 6,440,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 840,000 additional shares of common stock at an offering price of $36.00 per share for net proceeds of approximately $217.9 million, after deducting underwriting discounts and commissions of $13.9 million.

Cash Flows

The following table summarizes a summary of the net cash flow activity for three months ended March 31, 2019 and 2018.

	Three Months Ended March 31,	
(in thousands)	**2019**	**2018**
Net cash provided by (used in)		
Operating activities	$ (23,842)	$ (15,096)
Investing activities	10,019	(5,431)
Financing activities	(1,421)	23,235
Net increase (decrease) in cash and cash equivalents	$ (15,244)	$ 2,708

Cash Used in Operating Activities

During the three months ended March 31, 2019, cash used in operating activities was $23.8 million, which consisted of a net loss of $37.9 million, adjusted by cash provided by changes in our operating assets and liabilities of $11.1 million and non-cash charges of $2.9 million. The changes in our operating assets and liabilities were primarily due to an increase in accrued expenses and other current liabilities of $14.5 million and decrease in prepaid and other assets of $0.2 million, partially offset by a decrease in accounts payable of $3.4 million and operating lease liabilities of $0.2 million. The non-cash charges consisted primarily of stock-based compensation of $2.7 million, amortization of term loan discounts and issuance costs of $0.5 million, net changes in the fair value of the warrants and compound derivative liabilities of $0.2 million, amortization of operating lease right-of-use assets of $0.2 million and depreciation and amortization of $0.2 million, partially offset by net amortization of premiums and discounts on investments of $0.8 million.

During the three months ended March 31, 2018, cash used in operating activities was $15.1 million, which consisted of a net loss of $20.5 million, adjusted by changes in cash used in our operating assets and liabilities of $4.8 million and non-cash charges of $0.6 million. The changes in our operating assets and liabilities were primarily due to an increase in accounts payable of $4.7 million and a decrease in prepaid and other assets of $1.1 million partially offset by a decrease in accrued expenses and other current liabilities of $1.0 million. The non-cash charges consisted primarily of stock-based compensation of $0.4 million, depreciation and amortization of $0.1 million, net changes in the fair value of the warrants and compound derivative liabilities of $0.1 million and amortization of term loan discounts and issuance costs of $0.1 million, partially offset by net amortization of premiums and discounts on investments of $0.1 million.

Cash Used in Investing Activities

Net cash provided by and used in investing activities was $10.0 million and $5.4 million for the three months ended March 31, 2019 and 2018, respectively. The net cash provided by investing activities during the three months ended March 31, 2019 was due to maturities of investments of $55.0 million, partially offset by purchases of investments of $44.8 million and purchases of property and equipment of $0.2 million. The net cash used in investing activities during the three months ended March 31, 2018 was primarily due to purchases of investments of $16.8 million and purchases of property and equipment of $0.5 million, partially offset by maturities of investments of $11.9 million.

Cash Provided by Financing Activities

Net cash used in and provided by financing activities was $1.4 million and $23.2 million for the three months ended March 31, 2019 and 2018, respectively. The net cash used in financing activities during the three months ended March 31, 2019 was primarily the result of facility and legal fees related to the third amendment to the Term Loan of $1.3 million and payments of equity offering costs of $0.3 million, partially offset by proceeds from the issuance of common stock from stock option exercises of $0.3 million. The net cash provided by financing activities during the three months ended March 31, 2018 was primarily the result of the Hercules Term Loan funding, net of issuance costs, of $23.6 million.

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.

Contractual Obligations and Commitments

For additional details regarding our contractual obligations, see Note 7 “Commitments and Contingencies” to our condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Jumpstart Our Business Startups Act

We are an emerging growth company, as defined in the Jumpstart our Business Startups Act, or 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. However, we do 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. 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 IPO, (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.

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. 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. There have been no new or material changes to the

critical accounting estimates discussed in our Annual Report on Form 10-K for the year ended December 31, 2018, that are of significance, or potential significance to us.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks, including changes in interest rates. There have been no material changes in our market risk during the three months ended March 31, 2019, compared to the year ended December 31, 2018. For quantitative and qualitative disclosures about market risk, refer to Part II, Item 7A. "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2018.

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 Securities and Exchange Commission's rules and forms and (2) accumulated and communicated to our management, including our Chief Executive Officer and President, 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 March 31, 2019, 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 March 31, 2019, 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 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the information contained elsewhere in this Quarterly Report on Form 10-Q, including Part I, Item 1. "Financial Statements" and Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as our other filings with the Securities and Exchange Commission, or SEC, 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, veverimer (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 pharmaceutical company focused on the development and commercialization of our product candidate, veverimer, a non-absorbed, orally-administered polymer designed as a potential treatment for metabolic acidosis in patients with chronic kidney disease, or CKD. 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 2013. Our net losses were $37.9 million and $20.5 million for the three months ended March 31, 2019 and 2018. As of March 31, 2019, we had an accumulated deficit of $230.1 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 veverimer. 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, veverimer, prepare for potential commercialization of veverimer and continue to operate as a public company and comply with legal, accounting and other regulatory requirements.

If veverimer 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.

Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

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 veverimer.

We are currently advancing veverimer through clinical development. As of March 31, 2019, we had working capital of $195.2 million and cash, cash equivalents and investments of $219.0 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 veverimer 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 veverimer.

We believe that our existing cash, cash equivalents and investments of $219.0 million, additional borrowings under our Loan and Security Agreement, or Term Loan, with Hercules Capital, Inc., or Hercules, and net proceeds of $217.9 million from our underwritten public offering consummated on April 8, 2019, 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 veverimer and any future product candidates that we develop, in-license or acquire;
- our ability to obtain approval for veverimer under the Accelerated Approval Program;
- the costs of confirmatory postmarketing studies or trials for veverimer that could be required by regulatory agencies or that we might otherwise choose to conduct;
- the costs of obtaining commercial supplies of veverimer;
- our ability to successfully commercialize veverimer;
- the manufacturing, selling and marketing costs associated with veverimer, including the cost and timing of expanding our sales and marketing capabilities;
- the timing and costs related to the optimization and scale-up of our manufacturing processes for veverimer and commercial supply of veverimer;
- the amount of sales and other revenue from veverimer, including the sales price and the availability of adequate third-party reimbursement;
- the timing, receipt and amount of sales of, or royalties on, veverimer, 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 our confirmatory postmarketing trial, VALOR-CKD (also known as TRCA-303), or 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 and debt financing, 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 veverimer, 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.

Risks Related to Our Business

We are dependent on the success of veverimer, our only product candidate. If we are unable to successfully develop, obtain regulatory approval for and commercialize veverimer, 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 veverimer, 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 veverimer. In May 2018, we completed our multicenter, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial for veverimer, 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 extension trial, TRCA-301E, and we completed the TRCA-301E trial in March 2019. While we believe that these trials successfully met their primary and secondary endpoints, we cannot assure you that the U.S. Food and Drug Administration, or FDA, or any foreign regulatory agency will approve veverimer for marketing. Furthermore, even if we obtain regulatory approval for veverimer, we will still need to develop a commercial organization, or collaborate with a third party for the commercialization of veverimer, establish commercially viable pricing and obtain approval for coverage and adequate reimbursement from third parties, including government payers. If we are unable to successfully commercialize veverimer, we may not be able to generate sufficient revenue 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 veverimer 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 veverimer outside the United States. The clinical and commercial success of veverimer will depend on a number of factors, including the following:

- our ability to demonstrate veverimer's safety and efficacy to the satisfaction of the FDA and/or foreign regulatory agencies;
- the timely reporting of our confirmatory postmarketing trial, known as the VALOR-CKD trial;
- whether we are required by the FDA and/or foreign regulatory agencies to conduct additional clinical trials prior to approval to market veverimer;

- the prevalence and severity of adverse side effects of veverimer 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 veverimer;
- our ability to obtain U.S. marketing approval for veverimer under the Accelerated Approval Program;
- our ability to successfully conduct our confirmatory postmarketing trial, VALOR-CKD, and confirm renal benefit of veverimer, assuming veverimer is initially approved under the FDA's Accelerated Approval Program;
- our ability to successfully commercialize veverimer, if approved for marketing and sale by the FDA and/or foreign regulatory agencies;
- our ability to manufacture clinical trial and commercial quantities of veverimer drug substance and drug product and to develop, validate and maintain commercially viable manufacturing processes that are 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 veverimer;
- our success in educating physicians and patients about the benefits, risks, administration and use of veverimer;
- acceptance of veverimer 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 veverimer by third-party payers;
- 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 veverimer; 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 veverimer. If we are not successful in commercializing veverimer, or are significantly delayed in doing so, our business will be materially harmed.

We will attempt to secure approval of veverimer 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 veverimer 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, veverimer, 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 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 veverimer, 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 veverimer 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 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 veverimer, 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 veverimer 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 veverimer 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 veverimer 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, veverimer. Based on the results of our pivotal Phase 3 clinical trial, TRCA-301, and extension trial, TRCA-301E, we plan to prepare and submit an NDA seeking approval under the FDA's Accelerated Approval Program to market veverimer. Veverimer 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, and our extension trial, TRCA-301E. The FDA and other foreign regulatory agencies have substantial discretion in evaluating the results of our pivotal Phase 3 clinical trial, TRCA-301, our extension trial, TRCA-301E, 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 extension trial, TRCA-301E, do not support approval of an NDA for veverimer. Clinical data often are 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 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 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 veverimer 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 veverimer.

While there are comparable approval pathways outside the United States that are similar to the Accelerated Approval Program, we have not yet explored whether veverimer 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 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 veverimer could mean that we need to cease operations, and a delay in obtaining such approval could delay commercialization of veverimer and adversely impact our ability to generate revenue, our business and our results of operations.

If we are not successful in commercializing veverimer, 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 veverimer, 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 veverimer 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 veverimer for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency that veverimer is safe and effective for the requested indication;
- our inability to gain agreement from the FDA that veverimer is appropriate for approval under FDA's Accelerated Approval Program;
- our inability to gain agreement from applicable foreign regulatory authorities that veverimer 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 veverimer 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 veverimer;
- 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 veverimer, 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 veverimer 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 veverimer. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of veverimer 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 veverimer, 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, our pivotal Phase 3 trial, TRCA-301, and our extension trial, TRCA-301E, for veverimer do not ensure that our postmarketing trial, VALOR-CKD, or other future clinical trials 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 our extension trial, TRCA-301E, and even if 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 veverimer in the time frame we anticipate, or at all. Additional clinical trial results may inform our understanding of the safety and efficacy of veverimer and could impact the design and conduct of ongoing and future clinical trials.

For approval of veverimer 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 enrolling an adequate number of patients in our confirmatory postmarketing trial, VALOR-CKD, which could affect the timing of our NDA submission, which we currently anticipate will be submitted in

the second half of 2019. 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, terminated early 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, veverimer, the commercial prospects of veverimer may be harmed, and our ability to generate product revenue from veverimer will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our veverimer development and approval process and jeopardize our ability to commence product sales and generate revenue. 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 veverimer.

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 veverimer. Any new postmarketing adverse events may significantly impact our ability to market veverimer and may require that we recall and discontinue commercialization of the product. Furthermore, if the confirmatory postmarketing trial, VALOR-CKD, fails to confirm veverimer's clinical profile or clinical benefits, the FDA may withdraw its approval of veverimer. 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 veverimer, 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 veverimer. 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, or ICH, guidelines and GCPs, the informed consent process, protocol-specified requirements, safety reporting requirements, data collection guidelines and all study-specific blinding procedures.

Our extension trial, TRCA-301E, was conducted at 37 sites in the United States and Europe. Our confirmatory postmarketing trial, VALOR-CKD, is being conducted in a significantly greater number of countries and a significantly greater number of sites than TRCA-301E. 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 veverimer, 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 veverimer drug substance and drug product, and we intend to rely on third parties to produce commercial supply of veverimer 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 veverimer on a clinical or commercial scale. As such, we contract with third-party service providers to manufacture veverimer 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 veverimer 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 veverimer 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 veverimer drug substance or drug product, which would negatively impact our ability to develop, obtain regulatory approval for, or market veverimer, if approved, and materially adversely affect our financial condition.

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

We cannot be certain that our drug substance supplier will continue to provide us with sufficient quantities of veverimer 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 veverimer. Our current dependence on a single supplier for our drug substance and the challenges we may face in obtaining adequate supply of veverimer drug substance involves several risks, including limited control over pricing, availability, quality and delivery schedules. Any supply interruption in veverimer 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 veverimer, 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 veverimer 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 veverimer drug substance. We are currently negotiating the terms of a commercial supply agreement with our current drug substance supplier and engaging in discussions with a potential second supplier for commercial drug substance. These negotiations may not lead to a definitive agreement on acceptable terms, or at all, which would have a material adverse effect on our business. 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 veverimer, 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 veverimer 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 veverimer 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 veverimer drug substance, the ability of veverimer to reach its market potential or to be timely launched, would be delayed or suffer from a shortage in supply, which would impair our ability to generate revenue from the sale of veverimer. If there is a disruption to our contract manufacturers' or suppliers' relevant operations, we will have no other means of producing veverimer 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 veverimer 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 interrupt the execution of our confirmatory postmarketing trial, VALOR-CKD, and potentially impact the commercialization of veverimer, if approved.

While we believe we have sufficient drug substance to supply the anticipated demand for at least the first 12 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, is being increased from approximately 340 kg/batch and the scale of the second step in our manufacturing process, step two, is being increased from approximately 65 kg/batch 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 and optimizing the current production methods to meet our anticipated commercial needs without introducing changes to key veverimer 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 or optimization 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 veverimer drug product manufactured to successfully conduct our confirmatory postmarketing trial, VALOR-CKD, or (iii) have sufficient quantities of veverimer drug substance and drug product to supply commercial supply of veverimer, 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 veverimer 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 veverimer 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 veverimer, 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 veverimer, if approved, will be delayed or severely compromised and our results of operations may be harmed.

Even if veverimer 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 payers and the medical community.

Even if we obtain FDA or other regulatory approvals, veverimer may not achieve market acceptance among physicians, patients, patient advocacy groups, health care payers or the medical community, and may not be commercially successful. If approved, market acceptance of veverimer 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 veverimer 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 veverimer;
- the cost of treatment in relation to alternative treatments and willingness to pay for veverimer, if approved, on the part of patients;
- relative convenience and ease of administration of veverimer; 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 veverimer are based on estimates and third-party sources. If the market opportunity for veverimer 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 veverimer will depend on, among other things, acceptance of veverimer 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 veverimer, 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.

Veverimer, 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 veverimer development program may serve as a template for a fast follower to develop a competing product candidate. Furthermore, we expect veverimer to compete against non-approved options for increasing blood bicarbonate levels, including oral alkali supplementation such as sodium bicarbonate, sodium citrate or potassium citrate. Veverimer 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 veverimer 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 veverimer, we may not be able to effectively generate product revenue.

We currently have limited sales or marketing capabilities. In order to commercialize veverimer, 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 veverimer 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 veverimer. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize veverimer 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 revenue, 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 veverimer may experience. The number of subjects exposed to veverimer 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 veverimer 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 veverimer 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 veverimer 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 veverimer may experience adverse reactions. The most commonly reported adverse effect of veverimer 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 veverimer does not interact with medications commonly used by CKD patients, if significant DDIs occur in the future, veverimer may no longer be compatible with some of the medications used to treat CKD patients. If safety problems occur or are identified after veverimer reaches the market, the FDA may require that we amend the labeling of veverimer, recall veverimer, or even withdraw approval for veverimer.

The FDA may not agree that the safety of veverimer 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 1,500 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 veverimer safety database will be significantly smaller than the guidance suggests. Given the toxicology study results and clinical safety profile observed to date for veverimer, as well as the non-absorbed nature of the drug, we believe our proposed safety database will be adequate for the filing of the veverimer 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, veverimer, 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 veverimer 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 $15 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 veverimer and decreased demand for our product, if approved for marketing.

Additionally, if veverimer 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 veverimer 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 March 31, 2019, we had 82 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 veverimer. 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 veverimer 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 veverimer, conduct our clinical trials and commercialize veverimer, 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 veverimer. 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, or IPO, 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 veverimer outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If veverimer is approved for commercialization outside the United States, we may enter into agreements with third parties to market veverimer 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 revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- 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 result in 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 veverimer;
- 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 continue to incur significant costs as a result of operating as a public company, and our management will continue to 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 continue to 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 devote and will need to continue to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations have increased our legal and financial compliance costs and will continue to 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. The ongoing process improvements of our ERP system 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 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 Jumpstart Our Business Startups Act, or 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 IPO, (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.

In the past, 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 affected.

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 of 2002. During our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. In the past, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting, all of which have since been remediated. We did not identify any material weakness for the period ended March 31, 2019.

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 are 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 veverimer.

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 veverimer outside of the United States and we may seek similar arrangements for the development or commercialization of veverimer. 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 veverimer, 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 veverimer 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 as well as unexpected changes in tariffs or trade barriers could also strain our suppliers, possibly resulting in supply disruption or increased prices. 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 veverimer 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 veverimer.

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 veverimer 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 veverimer 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 veverimer 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 veverimer'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 veverimer. If unable to obtain approval under the Accelerated Approval Program, we will have to pursue a conventional approval pathway for veverimer. 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 veverimer 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 veverimer;
- 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 veverimer 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 veverimer in our label, delays approval to market veverimer or limits the use of veverimer, our business and results of operations may be harmed.

We had multiple interactions with the FDA to finalize the protocol for the VALOR-CKD trial and initiated the trial in late 2018. Currently, we believe there are no outstanding questions or topics regarding the VALOR-CKD protocol with the FDA. However, the trial design may be impacted by clinical data generated while the VALOR-CKD trial is ongoing, including data that may affect key assumptions regarding sample size, endpoints, duration or the underlying standard of care, 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 had multiple interactions with the FDA to finalize the protocol for the VALOR-CKD trial and initiated the trial in late 2018 in the United States and other countries with an anticipated sample size of approximately 1,600 subjects. 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 veverimer. Our NDA submission may be delayed if 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. Although we believe there are no outstanding questions or topics regarding the protocol for the VALOR-CKD trial with the FDA, the trial design may be impacted by clinical data generated while the VALOR-CKD trial is ongoing, including data that may affect key assumptions regarding sample size, endpoints, duration or the underlying standard of care. If we are required to modify our planned clinical trials, or conduct additional clinical trials, before we can submit the NDA or comparable foreign applications, any such modification 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 veverimer.

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, and our 40-week extension study, TRCA-301E, will be sufficient for approval of veverimer.

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, veverimer, 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 veverimer, 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, the extension trial, TRCA-301E, and the VALOR-CKD 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 veverimer, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, veverimer, 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 veverimer.

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 veverimer 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 veverimer. 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 veverimer for indications or uses for which it does not have FDA approval.

If veverimer 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 veverimer's clinical profile or risks and benefits, the FDA may withdraw its approval. If a regulatory agency discovers previously unknown problems with veverimer, 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 revenue from veverimer. 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 revenue from the sale of

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

We intend to seek FDA approval to market veverimer for the treatment of metabolic acidosis and slowing of kidney disease progression in CKD patients with metabolic acidosis, but we cannot be certain what indication and what labeling language will be approved for veverimer until the NDA review and potentially as late as approval. If veverimer 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 veverimer 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 veverimer 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 veverimer 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 veverimer, 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 veverimer 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, veverimer 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 veverimer, most commonly mild-to-moderate GI events, such as diarrhea, flatulence, nausea and constipation. If we are successful in commercializing veverimer, 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 veverimer. 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 veverimer, 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, veverimer 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 veverimer in the United States. If we want to expand the geographies in which we may market veverimer, we will need to obtain additional regulatory approvals.

We currently plan to seek regulatory approval for veverimer in the United States. In the future, we may attempt to develop and seek regulatory approval to promote and commercialize veverimer 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 veverimer outside of the United States. If we do not obtain regulatory approvals for veverimer 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 veverimer 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 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 veverimer in any market. If we do not obtain regulatory approvals for veverimer 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, including healthcare statutory and regulatory requirements and enforcement by the U.S. federal and state governments and the foreign governments of the countries in which we conduct our business. Even though we are not in a position to make patient referrals and do not bill Medicare, Medicaid, or other government or commercial third-party payers, the federal and state healthcare fraud and abuse laws and regulations may be applicable to our business. The healthcare regulatory laws that affect our current and future operations include, among others:

- the federal Anti-Kickback Statute, which is a criminal law that prohibits, among other things, any person from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward referrals, purchases, orders, or arranging for or recommending the purchase, order, or referral of any item or service for which payment may be made in whole or in part by a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. The Patient Protection and Affordable Care Act, or PPACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute, so that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and individuals, such as prescribers, patients, purchasers, and formulary managers on the other the other hand. A conviction for violation of the Anti-Kickback Statute results in criminal fines and requires mandatory exclusion from participation in federal health care programs. Although there are a number of statutory exceptions and regulatory safe harbors to the federal Anti-Kickback Statute that protect certain common, industry practices from prosecution, the exceptions and safe harbors are drawn narrowly, and arrangements may be subject to scrutiny or penalty if they do not fully satisfy all elements of an available exception or safe harbor. The Anti-Kickback Statute safe harbors, particularly the discount safe harbor, are the subject of possible reform. Any changes to the safe harbors may impact how we contract with customers in the future and impact our future pricing strategies with payers;

- 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 (or “whistleblower”) actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented claims to the government that are false or fraudulent, or 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. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $11,181 to $22,363 per false claim or statement for penalties assessed after January 29, 2018, with respect to violations occurring after November 2, 2015. For example, among other things, 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 (e.g., under the Medicaid Drug Rebate Program), and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the 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. Manufacturers can be held liable under the FCA even when they do not submit claims directly to

government payers if they are deemed to "cause" the submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false or fraudulent claim to the federal government;

- 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;

- under the HIPAA criminal federal healthcare fraud statute, it is a crime to knowingly and willfully execute, or attempt to execute, a scheme or artifice to defraud any health care benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services;

- U.S. and European reporting requirements detailing interactions with and payments to healthcare providers, such as the U.S. federal Physician Payments Sunshine Act, which requires, among others, "applicable manufacturers" of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to the Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to payments and other transfers of value provided to "covered recipients." The term covered recipients includes U.S.-licensed physicians and teaching hospitals, and, for reports submitted on or after January 1, 2022, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. In addition, several U.S. states and localities have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports, and/or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. 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 several recently passed state laws that require disclosures to state agencies and/or commercial purchasers with respect to certain price increases that exceed a certain level as identified in the relevant statutes; and

- state law equivalents of each of the above federal laws, such as the Anti-Kickback Statute and FCA which may apply to items or services reimbursed by any third-party payer, including commercial insurers (i.e., so-called "all-payor anti-kickback laws"), as well as state 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 veverimer outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. 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, federal and state governments are active in regulating payments made manufacturers to physicians. Some states mandate implementation of compliance programs and/or the tracking and reporting of gifts, compensation, and other remuneration to physicians. The evolving enforcement 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, and fines; the curtailment or restructuring of our operations; contractual damages; disgorgement; reputational harm; additional oversight and reporting obligations pursuant to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws; exclusion from participation in federal and state healthcare programs; and individual imprisonment, any of which could adversely affect our ability to market veverimer, 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 veverimer 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 veverimer. 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 veverimer; 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 payers 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.

On December 14, 2018, a federal district court in Texas ruled the individual mandate was unconstitutional and inseverable from the PPACA. As a result, the court ruled the remaining provisions of the PPACA were also invalid, though the court declined to issue a preliminary injunction with respect to the PPACA. The court subsequently stayed its ruling on December 31, 2018, pending the outcome of appeals. The court's ruling has been appealed to the U.S. Court of Appeals for the Fifth Circuit (the "Fifth Circuit"). On March 25, 2019, the DOJ stated in a legal filing with the Fifth Circuit that the district court's ruling that the PPACA was invalid should be upheld. It remains unclear whether the district court's ruling will be upheld by appellate courts.

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 veverimer 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 veverimer by third-party payers, 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 payer, such as Medicare, Medicaid or a private health insurer, to pay for such treatment. There will be no commercially viable market for veverimer without coverage and reimbursement from third-party payers. Additionally, even if we obtain third-party payer coverage and reimbursement for veverimer, 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 payer 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 payer. We cannot be certain if and when we will obtain formulary approval to allow us to sell veverimer, if approved, into our target markets. Even if we do obtain formulary approval, third-party payers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drugs. Reimbursement rates from third-party payers vary depending on the payer, the insurance plan and other factors. A current trend in the United States health care industry is toward cost containment. Large public and private payers, 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 payers, including Medicare, are questioning the coverage of, and challenging the prices charged for medical products and services, and many third-party payers 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 payers, 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 payer may depend upon a number of factors, including the third-party payer'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 veverimer 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 payers 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, veverimer, if approved. Assuming we obtain coverage for veverimer by a third-party payer, 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 payers to reimburse all or part of the costs associated with those medications. Patients are unlikely to use veverimer unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of veverimer. 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 veverimer, if approved.

These cost-control initiatives could decrease the price we might establish for veverimer, which could result in product revenue being lower than anticipated. The pricing, coverage and reimbursement of veverimer, if approved, must be adequate to support a commercial infrastructure. If the price for veverimer decreases or if governmental and other third-party payers 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 veverimer. 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 veverimer, if approved. Accordingly, in markets outside the United States, the reimbursement for veverimer 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 veverimer 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 veverimer.

Our success depends in part on our ability to develop, manufacture, market and sell veverimer, 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 veverimer 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 veverimer. There may also be issued patents or pending patent applications that we are aware of, but that we think are irrelevant to veverimer, which may ultimately be found to be infringed by the manufacture, sale, or use of veverimer. 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, veverimer 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 veverimer.

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 veverimer 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 veverimer 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 veverimer. 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 veverimer, 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 veverimer 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 veverimer is successfully challenged, then our ability to commercialize veverimer 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 veverimer 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 veverimer, 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 veverimer, we would lose at least part, and perhaps all, of the patent protection on veverimer. 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 veverimer. 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, veverimer.

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 veverimer 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 veverimer 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 veverimer 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 veverimer 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 veverimer. 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, veverimer, 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 veverimer 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, veverimer, patents protecting veverimer might expire before or shortly after veverimer 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 veverimer 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 fluctuate substantially 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 has been and is likely to continue to be highly volatile and is subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- announcements of regulatory approval or a complete response letter to veverimer, 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 veverimer, whether or not related to our product candidate;
- changes or developments in laws or regulations applicable to veverimer;
- 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 scale-up and optimize our manufacturing process;
- 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.

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

The trading market for our common stock is and will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who currently cover us issue, or in the event we obtain additional coverage and any new analyst issues, 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 IPO, (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 IPO sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline.

As of March 31, 2019, we have outstanding a total of 42,676,106 shares. All of our outstanding shares of common stock (other than shares held by an officer or director of the Company and shares held by certain other stockholders, which are subject to a lock-up agreement), are currently freely tradable in the public market. The underwriters may, at their sole discretion, permit our officers, directors and the stockholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

The lock-up agreements pertaining to our follow-on offering, as consummated on April 8, 2019, will expire 90 days from that date, following which approximately 25.6 million shares of common stock will be eligible for sale in the public market.

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 2018 Plan, or our Employee Stock Purchase Plan, or ESPP, 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 the 2018 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 the 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 28.7 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.

As of March 31, 2019, 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, 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.

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 contain provisions that could significantly reduce the value of our shares to a potential acquiror 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 include 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 66 2⁄3% 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, which became effective immediately prior to the completion of our IPO 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 is 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 $5.5 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately $62.0 million (as of March 29, 2019, based on The Nasdaq Global Select Market closing price of $38.62 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.

We have incurred substantial losses during our history. Our ability to utilize 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 IPO or otherwise. 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 Tax Cut and Jobs Act, or 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

None, other than as previously disclosed.

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 initial public offering, or IPO, to the public at an IPO 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 $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.

We invested the funds received in accordance with our investment policy. There has been no material change in the planned use of proceeds from our initial public offering, as described in our final prospectus filed with the SEC on June 29, 2018 pursuant to Rule 424(b) under the Securities Act.

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	Incorporated by Reference from Form	Incorporated by Reference from Exhibit Number	Date Filed
10.1	Third Amendment to Loan and Security Agreement, dated as of March 27, 2019 among Tricida, Inc., Hercules Capital, Inc. and the several banks and other financial institutions or entities from time to time parties thereto.	8-K	10.1	03/28/2019
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.	Filed herewith		
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.	Filed herewith		
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.	Filed herewith		
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			

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: May 10, 2019

TRICIDA, INC.

By: /s/ Gerrit Klaerner, Ph.D.
Gerrit Klaerner, Ph.D.
Chief Executive Officer and President
(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 PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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: May 10, 2019

/s/ Gerrit Klaerner, Ph.D.

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

Exhibit 31.2

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

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: May 10, 2019

/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 March 31, 2019, as filed with the Securities and Exchange Commission (the "Report"), each of Gerrit Klaerner, Ph.D., Chief Executive Officer and President 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: May 10, 2019

/s/ Gerrit Klaerner, Ph.D.

Gerrit Klaerner, Ph.D.

Chief Executive Officer and President

(Principal Executive Officer)

/s/ Geoffrey M. Parker

Geoffrey M. Parker

Chief Financial Officer and Senior Vice President

(Principal Financial Officer)