# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

# FORM 10-Q

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

For the quarterly period ended September 30, 2021
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**<br>(State or other jurisdiction of incorporation or organization) | **46-3372526**<br>(I.R.S. Employer Identification Number) |
|---|---|---|

**7000 Shoreline Court, Suite 201, South San Francisco, CA 94080**
(Address of principal executive offices, including zip code)

**(415) 429-7800**
(Registrant's telephone number, including area code)

**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 |

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 ☒

On October 29, 2021, the registrant had 50,447,578 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 (also known as TRC101), our only investigational drug candidate, which is still in development;
- our ability to obtain approval of our New Drug Application, or NDA, for veverimer from the U.S. Food and Drug Administration, or FDA, under either traditional approval or the Accelerated Approval Program, if at all;
- our ability to resolve the deficiencies identified by the FDA in the Complete Response Letter and issues raised in the Appeal Denied Letter related to our NDA for veverimer;
- our expectations regarding the timing of the completion or early termination of the VALOR-CKD trial and any other nonclinical or clinical study or trial;
- the design of our renal outcomes trial, VALOR-CKD (also known as TRCA-303), including the sample size, trial duration, endpoint definition, event rate assumptions and eligibility criteria;
- our expectations regarding the timing and location of the enrollment, distribution of enrollment across geographic regions, endpoint accrual, continuation, completion, outcome and reporting of results of our ongoing VALOR-CKD trial;
- the outcome and results of our ongoing VALOR-CKD trial;
- the 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 the safety, efficacy and clinical benefit of veverimer;
- our ability to achieve and maintain regulatory approval of veverimer, and any related requirements, 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;
- our 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;
- 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;
- the potential impact of pandemics, including COVID-19, on the health care system, financial markets and economy generally and on our business in particular; 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 under Part II, 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)**

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 16,988 | $ 137,857 |
| Short-term investments | 129,782 | 171,670 |
| Prepaid expenses and other current assets | 4,404 | 4,488 |
| Total current assets | 151,174 | 314,015 |
| Long-term investments | — | 22,757 |
| Property and equipment, net | 836 | 1,112 |
| Operating lease right-of-use assets | 12,576 | 13,801 |
| Total assets | $ 164,586 | $ 351,685 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,261 | $ 3,508 |
| Current operating lease liabilities | 2,716 | 2,079 |
| Accrued expenses and other current liabilities | 19,754 | 28,671 |
| Total current liabilities | 25,731 | 34,258 |
| | | |
| Term Loan, net | — | 76,638 |
| Convertible Senior Notes, net | 125,194 | 118,670 |
| Non-current operating lease liabilities | 11,759 | 13,046 |
| Other long-term liabilities | — | 202 |
| Total liabilities | 162,684 | 242,814 |
| Commitments and contingencies (Note 5) | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value; 40,000,000 shares authorized, no shares issued or outstanding as of September 30, 2021 and December 31, 2020 | — | — |
| Common stock, $0.001 par value; 400,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 50,447,578 and 50,210,779 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively | 50 | 50 |
| Additional paid-in capital | 762,317 | 742,555 |
| Accumulated other comprehensive income (loss) | (77) | 64 |
| Accumulated deficit | (760,388) | (633,798) |
| Total stockholders' equity | 1,902 | 108,871 |
| Total liabilities and stockholders' equity | $ 164,586 | $ 351,685 |

*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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Operating expenses: | | | | |
| Research and development | $ 26,635 | $ 42,996 | $ 78,591 | $ 121,134 |
| General and administrative | 9,052 | 29,273 | 28,497 | 81,217 |
| Total operating expenses | 35,687 | 72,269 | 107,088 | 202,351 |
| Loss from operations | (35,687) | (72,269) | (107,088) | (202,351) |
| Other income (expense), net | 6 | 907 | 155 | 4,395 |
| Interest expense | (3,994) | (6,267) | (13,533) | (12,043) |
| Loss on early extinguishment of Term Loan | — | — | (6,124) | — |
| Loss before income taxes | (39,675) | (77,629) | (126,590) | (209,999) |
| Income tax benefit (expense) | — | (36) | — | 50 |
| Net loss | (39,675) | (77,665) | (126,590) | (209,949) |
| Other comprehensive income (loss): | | | | |
| Net unrealized gain (loss) on available-for-sale investments, net of tax | (15) | (431) | (141) | 239 |
| Total comprehensive loss | $ (39,690) | $ (78,096) | $ (126,731) | $ (209,710) |
| Net loss per share, basic and diluted | $ (0.79) | $ (1.55) | $ (2.52) | $ (4.20) |
| Weighted-average number of shares outstanding, basic and diluted | 50,434,879 | 50,120,086 | 50,326,474 | 49,974,388 |

*See accompanying notes to condensed financial statements (unaudited).*

**TRICIDA, INC.**

**CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY**
**(in thousands, except share amounts)**

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance at December 31, 2020** | 50,210,779 | $ 50 | $ 742,555 | $ 64 | $ (633,798) | $ 108,871 |
| Issuance of common stock under equity incentive plans | 61,946 | — | 115 | — | — | 115 |
| Stock-based compensation | — | — | 6,042 | — | — | 6,042 |
| Net unrealized gain (loss) on available-for-sale investments, net of tax | — | — | — | (105) | — | (105) |
| Net loss | — | — | — | — | (53,362) | (53,362) |
| **Balance at March 31, 2021** | 50,272,725 | 50 | 748,712 | (41) | (687,160) | 61,561 |
| Issuance of common stock under equity incentive plans | 156,009 | — | 333 | — | — | 333 |
| Stock-based compensation | — | — | 6,609 | — | — | 6,609 |
| Net unrealized gain (loss) on available-for-sale investments, net of tax | — | — | — | (21) | — | (21) |
| Net loss | — | — | — | — | (33,553) | (33,553) |
| **Balance at June 30, 2021** | 50,428,734 | 50 | 755,654 | (62) | (720,713) | 34,929 |
| Issuance of common stock under equity incentive plans | 18,844 | — | 14 | — | — | 14 |
| Stock-based compensation | — | — | 6,649 | — | — | 6,649 |
| Net unrealized gain (loss) on available-for-sale investments, net of tax | — | — | — | (15) | — | (15) |
| Net loss | — | — | — | — | (39,675) | (39,675) |
| **Balance at September 30, 2021** | 50,447,578 | $ 50 | $ 762,317 | $ (77) | $ (760,388) | $ 1,902 |

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance at December 31, 2019** | 49,763,176 | $ 50 | $ 632,647 | $ 193 | $ (369,007) | $ 263,883 |
| Issuance of common stock under equity incentive plans | 150,056 | — | 550 | — | — | 550 |
| Stock-based compensation | — | — | 8,374 | — | — | 8,374 |
| Net unrealized gain (loss) on available-for-sale investments, net of tax | — | — | — | (232) | — | (232) |
| Net loss | — | — | — | — | (74,114) | (74,114) |
| **Balance at March 31, 2020** | 49,913,232 | 50 | 641,571 | (39) | (443,121) | 198,461 |
| Equity component of Convertible Senior Notes, net of underwriter discounts and issuance costs | — | — | 79,498 | — | — | 79,498 |
| Issuance of warrants in connection with Term Loan | — | — | 112 | — | — | 112 |
| Issuance of common stock under equity incentive plans | 126,355 | — | 1,098 | — | — | 1,098 |
| Stock-based compensation | — | — | 9,079 | — | — | 9,079 |
| Net unrealized gain (loss) on available-for-sale investments, net of tax | — | — | — | 902 | — | 902 |
| Net loss | — | — | — | — | (58,170) | (58,170) |
| **Balance at June 30, 2020** | 50,039,587 | 50 | 731,358 | 863 | (501,291) | 230,980 |
| Issuance of common stock upon exercises of warrants in connection with Term Loan | 68,816 | — | — | — | — | — |
| Issuance of common stock under equity incentive plans | 75,837 | — | 234 | — | — | 234 |
| Stock-based compensation | — | — | 7,655 | — | — | 7,655 |
| Net unrealized gain (loss) on available-for-sale investments, net of tax | — | — | — | (431) | — | (431) |
| Net loss | — | — | — | — | (77,665) | (77,665) |
| **Balance at September 30, 2020** | 50,184,240 | $ 50 | $ 739,247 | $ 432 | $ (578,956) | $ 160,773 |

*See accompanying notes to condensed financial statements (unaudited).*

**TRICIDA, INC.**

**CONDENSED STATEMENTS OF CASH FLOWS**
**(Unaudited)**
**(In thousands)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2021** | **2020** |
| **Operating activities:** | | |
| Net loss | $ (126,590) | $ (209,949) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 351 | 716 |
| Non-cash operating lease costs | 574 | 597 |
| Amortization of premiums and accretion of discounts on investments, net | 440 | (264) |
| Accretion of Term Loan and Convertible Senior Notes | 7,047 | 5,246 |
| Loss on early extinguishment of Term Loan | 6,124 | — |
| Stock-based compensation | 19,300 | 25,108 |
| Changes in compound derivative liability | (202) | (699) |
| Other non-cash items | (29) | (50) |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | 105 | (3,341) |
| Accounts payable | (245) | (4,113) |
| Accrued expenses and other liabilities | (8,871) | (2,069) |
| Net cash used in operating activities | (101,996) | (188,818) |
| **Investing activities:** | | |
| Purchases of investments | (136,345) | (276,958) |
| Proceeds from maturities of investments | 200,409 | 268,015 |
| Purchases of property and equipment | (76) | (1,197) |
| Net cash provided by (used in) investing activities | 63,988 | (10,140) |
| **Financing activities:** | | |
| Proceeds from issuance of common stock under equity incentive plans | 462 | 1,897 |
| Proceeds from Convertible Senior Notes, net | — | 193,285 |
| Repayment of leasehold improvement loan | (38) | (57) |
| Cash paid for early extinguishment of Term Loan | (83,285) | — |
| Proceeds from Term Loan, net | — | 14,971 |
| Net cash provided by (used in) financing activities | (82,861) | 210,096 |
| Net increase (decrease) in cash and cash equivalents | (120,869) | 11,138 |
| Cash and cash equivalents at beginning of period | 137,857 | 18,574 |
| Cash and cash equivalents at end of period | $ 16,988 | $ 29,712 |
| **Supplemental disclosures** | | |
| Cash paid for interest | $ 5,274 | $ 4,137 |
| **Supplemental disclosures of non-cash investing and financing activities** | | |
| Right-of-use assets obtained in exchange for lease obligations | $ — | $ 5,820 |
| Issuance of warrants related to Term Loan | $ — | $ 112 |
| Purchases of property and equipment included in accounts payable and accrued expenses | $ — | $ 644 |

*See accompanying notes to condensed financial statements (unaudited).*

***NOTE 1. ORGANIZATION AND BASIS OF PRESENTATION***

**Organization**—Tricida, Inc., or the Company, was incorporated in the state of Delaware on May 22, 2013. The Company is focused on the development and commercialization of its investigational drug candidate, veverimer (also known as TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis and slow chronic kidney disease, or CKD, progression in patients with CKD.

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. Through September 30, 2021, the Company has relied primarily on the proceeds from equity offerings and debt financing to finance its operations.

The Company believes that its existing cash, cash equivalents and investments are sufficient to fund its operations for the twelve-month period following the filing of this Quarterly Report on Form 10-Q. However, its existing cash, cash equivalents and investments are not likely to be sufficient to fund the operations of the Company following the end of 2022. The Company recognizes that it will need to raise additional capital to fully implement its business plan, and if market conditions are favorable or if the Company identifies specific strategic opportunities or needs, intends to do so through the issuance of equity, borrowings, or strategic alliances with partner companies. However, if such financing is not available at adequate levels, on reasonable terms or within a reasonable time frame, the Company will need to reevaluate its operating plans and could be required to significantly reduce operating expenses and delay, reduce the scope of or eliminate some of its development programs or its future commercialization efforts, out-license intellectual property rights to its investigational drug candidates and sell unsecured assets, or a combination of the above, any of which may have a material adverse effect on its business, results of operations, financial condition and/or its ability to fund its scheduled obligations on a timely basis or at all.

**Basis of Presentation**—The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The condensed financial statements as of and for the three and nine months ended September 30, 2021 and 2020 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The condensed balance sheet as of December 31, 2020 has been derived from audited financial statements.

Although the Company believes that the disclosures in these condensed 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 condensed 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, 2020.

***NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES***

There have been no material changes to the significant accounting policies discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

**Recent Accounting Pronouncements**

*Adopted Standards*

Effective January 1, 2021, the Company adopted, on a prospective basis, Accounting Standards Update, or ASU, No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, or ASU 2019-12,

which simplifies the accounting for income taxes. The adoption of ASU 2019-12 did not have a significant impact on the Company's condensed financial statements.

*Standards Not Yet Effective*

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40),* or ASU 2020-06. ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance in *Accounting Standards Codification, or ASC, 470-20, Debt – Debt with Conversion and Other Options*, or ASC 470-20, that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The guidance in ASC 470-20 applies to convertible instruments for which the embedded conversion features are not required to be bifurcated from the host contract and accounted for as derivatives. In addition, the amendments revise the scope exception from derivative accounting in *ASC 815-40, Derivatives and Hedging – Contracts in Entity's Own Equity,* for freestanding financial instruments and embedded features that are both indexed to the issuer's own stock and classified in stockholders' equity, by removing certain criteria required for equity classification. These amendments are expected to result in more freestanding financial instruments qualifying for equity classification (and, therefore, not accounted for as derivatives), as well as fewer embedded features requiring separate accounting from the host contract. The amendments in ASU 2020-06 further revise the guidance in *ASC 260, Earnings Per Share*, to require entities to calculate diluted earnings per share, or EPS, for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted EPS when an instrument may be settled in cash or shares. ASU 2020-06 is effective for public business entities for annual reporting periods, and interim reporting periods within those annual periods, beginning after December 15, 2021 on a prospective basis, and early adoption is permitted. The Company will adopt ASU 2020-06 effective January 1, 2022, and expects to use the modified retrospective method. On adoption, the Company expects to account for the Convertible Senior Notes as a single liability measured at amortized cost resulting in reduced non-cash interest expense due to the de-recognition of the remaining debt discount associated with the equity component.

***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 the FASB's ASC Topic 820, *Fair Value Measurements and Disclosures,* or Topic 820. 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 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.

Our financial instruments consist primarily of cash and cash equivalents, short-term and long-term investments, accounts payable and the Convertible Senior Notes.

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 and U.S. Treasury securities as Level 1. When quoted market prices are not available for a 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 incorporate expected 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 U.S. government agency securities, commercial paper and corporate debt securities as Level 2. The Company's short-term and long-term investments are classified as available-for-sale.

The following tables set forth the value of the Company's financial assets remeasured on a recurring basis based on the three-tier fair value hierarchy by significant investment category as of September 30, 2021 and December 31, 2020.

| | September 30, 2021 | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | 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 | $ 1,332 | $ — | $ — | $ 1,332 | $ 1,332 | $ — | $ — |
| Level 1: | | | | | | | |
| Money market funds | 12,656 | — | — | 12,656 | 12,656 | — | — |
| U.S. Treasury securities | 6,020 | 1 | — | 6,021 | — | 6,021 | — |
| Subtotal | 18,676 | 1 | — | 18,677 | 12,656 | 6,021 | — |
| Level 2: | | | | | | | |
| U.S. government agency securities | 29,068 | 2 | — | 29,070 | — | 29,070 | — |
| Commercial paper | 97,679 | 14 | (2) | 97,691 | 3,000 | 94,691 | — |
| Subtotal | 126,747 | 16 | (2) | 126,761 | 3,000 | 123,761 | — |
| Total assets measured at fair value | $ 146,755 | $ 17 | $ (2) | $ 146,770 | $ 16,988 | $ 129,782 | $ — |

| | December 31, 2020 | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | 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 | $ 2,011 | $ — | $ — | $ 2,011 | $ 2,011 | $ — | $ — |
| Level 1: | | | | | | | |
| Money market funds | 25,862 | — | — | 25,862 | 25,862 | — | — |
| U.S. Treasury securities | 8,157 | 1 | (1) | 8,157 | — | 8,157 | — |
| Subtotal | 34,019 | 1 | (1) | 34,019 | 25,862 | 8,157 | — |
| Level 2: | | | | | | | |
| U.S. government agency securities | 64,370 | 15 | (3) | 64,382 | — | 41,625 | 22,757 |
| Commercial paper | 159,183 | 16 | (6) | 159,193 | 97,989 | 61,204 | — |
| Corporate debt securities | 72,546 | 134 | (1) | 72,679 | 11,995 | 60,684 | — |
| Subtotal | 296,099 | 165 | (10) | 296,254 | 109,984 | 163,513 | 22,757 |
| Total assets measured at fair value | $ 332,129 | $ 166 | $ (11) | $ 332,284 | $ 137,857 | $ 171,670 | $ 22,757 |

There were no gross realized gains and gross realized losses for the three and nine months ended September 30, 2021 and 2020. All available-for-sale investments held as of September 30, 2021 have a maturity of one year of less.

The following table presents a reconciliation of financial liabilities related to the compound derivative liability associated with the Loan and Security Agreement, or Term Loan, with Hercules Capital Inc., or Hercules, measured at fair value on a recurring basis using Level 3 unobservable inputs for the nine months ended September 30, 2021 and 2020. The key valuation assumptions used were the discount rate and the probability of the occurrence of certain events. In conjunction with early extinguishment of the Term Loan on March 12, 2021, the Company extinguished the compound derivative liability associated with the Term Loan.

| | Nine Months Ended September 30, | |
|---|---|---|
| *(in thousands)* | 2021 | 2020 |
| Fair value at beginning of period | $ 202 | $ 977 |
| Change in fair value | — | (699) |
| Extinguishment of compound derivative liability upon extinguishment of Term Loan | (202) | — |
| Fair value at end of period | $ — | $ 278 |

The estimated fair value of the Convertible Senior Notes was $90.7 million as of September 30, 2021 measured using Level 3 inputs. The key valuation assumptions used consist of the discount rate of 21.8% and volatility of 87.0%.

## *NOTE 4. BORROWINGS*

### Term Loan

On March 12, 2021, the Company repaid the outstanding principal of $75.0 million and fees in the amount of $8.3 million to Hercules under the Term Loan. The Company recognized a loss on early debt extinguishment of $6.1 million which represents the remaining unamortized issuance costs. In conjunction with early extinguishment of the Term Loan on March 12, 2021, the Company extinguished the compound derivative liability associated with the Term Loan.

### Convertible Senior Notes

On May 22, 2020, the Company issued $200.0 million aggregate principal amount of 3.50% convertible senior notes due 2027, or the Convertible Senior Notes. The Convertible Senior Notes are convertible into cash, shares of the Company’s common stock or a combination of cash and shares of the Company’s common stock at the Company’s election at an initial conversion rate of 30.0978 shares of the Company’s common stock per $1,000 principal amount of the Convertible Senior Notes, which is equivalent to an initial conversion price of approximately $33.23 per share of the Company’s common stock. The conversion rate is subject to customary adjustments for certain events as described in the Indenture. It is the Company’s current intent to settle conversions through combination settlement, which involves repayment of the principal portion in cash and any excess of the conversion value over the principal amount in shares of its common stock. As of September 30, 2021, the “if-converted value” did not exceed the remaining principal amount of the Convertible Senior Notes.

At issuance, the Convertible Senior Notes were bifurcated into liability and equity components and accounted for separately. The carrying amount of the liability component was calculated to be $117.7 million by measuring the fair value of similar debt instruments that do not have an associated convertible feature. The carrying amount of the equity component, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the Convertible Senior Notes. The carrying amount of the equity component was calculated to be $82.3 million and was recorded in additional paid-in capital. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. The allocation of proceeds into the equity component resulted in a debt discount for the Convertible Senior Notes that is amortized to interest expense at an effective interest rate of 13.5% over the effective life of the Convertible Senior Notes of 7.0 years, using the effective interest method.

The following table presents the carrying amount of the liability and equity components of the Convertible Senior Notes as of September 30, 2021.

| *(in thousands)* | | September 30, 2021 |
|---|---|---|
| Liability component: | | |
| Principal | $ | 200,000 |
| Unamortized discount - equity component | | (71,170) |
| Unamortized underwriter discounts and issuance costs | | (3,636) |
| Net carrying amount | $ | 125,194 |
| | | |
| Equity component, net of underwriter discounts and issuance costs | $ | 79,498 |

The remaining unamortized debt discount is being amortized over approximately 5.7 years which is also the remaining life of the Senior Convertible Notes.

The following table presents the interest expense related to the Convertible Senior Notes for the three and nine months ended September 30, 2021 and 2020.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| *(in thousands)* | 2021 | 2020 | 2021 | 2020 |
| Contractual interest expense | $ 1,750 | $ 1,750 | $ 5,250 | $ 2,508 |
| Amortization of debt discount | 2,175 | 1,930 | 6,334 | 2,767 |
| Amortization of underwriter discounts and issuance costs | 69 | 50 | 192 | 72 |
| Total interest expense | $ 3,994 | $ 3,730 | $ 11,776 | $ 5,347 |

***NOTE 5. COMMITMENTS AND CONTINGENCIES***

The Company has contractual obligations relating to its Convertible Senior Notes, operating lease, manufacturing and service contracts, and other research and development activities. The following table aggregates the Company's material expected contractual obligations and commitments as of September 30, 2021.

| | September 30, 2021 | | | | |
|---|---|---|---|---|---|
| *(in thousands)* | Total | 2021[4] | 2022 - 2023 | 2024 - 2025 | Thereafter |
| Convertible Senior Notes[1] | $ 242,000 | $ 3,500 | $ 14,000 | $ 14,000 | $ 210,500 |
| Lease obligations[2] | 17,999 | 705 | 5,780 | 6,131 | 5,383 |
| Manufacturing and service contracts[3] | 591,046 | 20,428 | 82,164 | 114,930 | 373,524 |
| **Total contractual obligations and commitments** | $ 851,045 | $ 24,633 | $ 101,944 | $ 135,061 | $ 589,407 |

(1) Comprised of interest payable and principal repayment due under the Convertible Senior Notes' Indenture.
(2) Comprised of rent payments under the amended lease for the Company's offices and laboratory space executed on August 14, 2019.
(3) The purchase obligations are comprised of the Company's non-cancelable purchase commitments under the Supply Agreement with Patheon. These amounts are based on forecasts that may include estimates of future market demand, quantity discounts and manufacturing efficiencies.
(4) Remaining three months.

**Other Commitments**

On October 4, 2019, the Company and Patheon Austria GmbH & Co KG, or Patheon, entered into a multi-year Manufacturing and Commercial Supply Agreement as amended by Amendment No. 1 dated March 30, 2021, and Amendment No. 2 dated August 26, 2021, collectively the Supply Agreement, under which Patheon agreed to manufacture and supply veverimer to support the Company's commercialization efforts. Patheon has also agreed to manufacture and supply veverimer to support the Company's drug development and clinical trial activities. Under the Supply Agreement, the Company is obligated to make certain purchases of API. The Company and Patheon are also parties to a Master Development/Validation Services and Clinical/Launch Supply Agreement, or the MDA, pursuant to which Patheon agreed to manufacture and supply veverimer. Certain manufacturing activities previously governed by the MDA are now subject to the Supply Agreement, whereas other ongoing manufacturing activities under the MDA will continue to be governed by the MDA until such activities are complete.

The Supply Agreement may be terminated by either party following an uncured material breach by the other party, in the event the other party becomes insolvent or subject to bankruptcy proceedings, or in connection with a force majeure event that continues beyond 12 months. In addition, the Supply Agreement may be terminated by the Company upon the occurrence of certain regulatory events or actions, including: (i) if the Company does not obtain regulatory approval for veverimer by a specified date or (ii) if the Company terminates its commercialization of veverimer or fails to launch veverimer by a specified date. The Company's obligation to purchase veverimer is subject to minimum and maximum annual commitments, with the minimum commitments subject to modest reduction in certain circumstances. Patheon has agreed to make facility improvements under the Supply Agreement and will be the exclusive owner of the purchased equipment and facility improvements. Patheon may manufacture other products with the facility improvements when not occupied by manufacturing veverimer. Under the Supply Agreement, the Company has agreed to reimburse Patheon up to a specified amount for plant modifications. These payments will be expensed to research and development prior to FDA approval of veverimer.

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

**Contingencies**

On January 6, 2021, a putative securities class action was filed in the U.S. District Court for the Northern District of California against the Company and its CEO and CFO, Pardi v. Tricida, Inc., et al., 21-cv-00076 (the "Securities Class Action"). In April 2021, the court appointed Jeffrey Fiore as lead plaintiff and Block & Leviton LLP as lead plaintiffs' counsel. In June 2021, the lead plaintiff filed an amended complaint which alleges that during the period between June 28, 2018 through February 25, 2021, the Company and its senior officers violated federal securities laws, including under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, through alleged public misrepresentations and/or omissions of material facts concerning the Company's NDA for veverimer and the likelihood and timing of approval of veverimer by the FDA. The amended complaint makes claims against the Company and its CEO. In July 2021, the defendants filed a motion to dismiss the amended complaint and a hearing on the defendants' motion is currently scheduled for December 2021. No damages amount is specified in the Securities Class Action.

On February 15, 2021, a derivative action was filed in the District of Delaware, brought by and on behalf of Tricida, Inc. as a Nominal Defendant, against the Company's directors as well as its CEO and CFO, Ricks v. Alpern et al., Case No, 1:21-cv-000205 (the "Ricks Derivative Case"). The Ricks Derivative Case is based on the allegations of the Securities Class Action and asserts that by allowing the Company and senior executives to make the allegedly false and misleading statements at issue in the Securities Class Action, the defendants breached their fiduciary duties and wasted corporate assets. Additionally, the complaint asserts claims against the senior officers for violation of Sections 10(b) and 21D of the Securities Exchange Act of 1934. No damages amount is specified in the Ricks Derivative Case.

On April 8, 2021 a second derivative action was filed in the District of Delaware, brought by and on behalf of Tricida, Inc. as a Nominal Defendant, against the Company's directors as well as its CEO and CFO, Goodman v. Klaerner et al., Case No, 1:21-cv-00510 (the "Goodman Derivative Case"). As with the Ricks Derivative Case, the Goodman Derivative Case is based on the allegations of the Securities Class Action and asserts that by allowing the Company and senior executives to make the allegedly false and misleading statements at issue in the Securities Class Action, the defendants breached their fiduciary duties. Additionally, the complaint asserts claims against the senior officers for violation of Sections 10(b) and 21D of the Securities Exchange Act of 1934. No damages amount is specified in the Goodman Derivative Case.

On May 27, 2021, a third derivative action was filed in the District of Delaware, brought by and on behalf of Tricida, Inc. as a Nominal Defendant, against the Company's directors as well as its CEO and CFO, Verica v. Veitinger et al., Case No, 1:21-cv-00759 (the "Verica Derivative Case" and collectively with the Goodman Derivative Case and Ricks Derivative Case, the "Derivative Cases"). As with the Goodman Derivative Case and Ricks Derivative Case, the Verica Derivative Case is based on the allegations of the Securities Class Action and asserts that by allowing the Company and senior executives to make the allegedly false and misleading statements at issue in the Securities Class Action, the defendants breached their fiduciary duties. Additionally, the complaint asserts claims for violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 and for unjust enrichment and waste of corporate assets. No damages amount is specified in the Verica Derivative Case.

The Derivative Cases have been consolidated by order of the District of Delaware Court and lead plaintiffs' counsel has been appointed. Pursuant to an agreement between the parties, the Delaware court issued an order on October 12, 2021 staying the consolidated derivative case pending final resolution of any motions to dismiss filed in the Securities Class Action. A consolidated derivative complaint has not yet been filed.

As of September 30, 2021, the Company has not provided for a loss contingency in its condensed financial statements relating to the Securities Class Action and the Derivative Cases since it is not probable that a loss has been incurred.

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. Further, while there are no other material legal proceedings that the Company is

aware of, the Company may become party to various claims and complaints arising in the ordinary course of business.

***NOTE 6. RESTRUCTURING***

***Third Quarter 2020 Restructuring***

In August 2020, the Company received a Complete Response Letter, or CRL, from the FDA related to its NDA for veverimer. Due to the resulting delay in regulatory approval and commercialization of veverimer, on September 10, 2020, the Compensation Committee of the Board of Directors approved the Tricida, Inc. 2020 Reduction in Force Severance Benefit Plan, or 2020 Restructuring Plan. On September 18, 2020, the Company implemented a restructuring, or Third Quarter 2020 Restructuring, under the 2020 Restructuring Plan to streamline the organization and preserve capital that included the elimination of approximately 21.5% of the Company's workforce and other cost reductions.

Following is a summary of accrued restructuring costs related to the Third Quarter 2020 Restructuring as of September 30, 2021 and December 31, 2020.

| *(in thousands)* | Severance and Benefits Costs | Contract Termination Costs | Total |
|---|---|---|---|
| Balance at January 1, 2020 | $ — | $ — | $ — |
| Charges | 2,524 | 136 | 2,660 |
| Cash payments made | (2,456) | (137) | (2,593) |
| Non-cash and other adjustments | (6) | 1 | (5) |
| Balance at December 31, 2020 | 62 | — | 62 |
| Non-cash and other adjustments | (62) | — | (62) |
| Balance at September 30, 2021 | $ — | $ — | $ — |

***Fourth Quarter 2020 Restructuring***

On October 25, 2020, the Company's Board of Directors approved and on October 28, 2020, the Company implemented a restructuring under the 2020 Restructuring Plan, or Fourth Quarter 2020 Restructuring, to reduce operating costs and better align its workforce with the needs of its business following the completion of the Type A meeting with the FDA in October 2020. The Fourth Quarter 2020 Restructuring resulted in the elimination of approximately 60.0% of the Company's workforce and included one-time termination severance payments and other employee-related costs, and exit costs including contract termination costs and accelerated depreciation of capitalized software.

Following is a summary of accrued restructuring costs related to the Fourth Quarter 2020 Restructuring as of September 30, 2021 and December 31, 2020.

| *(in thousands)* | Severance and Benefits Costs | Contract Termination Costs | Other Associated Costs | Total |
|---|---|---|---|---|
| Balance at January 1, 2020 | $ — | $ — | $ — | $ — |
| Charges | 7,338 | 3,077 | 679 | 11,094 |
| Cash payments made | (3,555) | (2,032) | — | (5,587) |
| Non-cash and other adjustments | — | (34) | (679) | (713) |
| Balance at December 31, 2020 | 3,783 | 1,011 | — | 4,794 |
| Cash payments made | (4,013) | (727) | — | (4,740) |
| Non-cash and other adjustments | 230 | (84) | — | 146 |
| Balance at September 30, 2021 | $ — | $ 200 | $ — | $ 200 |

Restructuring costs of $0.1 million were recorded in operating expenses in our condensed statements of operations and comprehensive loss for the nine months ended September 30, 2021.

## *NOTE 7. 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 and nine months ended September 30, 2021 and 2020.

| *(In thousands, except share and per share amounts)* | Three Months Ended September 30, 2021 | Three Months Ended September 30, 2020 | Nine Months Ended September 30, 2021 | Nine Months Ended September 30, 2020 |
|---|---|---|---|---|
| Numerator: | | | | |
| Net loss | $ (39,675) | $ (77,665) | $ (126,590) | $ (209,949) |
| Denominator: | | | | |
| Weighted-average common shares outstanding | 50,434,879 | 50,121,784 | 50,326,474 | 49,977,339 |
| Less: weighted-average shares subject to repurchase | — | (1,698) | — | (2,951) |
| Weighted-average number of shares used in basic and diluted net loss per share | 50,434,879 | 50,120,086 | 50,326,474 | 49,974,388 |
| Net loss per share, basic and diluted | $ (0.79) | $ (1.55) | $ (2.52) | $ (4.20) |

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.

| | September 30, 2021 | September 30, 2020 |
|---|---|---|
| Warrants to purchase common stock | 31,352 | 31,352 |
| Assumed conversion of Convertible Senior Notes | 6,019,560 | 6,019,560 |
| Common stock subject to repurchase | — | 1,260 |
| Stock options and RSUs issued and outstanding | 11,142,994 | 9,894,957 |
| Total potential common shares excluded from the computation of diluted net loss per share | 17,193,906 | 15,947,129 |

## *NOTE 8. STOCK-BASED COMPENSATION*

### *Equity Incentive Plans*

The following table summarizes stock option activity under the 2013 Equity Incentive Plan and the 2018 Equity Incentive Plan, or 2018 Plan, for the nine months ended September 30, 2021.

| | Shares | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term *(years)* | Aggregate Intrinsic Value *(thousands)* |
|---|---|---|---|---|
| Balance at December 31, 2020 | 8,030,415 | $ 19.25 | 7.1 | $ 10,137 |
| Granted | 4,792,580 | 6.71 | | |
| Granted due to Exchange Offer | 621,406 | 3.88 | | |
| Exercised | (125,431) | 1.43 | | |
| Forfeited or canceled | (908,212) | 25.92 | | |
| Canceled due to Exchange Offer | (1,419,182) | 30.25 | | |
| Balance at September 30, 2021 | 10,991,576 | $ 11.15 | 7.9 | $ 5,721 |
| Vested and expected to vest at September 30, 2021 | 9,725,705 | $ 11.20 | 7.8 | $ 5,682 |
| Exercisable at September 30, 2021 | 4,921,902 | $ 16.17 | 6.8 | $ 5,243 |

The following table summarizes restricted stock units, or RSUs, activity under the 2018 Plan for the nine months ended September 30, 2021.

| | Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Unvested balance at December 31, 2020 | 90,020 | $ 16.88 |
| Granted | 98,418 | 4.92 |
| Vested | (34,020) | 25.40 |
| Forfeited | (3,000) | 11.71 |
| Unvested balance at September 30, 2021 | 151,418 | $ 7.30 |

*Stock Option Exchange Program*

On July 16, 2021, the Company commenced a tender offer to its employees, excluding executive officers, to exchange eligible stock options for replacement stock options with modified terms, or Exchange Offer. Pursuant to the Exchange Offer, the Company offered employees who held outstanding stock options under the 2018 Plan with an exercise price equal to or greater than $20.00 per share, or eligible options, the opportunity to tender each eligible option in exchange for a new replacement stock option with modified terms, or new options.

The Exchange Offer expired on August 12, 2021. Pursuant to the Exchange Offer, employees elected to exchange outstanding stock options to purchase an aggregate of 1,419,182 shares of common stock for new options to purchase 621,406 shares of common stock. The new options have an exercise price of $3.88 per share, which was the closing price per share of the Company's common stock on the grant date of August 16, 2021. As a result, 797,776 shares of common stock returned to the 2018 Plan reserve and became available for future issuance under the 2018 Plan. Each new option granted in exchange for a vested option will vest in full on the 1-year anniversary following the grant date of the new option. Each new option granted in exchange for an unvested option will vest one-third on the one-year anniversary following the grant date of the new option and followed by equal monthly installments over the remaining two year period. Each new option has a maximum term of 7 years and was granted as a nonqualified stock option under the 2018 Plan.

The exchange of stock options was treated as a modification for accounting purposes. The incremental expense of $0.3 million for the new options was calculated using the Black-Scholes option pricing model and will be recognized over the new service period. The unamortized expense remaining on the exchanged options as of the modification date of August 16, 2021, will continue to be recognized over the remainder of the original requisite service period.

***Employee Stock Purchase Plan***

In June 2018, the Company's Board of Directors and stockholders approved the Tricida Inc. Employee Stock Purchase Plan, or ESPP. The ESPP allowed eligible employees to have up to 15.0% of their eligible compensation withheld and used to purchase common stock, subject to a maximum of $25,000 worth of stock purchased in a calendar year or no more than 2,500 shares in an offering period, whichever is less. An offering period consisted of a six-month purchase period, with a look back feature to our stock price at the commencement of the offering period. Eligible employees could purchase the Company's common stock at the end of the offering period at 85.0% of the lower of the closing price of the Company's common stock on The Nasdaq Global Select Market on the first and last days of the offering periods. In June 2021, the Compensation Committee of the Company's Board of Directors approved modifications to the ESPP, including extending the offering period from six months to 24 months with four six-month purchase periods within each offering period, adjusted the purchase dates from June 30 and December 31 of each calendar year to May 31 and November 30, respectively and increased the maximum number of shares available for purchase during each purchase period to 10,000.

The initial number of shares of common stock available for issuance under the ESPP, was 800,000. Unless the Company's Board of Directors provides otherwise, beginning on January 1, 2019, the maximum number of shares which shall be made available for sale under the ESPP will automatically increase on the first trading day in January of each calendar year during the term of the ESPP by an amount equal to the lesser of (i) 1.0% of the total number of shares issued and outstanding on December 31 of the immediately preceding calendar year, (ii) 800,000 shares or (iii) an amount determined by the Board of Directors. The Company issued 77,348 shares under the ESPP, representing approximately $0.3 million in employee contributions, for the nine months ended September 30, 2021.

***Stock-Based Compensation***

The following table presents stock-based compensation expense as reported in the Company's condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2021 and 2020.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| ***(in thousands)*** | **2021** | **2020** | **2021** | **2020** |
| Research and development | $ 2,819 | $ 2,937 | $ 7,948 | $ 9,261 |
| General and administrative | 3,830 | 4,718 | 11,352 | 15,847 |
| Total | $ 6,649 | $ 7,655 | $ 19,300 | $ 25,108 |

The following table presents stock-based compensation expense by award type as reported in the Company's condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2021 and 2020.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| ***(in thousands)*** | **2021** | **2020** | **2021** | **2020** |
| Stock options | $ 6,210 | $ 7,284 | $ 17,902 | $ 24,211 |
| RSUs | 246 | 238 | 929 | 459 |
| ESPP | 193 | 133 | 469 | 438 |
| Total | $ 6,649 | $ 7,655 | $ 19,300 | $ 25,108 |

## 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 Part II, 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

Our goal is to slow the progression of chronic kidney disease, or CKD, in patients with metabolic acidosis and CKD. We are a pharmaceutical company focused on the development and commercialization of our investigational drug candidate, veverimer (also known as TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis and slow CKD progression by binding and removing acid from the gastrointestinal tract. Metabolic acidosis is a serious condition commonly caused by CKD and is believed to accelerate the progression of kidney deterioration. It can also lead to bone loss, muscle wasting and impaired physical function. Metabolic acidosis in patients with CKD is typically a chronic disease and, as such, requires long-term treatment to mitigate its deleterious consequences.

There are currently no therapies approved by the U.S. Food and Drug Administration, or FDA, to slow progression of kidney disease by correcting chronic metabolic acidosis in patients with CKD. We estimate that metabolic acidosis affects approximately 3 million patients with CKD in the United States, and we believe that slowing the progression of CKD in patients with metabolic acidosis and CKD represents a significant unmet medical need and market opportunity. In addition, considering that acid retention is thought to occur in patients with CKD prior to clinical diagnosis of metabolic acidosis (serum bicarbonate less than 22 mEq/L), we believe there may be potential to pursue a development pathway for veverimer which, with additional data, could expand the market opportunity beyond metabolic acidosis to include patients with CKD and eubicarbonatemia, also known as latent acidosis, who may also benefit from a therapy that aids in acid removal.

Veverimer is an in-house discovered, new chemical entity. We have a broad intellectual property estate that we believe will provide patent protection for veverimer until at least 2038 in the United States, at least 2035 in Europe, Hong Kong, Israel, Japan, Mexico and Russia, and at least 2034 in Australia, China, and certain other markets.

Veverimer is a low-swelling, spherical polymer bead that is approximately 100 micrometers in diameter. It is a single, high molecular weight, crosslinked polyamine molecule. The size of veverimer prevents systemic absorption from the GI tract. The high degree of cross-linking within veverimer limits swelling and the overall volume in the GI tract, with the goal of facilitating good GI tolerability. The high amine content of veverimer provides proton binding capacity of approximately 10 mEq/gram of polymer. The size exclusion built into the three-dimensional structure of the polymer enables preferential binding of chloride versus larger inorganic and organic anions, including phosphate, citrate, fatty acids and bile acids. This size exclusion mechanism allows a majority of the binding capacity to be used for hydrochloric acid binding.

We submitted our New Drug Application, or NDA, for veverimer through the Accelerated Approval Program as a chronic treatment for metabolic acidosis and slowing of kidney disease progression in patients with metabolic acidosis associated with CKD for review by the FDA in August 2019. Results from our Phase 3, 12-week efficacy trial, TRCA-301, and a follow-on 40-week extension trial, TRCA-301E, formed the primary basis of our NDA submission. 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). The TRCA-301E trial met its primary and all secondary endpoints. The Lancet published the results of the TRCA-301 trial in March 2019 and the results of the TRCA-301E trial in June 2019. We commenced our ongoing VALOR-CKD renal outcomes trial in the fourth quarter of 2018 to confirm veverimer's ability to slow CKD progression through the treatment of metabolic acidosis in patients with CKD.

In August 2020, we received a Complete Response Letter, or CRL, from the FDA related to our NDA for veverimer. According to the CRL, the FDA is seeking additional data beyond the TRCA-301/TRCA-301E trial regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and expressed concern regarding whether the demonstrated effect size would be reasonably likely to

predict clinical benefit. In addition, the CRL questioned the applicability of the treatment effect to the U.S. population and the practice of medicine in the United States. The FDA also expressed concern as to the reliability of the findings given that the findings for the TRCA-301/TRCA-301E trial, were driven by a single, high-enrolling trial site located in Eastern Europe. The CRL did not raise any concerns related to FDA's completed inspection of the highest enrolling clinical trial site in the TRCA-301/TRCA-301E trial and there was no FDA Form 483 issued. There were no safety, clinical pharmacology/biopharmaceutics, CMC, or non-clinical issues identified in the CRL. The CRL provided multiple options for resolving the identified deficiencies, including submission of the data from at least one additional adequate and well-controlled trial demonstrating the efficacy of veverimer for the treatment of metabolic acidosis associated with CKD.

We held an End-of-Review Type A meeting, or Type A meeting, with the FDA's Division of Cardiology and Nephrology, or the Division, in October 2020. The Division agreed, in principle, that an interim analysis of serum bicarbonate data from the VALOR-CKD trial proposed by Tricida could address the Division's concerns regarding the reliability of the TRCA-301/TRCA-301E trial data and the relevance of those trial findings to the U.S. population provided certain conditions were met. Based on other feedback from the FDA during the Type A meeting, we believed the Division would also require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for accelerated approval and that the FDA would be unlikely to rely solely on serum bicarbonate data for determination of efficacy. Accordingly, we submitted a Formal Dispute Resolution Request, or FDRR, solely requesting that the Office of New Drugs, or OND, find that the magnitude of serum bicarbonate change seen in the TRCA-301/TRCA-301E trial is reasonably likely to predict clinical benefit in the treatment of metabolic acidosis associated with CKD and that it can therefore serve as the basis for accelerated approval.

In February 2021, the OND issued a decision on our FDRR. While the OND acknowledged that the TRCA-301 and TRCA-301E trials met their serum bicarbonate endpoints with statistical significance, the OND denied the appeal. In its Appeal Denied Letter, or ADL, the OND not only addressed the issue of magnitude of serum bicarbonate change, but cited all of the deficiencies in the CRL in concluding that the data provided in support of the veverimer NDA did not support approval through the Accelerated Approval Program. The OND concluded that the magnitude of the increases in serum bicarbonate levels shown in the TRCA-301/TRCA-301E trial was not of sufficient size or duration to establish that treatment with veverimer would be reasonably likely to provide a discernible reduction in CKD progression. In addition, the OND found that the intended confirmatory trial, VALOR-CKD (also known as TRCA-303), was underpowered to detect a 13% reduction in slowing of CKD progression. This finding was based on information included in the initial NDA submission including the placebo-subtracted LS mean change from baseline in serum bicarbonate observed in the TRCA-301/TRCA-301E trial and the original Predictive MA Model. The OND also raised concerns regarding the robustness of the study results given that the veverimer NDA was supported by a single registrational trial (TRCA-301/TRCA-301E), which must, alone, provide persuasive evidence of benefit. Specifically, the OND noted concerns around adequate blinding, the trial results being strongly influenced by a single site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population. The OND also stated that, while trial results in the TRCA-301/TRCA-301E trial showed improvement in two patient-reported measures, the KDQOL Physical Functioning Survey and the Repeated Chair Stand Test, the OND viewed this subjective data from a single trial with skepticism in the absence of data from a second trial with similar results, and noted that both endpoints would require rigorous blinding to support robust conclusions. However, the OND noted that both of these changes, if eventually established by one or more additional trials, would indicate a potentially meaningful benefit of veverimer treatment—especially in CKD patients who have physical functional impairments. Separate from the ADL, we previously received feedback from the Division of Clinical Outcome Assessment, or DCOA, that reliance on these physical function endpoints for approval may require further validation.

Based on the ADL, we believe that we now have greater clarity on the potential path for approval of veverimer through the Accelerated Approval Program. The OND suggested that we meet with the Division to discuss submission of Week 52 serum bicarbonate results from the full randomized trial population of VALOR-CKD and that the trial should include a substantial portion of patients from the United States or from regions with “U.S.-like” patients. If the results of this trial were to demonstrate that veverimer provides a meaningfully larger treatment effect than seen in the TRCA-301/TRCA-301E trial, then this trial, along with the results from the TRCA-301/TRCA-301E trial, could address the concerns raised in the CRL regarding the limitations and the size of the treatment response observed in the TRCA-301/TRCA-301E trial. However, whether the extent of increase in serum bicarbonate in any subsequent submission based on VALOR-CKD would support accelerated approval would be a review issue, and would, in part, reflect the Division’s assessment of the adequacy (i.e., power) of VALOR-CKD to detect the

anticipated treatment effect of CKD progression in a reasonable timeframe.

We believe the timeline to meet the requirements for accelerated approval as suggested in the ADL may not result in the most rapid pathway for resubmission of the NDA for veverimer or be achievable with our current resources. Based on the current enrollment rate, the week 52 serum bicarbonate data from the fully enrolled VALOR-CKD trial suggested in the ADL would not be available until at least early 2023, but there are scenarios where renal outcomes data from the VALOR-CKD trial would become available earlier and could potentially enable resubmission of the NDA through the traditional approval process, but it may or may not be sufficient. At this time, we no longer believe it is practical to pursue approval on the basis of serum bicarbonate data alone and we are focused on obtaining outcomes data from the VALOR-CKD trial.

Our ongoing VALOR-CKD trial is a randomized double-blind, placebo-controlled time-to-event trial. The primary endpoint event in VALOR-CKD is defined as renal death, end-stage renal disease, or ESRD, or a confirmed ≥ 40% reduction in estimated glomerular filtration rate (eGFR) (DD40). We designed the study to randomize approximately 1,600 subjects and the trial is currently designed to terminate when the independent blinded Clinical Endpoint Adjudication Committee, or CEAC, has positively adjudicated 511 subjects with primary endpoint events, which is anticipated to occur in the first half of 2024. The current VALOR-CKD trial protocol includes the ability to stop the trial early for administrative reasons and for a single interim analysis for early stopping for efficacy after 250 subjects with primary endpoint events have accrued (anticipated in mid-2022, based on the current rate of primary endpoint event accrual). The current protocol provides for the interim analysis to be conducted by an independent unblinded Interim Analysis Committee. If the Interim Analysis Committee recommends stopping the trial early for efficacy, and we agree with that recommendation, the study will be terminated and data from the trial will be analyzed according to the pre-specified statistical analysis plan. However, if the Interim Analysis Committee does not recommend stopping the trial early for efficacy, we will receive no information from the interim analysis. The VALOR-CKD trial protocol also includes, as its first two secondary efficacy endpoints, evaluation of the effect of veverimer versus placebo after one year of treatment on patient-reported and objective measures of physical functioning, using the KDQOL Physical Functioning Survey and the Repeated Chair Stand test, respectively. Although not part of any efficacy endpoints, the VALOR-CKD trial will also provide information regarding the change from baseline in serum bicarbonate in veverimer and placebo-treated subjects.

There is a substantial likelihood that we will not have, or be able to obtain on reasonable terms in the necessary timeframe, adequate resources to continue the VALOR-CKD trial until we reach the current target of 511 subjects with positively adjudicated primary endpoint events, which we anticipate would not be reached until 2024. As such, we have considered various options to terminate the VALOR-CKD trial early. We requested and were granted a Type A meeting with the FDA to discuss approaches to stopping the VALOR-CKD trial early based on financial resources and the procedures for study close-out. Consistent with feedback provided by the FDA in its preliminary comments for the Type A meeting, we believe that, among the alternatives considered, stopping the VALOR-CKD trial early for administrative reasons pursuant to the existing protocol is likely to provide the most complete and interpretable data, reduce the risk of missing data required for key efficacy analyses, and maintain the integrity of the trial. While the exact timing of the administrative stop will be determined by our financial runway, we anticipate that an administrative stop would occur in the first half of 2022. Accordingly, we are not likely to conduct the 250-event interim analysis. Based on feedback from the FDA, we will halt enrollment of additional patients in the VALOR-CKD trial in order to focus resources on maximizing the duration of follow-up in subjects who are currently enrolled in the trial. Stopping the VALOR-CKD trial early could increase the risk that the trial will not be successful. For the VALOR-CKD trial to be successful if stopped early, veverimer will need to demonstrate greater efficacy compared to placebo than if the trial were continued to 511 subjects with primary endpoint events. Even if the VALOR-CKD trial meets its primary endpoint, the data obtained from the trial may not be sufficient to support a resubmission and/or approval of the NDA.

We initiated enrollment in the VALOR-CKD trial in the fourth quarter of 2018 and have established sites throughout North America, Europe, Latin America and Asia-Pacific. As of November 5, 2021, the VALOR-CKD trial has randomized over 1,470 of 1,600 subjects with an average treatment duration of approximately 19 months and has accrued 159 subjects with positively adjudicated primary endpoint events. In November 2020, based on feedback from the FDA, recruitment for VALOR-CKD was closed in all regions except for the United States, Canada and Western Europe; however, we later reopened recruitment at sites in Latin America and Asia-Pacific. Based on feedback from the FDA in its preliminary comments for the Type A meeting received November 4, 2021, we will halt enrollment of additional patients in the VALOR-CKD trial. As of November 5, 2021, 72% of subjects have been enrolled at Eastern European sites, 11% at U.S., Western European and Canadian sites, and the remainder at Latin American and Asia-Pacific region sites. Due to the time required for enrolled subjects to experience endpoint

events, if the VALOR-CKD trial is terminated in 2022, the number of endpoint events being contributed from subjects in the United States or regions with “U.S.-like” subjects will likely be smaller as a percentage of total events than if the trial were continued until 511 events. If the VALOR-CKD trial is terminated in 2022, the number of endpoint events from subjects in the United States or regions with "U.S.-like" subjects is likely to be less than 10%. We intend that no single site in the VALOR-CKD trial provides ≥ 5% of the total number of trial subjects. However, if the trial is terminated in 2022, it is possible that one or more sites may slightly exceed this threshold.

We believe data from the VALOR-CKD trial will be very important to inform our decisions regarding the viability of and the appropriate regulatory path for resubmission of the NDA for veverimer. For example, if the VALOR-CKD trial is stopped in 2022, additional data on the effect of veverimer on (1) CKD progression; (2) physical functioning; and (3) serum bicarbonate will become available then. The data obtained from the VALOR-CKD trial may or may not be sufficient to support resubmission and/or approval of the NDA. Regardless of the regulatory pathway, the FDA’s acceptance of the VALOR-CKD data in support of an NDA resubmission, including its assessment of the magnitude and durability of the veverimer treatment effect across the various geographic regions where the study is conducted and the acceptability of the data from non-U.S. countries or regions which will comprise a substantial proportion of the data from the trial, will ultimately be a review issue. Resubmission and approval of the veverimer NDA could also require additional clinical data beyond that provided by the VALOR-CKD trial.

Together with our investigators, contract research organizations, or CROs, and other contract service providers, we are regularly assessing the impact of the COVID-19 pandemic on recruitment and retention of subjects in, and power of, our ongoing VALOR-CKD trial. At this time, safety monitoring activities, adjudication of endpoint events and provision of clinical trial supplies have not been materially affected by COVID-19. The annualized rate of all-cause mortality in VALOR-CKD is higher than we estimated when designing the trial, in part due to the COVID-19 pandemic. We estimated the study would have an annualized study discontinuation rate, which comprises deaths, subjects lost to follow up and those who withdraw their consent to continue to participate and be followed in the study, of 5%; currently the annualized study discontinuation rate is approximately 7%. To the extent current trends continue, there may be negative impacts on the trial in the future, including but not limited to patient retention, compliance with the study protocol and powering due to the impact of COVID-19. We have provided investigators additional guidance per general FDA and European Medicines Agency, or EMA, recommendations on clinical trial conduct during COVID-19 to ensure the ongoing VALOR-CKD trial is effectively conducted with the utmost attention to trial subject and investigator safety while maintaining compliance with applicable clinical trial regulations and principles of Good Clinical Practice and minimizing risks to the trial’s integrity. We will continue to monitor the potential impact that COVID-19 may have on our ongoing VALOR-CKD trial.

At this time, we believe we have sufficient drug substance and access to sufficient drug product manufacturing capacity to supply the anticipated demand of our ongoing VALOR-CKD trial through conclusion of the trial. Veverimer drug substance manufacturing is conducted for us by Patheon Austria GmbH & Co KG, or Patheon, in their Linz, Austria facility. We are in regular communication with Patheon and PCI Pharma Services, our drug product manufacturer and, to our knowledge, there have not been business disruptions at these sites due to COVID-19 affecting the production of veverimer drug substance and drug product. At this time, we have not experienced any material disruption in the distribution network for veverimer, including the provision of raw materials, the shipping of drug substance and drug product and the provision of clinical trial supplies to trial participants.

We have no products approved for marketing, and we have not generated any revenue from product sales or other arrangements. From our inception in 2013 through September 30, 2021, we have primarily funded our operations through the sale of $152.4 million of convertible preferred stock, net proceeds of $237.7 million from our initial public offering, or IPO, on July 2, 2018, net proceeds of $217.9 million from our underwritten public offering on April 8, 2019 and net proceeds of $193.3 million from the issuance of $200.0 million aggregate principal amount of 3.50% convertible senior notes due 2027, or the Convertible Senior Notes, on May 22, 2020 and net borrowing of $72.1 million after fees of $2.9 million under the Loan and Security Agreement, or Term Loan, entered into with Hercules Capital Inc., or Hercules, on February 28, 2018. We have incurred losses in each year since our inception in 2013. Our net losses were $39.7 million and $77.7 million for the three months ended September 30, 2021 and 2020, respectively, and $126.6 million and $209.9 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $760.4 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 pre-commercialization activities and administrative functions. At this time, COVID-19 has not materially impacted our current financial resources or our outlook.

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 continue in connection with our ongoing activities as we:

- conduct clinical studies of veverimer, including the ongoing VALOR-CKD trial;
- continue to optimize the manufacturing processes and manufacture drug substance and drug product to support the ongoing VALOR-CKD trial and the commercial launch, if approved;
- increase our research and development efforts;
- create additional infrastructure to support our product development;
- seek regulatory approval for veverimer, including any activities necessary for the resubmission of the NDA for veverimer;
- maintain, expand and protect our intellectual property portfolio; and
- maintain 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. 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 equity offerings and the Convertible Senior Note issuance, 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. We believe that our existing cash, cash equivalents and investments are not likely to be sufficient to fund our operations following the end of 2022.

**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 includes salaries, bonuses, benefits, travel and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions; expenses incurred under agreements with CROs, investigative sites and consultants that conduct our nonclinical and clinical studies; manufacturing processes optimization and the cost of manufacturing drug substance for commercial and clinical use as well as drug product to support the ongoing VALOR-CKD trial; 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 ongoing VALOR-CKD trial. 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, bonuses, 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, medical affairs costs and recruiting services for the potential launch of veverimer and other related costs.

***Restructuring Costs***

Expenses related to restructuring activities are recorded in operating expenses as part of research and development expense and general and administrative expense as appropriate.

On September 10, 2020, the Compensation Committee of the Board of Directors approved the Tricida, Inc. 2020 Reduction in Force Severance Benefit Plan, or 2020 Restructuring Plan. On September 18, 2020, we implemented a restructuring, or Third Quarter 2020 Restructuring, under the 2020 Restructuring Plan to streamline the organization and preserve capital that included the elimination of approximately 21.5% of our workforce and other cost reductions. On October 25, 2020, our Board of Directors approved and on October 28, 2020, we implemented a restructuring under the 2020 Restructuring Plan, or Fourth Quarter 2020 Restructuring, to reduce operating costs and better align our workforce with the needs of our business following the completion of the Type A meeting with the FDA in October 2020. The Fourth Quarter 2020 Restructuring resulted in the elimination of approximately 60.0% of our workforce and included one-time termination severance payments and other employee-related costs, and exit costs including contract termination costs and accelerated depreciation of capitalized software. Restructuring costs of $0.1 million were recorded in operating expenses in our condensed statements of operations and comprehensive loss for the nine months ended September 30, 2021.

**Results of Operations**

The following table presents our results of operations for the three and nine months ended September 30, 2021 and 2020.

| | Three Months Ended September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|---|---|---|---|
| ***(in thousands)*** | **2021** | **2020** | **$** | **%** | **2021** | **2020** | **$** | **%** |
| Operating expenses: | | | | | | | | |
| Research and development | $ 26,635 | $ 42,996 | $ (16,361) | (38) % | $ 78,591 | $ 121,134 | $ (42,543) | (35) % |
| General and administrative | 9,052 | 29,273 | (20,221) | (69) % | 28,497 | 81,217 | (52,720) | (65) % |
| Total operating expenses | 35,687 | 72,269 | (36,582) | (51) % | 107,088 | 202,351 | (95,263) | (47) % |
| Loss from operations | (35,687) | (72,269) | 36,582 | (51) % | (107,088) | (202,351) | 95,263 | (47) % |
| Other income (expense), net | 6 | 907 | (901) | (99) % | 155 | 4,395 | (4,240) | (96) % |
| Interest expense | (3,994) | (6,267) | 2,273 | (36) % | (13,533) | (12,043) | (1,490) | 12 % |
| Loss on early extinguishment of Term Loan | — | — | — | *N/M* | (6,124) | — | (6,124) | *N/M* |
| Loss before income taxes | (39,675) | (77,629) | 37,954 | (49) % | (126,590) | (209,999) | 83,409 | (40) % |
| Income tax benefit (expense) | — | (36) | 36 | (100) % | — | 50 | (50) | (100) % |
| Net loss | $ (39,675) | $ (77,665) | $ 37,990 | (49) % | $ (126,590) | $ (209,949) | $ 83,359 | (40) % |

*N/M = Not meaningful*

***Research and Development Expense***

The following table presents our research and development expense for the three months ended September 30, 2021 and 2020.

| | Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| ***(in thousands)*** | **2021** | **2020** | **$** | **%** |
| Clinical development costs | $ 20,060 | $ 36,473 | $ (16,413) | (45) % |
| Personnel and related costs | 2,880 | 2,937 | (57) | (2) % |
| Stock-based compensation expense | 2,819 | 2,937 | (118) | (4) % |
| Other research and development costs | 876 | 649 | 227 | 35 % |
| Total research and development expense | $ 26,635 | $ 42,996 | $ (16,361) | (38) % |

*Comparison of the three months ended September 30, 2021 and 2020*

Research and development expense was $26.6 million and $43.0 million for the three months ended September 30, 2021 and 2020, respectively. The decrease of $16.4 million was due to decreased activities in connection with our veverimer clinical development program, resulting in a decrease of clinical development costs of $16.4 million related to manufacturing process optimization and drug substance manufacturing costs related to our VALOR-CKD trial; decreased personnel and related costs of $0.1 million related to the workforce reduction following the Third Quarter 2020 Restructuring and the Fourth Quarter 2020 Restructuring; decreased stock-based compensation expense of $0.1 million related to performance awards granted in August 2019 and our workforce reduction, partially offset by higher costs related to annual awards granted in January 2021; partially offset by an increase in other research and development costs of $0.2 million due to facilities related costs.

The following table presents our research and development expense for the nine months ended September 30, 2021 and 2020.

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| ***(in thousands)*** | **2021** | **2020** | **$** | **%** |
| Clinical development costs | $ 58,855 | $ 98,530 | $ (39,675) | (40) % |
| Personnel and related costs | 9,160 | 10,818 | (1,658) | (15) % |
| Stock-based compensation expense | 7,948 | 9,261 | (1,313) | (14) % |
| Other research and development costs | 2,628 | 2,525 | 103 | 4 % |
| Total research and development expense | $ 78,591 | $ 121,134 | $ (42,543) | (35) % |

*Comparison of the nine months ended September 30, 2021 and 2020*

Research and development expense was $78.6 million and $121.1 million for the nine months ended September 30, 2021 and 2020, respectively. The decrease of $42.5 million was due to decreased activities in connection with our veverimer clinical development program, resulting in a decrease of clinical development costs of $39.7 million related to manufacturing process optimization and drug substance manufacturing costs related to our VALOR-CKD trial; decreased personnel and related costs of $1.7 million related to the workforce reduction following the Third Quarter 2020 Restructuring and the Fourth Quarter 2020 Restructuring; decreased stock-based compensation expense of $1.3 million related to performance awards granted in August 2019 and our workforce reduction, partially offset by higher costs related to annual awards granted in January 2021; partially offset by an increase in other research and development costs of $0.1 million due to facilities related costs.

***General and Administrative Expense***

The following table presents our general and administrative expense for the three months ended September 30, 2021 and 2020.

| | Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| ***(in thousands)*** | **2021** | **2020** | **$** | **%** |
| Personnel and related costs | $ 2,255 | $ 10,174 | $ (7,919) | (78) % |
| Stock-based compensation expense | 3,830 | 4,718 | (888) | (19) % |
| Other general and administrative costs | 2,967 | 14,381 | (11,414) | (79) % |
| Total general and administration expense | $ 9,052 | $ 29,273 | $ (20,221) | (69) % |

*Comparison of the three months ended September 30, 2021 and 2020*

General and administrative expense was $9.1 million and $29.3 million for the three months ended September 30, 2021 and 2020, respectively. The decrease of $20.2 million was due to a decrease in pre-commercialization and administrative activities in connection with our veverimer clinical development program, resulting in decreased personnel and related costs of $7.9 million due to the workforce reduction following the Third Quarter 2020 Restructuring and the Fourth Quarter 2020 Restructuring; decreased stock-based compensation expense of $0.9 million related to our workforce reduction and performance awards granted in August 2019, partially offset by higher costs related to annual awards granted in January 2021; and a decrease in other general and administrative costs of $11.4 million primarily related to reduction in pre-commercialization activities, medical affairs activities, legal, recruiting and training costs.

The following table presents our general and administrative expense for the nine months ended September 30, 2021 and 2020.

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| ***(in thousands)*** | **2021** | **2020** | **$** | **%** |
| Personnel and related costs | $ 7,097 | $ 24,848 | $ (17,751) | (71) % |
| Stock-based compensation expense | 11,352 | 15,847 | (4,495) | (28) % |
| Other general and administrative costs | 10,048 | 40,522 | (30,474) | (75) % |
| Total general and administration expense | $ 28,497 | $ 81,217 | $ (52,720) | (65) % |

*Comparison of the nine months ended September 30, 2021 and 2020*

General and administrative expense was $28.5 million and $81.2 million for the nine months ended September 30, 2021 and 2020, respectively. The decrease of $52.7 million was due to a decrease in pre-commercialization and administrative activities in connection with our veverimer clinical development program, resulting in decreased personnel and related costs of $17.8 million due to the workforce reduction following the Third Quarter 2020 Restructuring and the Fourth Quarter 2020 Restructuring; decreased stock-based compensation expense of $4.5 million related to our workforce reduction and performance awards granted in August 2019, partially offset by higher costs related to annual awards granted in January 2021; and a decrease in other general and administrative costs of $30.5 million primarily related to reduction in pre-commercialization activities, medical affairs activities, recruiting and training costs.

**Liquidity and Capital Resources**

***Sources of Liquidity***

From our inception in 2013 through September 30, 2021, we have primarily funded our operations through the sale of $152.4 million of convertible preferred stock, net proceeds of $237.7 million from our IPO on July 2, 2018, net proceeds of $217.9 million from our underwritten public offering of common stock on April 8, 2019, net proceeds of $193.3 million from the issuance of Convertible Senior Notes on May 22, 2020 and net borrowing of $72.1 million under the Term Loan. As of September 30, 2021, we had cash, cash equivalents and investments of $146.8 million.

***Hercules Loan and Security Agreement***

On March 12, 2021, we repaid the outstanding principal of $75.0 million and fees in the amount of $8.3 million to Hercules under the Term Loan. We recognized a loss on early debt extinguishment of $6.1 million which represents the remaining unamortized issuance costs.

***Convertible Senior Notes***

On May 22, 2020, we issued $200.0 million aggregate principal amount of Convertible Senior Notes pursuant to an indenture, dated as of May 22, 2020, or the Indenture, between us and U.S. Bank National Association, as trustee, or the Trustee. Net proceeds from the offering were $193.3 million after deducting underwriting discounts and commissions and other offering costs of approximately $6.7 million.

Our Convertible Senior Notes are senior unsecured obligations, and interest is payable semi-annually in arrears at a rate of 3.5% per year on May 15 and November 15 of each year, beginning on November 15, 2020. The

Convertible Senior Notes mature on May 15, 2027, unless earlier repurchased, redeemed or converted and are not redeemable prior to May 20, 2024. We may redeem for cash all or any portion of the Convertible Senior Notes, at our option, on or after May 20, 2024 and on or before the 40th scheduled trading day immediately prior to the maturity date, if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive), including the trading day immediately preceding the date on which we provide notice of redemption, during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the Convertible Senior Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. We are not required to and no sinking fund is provided for the Convertible Senior Notes.

The Convertible Senior Notes are convertible into cash, shares of our common stock or a combination of cash and shares of our common stock at our election at an initial conversion rate of 30.0978 shares of our common stock per $1,000 principal amount of the Convertible Senior Notes, which is equivalent to an initial conversion price of approximately $33.23 per share of our common stock. The conversion rate is subject to customary adjustments for certain events as described in the Indenture. It is our current intent to settle conversions through combination settlement, which involves repayment of the principal portion in cash and any excess of the conversion value over the principal amount in shares of our common stock. As of September 30, 2021, the “if-converted value” did not exceed the remaining principal amount of the Convertible Senior Notes.

***Funding Requirements***

We have incurred losses and negative cash flows from operations since our inception in 2013 and anticipate that we will continue to incur net losses for the foreseeable future. As of September 30, 2021, we had an accumulated deficit of $760.4 million. Based on our cash, cash equivalents and investments as of September 30, 2021, we believe we have sufficient capital to continue funding our operations for the twelve-month period following the filing of this Quarterly Report on Form 10-Q. However, our existing cash, cash equivalents and investments are not likely to be sufficient to fund our operations following the end of 2022 as we expect to incur additional losses in the future to conduct research and development and to conduct pre-commercialization activities and recognize that we will 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:

- the progress, outcome and results of our ongoing VALOR-CKD trial;
- the impact of termination of our VALOR-CKD trial;
- the costs, timing and success of addressing the deficiencies identified by the FDA in the CRL and issues raised in the ADL related to our NDA for veverimer;
- our ability to obtain approval of our NDA for veverimer from the FDA under either traditional approval or the Accelerated Approval Program, if at all;
- the findings of the FDA during their routine inspections of our facility and the facilities of our contract manufacturers and clinical trial sites during the NDA review process and our ability to promptly and adequately address any such findings;
- the revenue, if any, received from commercial sales of veverimer should we 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 the scale-up and optimization of the process of manufacturing veverimer, and our minimum and maximum commitments under the Manufacturing and Commercial Supply Agreement with Patheon, as the same may be amended from time to time;
- 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;
- the cost of fulfilling our minimum contractual obligations to our suppliers and vendors; 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 investigational drug candidates and sell unsecured assets, cease operations altogether 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 and issued and sold an aggregate of 13,455,000 shares of common stock, including the underwriters' exercise in full of their over-allotment option, a public offering price of $19.00 per share. Net proceeds were approximately $237.7 million, after deducting underwriting discounts and commissions of $17.9 million.

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.

On May 22, 2020, we issued $200.0 million aggregate principal amount of Convertible Senior Notes due 2027. The issuance included the exercise in full by the initial purchasers of their option to purchase an additional $25.0 million aggregate principal amount of Convertible Senior Notes. Net proceeds from the offering were $193.3 million after deducting underwriting discounts and commissions and other offering costs of approximately $6.7 million.

***Cash Flows***

The following table presents a summary of the net cash flow activity for the nine months ended September 30, 2021 and 2020.

| | Nine Months Ended September 30, | |
|---|---|---|
| ***(in thousands)*** | **2021** | **2020** |
| Net cash provided by (used in): | | |
| Operating activities | $ (101,996) | $ (188,818) |
| Investing activities | 63,988 | (10,140) |
| Financing activities | (82,861) | 210,096 |
| Net increase (decrease) in cash and cash equivalents | $ (120,869) | $ 11,138 |

***Cash Used in Operating Activities***

During the nine months ended September 30, 2021, cash used in operating activities was $102.0 million, which consisted of a net loss of $126.6 million, adjusted by non-cash charges of $33.6 million and changes in cash used in operating assets and liabilities of $9.0 million. The non-cash charges consisted primarily of stock-based compensation of $19.3 million, accretion of Term Loan and Convertible Senior Notes of $7.0 million, loss on early extinguishment of Term Loan of $6.1 million, non-cash operating lease costs of $0.6 million, net amortization of premiums and accretion of discounts on investments of $0.4 million and depreciation and amortization of $0.4 million, partially offset by changes in compound derivative liability of $0.2 million. The changes in cash used in our operating assets and liabilities were primarily due to a decrease in accrued expenses and other liabilities of $8.9

million and a decrease in accounts payable of $0.2 million, partially offset by a decrease in prepaid expenses and other assets of $0.1 million.

During the nine months ended September 30, 2020, cash used in operating activities was $188.8 million, which consisted of a net loss of $209.9 million, adjusted by non-cash charges of $30.7 million and changes in cash used in operating assets and liabilities of $9.5 million. The non-cash charges consisted primarily of stock-based compensation of $25.1 million, accretion of Term Loan and Convertible Senior Notes of $5.2 million, depreciation and amortization of $0.7 million and non-cash operating lease costs of $0.6 million, partially offset by changes in fair value of compound derivative liability of $0.7 million and net amortization of premiums and accretion of discounts on investments of $0.3 million. The changes cash used in our operating assets and liabilities were primarily due to a decrease in accounts payable of $4.1 million, an increase in prepaid expenses and other assets of $3.3 million and a decrease in accrued expenses and other liabilities of $2.1 million.

***Cash Provided by (Used in) Investing Activities***

Net cash provided by investing activities was $64.0 million for the nine months ended September 30, 2021 and net cash used in investing activities was $10.1 million for the nine months ended September 30, 2020. The net cash provided by investing activities during the nine months ended September 30, 2021 was due to maturities of investments of $200.4 million, partially offset by purchases of investments of $136.3 million and purchases of property and equipment of $0.1 million. The net cash used in investing activities during the nine months ended September 30, 2020 was due to purchases of investments of $277.0 million and purchases of property and equipment of $1.2 million, partially offset by maturities of investments of $268.0 million.

***Cash Provided by (Used in) Financing Activities***

Net cash used in financing activities was $82.9 million for the nine months ended September 30, 2021 and net cash provided by financing activities was $210.1 million for the nine months ended September 30, 2020. The net cash used in financing activities during the nine months ended September 30, 2021 was primarily due to cash paid for early extinguishment of the Term Loan of $83.3 million, partially offset by proceeds from issuance of common stock under equity incentive plans of $0.5 million. The net cash provided by financing activities during the nine months ended September 30, 2020 was primarily due to net proceeds from the issuance of Convertible Senior Notes of $193.3 million, Term Loan funding of $15.0 million and proceeds from issuance of common stock under equity incentive plans of $1.9 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 Securities and Exchange Commission.

**Contractual Obligations and Commitments**

Based on our cash, cash equivalents and investments as of September 30, 2021, we believe we have sufficient capital to continue meeting our contractual obligations for the twelve-month period following the filing of this Quarterly Report on Form 10-Q. However, our existing cash, cash equivalents and investments are not likely to be sufficient to meet our contractual obligations following the end of 2022. For additional details regarding our contractual obligations, see Note 5. “Commitments and Contingencies” to our condensed financial statements in Part I, Item 1. of this Quarterly Report on Form 10-Q.

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

Our management’s discussion and analysis of financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these condensed 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 material changes to the critical accounting estimates discussed in our Annual Report on Form 10-K for the year ended December 31, 2020.

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

There have been no material changes in our market risk during the nine months ended September 30, 2021, compared to the year ended December 31, 2020. 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, 2020.

**ITEM 4. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the Company's reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to management, including the Company's Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

The Company's management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a–15(e) and 15d–15(e) of the Exchange Act, as of September 30, 2021. Based on the evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective as of September 30, 2021.

**Changes in Internal Control over Financial Reporting**

There have been no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Limitation on the Effectiveness of Controls**

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control systems are met.

## PART II - OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

For a discussion of legal proceedings, please read the information under the heading “Contingencies” in Part I, Item 1., Note 5. "Commitments and Contingencies", to our condensed financial statements included in this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

### 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 other information contained elsewhere in this Quarterly Report on Form 10-Q, including Part I, Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Part I, Item 1. "Financial Statements," 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.*

**Summary of Risk Factors**

*Investing in our securities involves a high degree of risk. You should carefully consider all of the risks discussed in Part II, Item 1A. "Risk Factors" of this Quarterly Report on Form 10-Q, not just those discussed under this “Summary of Risk Factors” before making a decision to invest in our securities. The following is a list of some of these risks:*

- 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 investigational drug candidate, veverimer (also known as TRC101), which is still in clinical trials and has no commercial sales.
- We are dependent on the success of veverimer and, if we are unable to conduct a successful VALOR-CKD trial, obtain regulatory approval, or commercialize veverimer, our business will be materially harmed. Based on the Complete Response Letter, or CRL, received from the FDA in August 2020, and the Appeal Denied Letter, or ADL, received in February 2021, we believe the criteria and pathway for resubmission and approval of our New Drug Application, or NDA, for veverimer is more clear, but the timing of any such approval is uncertain. The regulatory approval process is highly uncertain, and we may not obtain approval through the Accelerated Approval Program or the traditional approval process, as required for the commercialization of veverimer. We could be required to conduct additional nonclinical and clinical studies and trials beyond those that we currently contemplate, which would increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, marketing approval for veverimer.
- The design of our ongoing renal outcomes trial, VALOR-CKD (also known as TRCA-303), may be impacted by additional information that becomes available to us or 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 the design of this trial or conduct additional clinical trials. Stopping the VALOR-CKD trial early could increase the risk that the trial will not be successful. Even if the VALOR-CKD trial meets it primary endpoint, the data obtained from the trial may not be sufficient to support a resubmission and/or approval of the NDA.
- A continued delay in obtaining approval could further delay commercialization of veverimer and adversely impact our ability to generate revenue, our business and our results of operations. The denial of regulatory approval for veverimer could mean that we need to cease operations altogether. Even if we are able to obtain approval of veverimer through the Accelerated Approval Program, if our renal outcomes trial, VALOR-CKD, which would serve as a confirmatory postmarketing trial, does not verify clinical benefit, or if we are subject to and do not comply with rigorous postmarketing requirements, the FDA may seek to withdraw the approval.

- Together with our limited operating history and our requirements for substantial additional financing to achieve our goals, including the completion of our ongoing clinical trial, VALOR-CKD, it is difficult to assess our future viability. We require substantial additional financing to achieve our goals, including completion of the VALOR-CKD trial. 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 clinical trials, product development, commercialization efforts of veverimer, or further reduce or cease our operations altogether. Our current 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.

- 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.

- We do not have commercial capabilities that would be required for a successful commercial launch of veverimer, if approved. Development of such capabilities would require significant additional capital and financial investment as well as recruitment of key personnel. An inability to develop such commercial capabilities or a delay, could meaningfully impact our business.

- Our business operations are heavily dependent on third parties to perform functions critical to our success. We currently rely completely on third-party suppliers to manufacture, package and label our clinical drug supply of veverimer drug substance and drug product, and we intend to rely completely on third parties to manufacture, package and label commercial supply of veverimer drug substance and drug product, if approved. Any interruption or performance failure on the part of our suppliers could delay the development and potential regulatory approval and commercialization of veverimer. In addition, we have relied and continue to rely on third parties, particularly consultants and CROs, to conduct and complete our clinical trials, including our ongoing clinical trial, VALOR-CKD. 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.

- An epidemic or pandemic disease outbreak, including the COVID-19 outbreak, could disrupt our business operations, including the conduct and results of our ongoing clinical trial, VALOR-CKD, as well as the business or operations of our third-party manufacturers and testing laboratories, our CROs, clinical data management organizations, medical institutions and clinical investigators, the FDA or other regulatory authorities, or other third parties with whom we conduct business, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

- If we fail to attract and keep senior management and other key personnel, we may be unable to successfully develop veverimer, conduct our clinical trials and commercialize veverimer, if approved.

- 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.

**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 investigational drug candidate, veverimer (also known as TRC101), which is still in clinical trials and has no commercial sales. We received a Complete Response Letter, or CRL, from the FDA related to our New Drug Application, or NDA, for veverimer. Further, the Office of New Drugs, or OND, issued an Appeal Denied Letter, or ADL, to our Formal Dispute Resolution Request, or FDRR. Together with our limited operating history, these factors make it difficult to assess our future viability.***

We are a pharmaceutical company focused on the development and commercialization of our investigational drug candidate, veverimer (also known as TRC101), a non-absorbed, orally-administered polymer designed to treat 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. Our net losses were $39.7 million and $77.7 million for the three months ended September 30, 2021 and 2020, respectively, and $126.6 million and $209.9 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $760.4 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 drug 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 investigational drug 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 we are unable to address the deficiencies identified in the CRL from the FDA related to our NDA or the issues raised in the ADL issued by the OND to our FDRR, because of a lack of capital or otherwise, 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 clinical trials, product development, other operations or commercialization efforts of veverimer, or to cease operations altogether.***

We are currently advancing veverimer through clinical development. As of September 30, 2021, we had working capital of $125.4 million and cash, cash equivalents and investments of $146.8 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 drug 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, including in connection with attempting to address the deficiencies identified in the CRL from the FDA related to our NDA or the issues raised in the ADL issued by the OND on our FDRR and resubmission of the NDA. Because the outcome of any clinical trial and the regulatory approval process is highly uncertain, we cannot reasonably estimate the actual expenditures necessary to successfully complete the development, regulatory approval process and commercialization of veverimer.

We believe that our cash, cash equivalents and investments of $146.8 million as of September 30, 2021, will allow us to fund our operating plan through the twelve-month period following the filing of this Quarterly Report on Form 10-Q. However, our existing cash, cash equivalents and investments are not likely to be sufficient to fund our operations following the end of 2022. 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 or 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 drug candidates that we develop, in-license or acquire;
- our ability to obtain approval for veverimer through the Accelerated Approval Program or traditional approval process;
- the costs associated with addressing the deficiencies identified in the CRL from the FDA related to our NDA or the issues raised in the ADL issued by the OND on our FDRR and resubmission of our NDA, and any increased costs associated with raising capital in light of such deficiencies or resulting delays;
- the progress, timing, scope and costs of conducting our nonclinical and clinical studies and trials, including our ongoing VALOR-CKD trial, in a timely manner, or potential future nonclinical and/or clinical studies and trials we may be required to conduct;
- the costs associated with conducting additional clinical trials for veverimer, if any, that the FDA and/or foreign regulatory agencies may require us to conduct prior to approval to market veverimer;
- the costs of postmarketing studies or clinical 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 establishing our sales and marketing and medical affairs capabilities;
- the cost of fulfilling our minimum contractual obligations to our suppliers and vendors;
- the timing and costs related to the optimization and scale-up of our manufacturing processes for veverimer and commercial supply of veverimer;
- the amount and timing of sales, royalties and other revenue from veverimer, if approved, including the sales price and the availability of adequate third-party reimbursement;
- 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 drug candidates, if any;
- the costs of hiring and retaining personnel;
- the time and cost necessary to respond to technological and market developments;
- the potential impact of pandemics, including COVID-19, on the health care system, financial markets and economy generally and on our business in particular, including the potential impact on retention of patients in the VALOR-CKD trial, subject compliance with the study protocol, or the power of our VALOR-CKD trial;
- 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; and
- the costs of defending against claims brought against the Company, its management and/or its Board of Directors, including litigation costs associated with shareholder, class action and derivative suits.

We cannot assure you that anticipated additional financing will be available to us on favorable terms, or at all. 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 of veverimer, and commercialization, if approved, and other business activities, we could be forced to significantly delay, scale back or abandon or terminate 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 investigational drug candidate. If we are unable to conduct a successful VALOR-CKD trial, develop, obtain regulatory approval for and commercialize veverimer, or continue to experience significant delays in doing so, our business will be materially harmed. Stopping the VALOR-CKD trial early could increase the risk that the trial will not be successful. Even if the VALOR-CKD trial meets its primary endpoint, the data obtained from the trial may not be sufficient to support a resubmission and/or approval of the NDA.***

To date, we have invested all of our efforts and financial resources in the research and development and potential commercial launch of veverimer, which is our only investigational drug candidate. Our business and future success depends on our ability to conduct a successful VALOR-CKD trial which would demonstrate slowing of CKD progression by veverimer compared to placebo, and to develop, obtain regulatory approval for, and commercialize veverimer. We are currently conducting a renal outcomes clinical trial, VALOR-CKD (also known as TRCA-303), to determine if veverimer slows CKD progression in patients with metabolic acidosis associated with CKD. Our VALOR-CKD trial is a randomized, double-blind, placebo-controlled, time-to-event trial. In May 2018, we completed our multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial for veverimer, known as TRCA-301. The TRCA-301 trial enrolled 217 subjects with metabolic acidosis and CKD. Eligible subjects who completed the 12-week treatment period in our 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 these trials met their primary and secondary endpoints, the FDA has indicated that these trials alone are not sufficient to support approval of veverimer. Further, we cannot assure you that any foreign regulatory agency will approve veverimer for marketing.

We submitted our New Drug Application, or NDA, for veverimer through the Accelerated Approval Program in August 2019, and in August 2020, we received a Complete Response Letter, or CRL, from the FDA related to our NDA for veverimer. According to the CRL, the FDA is seeking additional data beyond the TRCA-301/TRCA-301E trial regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and expressed concern regarding whether the demonstrated effect size would be reasonably likely to predict clinical benefit. In addition, the CRL questioned the applicability of the treatment effect to the U.S. population and the practice of medicine in the United States. The FDA also expressed concern as to the reliability of the findings given that the findings for the TRCA-301/TRCA-301E trial were driven by a single, high-enrolling trial site located in Eastern Europe. The CRL did not raise any concerns related to FDA's completed inspection of the highest enrolling clinical trial site in the TRCA-301/TRCA-301E trial and there was no FDA Form 483 issued. There were no safety, clinical pharmacology/biopharmaceutics, CMC, or non-clinical issues identified in the CRL. The CRL provided multiple options for resolving the identified deficiencies, including submission of the data from at least one additional adequate and well-controlled trial demonstrating the efficacy of veverimer for the treatment of metabolic acidosis associated with CKD.

We held an End-of-Review Type A meeting, or Type A meeting, with the FDA's Division of Cardiology and Nephrology, or the Division, in October 2020. The Division agreed, in principle, that an interim analysis of serum bicarbonate data from the VALOR-CKD trial proposed by Tricida could address the Division's concerns regarding the reliability of the TRCA-301/TRCA-301E trial data and the relevance of those trial findings to the U.S. population provided certain conditions were met. Based on other feedback from the FDA during the Type A meeting, we believed the Division would also require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for accelerated approval and that the FDA would be unlikely to rely solely on serum bicarbonate data for determination of efficacy. Accordingly, we submitted a Formal Dispute Resolution Request, or FDRR, solely requesting that the Office of New Drugs, or OND, find that the magnitude of serum bicarbonate change seen in the TRCA-301/TRCA-301E trial is reasonably likely to predict clinical benefit in the

treatment of metabolic acidosis associated with CKD and that it can therefore serve as the basis for accelerated approval.

In February 2021, the OND issued a decision on our FDRR. While the OND acknowledged that the TRCA-301 and TRCA-301E trials met their serum bicarbonate endpoints with statistical significance, the OND denied the appeal. In its Appeal Denied Letter, or ADL, the OND not only addressed the issue of magnitude of serum bicarbonate change, but cited all of the deficiencies in the CRL in concluding that the data provided in support of the veverimer NDA did not support approval through the Accelerated Approval Program. The OND concluded that the magnitude of the increases in serum bicarbonate levels shown in the TRCA-301/TRCA-301E trial was not of sufficient size or duration to establish that treatment with veverimer would be reasonably likely to provide a discernible reduction in CKD progression. In addition, the OND found that the intended confirmatory trial, VALOR-CKD (also known as TRCA-303), was underpowered to detect a 13% reduction in slowing of CKD progression. This finding was based on information included in the initial NDA submission, including the placebo-subtracted LS mean change from baseline in serum bicarbonate observed in the TRCA-301/TRCA-301E trial and the original Predictive MA Model. The OND also raised concerns regarding the robustness of the study results given that the veverimer NDA was supported by a single registrational trial (TRCA-301/TRCA-301E), which must, alone, provide persuasive evidence of benefit. Specifically, the OND noted concerns around adequate blinding, the trial results being strongly influenced by a single site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population. The OND also stated that, while trial results in the TRCA-301/TRCA-301E trial showed improvement in two patient-reported measures, the KDQOL Physical Functioning Survey and the Repeated Chair Stand Test, the OND viewed this subjective data from a single trial with skepticism in the absence of data from a second trial with similar results and noted that both endpoints would require rigorous blinding to support robust conclusions. However, the OND noted that both of these changes, if eventually established by one or more additional trials, would indicate a potentially meaningful benefit of veverimer treatment—especially in CKD patients who have physical functional impairments. Separate from the ADL, we previously received feedback from the Division of Clinical Outcome Assessment, or DCOA, that reliance on these physical function endpoints for approval may require further validation.

Based on the ADL, we believe that we now have greater clarity on the potential path for approval of veverimer through the Accelerated Approval Program. The OND suggested that we meet with the Division to discuss submission of Week 52 serum bicarbonate results from the full randomized trial population of VALOR-CKD and that the trial should include a substantial portion of patients from the United States or from regions with “U.S.-like” patients. If the results of this trial were to demonstrate that veverimer provides a meaningfully larger treatment effect than seen in the TRCA-301/TRCA-301E trial, then this trial, along with the results from the TRCA-301/TRCA-301E trial, could address the concerns raised in the CRL regarding the limitations and the size of the treatment response observed in the TRCA-301/TRCA-301E trial. However, whether the extent of increase in serum bicarbonate in any subsequent submission based on VALOR-CKD would support accelerated approval would be a review issue, and would, in part, reflect the Division’s assessment of the adequacy (i.e., power) of VALOR-CKD to detect the anticipated treatment effect of CKD progression in a reasonable timeframe.

We believe the timeline to meet the requirements for accelerated approval as suggested in the ADL may not result in the most rapid pathway for resubmission of the NDA for veverimer or be achievable with our current resources. Based on the current enrollment rate, the week 52 serum bicarbonate data from the fully enrolled VALOR-CKD trial suggested in the ADL would not be available until at least early 2023, but there are scenarios where renal outcomes data from the VALOR-CKD trial would become available earlier and could potentially enable resubmission of the NDA through the traditional approval process, but it may or may not be sufficient. At this time, we no longer believe it is practical to pursue approval on the basis of serum bicarbonate data alone and we are focused on obtaining outcomes data from the VALOR-CKD trial.

There is a substantial likelihood that we will not have, or be able to obtain on reasonable terms in the necessary timeframe, adequate resources to continue the VALOR-CKD trial until we reach the current target of 511 subjects with positively adjudicated primary endpoint events, which we anticipate would not be reached until 2024. As such, we have considered various options to terminate the VALOR-CKD trial early. We requested and were granted a Type A meeting with the FDA to discuss approaches to stopping the VALOR-CKD trial early based on financial resources and the procedures for study close-out. Consistent with feedback provided by the FDA in its preliminary comments for the Type A meeting, we believe that, among the alternatives considered, stopping the VALOR-CKD trial early for administrative reasons pursuant to the existing protocol is likely to provide the most complete and interpretable data, reduce the risk of missing data required for key efficacy analyses, and maintain the integrity of

the trial. While the exact timing of the administrative stop will be determined by our financial runway, we anticipate that an administrative stop would occur in the first half of 2022. Accordingly, we are not likely to conduct the 250-event interim analysis. Based on feedback from the FDA, we will halt enrollment of additional patients in the VALOR-CKD trial in order to focus resources on maximizing the duration of follow-up in subjects who are currently enrolled in the trial. Stopping the VALOR-CKD trial early could increase the risk that the trial will not be successful. For the VALOR-CKD trial to be successful if stopped early, veverimer will need to demonstrate greater efficacy compared to placebo than if the trial were continued to 511 subjects with primary endpoint events. Even if the VALOR-CKD trial meets its primary endpoint, the data obtained from the trial may not be sufficient to support a resubmission and/or approval of the NDA.

We believe data from VALOR-CKD will be very important in furthering our understanding of, and informing decisions regarding, the appropriate regulatory path for resubmission of the NDA for veverimer. For example, if the VALOR-CKD trial is stopped in 2022, additional data on the effect of veverimer on (1) CKD progression; (2) physical functioning; and (3) serum bicarbonate will become available then. As such, we intend to continue the execution of the VALOR-CKD trial with consideration of both the accelerated and traditional approval pathways. Regardless of the regulatory pathway, the FDA's acceptance of the VALOR-CKD data in support of an NDA resubmission, including its assessment of the magnitude and durability of the veverimer treatment effect across the various geographical regions where the study is conducted and the acceptability of the data from non-U.S. countries or regions which will comprise a substantial proportion of the data from the trial, will ultimately be a review issue. Resubmission and approval of the veverimer NDA could also require additional clinical data beyond that provided by the VALOR-CKD trial.

Even if we obtain regulatory approval for veverimer, we will 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, regulatory approval 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 conduct a successful VALOR-CKD trial, whether the trial is conducted under the current protocol specifying 511 subjects with primary endpoint events or otherwise, and the ability of the results of this trial to demonstrate slowing of CKD progression by veverimer compared to placebo;
- 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 ongoing VALOR-CKD trial;
- the continued participation in our VALOR-CKD trial by a sufficient number of subjects to demonstrate applicability to the U.S. population;
- the continued participation in our VALOR-CKD trial by a sufficient number of subjects over a sufficient number of clinical sites to avoid the potential for trial results to be driven by a single high-enrolling site;
- the VALOR-CKD trial demonstrating statistically significant primary endpoint results so that hierarchical testing of the secondary efficacy endpoints, such as physical functioning endpoints, may be performed per the statistical analysis plan;
- whether we are required by the FDA and/or foreign regulatory agencies to conduct additional clinical trials prior to or after approval to market veverimer, in addition to our VALOR-CKD trial;
- 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/or foreign regulatory agencies for veverimer;
- our ability to obtain U.S. marketing approval for veverimer through the Accelerated Approval Program or traditional approval process, including our ability to address any deficiencies identified by the FDA in the CRL or issues identified in the ADL issued by the OND on our FDRR;
- 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 and maintain commercially viable and validated 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 potential 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;
- the impact of pandemics, such as COVID-19, on our business in particular, including the potential impact on our VALOR-CKD trial; 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 gaining approval of or in commercializing veverimer, or are significantly delayed in doing so, our business will be materially harmed.

***If we pursue and are unable to obtain approval of veverimer through the Accelerated Approval Program in the United States, and/or are required to conduct additional nonclinical and clinical studies and trials beyond those that we have completed or currently contemplate, that 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 through the Accelerated Approval Program, if the ongoing VALOR-CKD trial, which would serve as a confirmatory postmarketing trial, or any additional confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous postmarketing requirements, the FDA may seek to withdraw the approval.***

As described in the "Risks Related to 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. The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides a meaningful advantage over available therapies 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, which, is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. Approval through the Accelerated Approval Program is subject, however, to the requirement that the applicant conduct at least one additional confirmatory postmarketing clinical trial 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 a postmarketing clinical trial shows that the drug provides a clinically meaningful positive therapeutic effect, that is, an effect on how a patient feels, functions, or survives. 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 through 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 through the Accelerated Approval Program, we may not experience a faster development process, review or approval compared to the traditional approval process.

Our NDA for veverimer was reviewed by the FDA through the Accelerated Approval Program based on the results of our Phase 1/2 trial, TRCA-101, our Phase 3 clinical trial, TRCA-301, and our 40-week extension trial, TRCA-301E. Thus far, we have been unable to obtain approval of veverimer through the Accelerated Approval Program. In August 2020, we received a CRL from the FDA related to our NDA for veverimer. According to the CRL, the FDA is seeking additional data beyond the TRCA-301/TRCA-301E trial regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and expressed concern regarding whether the demonstrated effect size would be reasonably likely to predict clinical benefit. In addition, the CRL questioned the applicability of the treatment effect to the U.S. population and the practice of medicine in the United States. The FDA also expressed concern as to the reliability of the findings given that the findings for the TRCA-301/TRCA-301E trial were driven by a single, high-enrolling trial site located in Eastern Europe. The CRL did not raise any concerns related to FDA's completed inspection of the highest enrolling clinical trial site in the TRCA-301/TRCA-301E trial and there was no FDA Form 483 issued. There were no safety, clinical pharmacology/biopharmaceutics, CMC, or non-clinical issues identified in the CRL. The CRL provided multiple options for resolving the identified deficiencies, including submission of the data from at least one additional adequate and well-controlled trial demonstrating the efficacy of veverimer for the treatment of metabolic acidosis associated with CKD.

We held an End-of-Review Type A meeting, or Type A meeting, with the FDA's Division of Cardiology and Nephrology, or the Division, in October 2020. The Division agreed, in principle, that an interim analysis of serum bicarbonate data from the VALOR-CKD trial proposed by Tricida could address the Division's concerns regarding the reliability of the TRCA-301/TRCA-301E trial data and the relevance of those trial findings to the U.S. population provided certain conditions were met. Based on other feedback from the FDA during the Type A meeting, we believed the Division would also require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for accelerated approval and that the FDA would be unlikely to rely solely on serum bicarbonate data for determination of efficacy. Accordingly, we submitted a Formal Dispute Resolution Request, or FDRR, solely requesting that the Office of New Drugs, or OND, find that the magnitude of serum bicarbonate change seen in the TRCA-301/TRCA-301E trial is reasonably likely to predict clinical benefit in the treatment of metabolic acidosis associated with CKD and that it can therefore serve as the basis for accelerated approval.

In February 2021, the OND issued a decision on our FDRR. While the OND acknowledged that the TRCA-301 and TRCA-301E trials met their serum bicarbonate endpoints with statistical significance, the OND denied the appeal. In its Appeal Denied Letter, or ADL, the OND not only addressed the issue of magnitude of serum bicarbonate change, but cited all of the deficiencies in the CRL in concluding that the data provided in support of the veverimer NDA did not support approval through the Accelerated Approval Program. The OND concluded that the magnitude of the increases in serum bicarbonate levels shown in the TRCA-301/TRCA-301E trial was not of sufficient size or duration to establish that treatment with veverimer would be reasonably likely to provide a discernible reduction in CKD progression. In addition, the OND found that the intended confirmatory trial, VALOR-CKD (also known as TRCA-303), was underpowered to detect a 13% reduction in slowing of CKD progression. This finding was based on information included in the initial NDA submission, including the placebo-subtracted LS mean change from baseline in serum bicarbonate observed in the TRCA-301/TRCA-301E trial and the original Predictive MA Model. The OND also raised concerns regarding the robustness of the study results given that the veverimer NDA was supported by a single registrational trial (TRCA-301/TRCA-301E), which must, alone, provide persuasive evidence of benefit. Specifically, the OND noted concerns around adequate blinding, the trial results being strongly influenced by a single site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population. The OND also stated that, while trial results in the TRCA-301/TRCA-301E trial showed improvement in two patient-reported measures, the KDQOL Physical Functioning Survey and the Repeated Chair Stand Test, the OND viewed this subjective data

from a single trial with skepticism in the absence of data from a second trial with similar results, and noted that both endpoints would require rigorous blinding to support robust conclusions. However, the OND noted that both of these changes, if eventually established by one or more additional trials, would indicate a potentially meaningful benefit of veverimer treatment—especially in CKD patients who have physical functional impairments. Separate from the ADL, we previously received feedback from the Division of Clinical Outcome Assessment, or DCOA, that reliance on these physical function endpoints for approval may require further validation.

Based on the ADL, we believe that we now have greater clarity on the potential path for approval of veverimer through the Accelerated Approval Program. The OND suggested that we meet with the Division to discuss submission of Week 52 serum bicarbonate results from the full randomized trial population of VALOR-CKD and that the trial should include a substantial portion of patients from the United States or from regions with "U.S.-like" patients. If the results of this trial were to demonstrate that veverimer provides a meaningfully larger treatment effect than seen in the TRCA-301/TRCA-301E trial, then this trial, along with the results from the TRCA-301/TRCA-301E trial, could address the concerns raised in the CRL regarding the limitations and the size of the treatment response observed in the TRCA-301/TRCA-301E trial. However, whether the extent of increase in serum bicarbonate in any subsequent submission based on VALOR-CKD would support accelerated approval would be a review issue, and would, in part, reflect the Division's assessment of the adequacy (i.e., power) of VALOR-CKD to detect the anticipated treatment effect of CKD progression in a reasonable timeframe.

We believe the timeline to meet the requirements for accelerated approval as suggested in the ADL may not result in the most rapid pathway for resubmission of the NDA for veverimer or be achievable with our current resources. Based on the current enrollment rate, the week 52 serum bicarbonate data from the fully enrolled VALOR-CKD trial suggested in the ADL would not be available until at least early 2023 but there are scenarios where renal outcomes data from the VALOR-CKD trial would become available earlier and could potentially enable resubmission of the NDA through the traditional approval process, but it may or may not be sufficient. At this time, we no longer believe it is practical to pursue approval on the basis of serum bicarbonate data alone and we are focused on obtaining outcomes data from the VALOR-CKD trial.

There is a substantial likelihood that we will not have, or be able to obtain on reasonable terms in the necessary timeframe, adequate resources to continue the VALOR-CKD trial until we reach the current target of 511 subjects with positively adjudicated primary endpoint events, which we anticipate would not be reached until 2024. As such, we have considered various options to terminate the VALOR-CKD trial early. We requested and were granted a Type A meeting with the FDA to discuss approaches to stopping the VALOR-CKD trial early based on financial resources and the procedures for study close-out. Consistent with feedback provided by the FDA in its preliminary comments for the Type A meeting, we believe that, among the alternatives considered, stopping the VALOR-CKD trial early for administrative reasons pursuant to the existing protocol is likely to provide the most complete and interpretable data, reduce the risk of missing data required for key efficacy analyses, and maintain the integrity of the trial. While the exact timing of the administrative stop will be determined by our financial runway, we anticipate that an administrative stop would occur in the first half of 2022. Accordingly, we are not likely to conduct the 250-event interim analysis. Based on feedback from the FDA, we will halt enrollment of additional patients in the VALOR-CKD trial in order to focus resources on maximizing the duration of follow-up in subjects who are currently enrolled in the trial. Stopping the VALOR-CKD trial early could increase the risk that the trial will not be successful. For the VALOR-CKD trial to be successful if stopped early, veverimer will need to demonstrate greater efficacy compared to placebo than if the trial were continued to 511 subjects with primary endpoint events. Even if the VALOR-CKD trial meets its primary endpoint, the data obtained from the trial may not be sufficient to support a resubmission and/or approval of the NDA.

We believe data from VALOR-CKD will be very important in furthering our understanding of, and informing decisions regarding, the appropriate regulatory path for resubmission of the NDA for veverimer. For example, if the VALOR-CKD trial is stopped in 2022, additional data on the effect of veverimer on (1) CKD progression; (2) physical functioning; and (3) serum bicarbonate will become available then. As such, we intend to continue the execution of the VALOR-CKD trial with consideration of both the accelerated and traditional approval pathways. Regardless of the regulatory pathway, the FDA's acceptance of the VALOR-CKD data in support of an NDA resubmission, including its assessment of the magnitude and durability of the veverimer treatment effect across the various geographical regions where the study is conducted and the acceptability of the data from non-U.S. countries or regions which will comprise a substantial proportion of the data from the trial, will ultimately be a review issue. Resubmission and approval of the veverimer NDA could also require additional clinical data beyond that provided by the VALOR-CKD trial.

If we decide to continue to develop our investigational drug candidate for the treatment of a disease or condition on the basis of an unvalidated surrogate endpoint, there are increased risks that the FDA may have difficulty analyzing and interpreting the results of our clinical program. In addition, the FDA may find that the demonstrated effect on a surrogate endpoint is not reasonably likely to predict clinical benefit. As a result, they may delay or refuse to approve veverimer. Thus far, the FDA has not been satisfied that the demonstrated magnitude and durability of effect of veverimer on the surrogate endpoint has been sufficient to support approval.

If we are able to obtain accelerated approval for veverimer, we will be subject to rigorous postmarketing requirements, including the completion of our ongoing VALOR-CKD trial, which we believe would serve as a confirmatory postmarketing trial, or such other confirmatory 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 postmarketing trial with due diligence, our 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.

There can be no assurance that data from VALOR-CKD can be obtained on a timely basis or that they will be sufficient to support approval of veverimer. Any further delay in obtaining, or inability to obtain, approval would delay or prevent commercialization of veverimer and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects. The denial of regulatory approval for veverimer could mean that we need to cease operations altogether.

***We may be unable to obtain regulatory approval for veverimer under the traditional FDA approval process.***

We may decide to pursue traditional approval of veverimer for the slowing of kidney disease progression or improving physical functioning in patients with metabolic acidosis associated with CKD rather than accelerated approval. To obtain traditional approval to market a drug product, we must provide the FDA with clinical data that adequately demonstrate the safety and efficacy of veverimer for the intended indication sought in the NDA.

The FDA generally requires at least two adequate and well-controlled studies to support approval of an NDA. A single Phase 3 clinical trial may be sufficient in rare instances, including (1) where the clinical trial is a large multicenter clinical trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second clinical trial would be practically or ethically impossible or (2) when in conjunction with other confirmatory evidence. If the VALOR-CKD trial is successful, and we decide to pursue traditional approval, it would be based on our belief that our VALOR-CKD trial, supported by the TRCA-301/TRCA-301E trial, will provide sufficient evidence for FDA to approve veverimer for the slowing of kidney disease progression and potentially improving physical functioning in patients with metabolic acidosis associated with CKD. However, it is possible that the FDA will disagree. The FDA has broad discretion in determining whether to approve a drug, and the FDA could find data from the VALOR-CKD trial, in whole or in part, to be insufficient for a number of reasons, including the following reasons:

- concerns regarding the robustness of the VALOR-CKD trial results;
- concerns regarding the integrity of the VALOR-CKD trial data;
- concerns that the VALOR-CKD results are not generalizable to patients in the United States, including if the outcome events are driven by events in Eastern European subjects, treatment effects are dissimilar in U.S. and non-U.S. patients, or there is an insufficient number of events in U.S. or “U.S.-like” subjects;
- concerns that the tools used to assess our patient-reported measures, the KDQOL Physical Functioning Survey and the Repeated Chair Stand Test, are not sufficiently validated for purposes of regulatory approval; and
- concerns that potential blinding issues could affect our trial results, including patient-reported measures, which are subjective.

If the FDA were to find that the results of our VALOR-CKD trial, either in whole or in part, are inadequate for approval of veverimer, the FDA would not approve our NDA.

***A continued delay in obtaining regulatory approval could further delay commercialization of veverimer and adversely impact our ability to generate revenue, our business and our results of operations and the denial of such approval for veverimer could mean that we need to cease operations.***

If we are not successful in obtaining approval to commercialize veverimer, or are significantly delayed in doing so, our business will be materially harmed, and we may need to curtail or cease operations. We are not permitted to market veverimer in the United States until we receive approval to market veverimer from the FDA. Similarly, we are not permitted to market veverimer in other countries until we receive approval to market veverimer from comparable foreign regulatory agencies.

We currently have no drug products approved for sale, and we may never obtain regulatory approval to market veverimer, either through the FDA's Accelerated Approval Program or the traditional approval process. If we are unable to address the deficiencies identified in the CRL and the concerns identified in the ADL to the satisfaction of the FDA, we will not obtain regulatory approval of veverimer.

The FDA or any foreign regulatory agency can further 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 through FDA's Accelerated Approval Program or through traditional approval;
- 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 statistically significant data with the number of endpoint events achieved if the VALOR-CKD trial is terminated in 2022;
- our ability to demonstrate that the results are applicable to the U.S. population or practice of medicine;
- our inability to demonstrate that the clinical and other benefits of veverimer outweigh any safety or other perceived risks;
- our inability to enroll an adequate number of subjects in our ongoing VALOR-CKD trial;
- 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 may require, as a condition of approval, modifications to existing, or additional, nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA's or the applicable foreign regulatory agency's failure to accept the manufacturing processes or third-party manufacturers with which we contract;
- the impact that pandemics, such as COVID-19, may have on the FDA's ability to review our NDA;
- the impact that pandemics, such as COVID-19, may have on our ability to retain an adequate number of subjects in the VALOR-CKD trial, subject compliance with the study protocol, or the power of our ongoing VALOR-CKD trial; 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 our 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 only approve veverimer subject to certain other conditions being met either before or 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 failure can occur at any stage of clinical development.***

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 investigational drug 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 Phase 3 trial, TRCA-301, and our 40-week extension trial, TRCA-301E, for veverimer do not ensure that our ongoing VALOR-CKD trial, or other future clinical trials will demonstrate similar results. Drug 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. Several 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. Additionally, clinical trials must be conducted in a manner that ensures the trial design and operations are carried out in a way that preserves double-blind, placebo-controlled status and maintains clinical trial data integrity. 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 registrational trial, TRCA-301/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 traditional approval process, 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.

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. In addition, results from compassionate use or investigator-initiated research programs, if implemented, may not be confirmed in Company-sponsored trials and/or may negatively impact the prospects for marketing approval for veverimer.

Subject enrollment and retention are significant factors in the conduct of clinical trials and they are affected by many factors, including the size and nature of the patient population, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and subjects' 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. The occurrence of pandemics, such as COVID-19, may negatively impact the ability to enroll, maintain and collect safety and efficacy data on subjects in a clinical trial. Based on feedback from the FDA in its preliminary comments for the Type A meeting received November 4, 2021, we will halt enrollment of additional patients in the VALOR-CKD trial. Due to the time required for enrolled subjects to experience endpoint events, if the VALOR-CKD trial is stopped

early, the number of endpoint events being contributed from subjects in the United States or regions with “U.S.-like” subjects will likely be smaller as a percentage of total events than if the trial were continued until 511 events. If the VALOR-CKD trial is terminated in 2022, the number of endpoint events from subjects in the United States or regions with “U.S.-like” subjects is likely to be less than 10%.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the ethics committees or institutional review boards, or IRBs, of the institutions in which such trials are being conducted, by an independent Data Monitoring Committee, or DMC, 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, significant findings from an inspection of the Company or our clinical trial sites by the FDA or other regulatory agencies, 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 subjects 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 our NDA approval in the United States. Foreign authorities may have similar reservations in accepting data from clinical trials conducted outside of their territory for future marketing approvals outside of the U.S. The CRL issued by FDA questions the applicability of the TRCA-301/TRCA-301E trial findings to the U.S. population and practice of medicine, and based on feedback received from the FDA, we focused later enrollment activities in our ongoing VALOR-CKD trial in the United States, Canada and Western Europe, and subsequently in other non-Eastern European regions (i.e., Latin America and Asia-Pacific). Based on feedback from the FDA in its preliminary comments for the Type A meeting received November 4, 2021, we will halt enrollment of additional patients in the VALOR-CKD trial. As of November 5, 2021, 72% of subjects have been enrolled at Eastern European sites, 11% at U.S., Western European and Canadian sites, and the remainder at Latin American and Asia-Pacific region sites. Additionally, our ongoing VALOR-CKD trial may have a large dropout rate of participants, or a low event rate, which could add time, expense and risk to the completion of the trial and could affect the results of the trial. In addition, the VALOR-CKD trial could be stopped early, which creates additional risks related to study termination and could also affect the results of the trial. Moreover, due to the time required for enrolled subjects to experience endpoint events, if the VALOR-CKD trial is stopped early, the number of endpoint events being contributed from subjects in the United States or regions with “U.S.-like” subjects will likely be smaller as a percentage of total events than if the trial were continued until 511 events. If the VALOR-CKD trial is terminated in 2022, the number of endpoint events from subjects in the United States or regions with "U.S.-like" subjects is likely to be less than 10%. We cannot assure you that the FDA will accept the VALOR-CKD data in support of an NDA resubmission or approval and the acceptability of the data will ultimately be a review issue.

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 subjects 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 consultants, CROs, other third-party contract service providers and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, other third-party contract service providers and trial sites;
- successfully execute contractual obligations by our consultants, CROs, other third-party contract service providers and clinical trial sites;
- obtain ethics committee or IRB approval at each site;
- recruit suitable trial subjects across an adequate number of suitable clinical trial sites and have such subjects remain on study drug, complete the clinical trial or return for post-treatment follow-up;
- ensure that clinical sites follow the trial protocol, comply with GCP, and continue to participate in a clinical trial;

- address any subject safety concerns that arise during the course of a clinical trial;
- ensure that subjects comply with and complete clinical trial protocols;
- 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 protocols or drop out of a clinical trial;
- ensure that the clinical trial design and operational integrity are conducted in a manner that preserves double-blind placebo-controlled status and maintains clinical trial data integrity;
- address any conflicts with new or existing laws or regulations;
- manufacture sufficient quantities of drug candidate for use in clinical trials and ensure clinical trial material is provided to clinical sites in a timely manner;
- adequately deal with the impact of pandemics, such as COVID-19; and
- adequacy of and compliance with the statistical analysis plan used to evaluate the clinical trial data.

If we experience delays in the start or completion of, or termination of, any clinical trial of our sole investigational drug 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 conducting CKD trials is particularly difficult because of the serious nature of the disease and the comorbidities experienced by these patients. If we obtain FDA approval for veverimer, differences in the safety and efficacy profile not identified in our prior clinical trials may first appear after we obtain approval and commercialize veverimer. For example, any new postmarketing adverse events may significantly impact our ability to market veverimer and may require that we make changes to the product label that could adversely impact our commercialization efforts, recall some or all of the product, or discontinue commercialization of the product. Furthermore, if we are able to obtain accelerated approval of veverimer and if the ongoing VALOR-CKD trial 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, consultants 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 GCP and the trial protocol, statistical analysis plan and other trial-specific documents (for example, safety management, clinical monitoring and blinding plans). Responsibilities of these third parties include, but are not limited to, monitoring of the trial sites and ensuring that the trial is conducted in compliance with International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, guidelines and GCP, the informed consent process, protocol-specified requirements, safety reporting requirements, data collection guidelines and all trial-specific blinding procedures.

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 GCP guidelines and other applicable GCP guidelines 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 GCP, 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 be impacted by pandemics, such as COVID-19, and/or 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, package and label our clinical drug supply of veverimer drug substance and drug product, and we intend to rely on third parties to produce, package and label 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, package and label veverimer on a clinical or commercial scale. As such, we contract with third-party service providers to manufacture veverimer drug substance and drug product, to perform analytical testing services and to package and label the product under cGMPs. Pharmaceutical manufacturing, testing and packaging 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 that can consistently or reliably be converted into drug product and meet any other requirements of our third-party suppliers, or 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 requirement, 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 commercialize veverimer, if approved, and materially adversely affect our financial condition.

***We currently depend on single third-party suppliers for the manufacture of veverimer drug substance and drug product, and 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 cannot be certain that our drug substance supplier will continue to provide us with sufficient quantities of veverimer drug substance, or that our drug product manufacturer 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. Further, even if we were able to identify an alternative third-party supplier, such supplier would be subject to significant technical and regulatory requirements. 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 entered into a commercial supply agreement with our current drug substance supplier. Our long-term commitment under the commercial supply agreement to purchase veverimer drug substance could create a significant financial obligation. 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 our contract manufacturer to produce veverimer could be impacted adversely. Effects of such supply interruption could include limiting veverimer's ability to reach its market potential or to be timely launched, possible delays or shortages in supply, or our impaired 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 and drug product 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 or the impact of a pandemic, such as COVID-19, may significantly impair our ability to manufacture veverimer on a timely basis.

***Any performance failure or time delay in further optimizing or scaling our drug substance and/or drug product manufacturing processes could materially adversely affect, delay or interrupt the execution of our ongoing VALOR-CKD trial and potentially impact the commercialization of veverimer, if approved.***

At this time, we believe we have sufficient drug substance and access to sufficient drug product manufacturing capacity to supply the anticipated demand of our ongoing VALOR-CKD trial. However, at this time, further increases in our drug substance manufacturing capacity will be required to meet our anticipated commercial demand, if approved. 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. Any difficulties experienced in the ongoing effort to further optimize and scale our drug substance and/or drug product manufacturing processes could materially adversely affect or delay our ability to (i) have sufficient quantities of veverimer drug substance and drug product manufactured to successfully conduct our ongoing VALOR-CKD trial, or (ii) 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.***

Once a product receives marketing approval, the manufacturing, distribution, processing, formulation, packaging, labeling, promotion and sale of pharmaceutical products are subject to extensive regulation by federal and state agencies, which are subject to change by the relevant federal, state and local agencies. For example, Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act, or DSCSA, has imposed new "track and trace" requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. The DSCSA requires product identifiers (i.e., serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. These requirements (some of which are still being phased in) preempt state drug pedigree requirements.

We do not currently have the infrastructure necessary for distributing pharmaceutical products to patients and there is a risk that we may be unable to comply with the serialization requirements of the DSCSA within the necessary time frames. Furthermore, compliance with the DSCSA or any future federal or state electronic pedigree requirements may increase the Company's operational expenses and impose significant administrative burdens.

While we have entered into a contract with a third-party logistics company to warehouse veverimer and distribute it, the distribution network will require significant coordination with our internal teams. Failure to coordinate financial systems could negatively impact our ability to accurately report product revenue. If we are unable to effectively establish and manage a compliant 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, third-party payers and the medical community.***

Even if we obtain FDA or other regulatory approvals, veverimer may not achieve market acceptance among physicians, patients, third-party 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 effectiveness of our commercial organization and distribution channels;
- the quality of our relationships with patient advocacy groups;
- the availability and sufficiency of third-party coverage and reimbursement;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective chronic daily treatment;
- willingness of physicians to prescribe veverimer and willingness of patients to try new treatments;
- 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;
- the impact of pandemics, such as COVID-19, on physician prescribing habits and patient prescription fulfillment and dosing compliance; 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 investigational drug 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.***

The pharmaceutical market is highly competitive and dynamic, and is characterized by rapid and substantial technological development and product innovations. The risk of competition is specifically important to us because veverimer is our only investigational drug candidate. Failure to compete effectively against available options or new products for treatment of patients with CKD would materially harm our business, financial condition and results of our operations. In particular, veverimer may not be able to compete effectively with non-approved options for increasing serum bicarbonate levels, existing drugs approved for the treatment of CKD, or other new drugs that may be developed by competitors.

We are not aware of any therapies approved by the FDA for the chronic treatment of metabolic acidosis and we expect veverimer to compete against non-approved options for increasing serum bicarbonate levels, including oral alkali supplementation such as sodium bicarbonate, sodium citrate or potassium citrate. We are aware, however, that AstraZeneca is conducting a clinical trial to explore the use of sodium zirconium cyclosilicate in patients with hyperkalemia and metabolic acidosis associated with chronic kidney disease.

In addition, if veverimer were to be approved for the treatment of slowing of CKD progression, we could face potential competition from sodium-glucose co-transporter-2 inhibitors, or SGLT2i, renin-angiotensin-aldosterone system inhibitors, or RAASi, mineralocorticoid receptor antagonists, or MRAs, or other products that are used for treatment of patients with CKD.

Our veverimer development program may serve as a template for a fast follower to develop a competing drug 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.

***We currently have no commercial capabilities. If we are unable to establish effective commercial 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 no commercial 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 through the deployment of specialty account managers who will target that subset of nephrologists most focused on treating patients with CKD. Building the requisite sales, marketing and 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 and retain 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 anti-corruption laws and 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, or health crises.

***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 compassionate use or investigator-initiated research programs, or veverimer used 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 effects experienced by more patients on veverimer than placebo in the TRCA-101 and TRCA-301/TRCA-301E trials combined were mild to moderate diarrhea and flatulence. It is possible that the FDA may ask for additional data regarding such matters. In addition, patients with CKD 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 patients with CKD, if significant DDIs occur in the future, veverimer may no longer be compatible with some of the medications used to treat patients with CKD. 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-E1: *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 submitting our NDA in August 2019, the veverimer safety database was 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 believed our proposed safety database was adequate for the FDA to file the veverimer NDA and review it under the Accelerated Approval Program, which the FDA did. In August 2020, we received a CRL from the FDA related to our NDA for veverimer. According to the CRL, if and when the Company resubmits its NDA for veverimer, it should include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b), including updated data from all nonclinical and clinical studies/trials of veverimer, as available.

***Our investigational drug 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 cause us, the DMC, regulatory authorities or the ethics committee/IRB to interrupt, delay, suspend or (temporarily) halt clinical studies, adversely affect patient enrollment in clinical studies, result in a negative opinion of our marketing authorization application by the EMA or the UK Medicines and Healthcare products Regulatory Agency, or MHRA, or result in the delay, denial or withdrawal of regulatory approval by the FDA, the European Commission, the MHRA, or other competent regulatory authorities. Undesirable side effects also could result in regulatory authorities mandating additional clinical testing prior to approval, postmarketing testing following approval, the implementation of risk minimization measures or a more restrictive prescribing label/indication 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 trials, including trials conducted under compassionate use or investigator-initiated research programs, or were not 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 $20.0 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 limits. 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 trial 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.

***If we fail to attract and keep senior management and other key personnel we may be unable to successfully develop veverimer, manufacture drug substance and drug product, conduct our clinical trials, obtain regulatory approval 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 and other key personnel. 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. As such, an extended delay in the approval of veverimer could impact our ability to attract and retain qualified senior management and other key personnel.

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. Further, an extended delay in the approval of veverimer could impact our ability to attract and retain qualified personnel. We will need to hire additional personnel if 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 or inappropriate activity by our employees, independent contractors, consultants, commercial partners and vendors. We have 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 comply with applicable laws or regulations.

Misconduct by our employees, independent contractors, consultants, commercial partners and vendors could include intentional failures to comply with the FDA or international regulations, provide accurate information to the FDA or other international regulatory bodies, comply with clinical trial standards, 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 or inappropriate 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 or falsification of clinical trial data.

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, natural disasters or national, regional, or global healthcare crises.

***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.***

We issued $200.0 million aggregate principal amount of 3.50% convertible senior notes due 2027, or the Convertible Senior Notes, pursuant to which we pay interest semiannually in arrears at a rate of 3.50% per year. The Convertible Senior Notes mature on May 15, 2027, unless earlier repurchased, redeemed or converted and are not redeemable prior to May 20, 2024. Our ability to make payments on our 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. 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 additional convertible securities, it would result in the issuance of additional shares of our capital stock, which would result in dilution to our stockholders. There can be no assurance we will be in a position to repay these obligations when due.

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.

***Transactions relating to our Convertible Senior Notes may dilute the ownership interest of our stockholders.***

The conversion of some or all of our outstanding Convertible Senior Notes would dilute the ownership interests of existing stockholders to the extent we deliver shares upon conversion of any such Convertible Senior Notes. If the Convertible Senior Notes become convertible under the terms of the indenture governing the Convertible Senior Notes, and if holders subsequently elect to convert the Convertible Senior Notes, we could be required to deliver to them a significant number of shares of our common stock. Any sales in the public market of the common stock issuable upon conversion could adversely affect prevailing market prices for our common stock. In addition, the existence of the Convertible Senior Notes may encourage short selling by market participants because the conversion of the Convertible Senior Notes could be used to satisfy short positions. Additionally, anticipated conversion of such Convertible Senior Notes into shares of our common stock could depress the price of our common stock.

***The conditional conversion feature of the Convertible Senior Notes, if triggered, may adversely affect our financial condition and operating results.***

In the event the conditional conversion feature of the Convertible Senior Notes is triggered, holders of Convertible Senior Notes will be entitled to convert the Convertible Senior Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Senior Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Convertible Senior Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Senior Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

***The accounting method for convertible indebtedness securities that may be settled in cash, such as the Convertible Senior Notes, could have a material effect on our reported financial results.***

Accounting Standards Codification Subtopic 470-20, or ASC 470-20, *Debt – Debt with Conversion and Other Options*, requires us to separately account for the liability and equity components of convertible indebtedness instruments (such as the Convertible Senior Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects our non-convertible indebtedness interest rate. Accordingly, the equity component of the Convertible Senior Notes is required to be included in the additional paid-in capital section of stockholders' equity on our balance sheet at the issuance date, and the value of the equity component is treated as original issue discount for purposes of accounting for the indebtedness component of the Convertible Senior Notes. As a result, we will be required to recognize a greater amount of non-cash interest expense in our statement of operations and comprehensive loss in the current and future periods presented as a result of the amortization of the discounted carrying value of the Convertible Senior Notes to their principal amount over the term of the Convertible Senior Notes. We will report greater net losses (or lower net income) in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the original issue discount and the instrument's non-convertible interest rate. This could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the Convertible Senior Notes.

In addition, under certain circumstances, in calculating earnings per share, convertible indebtedness instruments (such as the Convertible Senior Notes) that may be settled entirely or partly in cash may be accounted for utilizing the treasury stock method, the effect of which is that the shares of common stock issuable upon conversion of the Convertible Senior Notes, if any, are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Convertible Senior Notes exceeds their principal amount. Under the treasury stock method, diluted earnings per share is calculated as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, were issued. In addition, we cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the Convertible Senior Notes, if any, then our diluted earnings per share would be adversely affected. However, if reflecting the Convertible Senior Notes in diluted earnings per share in this manner is anti-dilutive, or if the conversion value of the Convertible Senior Notes does not exceed their principal amount for a reporting period, then the shares underlying the Convertible Senior Notes will not be reflected in our diluted earnings per share.

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40),* or ASU 2020-06, which may change the accounting for the convertible debt instruments described above. Under ASU 2020-06, an entity may no longer be required to separately account for the liability and equity components of convertible debt instruments. This could have the impact of reducing non-cash interest expense, and thereby increasing net income. Additionally, the treasury stock method for calculating earnings per share will no longer be allowed for convertible debt instruments. Rather, the if-converted method will be required. Application of the if-converted method may reduce our reported diluted earnings per share. ASU 2020-06 is effective for public business entities for annual reporting periods, and interim reporting periods within those annual periods, beginning after December 15, 2021 on a prospective basis, and early adoption is permitted. The Company will adopt ASU 2020-06 effective January 1, 2022 and expects to use the modified retrospective method. On adoption, the Company expects to account for the Convertible Senior Notes as a single liability measured at amortized cost resulting in reduced non-cash interest expense due to the de-recognition of the remaining debt discount associated with the equity component.

We cannot be sure whether other changes may be made to the current accounting standards related to the Convertible Senior Notes, or otherwise, that could have an adverse impact on our financial statements.

***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. Additionally, the recently filed securities and shareholder litigation (see Part I, Item 1., Note 5. "Commitments and Contingencies" for description) will require us to incur legal expenses to defend and may result in management time directed towards the litigation.

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.

Additionally, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404(a) of the Sarbanes-Oxley Act. We have been subject to the compliance requirements of Section 404(b) of the Sarbanes-Oxley Act, which has resulted in us incurring substantial expenses and expending significant management efforts to comply with the Act. We currently have only limited internal audit capabilities and utilize an external firm to provide internal audit services. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 or if we identify or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we

could be subject to sanctions or investigations by NASDAQ, the SEC, or other regulatory authorities, which would require additional financial and management resources.

***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 in the United States. 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 choose 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 drug 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, fires, 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, fires, 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.

***An epidemic or pandemic disease outbreak, including the COVID-19 pandemic, could disrupt our business or operations, including by impacting our ability to retain an adequate number of trial subjects and protocol compliance by enrolled subjects in VALOR-CKD. Additionally, such an event could also impact the business or operations of our third-party manufacturers and testing laboratories, our CROs, clinical data management organizations, medical institutions and clinical investigators, the FDA or other third parties with whom we conduct business which could have a material adverse effect on our business, results of operations, financial condition and prospects.***

An epidemic or pandemic disease outbreak, including the COVID-19 pandemic, could severely disrupt our operations or the operations of third parties that we depend on, including our single third-party contract manufacturers, our CROs, clinical data management organizations, medical institutions and clinical investigators, and the FDA and have a material adverse effect on our business, results of operations, financial condition and prospects. While there is significant uncertainty relating to the potential effect of COVID-19 on our business and operations, infections may become more widespread and travel restrictions may worsen.

Together with our investigators, consultants, CROs and other contract service providers, we are regularly assessing the potential impact of the COVID-19 pandemic on retention of subjects in the VALOR-CKD trial, subject compliance with the study protocol, and power of, our ongoing VALOR-CKD trial. At this time, safety monitoring activities, adjudication of endpoint events and provision of clinical trial supplies have not been materially affected by COVID-19. The annualized rate of all-cause mortality in VALOR-CKD is higher than we estimated when designing the trial, in part due to the COVID-19 pandemic. We estimated the study would have an annualized study discontinuation rate, which comprises deaths, subjects lost to follow up and those who withdraw their consent to continue to participate and be followed in the study, of 5%; currently the annualized study discontinuation rate is approximately 7%. In addition, the COVID-19 pandemic may impact how subjects feel and function in general which may impact their responses to the subjective physical function measurements used in the trial. To the extent current trends continue, there may be negative impacts on the trial in the future, including but not limited to patient retention, subject compliance with the study protocol and powering due to the impact of COVID-19.

As COVID-19 continues to rapidly spread and even after its spread slows, we may experience various temporary and/or permanent disruptions that could materially adversely affect our business, financial condition, results of operations and prospects, including:

- interruptions or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact approval timelines, including delays or difficulties in FDA trial site visits;
- any impact on our third-party manufacturers or their service, raw material or equipment providers could delay the availability of drug substance or drug product for clinical or commercial use;
- delays and other interruptions in our supply chain of veverimer that may affect our commercial launch and sales of veverimer;
- increased rates of subjects withdrawing from our ongoing VALOR-CKD trial, or stopping study drug treatment, following enrollment as a result of contracting COVID-19, being forced to quarantine or general noncompliance with the clinical trial protocol due to potential exposure to COVID-19;
- delays and other interruptions in our supply chain that may affect our clinical sites' receipt of the supplies and materials needed to conduct our ongoing VALOR-CKD trial;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which we conduct our ongoing VALOR-CKD trial which may result in unexpected costs, delays or discontinuance of the trial;
- interruption of key VALOR-CKD clinical trial activities, such as site monitoring, due to limitations on travel imposed or recommended by federal, state or foreign governments, employers and others, or interruption of clinical trial subject visits, data collection and other trial procedures, the occurrence of which could impact compliance with the study protocol and affect the integrity of our clinical trial data;
- risks that participants enrolled in our ongoing VALOR-CKD trial acquire COVID-19 while the trial is ongoing, which could impact the results of the trial, the reliability of the data collected in the trial, hinder the interpretation of the trial results, or otherwise affect the scientific value or medical relevance of the trial, including, without limitation, by increasing the number of deaths or other adverse events;
- risks that our ongoing VALOR-CKD trial is stopped early due to participants enrolled in our ongoing VALOR-CKD trial acquiring COVID-19 while the trial is ongoing, which could impact the results of the trial;
- risks that participants enrolled in our ongoing VALOR-CKD trial who acquire COVID-19 may drop out of the trial or die, which could potentially impair our ability to accrue the required number of primary endpoint events;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of medical facilities serving as trial sites for our ongoing VALOR-CKD trial and medical staff supporting the conduct of the trial;
- volatility in the price of our common stock causing difficulties in raising funds on acceptable terms; and

- limitations on employee resources that would otherwise be focused on conducting our ongoing VALOR-CKD trial and potential subsequent NDA resubmission including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions.

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

Despite the implementation of security measures, we and our CROs and other contractors and consultants regularly defend against, mitigate and respond to data security incidents, cybersecurity attacks or other IT business continuity risks, and our systems and data are vulnerable to damage from computer viruses, cyber attacks, data loss, ransomware, phishing attacks, industrial espionage, other unauthorized access, technological or human error, natural disasters, terrorism, war and telecommunication and electrical failures. Our defenses and cybersecurity response efforts may not be sufficient to mitigate the effects of a significant data security incident. Such events could cause interruptions to our operations and result in material disruptions to our drug development programs. For example, the compromise, corruption, loss or theft of clinical trial data from completed or ongoing clinical trials for our investigational drug candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Certain persons and entities may attempt to penetrate our network, the systems hosting our website or our other networks and systems and may otherwise seek to misappropriate our proprietary or confidential information. Our, or our CROs, contractors, consultants and other third-party service provider's back-up and redundant systems may be insufficient or may fail. To the extent that any disruption or security breach were to result in a compromise, corruption, loss or theft of or other damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and significant costs in remediating the incident, complying with regulatory requirements and defending against claims or regulatory investigations. We may be required to expend significant resources in the response, containment, mitigation of cybersecurity incidents as well as in defense against claims that our information security was unreasonable or otherwise violated applicable laws or contractual obligations. Such events could also adversely affect our competitive position, our reputation could be harmed and the further development of our investigational drug candidate could be delayed.

***We are subject to evolving privacy and data protection laws, including the Health Information Portability and Accountability Act, or HIPAA, the E.U. and U.K. General Data Protection Regulation (collectively, the "GDPR"), and various comprehensive U.S. state privacy laws like the California Consumer Protection Act, or CCPA. If we fail to protect personal information or comply with existing or future data protection regulations, our business, financial condition, results of operations and prospects may be materially adversely affected.***

Numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability, integrity, and other processing of personal information. HIPAA establishes a set of national privacy and security standards for the protection of protected health information (as defined in HIPAA), or PHI, by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. HIPAA requires covered entities and business associates, such as us, to develop and maintain policies with respect to the protection of, use and disclosure of electronic PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a data breach.

By virtue of our clinical trial activities in Europe, we are also subject to European data protection laws, including the GDPR (as implemented in the European Economic Area, or EEA and the United Kingdom, or U.K.). The GDPR establishes stringent requirements applicable to the processing of personal data (i.e., data which identifies an individual or from which an individual is identifiable), affords various data protection rights to individuals (e.g., the right to erasure of personal data) and imposes potential penalties for serious breaches of up to 4.0% annual worldwide turnover or €20 million/ £17.5 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 the GDPR, or the exercise of individual rights under the GDPR, would limit our ability to have access to and/or to utilize clinical trial data collected on study subjects. The GDPR imposes 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. The GDPR also prohibits the international transfer of personal data from the EEA/U.K. to countries outside of the EEA/U.K. unless made to a

country deemed to have adequate data privacy laws by the European Commission/U.K. Government (as applicable) or a data transfer mechanism has been put in place. One such data transfer mechanism was the EU-US Privacy Shield, which we are certified to for the facilitation of transfers of non-HR data. However, in July 2020 the Court of Justice of the European Union, or CJEU in *Schrems II* declared the E.U.-U.S. Privacy Shield to be invalid for purposes of international transfers of personal data. The CJEU upheld the validity of standard contractual clauses, or SCCs, as a legal mechanism to transfer personal data but companies relying on SCCs will need to carry out a transfer privacy impact assessment, which among other things, assesses laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under SCCs will need to be implemented to ensure an essentially equivalent level of data protection to that afforded in the EEA. The European Commission also recently published new E.U. SCCs which align more closely with the requirements of the GDPR and the *Schrems II* decision and as such, contain more onerous provisions. All new contracts entered into after September 27, 2021 and for which new E.U. SSCs are needed, need to incorporate on the new E.U. SCCs and, existing contracts entered into pre- September 27, 2021, will need to transition across to the new E.U. SCCs before the end of 2022. In turn, the findings of the CJEU and the publication of the new E.U. SCCs will have significant implications for cross-border data flows and may result in compliance costs. The new EU SCCs do not automatically apply in the U.K. since Brexit, and the U.K. Government has not yet formally acknowledged the new EU SCCs, i.e., as a valid data transfer mechanism under the U.K. GDPR. On August 11, 2021, the U.K. Information Commissioner's Office launched a public consultation on its draft international data transfer agreement and guidance. This included the publication of a draft U.K. addendum that can be used with the new EU SCCs – however, this is unlikely to be finalized before the end of 2021 and as such, for the time being transfers from the U.K. to a third country should continue to be made in reliance on the 'old' SCCs. The results of the consultation process and the clarification of obligations for data transfers from the U.K. may result in additional compliance costs. The new EU SCCs do not automatically apply in the U.K. since Brexit, and the U.K. Government has not yet formally acknowledged the new EU SCCs, i.e., as a valid data transfer mechanism under the U.K. GDPR. On August 11, 2021, the U.K. Information Commissioner's Office launched a public consultation on its draft international data transfer agreement and guidance. This included the publication of a draft U.K. addendum that can be used with the new EU SCCs – however, this is unlikely to be finalized before the end of 2021 and as such, for the time being transfers from the U.K. to a third country should continue to be made in reliance on the 'old' SCCs. The results of the consultation process and the clarification of obligations for data transfers from the U.K. may result in additional compliance costs.

In addition, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business.

In addition, we are subject to various U.S. state laws, including the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020. The CCPA, among other things, requires covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and gives such consumers certain qualified privacy rights, including the right to opt-out of certain sales of personal information. While the CCPA includes certain exemptions for data protected by HIPAA or in certain research contexts, the law covers a wide range of data we may process. The CCPA permits the imposition of civil penalties enforced by the California Attorney General and provides a private right of action for consumers in the event of a breach. Interpretations of the CCPA may continue to evolve with regulatory guidance, and the CCPA will be further amended, through the California Privacy Rights Act that passed by popular referendum in November 2020, and will go into effect in January 2023. Similarly, we are following the development of new data laws in several states around the country, including the new Virginia Consumer Data Protection Act and Colorado Privacy Act, as well as the potential for federal privacy legislation. We cannot yet predict the impact of the new and evolving privacy laws on our business or operations, these developments may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

**Risks Related to Government Regulation**

***The regulatory approval process is highly uncertain and we may not obtain approval 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 our NDA from the FDA. We have not obtained marketing approval for veverimer anywhere in the world. Obtaining regulatory approval of our NDA, whether through the Accelerated Approval Program or traditional approval process, 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 or untitled 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, or foreign regulatory equivalents.

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 were seeking approval for veverimer through 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 subject to rigorous postmarketing requirements, including the completion of one or more confirmatory postmarketing trials to verify the clinical benefit of veverimer. Thus far, we have been unable to obtain approval of veverimer through the Accelerated Approval Program. In August 2020, we received a CRL from the FDA related to our NDA for veverimer. We held an End-of-Review Type A meeting with the FDA's Division of Cardiology and Nephrology in October 2020. Thereafter, we submitted an FDRR requesting that the OND find that the magnitude of serum bicarbonate change seen in the TRCA-301/TRCA-301E trial is reasonably likely to predict clinical benefit in the treatment of metabolic acidosis associated with CKD and that it can therefore serve as the basis for accelerated approval.

In February 2021, the OND issued a decision on our FDRR. While the OND acknowledged that the TRCA-301 and TRCA-301E trials met their serum bicarbonate endpoints with statistical significance, the OND denied the appeal. In its Appeal Denied Letter, or ADL, the OND not only addressed the issue of magnitude of serum bicarbonate change, but cited all of the deficiencies in the CRL in concluding that the data provided in support of the veverimer NDA did not support approval through the Accelerated Approval Program. The OND concluded that the magnitude of the increases in serum bicarbonate levels shown in the TRCA-301/TRCA-301E trial was not of sufficient size or duration to establish that treatment with veverimer would be reasonably likely to provide a discernible reduction in CKD progression. In addition, the OND found that the intended confirmatory trial, VALOR-CKD (also known as TRCA-303), was underpowered to detect a 13% reduction in slowing of CKD progression. This finding was based on information included in the initial NDA submission, including the placebo-subtracted LS mean change from baseline in serum bicarbonate observed in the TRCA-301/TRCA-301E trial and the original Predictive MA Model. The OND also raised concerns regarding the robustness of the study results given that the veverimer NDA was supported by a single registrational trial (TRCA-301/TRCA-301E), which must, alone, provide persuasive evidence of benefit. Specifically, the OND noted concerns around adequate blinding, the trial results being strongly influenced by a single site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population. The OND also stated that, while trial results in the TRCA-301/TRCA-301E trial showed improvement in two patient-reported measures, the KDQOL Physical Functioning Survey and the Repeated Chair Stand Test, the OND viewed this subjective data

from a single trial with skepticism in the absence of data from a second trial with similar results, and noted that both endpoints would require rigorous blinding to support robust conclusions. However, the OND noted that both of these changes, if eventually established by one or more additional trials, would indicate a potentially meaningful benefit of veverimer treatment—especially in CKD patients who have physical functional impairments. Separate from the ADL, we previously received feedback from the Division of Clinical Outcome Assessment, or DCOA, that reliance on these physical function endpoints for approval may require further validation.

Based on the ADL, we believe that we now have greater clarity on the potential path for approval of veverimer through the Accelerated Approval Program. The OND suggested that we meet with the Division to discuss submission of Week 52 serum bicarbonate results from the full randomized trial population of VALOR-CKD and that the trial should include a substantial portion of patients from the United States or from regions with "U.S.-like" patients. If the results of this trial were to demonstrate that veverimer provides a meaningfully larger treatment effect than seen in the TRCA-301/TRCA-301E trial, then this trial, along with the results from the TRCA-301/TRCA-301E trial, could address the concerns raised in the CRL regarding the limitations and the size of the treatment response observed in the TRCA-301/TRCA-301E trial. However, whether the extent of increase in serum bicarbonate in any subsequent submission based on VALOR-CKD would support accelerated approval would be a review issue, and would, in part, reflect the Division's assessment of the adequacy (i.e., power) of VALOR-CKD to detect the anticipated treatment effect of CKD progression in a reasonable timeframe.

We believe the timeline to meet the requirements for accelerated approval as suggested in the ADL may not result in the most rapid pathway for resubmission of the NDA for veverimer or be achievable with our current resources. Based on the current enrollment rate, the week 52 serum bicarbonate data from the fully enrolled VALOR-CKD trial suggested in the ADL would not be available until at least early 2023 but there are scenarios where renal outcomes data from the VALOR-CKD trial would become available earlier and could potentially enable resubmission of the NDA through the traditional approval process, but it may or may not be sufficient. At this time, we no longer believe it is practical to pursue approval on the basis of serum bicarbonate data alone and we are focused on obtaining outcomes data from the VALOR-CKD trial.

There is a substantial likelihood that we will not have, or be able to obtain on reasonable terms in the necessary timeframe, adequate resources to continue the VALOR-CKD trial until we reach the current target of 511 subjects with positively adjudicated primary endpoint events, which we anticipate would not be reached until 2024. As such, we have considered various options to terminate the VALOR-CKD trial early. We requested and were granted a Type A meeting with the FDA to discuss approaches to stopping the VALOR-CKD trial early based on financial resources and the procedures for study close-out. Consistent with feedback provided by the FDA in its preliminary comments for the Type A meeting, we believe that, among the alternatives considered, stopping the VALOR-CKD trial early for administrative reasons pursuant to the existing protocol is likely to provide the most complete and interpretable data, reduce the risk of missing data required for key efficacy analyses, and maintain the integrity of the trial. While the exact timing of the administrative stop will be determined by our financial runway, we anticipate that an administrative stop would occur in the first half of 2022. Accordingly, we are not likely to conduct the 250-event interim analysis. Based on feedback from the FDA, we will halt enrollment of additional patients in the VALOR-CKD trial in order to focus resources on maximizing the duration of follow-up in subjects who are currently enrolled in the trial. Stopping the VALOR-CKD trial early could increase the risk that the trial will not be successful. For the VALOR-CKD trial to be successful if stopped early, veverimer will need to demonstrate greater efficacy compared to placebo than if the trial were continued to 511 subjects with primary endpoint events. Even if the VALOR-CKD trial meets its primary endpoint, the data obtained from the trial may not be sufficient to support a resubmission and/or approval of the NDA.

We believe data from VALOR-CKD will be very important in furthering our understanding of, and informing decisions regarding, the appropriate regulatory path for resubmission of the NDA for veverimer. For example, if the VALOR-CKD trial is stopped in 2022, additional data on the effect of veverimer on (1) CKD progression; (2) physical functioning; and (3) serum bicarbonate will become available then. As such, we intend to continue the execution of the VALOR-CKD trial with consideration of both the accelerated and traditional approval pathways. Regardless of the regulatory pathway, the FDA's acceptance of the VALOR-CKD data in support of an NDA resubmission, including its assessment of the magnitude and durability of the veverimer treatment effect across the various geographical regions where the study is conducted and the acceptability of the data from non-U.S. countries or regions which will comprise a substantial proportion of the data from the trial, will ultimately be a review issue. Resubmission and approval of the veverimer NDA could also require additional clinical data beyond that provided by the VALOR-CKD trial.

We may decide to pursue a traditional approval process for veverimer rather than accelerated approval. In such case, the FDA could determine that our VALOR-CKD trial as supported by our TRCA-301/TRCA-301E trial may not be sufficient to support approval through the traditional approval process. Results from nonclinical and clinical trials and studies can be interpreted in different ways. Even if we believe the clinical data for our drug candidate is promising, such data may not be sufficient to support approval by the FDA and other regulatory agencies.

Both accelerated and traditional 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 investigational drug 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.

***The design of our VALOR-CKD trial 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, or we may decide to stop the trial early. Stopping the VALOR-CKD trial early could increase the risk that the trial will not be successful. Even if the VALOR-CKD trial meets its primary endpoint, the data obtained from the trial may not be sufficient to support a resubmission and/or approval of the NDA.***

If 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, impacts the VALOR-CKD trial design, we may be required to modify our planned clinical trials, or conduct additional clinical trials, before we can obtain regulatory approval from the FDA or comparable foreign authorities, and any such modification or additional trial could have a material adverse effect on our expected clinical and regulatory timelines, business, prospects, financial condition and results of operations. There is a substantial likelihood that we will not have, or be able to obtain on reasonable terms in the necessary timeframe, adequate resources to continue the VALOR-CKD trial until we reach the current target of 511 subjects with positively adjudicated primary endpoint events, which we anticipate would not be reached until 2024. As such, we have considered various options to terminate the VALOR-CKD trial early. We requested and were granted a Type A meeting with the FDA to discuss approaches to stopping the VALOR-CKD trial early based on financial resources and the procedures for study close-out.

Consistent with feedback provided by the FDA in its preliminary comments for the Type A meeting, we believe that, among the alternatives considered, stopping the VALOR-CKD trial early for administrative reasons pursuant to the existing protocol is likely to provide the most complete and interpretable data, reduce the risk of missing data required for key efficacy analyses, and maintain the integrity of the trial. While the exact timing of the administrative stop will be determined by our financial runway, we anticipate that an administrative stop would occur in the first half of 2022. Accordingly, we are not likely to conduct the 250-event interim analysis. Based on feedback from the FDA,

we will halt enrollment of additional patients in the VALOR-CKD trial in order to focus resources on maximizing the duration of follow-up in subjects who are currently enrolled in the trial. Stopping the VALOR-CKD trial early could increase the risk that the trial will not be successful. For the VALOR-CKD trial to be successful if stopped early, veverimer will need to demonstrate greater efficacy compared to placebo than if the trial were continued to 511 subjects with primary endpoint events. Even if the VALOR-CKD trial meets its primary endpoint, the data obtained from the trial may not be sufficient to support a resubmission and/or approval of the NDA.

***We are conducting and may in the future conduct clinical trials for our investigational drug 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 GCP, 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, which may be affected by factors such as differences in clinical conditions or study populations.

We conducted the TRCA-101 and TRCA-301/TRCA-301E trials, and are conducting the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our investigational drug candidates outside the United States. In the TRCA-301 trial, 190 trial subjects were located in Eastern Europe, and 27 trial subjects were located in the U.S. In the TRCA-301E trial, 179 trial subjects were located in Eastern Europe and 17 trial subjects were located in the U.S. The CRL issued by the FDA questions the applicability of the TRCA-301/TRCA-301E trial findings to the U.S. population and practice of medicine. In the VALOR-CKD trial, 72% of the current trial subjects are located in Eastern Europe. If the VALOR-CKD trial is terminated in 2022, the number of endpoint events from subjects in the United States or regions with "U.S.-like" subjects is likely to be less than 10%. In VALOR-CKD, we intend that no single site in the VALOR-CKD trial provides ≥ 5% of the total number of trial subjects. However, if the trial is terminated in 2022, it is possible that one or more sites may slightly exceed this threshold. The FDA may not find such foreign clinical data to be applicable to U.S. patients or the U.S. practice of medicine, due to the potential differences in patient management, including diet and concomitant medications, may have on the treatment effect of veverimer. Based on feedback received from the FDA, in November 2020 we elected to focus enrollment activities in the VALOR-CKD trial in the United States, Canada and Western Europe; however, we subsequently reinitiated enrolling subjects in Latin America and Asia-Pacific as well. Based on feedback from the FDA in its preliminary comments for the Type A meeting received November 4, 2021, we will halt enrollment of additional patients in the VALOR-CKD trial. Despite our focus on geographic areas outside Eastern Europe for enrollment, the FDA may not be reassured that results of our VALOR-CKD trial are relevant to the U.S. population or practice of medicine. In which case, we could be required to conduct one or more additional 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 as well as new legislation addressing issues related to patient safety, patient rights and data integrity in clinical trials could result in delays or increased costs to assure compliance. In addition, if a drug receives approval through the FDA's Accelerated Approval Program, it will be subject to special postmarketing requirements, including the completion of 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 postmarketing trial with due diligence, a 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, it may 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, manufacturers' facilities and testing laboratories are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMP. As such, we, our contract manufacturers and testing laboratories are subject to continual review and periodic inspections to assess compliance with cGMP. Furthermore, we, our contract manufacturers and testing laboratories will be required to comply with FDA Pharmacovigilance, or PV, requirements and PV inspections by the FDA. Accordingly, we must conduct the 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 through the Accelerated Approval Program but we fail to conduct the required 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 or untitled 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.

***We are seeking regulatory approval to market veverimer for the slowing of kidney disease progression in patients with metabolic acidosis and CKD, unless we seek regulatory approval for additional or alternative indications, such as improving physical functioning, we will be prohibited from marketing veverimer for other indications.***

We are seeking FDA approval to market veverimer for the slowing of kidney disease progression in patients with metabolic acidosis associated with CKD, unless we seek regulatory approval for additional or alternative indications, such as improving physical functioning, we cannot be certain what indication and what labeling language will be approved for veverimer, if approved.

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.

***We are 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 are seeking 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.***

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. Data from clinical trials conducted in one country may not be accepted by regulatory agencies in other countries, or regulatory agencies may require that additional clinical trials be conducted in different regions or subpopulations to support a marketing approval application. 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. In order to market any product in the European Economic Area, or EEA, and many other foreign jurisdictions, separate regulatory approvals are required. In the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization by the European Commission or the competent regulatory authorities of the EEA Member States. Before granting a Marketing Authorization, the competent agencies make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Similarly, marketing any product in the United Kingdom requires a marketing authorization granted by the MHRA. 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.

***If we fail to comply or are found to have failed to comply with FDA and other laws and 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 laws and 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 or contracted agents 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, the federal criminal Anti-Kickback Statute, and other alleged violations in connection with the promotion of products for unapproved uses and government reimbursement (e.g., Medicare

and/or Medicaid). 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. Individuals can also be subject to imprisonment, and we can be excluded from participating in federal health care programs, such as Medicare and Medicaid, which means our products may not be reimbursed by federal healthcare programs and other entities that participate in federal healthcare programs cannot contract with us. Any such exclusions, 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.***

The most commonly reported adverse effects experienced by more patients on veverimer than placebo in the TRCA-101 and TRCA-301/TRCA-301E trials combined were mild to moderate diarrhea and flatulence. 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 the 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.

***Disruptions at the FDA and other government agencies caused by global health concerns, including the COVID-19 pandemic, could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA’s ability to perform routine functions. Disruptions at the FDA and other agencies may also slow the time necessary for new

drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through April 2020. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. In July 2020, FDA resumed certain domestic inspections in a prioritized fashion after developing a COVID-19 Advisory Rating system (COVID-19 Advisory Level). In May 2021, the FDA issued a report titled "Resiliency Roadmap for FDA Inspectional Oversight" outlining the agency's inspectional activities during the COVID-19 pandemic and its detailed plan to move toward a more consistent state of operations, including the FDA's priorities related to this work going forward. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA and other agencies to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***We may be subject to healthcare laws, regulation and enforcement; our failure to comply with these laws or regulations, or our potential involvement in enforcement activities, 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, or our contracted third parties, 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, overtly or covertly, 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 does not need to have actual knowledge of this statute or specific intent to violate it. The federal 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 hand. A conviction for violation of the federal 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 have been the subject of recent regulatory reforms. On November 20, 2020, the U.S. Department of Health and Human Services, Office of Inspector General, or OIG, issued two final regulations modifying safe harbors to the federal Anti-Kickback Statute. The first rule, which became effective January 19, 2021, created new safe harbors and modified existing safe harbors to promote certain value-based and coordinated care arrangements and to reduce regulatory burden. The second rule, or the Rebate Rule, created new safe harbors for (i) point-of-sale discounts from pharmaceutical manufacturers to Medicare Part D plans, Medicaid managed care organizations, and their contracted pharmacy benefit managers, or PBMs, and (ii) fixed fees for certain services that PBMs provide to pharmaceutical manufacturers. The Rebate Rule also revised the discount safe harbor to exclude price reductions (e.g., rebates) for pharmaceutical products from manufacturers to Part D plans when made directly or indirectly through a PBM, unless the reduction in price is required by law. Implementation of the Rebate Rule is uncertain due, at least in part, to a change in the U.S. presidential administration and ongoing litigation challenging the Rebate Rule. Specifically, the new safe harbor provisions in the Rebate Rule affecting certain point-of-sale discounts and PBM service fees were initially delayed from January 29, 2021 until March 22, 2021 pursuant to the January 20, 2021 White House memorandum, titled "Regulatory Freeze Pending Review," which directed federal agencies to take steps to facilitate the incoming Biden administration's review of regulatory

actions by the Trump administration, including delaying the effective dates of certain regulations. All provisions of the Rebate Rule were subsequently delayed until January 1, 2023 due to litigation challenging the Rebate Rule with the litigants further agreeing to hold the case in abeyance pending further review of the Rebate Rule by the Biden administration. Most recently, the bipartisan infrastructure legislation passed by the U.S. Senate included a moratorium on implementation of the Rebate Rule before January 1, 2026; however, it is unclear whether or when such legislation will be enacted. Given that implementation of the Rebate Rule is uncertain, we cannot predict the full impact of the rule and any subsequent related regulatory or legislative actions on our future contracts with customers and 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, prohibit 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 $11,665 to $23,331 per false claim or statement for penalties assessed after June 19, 2020, with respect to violations occurring after November 2, 2015. For example, among other things, pharmaceutical companies have been investigated and/or 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 under the federal criminal False Claims Act, which is similar to the federal Civil False Claims Act and imposes criminal liability for making or presenting a false, fictitious 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 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 and healthcare organizations, such as the U.S. federal Physician Payments Sunshine Act, or Sunshine Act, which requires, among other things, "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 and covering payments and other transfers of value during calendar year 2021, physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, 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. Some European countries have adopted laws similar to the Sunshine Act, applicable even in some cases to companies conducting clinical trials but that do not yet have marketing approval;

- 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, foreign governments or governmental bodies, 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 federal Anti-Kickback Statute and FCA which may apply to items or services reimbursed by any third-party payers, 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.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. 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.

Additionally, 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 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, 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 Patient Protection and Affordable Care Act, or 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. The framework of the PPACA continues to evolve as a result of executive, legislative, regulatory and administrative developments that have challenged the law and contribute to legal uncertainty that could affect the profitability of veverimer. 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.” On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge brought by several states arguing that, without the individual mandate, the entire PPACA was unconstitutional. The Supreme Court dismissed the lawsuit without ruling on the merits of the states' constitutionality arguments.

Effective January 1, 2019, the Bipartisan Budget Act of 2018, among other things, further amended portions of the Social Security Act implemented as part of the PPACA to increase from 50% to 70% the point-of-sale discount that pharmaceutical manufacturers participating in the Coverage Gap Discount Program must provide to eligible Medicare Part D beneficiaries during the coverage gap phase of the Part D benefit, commonly referred to as the “donut hole,” and to reduce standard beneficiary cost sharing in the coverage gap from 30% to 25% in most Medicare Part D plans. The Further Consolidated Appropriations Act of 2020, signed into law December 20, 2019, fully repealed the so-called “Cadillac” tax on certain high-cost employer-sponsored insurance plans, for tax years beginning after December 31, 2019; the annual fee imposed on certain health insurance providers based on market share, for calendar year 2021; and the medical device excise tax on non-exempt medical devices, for sales after December 31, 2019. On January 28, 2021, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the PPACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, policies that create barriers to obtaining access to health insurance coverage through the PPACA marketplaces. Most recently, on March 11, 2021, Congress enacted the American Rescue Plan Act of 2021, which included among its provisions a sunset of the PPACA’s cap on pharmaceutical manufacturers’ rebate liability under the Medicaid Drug Rebate Program. Under the PPACA, manufacturers’ rebate liability was capped at 100% of the average manufacturer price for a covered outpatient drug. Effective January 1, 2024, manufacturers’ Medicaid Drug Rebate Program rebate liability will no longer be capped, potentially resulting in a manufacturer paying more in Medicaid Drug Rebate Program rebates than it receives on the sale of certain covered outpatient drugs. The American Rescue Plan Act also temporarily increased premium tax credit assistance for individuals eligible for subsidies under the PPACA for 2021 and 2022 and removed the 400% federal poverty level limit that otherwise applies for purposes of eligibility to receive premium tax credits. In the future, there may be additional challenges and/or amendments to the PPACA. It remains to be seen precisely what any new legislation will provide, when or if it will be enacted, and what impact it will have on the availability and cost of healthcare items and services, including drug products.

In addition, other legislative changes have been adopted since PPACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions in Medicare payments to providers of up to 2% per fiscal year that started in April 2013 and, due to subsequent legislation, will continue into 2031, with the exception of a temporary suspension of the payment reduction from May 1, 2020 through December 31, 2021 due to the coronavirus pandemic, unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012, among other changes, reduced Medicare payments to several types of providers and

increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Future legislative changes may result in additional reductions in Medicare and other government healthcare program reimbursement and/or otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Recently, the cost of prescription pharmaceuticals has been the subject of considerable discussion in the United States at both the federal and state levels. While several proposed reform measures will require Congress to pass legislation to become effective, the Biden administration has expressed support for drug pricing legislation and administrative measures to control prescription drug costs. For example, on July 9, 2021, President Biden issued an Executive Order to promote competition in the U.S. economy that included several initiatives addressing prescription drugs. Among other provisions, the Executive Order stated that the Biden administration will "support aggressive legislative reforms that would lower prescription drugs, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and through other related reforms." The Executive Order also instructed the Department of Health and Human Services to issue a report to the White House within 45 days that includes a plan to, among other things, reduce prices for prescription drugs, including prices paid by the federal government for such drugs. There have also been several recent U.S. Congressional inquiries and proposed and enacted federal and state bills designed to, among other things, lower drug pricing, bring more transparency to drug pricing, review the relationship between pricing and manufacturer-sponsored patient support programs, and reform government program reimbursement methodologies for drugs. For example, the Consolidated Appropriations Act, 2021 included several drug price reporting and transparency measures, such as a new requirement for certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of HHS, Labor, and the Treasury.

At the state level, legislatures and agencies are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including constraints on pricing, discounting and reimbursement; restrictions on certain product access and marketing; cost disclosure and transparency measures that require detailed reporting of drug pricing and marketing information both at product launch and in the event of a price increase; and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. For example, the states of California and Oregon have passed legislation that requires drug manufacturers to notify the state at least 60 days prior to instituting price increases and Maryland passed legislation to create a Prescription Drug Affordability Board that will evaluate drug cost and recommend setting an upper limit or cap for therapies deemed too expensive. We cannot predict what other reforms may ultimately be implemented at the federal or state level or the effect of any future legislation or regulation and, accordingly, face uncertainties that may result from additional reforms and their impact on our operations. Further, 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/or those products for which we may receive regulatory approval in the future.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products, but monitor and control prescription volumes and may issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required for pharmaceutical products and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing and reimbursement negotiations, and these negotiations may continue after a reimbursement price has been obtained. Reference pricing used by various Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and

pricing arrangements for any products having received a marketing authorization either for the whole of the EU or for the respective Member State.

Further, there has been a recent tendency by different Member States to replace, inter alia, high priced pharmaceutical products with a marketing authorization (notably drugs against rare diseases) by copies of such products manufactured in pharmacies, notably in pharmacies of university hospitals, so-called pharmaceutical compounding. In theory, pharmaceutical compounding is reserved for the named patient supply of a product. However, this principle is more and more put aside or circumvented by collecting prescriptions for patients treated with a certain pharmaceutical product in order to manufacture larger amounts of the respective product through pharmaceutical compounding. Thus the market for the pharmaceutical treatment of specific diseases is cornered and, as a result, the effective marketing of pharmaceutical products with a marketing authorization is jeopardized.

***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.***

While we expect patients who have metabolic acidosis and CKD to need chronic treatment, 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, or if reimbursement requires stringent prior authorization or other forms of utilization management, our revenue and gross margins will be adversely affected.

Obtaining coverage and reimbursement 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 coverage to allow us to sell veverimer, if approved, into our target markets. Even if we do obtain coverage, third-party payers periodically review and may question the coverage of, and challenge the prices charged for, our products. 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, manufacturing, sales 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 coverage and 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. Although we may be able to provide co-pay assistance to some patients with commercial healthcare insurance, some commercial health insurance plans limit how this assistance may count towards a patient's deductible and other cost-sharing requirements. 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 investigational drug candidate due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and recent legislative proposals. 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 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 investigational drug 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 been 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. 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 investigational drug 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 are in the process of pursuing registered trademarks for a commercial trade name for veverimer in the United States and elsewhere and failure to secure such registrations could adversely affect our business.***

We are in the process of pursuing registered trademarks for a commercial trade name for veverimer in the United States and 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 or pursue a claim for trademark infringement. 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 investigational drug 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 drug 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 investigational drug 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 investigational drug 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 investigational drug 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 third parties, including our competitors, public interest groups, or investment firms that engage in short selling activities;
- 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 investigational drug 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:

- announcement of a CRL from the FDA related to our NDA;
- announcements related to our Type A meeting with the FDA;
- announcements related to our FDRR with the FDA;
- announcements of an ADL from the OND related to our FDRR;
- announcements of regulatory approval of 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;
- announcements regarding termination of our clinical trial, VALOR-CKD;
- failure to stop our clinical trial following the occurrence of the interim analysis for early stopping for efficacy;
- announcements regarding outcomes data from termination of our VALOR-CKD trial;
- adverse events experienced by the patient population taking veverimer, whether or not related to our investigational drug 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 drug 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;
- announcements regarding shareholder or other litigation;
- 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.

Following announcement of the deficiency letter from the FDA, there was a significant decline in our stock price. An additional decline occurred after our announcement of the results of the End-of-Review Type A meeting in late October 2020. On January 6, 2021, a putative securities class action was filed in the U.S. District Court for the Northern District of California against Tricida, Inc. and its CEO and CFO, Pardi v. Tricida, Inc., et al., 21-cv-00076 (the "Securities Class Action"). In April 2021, the court appointed Jeffrey Fiore as lead plaintiff and Block & Leviton LLP as lead plaintiffs' counsel. In June 2021, the lead plaintiff filed an amended complaint which alleges that during the period between June 28, 2018 and February 25, 2021 (the "Class Period"), Tricida and its senior officers violated the federal securities laws, including under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, through alleged public misrepresentations and/or omissions of material facts concerning Tricida's NDA for veverimer and the likelihood and timing of approval of veverimer by the FDA. The amended complaint makes claims against the Company and its CEO. In July 2021, defendants filed a motion to dismiss the amended complaint and a hearing on the defendants' motion is currently scheduled for December 2021. No damages amount is specified in the Complaint. On February 15, 2021, a derivative action was filed in the District of Delaware, brought by and on behalf of Tricida, Inc. as a Nominal Defendant, against the Company's directors as well as its CEO and CFO, Ricks v. Alpern et al., Case No, 1:21-cv-000205 (the "Ricks Derivative Case"). The Ricks Derivative Case is based on the allegations of the Securities Class Action and asserts that by allowing the Company and senior executives to make the allegedly false and misleading statements at issue in the Securities Class Action, the defendants breached their fiduciary duties and wasted corporate assets. Additionally, the complaint asserts claims against the senior officers for violation of Sections 10(b) and 21D of the Securities Exchange Act of 1934. No damages amount is specified in the Ricks Derivative Case. On April 8, 2021 a second derivative action was filed in the District of Delaware, brought by and on behalf of Tricida, Inc. as a Nominal Defendant, against the Company's directors as well as its CEO and CFO, Goodman v. Klaerner et al., Case No, 1:21-cv-00510 (the "Goodman Derivative Case"). As with the Ricks Derivative Case, the Goodman Derivative Case is based on the allegations of the Securities Class Action and asserts that by allowing the Company and senior executives to make the allegedly false and misleading statements at issue in the Securities Class Action, the defendants breached their fiduciary duties. Additionally, the complaint asserts claims against the senior officers for violation of Sections 10(b) and 21D of the Securities Exchange Act of 1934. No damages amount is specified in the Goodman Derivative Case. On May 27, 2021, a third derivative action was filed in the District of Delaware, brought by and on behalf of Tricida, Inc. as a Nominal Defendant, against the Company's directors as well as its CEO and CFO, Verica v. Veitinger et al., Case No, 1:21-cv-00759 (the "Verica Derivative Case" and collectively with the Goodman Derivative Case and Ricks Derivative Case, the "Derivative Cases"). As with the Goodman Derivative Case and Ricks Derivative Case, the Verica Derivative Case is based on the allegations of the Securities Class Action and asserts that by allowing the Company and senior executives to make the allegedly false and misleading statements at issue in the Securities Class Action, the defendants breached their fiduciary duties. Additionally, the complaint asserts claims for violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 and for unjust enrichment and waste of corporate assets. No damages amount is specified in the Verica Derivative Case. The Derivative Cases have been consolidated by order of the District of Delaware Court and lead plaintiffs' counsel has been appointed. Pursuant to an agreement between the parties, the Delaware court issued an order on October 12, 2021 staying the consolidated derivative case pending final resolution of any motions to dismiss filed in the Securities Class Action. A consolidated derivative complaint has not yet been filed. The defense of the Securities Class Action and the Derivative Cases may cause us to incur substantial costs and may divert the attention of management.

The stock markets in general, and the markets for pharmaceutical and biotechnology stocks in particular, have historically experienced extreme volatility that may have been unrelated to the operating performance of the issuer. Such volatility may continue in the future and may impact our common stock price. The spread of COVID-19, which has caused a broad impact globally, may also materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. 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.

***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 September 30, 2021, we had outstanding a total of 50,447,578 shares. 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, our Employee Stock Purchase Plan, or ESPP, or our 2020 Inducement Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. The number of shares of our common stock reserved for issuance under 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 trading 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.

As of September 30, 2021, all of our outstanding shares of common stock are freely tradable in the public market, other than approximately 18.8 million shares which are subject to trading restrictions. Holders of these shares of our common stock can 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 September 30, 2021, our executive officers, directors, holders of 5.0% or more of our capital stock and their respective affiliates beneficially owned approximately 57.2% 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 15.0% 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.

Furthermore, certain provisions in the Indenture governing our Convertible Senior Notes may make it more difficult or expensive for a third party to acquire us. For example, the Indenture require us, at the holders' election, to repurchase the Convertible Senior Notes for cash on the occurrence of a fundamental change and, in certain circumstances, to increase the conversion rate for a holder that converts its Convertible Senior Notes in connection with a make-whole fundamental change. A takeover of us may trigger the requirement that we repurchase the Convertible Senior Notes or increase the conversion rate, which could make it more costly for a third party to acquire us. The Indenture also prohibits us from engaging in a merger or acquisition unless, among other things, the surviving entity assumes our obligations under the Convertible Senior Notes and the Indenture. These and other provisions in the Indenture could deter or prevent a third party from acquiring us even when the acquisition may be favorable to holders of the Convertible Senior Notes or our stockholders.

***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. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. 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. These choice of forum provisions 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 cash payments for severance and other benefits and acceleration of vesting of stock options 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. 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 50.0% on a cumulative basis during a three-year period by persons or groups of persons owning 5.0% or more of our total equity value. In 2020, the Company performed a Section 382 analysis from inception through June 30, 2020 and concluded that the Company may have experienced multiple ownership changes. The annual limitation may have limited the Company's ability to utilize net operating losses against taxable income in a given year for both federal and state purposes, however, remaining net operating losses and credit will be available in future years before expiration during their respective carryforward periods. Moreover, we cannot provide any assurance that we will not undergo an ownership change in the future and 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 legislation enacted in 2017 commonly referred to as the 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 80.0% 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. Recent legislation ameliorates some of these restrictions for losses incurred through 2020, but due to our lack of taxable income our losses continue to be carried forward past 2020. 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

### 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. None of such payments were direct or indirect payments to any of our directors or officers (or their associates), to persons owning ten percent or more of our common stock or to any other affiliates. As described in our final prospectus filed with the SEC on June 29, 2018 pursuant to Rule 424(b) under the Securities Act, we expect to use the net proceeds from our IPO for supporting our activities for the approval process for veverimer (also known as TRC101), manufacturing activities related to veverimer, conducting our VALOR-CKD trial (also known as TRCA-303), and the remainder for working capital and general corporate purposes, which now include interest payments related to our $200.0 million aggregate principal amount of 3.50% convertible senior notes due 2027 and supporting activities for our New Drug Application resubmission.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

## 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† | Amendment No. 2 to the Manufacturing and Commercial Supply Agreement with Patheon Austria GmbH & Co KG. | Filed herewith | | |
| 10.2^ | Tricida, Inc. Executive Retention Agreement Template Amendment | Filed herewith | | |
| 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 | Furnished herewith | | |
| 101.INS | XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document | | | |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document | | | |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document | | | |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document | | | |
| 101.LAB | Inline XBRL Taxonomy Extension Labels Linkbase Document | | | |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document | | | |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) | | | |
| † | Certain confidential information contained in this exhibit, marked by [***], has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K. | | | |
| ^ | Management contracts and compensation plans and arrangements | | | |

**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: November 8, 2021

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 Operating Officer, Chief Financial Officer and Executive Vice President
*(Principal Financial Officer)*

By: /s/ Annie Yoshiyama
Annie Yoshiyama
Vice President of Finance and Chief Accounting Officer
*(Principal Accounting Officer)*

**Certain information contained in this document, marked by [***], has been omitted because it is both (i) not material and (ii) the type of information that Tricida, Inc. treats as private or confidential.**

## AMENDMENT NO. 2 TO MANUFACTURING AND COMMERCIAL SUPPLY AGREEMENT

This Amendment No. 2 to Manufacturing and Commercial Supply Agreement ("**Amendment No. 2**") is dated as of August 26, 2021 (the "**Amendment No. 2 Effective Date**") and is entered into between Patheon Austria GmbH & Co KG, with its principal offices located at St. Peter Strasse 25, A-4020 Linz, Austria ("**Patheon**"), and Tricida, Inc., a Delaware corporation, with its principal offices located at 7000 Shoreline Court, Suite 201, South San Francisco, CA 94080 ("**Tricida**"), in order to amend that certain Manufacturing and Commercial Supply Agreement between the parties dated as of October 4, 2019, as amended by Amendment No. 1 dated March 30, 2021 (collectively, the "**Agreement**"). Each of Patheon and Tricida are sometimes referred to herein as "**Party**" or "**Parties**".

WHEREAS, following the [***] of [***] for the [***] (also referred to as the [***]), the Parties wish to further modify the obligations of the Parties under the Agreement as set forth herein.

NOW, THEREFORE, the Parties hereby agree as follows:

1. Changes to Manufacturing Schedule.

   a. [***]. The [***] described in Section 5(b) of Amendment 1 to the Agreement will be [***] to [***] designated as the "[***]". The [***] teams of both Parties jointly developed the [***] (defined therein) for the [***] which is attached hereto as Appendix 1 (the "[***]"). The [***] will [***] and [***] according to the schedule set forth in the [***]. The Parties agree to work in good faith to assess the [***] during the [***] and [***], if any, to the [***]. In the event that the Parties are [***] within the [***], the Parties will work in good faith to assess what [***], and will schedule [***]. If the [***] set forth in the [***] are [***] by [***] (as may [***] as described above), the Parties will, acting in good faith, mutually agree [***] on the need for [***]. In consideration for the foregoing, Tricida will pay Patheon [***] for the Services described in the [***], with [***] payable in [***] and [***] payable in [***]. Any [***] of the [***] that is being conducted in the [***] shall be compensated [***] by Tricida based on the [***] and shall be modeled after the [***] described in the Agreement (so that Patheon will be compensated as if [***]).

   b. Payment for [***]. Without prejudice to other aspects of this Amendment No. 2 or waiving any of its other rights under the Agreement, Tricida agrees to pay Patheon at [***] upon delivery for the amount of [***] Product that meets the Product Warranty. The Parties currently anticipate the quantities to be delivered from the [***] will be approximately [***] at [***], which does not include [***] in which [***] and which are currently the subject of a [***]. Whether the [***] from the [***] can be Released and delivered to Tricida in [***] will be dependent on [***]: i) a [***] for the [***] is identified during the [***] (or during a [***] of the [***]as described in Section 1a above) based on [***] by the Parties, a [***] to support [***] of the [***] is [***], and the [***] teams of both Parties, acting reasonably and in good faith, mutually agree and finalize the [***] the Product by [***] (or, in case of [***] of the [***], by end of [***]); and ii) [***] of TRC-101 meeting [***] during the [***]. If [***] i and ii above are [***], the [***] from the [***] shall be delivered to Tricida and Patheon shall

invoice Tricida [***]. For the sake of clarity, the Parties agree that [***], which is also the subject of the aforementioned [***], but was [***], will [***] and Tricida will [***] Patheon [***].

c. [***]. The Parties agree that the [***] will be [***] to allow for the [***] within the [***] to the [***]. All references throughout the Agreement and Amendment No. 1 to the [***] shall be void, and neither Party shall have any obligation to the other Party for the [***].

d. [***] Pricing. The Parties agree that the amount of [***] (representing the [***] between the payment amount previously agreed upon for the [***] and the payment amount described herein for the [***], [***] the cost of [***]) will be [***] of Product delivered that meets the Product Warranty in the [***], effectively [***] the cost by [***] based [***]. To the extent that additional [***] are [***] during the [***] to [***] the [***] as described in Section 1a above, thereby [***] on a [***] the [***] that can be Manufactured in the [***], the amount of [***] will [***] over the [***]. Subject to the conditions stated above, Tricida agrees to pay this [***] for Product Manufactured in the [***] that is Released and meets Product Warranty. In the event that the [***], Tricida will – in lieu of the above described [***] – make a [***] payment to Patheon at the conclusion of the [***] in the amount of [***]. For clarity, this [***], if at all applicable, is in [***] to the compensation payable by Tricida for the [***] of the [***] that is being conducted in the [***]. It is the understanding of both Parties that [***] in the amount of approximately [***] are [***] in the price above (planned at the [***]) and will be separately payable by Tricida subject to standard and reasonable documentation.

2. [***]. Section 9 of Amendment No. 1 is hereby deleted in its entirety and replaced with the following:

"Based on [***] and [***] from the [***], the [***] teams of both Parties, acting reasonably and in good faith, will jointly agree on a [***] and appropriately document [***] as set forth in the [***]. In addition, it is the expectation of the Parties that [***] and that relevant [***], especially as it relates to [***]."

3. Miscellaneous. All capitalized terms used herein that are not otherwise defined shall have the meaning given to them in the Agreement. All references to Sections and Exhibits shall refer to Sections and Exhibit to the Agreement unless otherwise specifically stated. Except as expressly amended above, all the terms and conditions of the Agreement remain unchanged and in full force and effect. The Agreement, as amended by this Amendment No. 2, contains the entire understanding of the Parties with respect to the subject matter hereof. This Amendment No. 2 may be executed in counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same agreement. No modification, amendment, or waiver of this Amendment No. 2 will be effective unless in writing and executed and delivered by the Parties.

IN WITNESS THEREOF, the Parties have entered into this Amendment No. 2 as of the Amendment No. 2 Effective Date.

[Signature Page Follows]

**PATHEON AUSTRIA GMBH & CO KG** **TRICIDA, INC.**

**By:** _____ **By:** _____

**Name:** _____ **Name:** _____

**Title:** _____ **Title:** _____

**By:** _____ [***]

**Name:** _____ [***]

**Title:** _____

**APPENDIX 1**

**[***]**

[***]

**Exhibit 10.2**

# 2020 Retention Agreement Amendment

Dear <<Employee Name>>,

In recognition of the important role you have today and in anticipation of your contributions moving forward, Tricida, Inc. ("Company") previously offered you retention awards in the form of equity and cash pursuant to the terms of a Retention Agreement, dated September 10, 2020 (the "2020 Retention Agreement"). The equity and cash awards were also granted pursuant to, and subject to the terms of, the Tricida, Inc. 2018 Equity Incentive Plan (the "2018 Plan"), the applicable award agreement and the Terms and Conditions provided below. We are pleased to inform you that on October 18, 2021, the Compensation Committee of the Board of Directors ("Committee") approved certain amendments to the 2020 Retention Agreement, which we believe make the awards more attractive from an employee's perspective and support our objectives of retaining and incentivizing our employees during this critical period for the Company.

**Equity Awards**

You received a stock option grant that was originally scheduled to vest in three (3) tranches conditioned upon the successful completion of the applicable performance milestone. The Committee has amended the criteria for vesting to include two additional performance milestones, which must be achieved by December 31, 2022, subject to the terms of the Stock Option Agreement. Any portion of the option that does not vest based on completion of the performance milestones prior to December 31, 2022 will automatically be forfeited and canceled for no consideration. Vesting is capped at 100% of the shares subject to the stock option grant regardless of whether we achieve all of the performance milestones set forth below.

1) NDA resubmission - 25% vest
2) NDA approval – 50% vest
3) Commercial launch - 25% vest
4) *New Performance Milestone:* [Performance Milestone]
5) *New Performance Milestone:* [Performance Milestone]

**Cash Retention Awards**

You were previously awarded four (4) Cash Retention Awards under Article IV (Performance Awards) of the 2018 Plan, with each award valued at [XX]% of your then-current 2020 base salary and payable upon the successful completion of the performance milestones. You have already received payment for the first Cash Retention Award based on the occurrence of an End-of-Review Type A meeting in October 2020.

The Committee has amended and superseded the performance milestones necessary to receive the three remaining Cash Retention Awards, conditioned upon the successful completion of these performance milestones by December 31, 2022, and provided that you otherwise meet the Cash Retention Award Terms and Conditions provided below.

1. Type A meeting to occur by December 31, 2020 (achieved)
2. *New Performance Milestone:* Successful execution on VALOR-CKD, including subject recruitment and retention and event rate, as determined by the Committee
3. *New Performance Milestone:* [Performance Milestone]
4. *New Performance Milestone:* [Performance Milestone]

For the avoidance of doubt, the original performance milestones for NDA resubmission, approval and commercial launch by December 31, 2022 are no longer in effect for the Cash Retention Awards.

The equity and cash awards described above shall be subject to taxes and other required deductions.

Except as otherwise provided herein, all other terms and conditions of your 2020 Retention Agreement are unchanged. In order to reflect this change, we ask that you confirm acceptance of the modification of the performance milestones by signing in the space below.

Thank you for all your hard work and commitment to the Company and veverimer. We look forward to your continued contribution in 2021 and beyond.

Sincerely,

Acknowledgment, Acceptance and Agreement:

By signing below and returning this Amendment to Tricida, Inc., I hereby acknowledge and agree to be bound by the terms and conditions of this Amendment.

_____

Name: _____

Date: _____

# Cash Retention Award Terms and Conditions

Your right to the payment of the Cash Retention Award is subject to the achievement of the performance milestones and the following Terms and Conditions:

- You are actively employed by the Company on the payment date;
- You are in good standing with the Company on the payment date;
- With due diligence and good faith, you fulfill your job responsibilities and meet your performance objectives both related to your present position and/or related to any position at the Company held by you in the future; and
- You do not resign your employment for any reason before the payment date.

Please note that this letter is not intended to guarantee employment for any specific duration and your employment with the Company remains “at will.”

**Exhibit 31.1**

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

Date: November 8, 2021

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

**Exhibit 31.2**

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

Date: November 8, 2021

/s/ Geoffrey M. Parker
Geoffrey M. Parker

Chief Operating Officer, Chief Financial Officer and Executive Vice President
*(Principal Financial Officer)*

**Exhibit 32.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**
**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 September 30, 2021, as filed with the Securities and Exchange Commission (the "Report"), Gerrit Klaerner, Ph.D., Chief Executive Officer and 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: November 8, 2021

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

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**
**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 September 30, 2021, as filed with the Securities and Exchange Commission (the "Report"), Geoffrey M. Parker, Chief Operating Officer, Chief Financial Officer and Executive 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: November 8, 2021

/s/ Geoffrey M. Parker
Geoffrey M. Parker

Chief Operating Officer, Chief Financial Officer and Executive Vice President
*(Principal Financial Officer)*