UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2022

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** (State or other jurisdiction of incorporation or organization)	**46-3372526** (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 August 4, 2022, the registrant had 55,668,880 shares of common stock, par value $0.001 per share, outstanding.

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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;
- the design of our renal outcomes clinical trial, VALOR-CKD (also known as TRCA-303);
- our expectations regarding endpoint accrual, the geographic distribution of endpoint events, outcome and reporting of results of our VALOR-CKD trial;
- the outcome and results of our 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 conduct additional financings;

- our ability to establish collaborations in lieu of obtaining additional financing;
- the potential impact of epidemics and pandemics, including COVID-19, local or regional military actions, including the Russian invasion of Ukraine, or natural disasters, on the health care system, financial markets and economy generally and on our business, including on our VALOR-CKD trial, 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, or referenced in, 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)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 22,152	$ 21,113
Short-term investments	76,543	119,419
Prepaid expenses and other current assets	3,685	5,004
Total current assets	102,380	145,536
Long-term investments	—	10,043
Property and equipment, net	611	769
Operating lease right-of-use assets	11,297	12,158
Total assets	$ 114,288	$ 168,506
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,740	$ 10,023
Current operating lease liabilities	2,777	2,736
Accrued expenses and other current liabilities	13,530	16,721
Total current liabilities	20,047	29,480
Convertible Senior Notes, net	195,119	127,512
Non-current operating lease liabilities	10,346	11,296
Total liabilities	225,512	168,288
Commitments and contingencies (Note 5)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 40,000,000 shares authorized, no shares issued or outstanding as of June 30, 2022 and December 31, 2021.	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized as of June 30, 2022 and December 31, 2021; 55,661,343 and 55,363,461 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively.	56	55
Additional paid-in capital	745,394	810,618
Accumulated other comprehensive income (loss)	(475)	(91)
Accumulated deficit	(856,199)	(810,364)
Total stockholders' equity (deficit)	(111,224)	218
Total liabilities and stockholders' equity (deficit)	$ 114,288	$ 168,506

See accompanying notes to condensed financial statements (unaudited).

TRICIDA, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 16,859	$ 19,781	$ 35,363	$ 51,956
General and administrative	9,824	9,550	18,994	19,445
Total operating expenses	26,683	29,331	54,357	71,401
Loss from operations	(26,683)	(29,331)	(54,357)	(71,401)
Other income (expense), net	123	(296)	131	149
Interest expense	(1,976)	(3,926)	(3,949)	(9,539)
Loss on early extinguishment of Term Loan	—	—	—	(6,124)
Net loss	(28,536)	(33,553)	(58,175)	(86,915)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale investments, net of tax	(98)	(21)	(384)	(126)
Total comprehensive loss	$ (28,634)	$ (33,574)	$ (58,559)	$ (87,041)
Net loss per share, basic and diluted	$ (0.49)	$ (0.67)	$ (1.01)	$ (1.73)
Weighted-average number of shares outstanding, basic and diluted	57,825,636	50,294,787	57,772,602	50,271,373

See accompanying notes to condensed financial statements (unaudited).

TRICIDA, INC.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2021	55,363,461	$ 55	$ 810,618	$ (91)	$ (810,364)	$ 218
Cumulative effect of ASU 2020-06 adoption	—	—	(79,498)	—	12,340	(67,158)
Issuance of common stock under equity incentive plans	33,697	—	41	—	—	41
Stock-based compensation	—	—	6,524	—	—	6,524
Net unrealized gain (loss) on available-for-sale investments, net of tax	—	—	—	(286)	—	(286)
Net loss	—	—	—	—	(29,639)	(29,639)
Balance at March 31, 2022	55,397,158	55	737,685	(377)	(827,663)	(90,300)
Issuance of common stock under equity incentive plans	264,185	1	638	—	—	639
Stock-based compensation	—	—	7,071	—	—	7,071
Net unrealized gain (loss) on available-for-sale investments, net of tax	—	—	—	(98)	—	(98)
Net loss	—	—	—	—	(28,536)	(28,536)
Balance at June 30, 2022	55,661,343	$ 56	$ 745,394	$ (475)	$ (856,199)	$ (111,224)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	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

See accompanying notes to condensed financial statements (unaudited).

TRICIDA, INC.

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

	Six Months Ended June 30,	
	2022	**2021**
Operating activities:		
Net loss	$ (58,175)	$ (86,915)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	158	253
Non-cash operating lease costs	(49)	496
Amortization of premiums and accretion of discounts on investments, net	(37)	335
Accretion of Term Loan and Convertible Senior Notes	449	4,804
Loss on early extinguishment of Term Loan	—	6,124
Stock-based compensation	13,595	12,651
Changes in compound derivative liability	—	(202)
Other non-cash items	—	(29)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,320	(752)
Accounts payable	(6,284)	(769)
Accrued expenses and other liabilities	(2,961)	(9,103)
Net cash used in operating activities	(51,984)	(73,107)
Investing activities:		
Purchases of investments	(48,926)	(96,883)
Proceeds from maturities of investments	101,500	137,949
Purchases of property and equipment	—	(76)
Net cash provided by investing activities	52,574	40,990
Financing activities:		
Proceeds from equity offerings, net	(33)	—
Proceeds from issuance of common stock under equity incentive plans	680	448
Payments for taxes related to net share settlement of equity awards	(198)	—
Repayment of leasehold improvement loan	—	(38)
Cash paid for early extinguishment of Term Loan	—	(83,285)
Net cash provided by (used in) financing activities	449	(82,875)
Net increase (decrease) in cash and cash equivalents	1,039	(114,992)
Cash and cash equivalents at beginning of period	21,113	137,857
Cash and cash equivalents at end of period	$ 22,152	$ 22,865
Supplemental disclosures		
Cash paid for interest	$ 3,500	$ 5,274

See accompanying notes to condensed financial statements (unaudited).

TRICIDA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1. ORGANIZATION AND BASIS OF PRESENTATION

Organization—Tricida, Inc., 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 slow chronic kidney disease, or CKD, progression through the treatment of metabolic acidosis in patients with metabolic acidosis and CKD.

Funding Requirements—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 June 30, 2022, the Company has relied primarily on the proceeds from equity offerings and debt financing to finance its operations.

The Company has incurred losses and negative cash flows from operations since its inception in 2013 and management anticipates that the Company will continue to incur net losses for the foreseeable future. As of June 30, 2022, the Company had an accumulated deficit of $856.2 million. Existing cash, cash equivalents and investments are not likely to be sufficient to fund the Company's operations through the second quarter of 2023 as management expects to incur additional losses in the future to conduct research and development and pre-commercialization activities. Management recognizes that the Company will need to raise additional capital to fully implement its business plan. The Company plans to evaluate obtaining additional capital prior to the end of 2022. In addition, the Company has Common Warrants outstanding that are eligible for exercise at the discretion of the holders. See a full description of the Common Warrants in Note 6. "Stockholders' Equity".

If 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. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the date of the issuance of these condensed financial statements.

The accompanying unaudited condensed financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The unaudited condensed financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

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 six months ended June 30, 2022 and 2021 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, 2021, has been derived from audited financial statements. Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year.

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. 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, 2021.

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, 2021, other than the adoption of 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, as described below.

Recent Accounting Pronouncements

Adopted Standards

In August 2020, the FASB issued 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. 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 Company adopted ASU 2020-06 effective January 1, 2022, using the modified retrospective method. On adoption, the Company accounted for the Convertible Senior Notes as a single liability measured at amortized cost resulting in reduced prospective non-cash interest expense due to the de-recognition of the remaining debt discount associated with the equity component. The cumulative impact of the adoption of ASU 2020-06 reflected on the Company's condensed balance sheet as of January 1, 2022, is as follows.

in thousands	Balance at December 31, 2021	Cumulative Impact of ASU 2020-06 Adoption	Balance at January 1, 2022
Liabilities			
Convertible Senior Notes, net	$ 127,512	$ 67,158	$ 194,670
Stockholder's Equity			
Additional paid-in capital	810,618	(79,498)	731,120
Accumulated deficit	(810,364)	12,340	(798,024)

Under the modified retrospective method, financial information and disclosures for periods before January 1, 2022, will continue to be presented in accordance with ASC 470-20. The adoption did not impact previously reported amounts in our condensed statements of operations and comprehensive loss and cash flows and our basic and diluted net loss per share amounts.

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 June 30, 2022 and December 31, 2021.

	June 30, 2022						
					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	$ 1,394	$ —	$ —	$ 1,394	$ 1,394	$ —	$ —
Level 1:							
Money market funds	14,262	—	—	14,262	14,262	—	—
U.S. Treasury securities	31,041	—	(164)	30,877	—	30,877	—
Subtotal	45,303	—	(164)	45,139	14,262	30,877	—
Level 2:							
U.S. government agency securities	5,000	—	(52)	4,948	—	4,948	—
Commercial paper	45,367	1	(142)	45,226	6,496	38,730	—
Corporate debt securities	2,015	—	(27)	1,988	—	1,988	—
Subtotal	52,382	1	(221)	52,162	6,496	45,666	—
Total assets measured at fair value	$ 99,079	$ 1	$ (385)	$ 98,695	$ 22,152	$ 76,543	$ —

	December 31, 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	$ 2,965	$ —	$ —	$ 2,965	$ 2,965	$ —	$ —
Level 1:							
Money market funds	18,148	—	—	18,148	18,148	—	—
U.S. Treasury securities	8,028	—	(11)	8,017	—	—	8,017
Subtotal	26,176	—	(11)	26,165	18,148	—	8,017
Level 2:							
U.S. government agency securities	10,000	—	—	10,000	—	10,000	—
Commercial paper	107,397	20	(4)	107,413	—	107,413	—
Corporate debt securities	4,036	—	(4)	4,032	—	2,006	2,026
Subtotal	121,433	20	(8)	121,445	—	119,419	2,026
Total assets measured at fair value	$ 150,574	$ 20	$ (19)	$ 150,575	$ 21,113	$ 119,419	$ 10,043

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., measured at fair value on a recurring basis using Level 3 unobservable inputs for the six months ended June 30, 2021. 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.

(in thousands)	Six Months Ended June 30, 2021
Fair value at beginning of period	$ 202
Extinguishment of compound derivative liability upon extinguishment of Term Loan	(202)
Fair value at end of period	$ —

The estimated fair value of the Convertible Senior Notes was $100.4 million as of June 30, 2022 measured using Level 3 inputs. The key valuation assumptions used consist of the discount rate of 26.0% and volatility of 102.0%.

NOTE 4. BORROWINGS

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 June 30, 2022, 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 did 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 allocation of proceeds into the equity component resulted in a debt discount for the Convertible Senior Notes that was amortized to interest expense at an effective interest rate of 13.5% through December 31, 2021, over the effective life of the Convertible Senior Notes of 7.0 years, using the effective interest method.

As discussed in Note 2. "Summary of Significant Accounting Policies", effective January 1, 2022, the Company adopted ASU 2020-06 using the modified retrospective method and, as a result, accounted for the Convertible Senior Notes as a single liability measured at amortized cost. The following table presents the Convertible Senior Notes' outstanding balances as of June 30, 2022 and December 31, 2021.

(in thousands)	June 30, 2022	December 31, 2021
Liability component:		
Principal	$ 200,000	$ 200,000
Unamortized discount - equity component	—	(68,926)
Unamortized underwriter discounts and issuance costs	(4,881)	(3,562)
Net carrying amount	$ 195,119	$ 127,512
Equity component, net of underwriter discounts and issuance costs	$ —	$ 79,498

The remaining unamortized debt discount is being amortized to interest expense at an effective interest rate of 4.1% over 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 six months ended June 30, 2022 and 2021.

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2022	2021	2022	2021
Contractual interest expense	$ 1,750	$ 1,750	$ 3,500	$ 3,500
Amortization of debt discount	—	2,112	—	4,159
Amortization of underwriter discounts and issuance costs	226	64	449	123
Total interest expense	$ 1,976	$ 3,926	$ 3,949	$ 7,782

NOTE 5. COMMITMENTS AND CONTINGENCIES

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, Amendment No. 2 dated August 26, 2021 and Amendment No. 3 dated July 1, 2022, or Amendment No. 3, 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 U.S. Food and Drug Administration, or FDA, approval of veverimer.

The Company has contractual obligations from its manufacturing service contracts as of June 30, 2022. The purchase obligations are comprised of 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. In addition, purchase commitments under the Supply Agreement are denominated in Euro and therefore subject to changes in foreign exchange rates. The amounts disclosed below are applicable under the terms of Amendment No. 3 effective as of July 1, 2022.

(in thousands)	Total	2022	2023 - 2024	2025 - 2026	Thereafter
Manufacturing and service contracts	$ 512,489	$ 11,524	$ 113,881	$ 103,222	$ 283,862

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 New Drug Application, or 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. On July 29, 2022, the court issued an order granting in part and denying in part the defendants' motion to dismiss. The court granted the defendants' motion with respect to all but one of the alleged misrepresentations on the grounds that the lead plaintiff had failed to meet the required pleading standards for a securities fraud claim, but ruled that those requirements had been satisfied with respect to one alleged misrepresentation from May 7, 2020. The court granted the lead plaintiff leave to file an amended complaint within 21 days of the court's order. 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 June 30, 2022, 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. STOCKHOLDERS' EQUITY

On November 15, 2021, the Company entered into a securities purchase agreement with several investors and an officer of the Company, or Registered Direct Equity Financing, pursuant to which the Company agreed to issue and sell to the investors, in a private placement, an aggregate of (i) 4,666,667 shares of the Company's common

stock, together with warrants, or the Common Warrants, to purchase up to 4,666,667 shares of common stock, with each Common Warrant exercisable for one share of common stock at a price of $11.00, and (ii) 2,333,333 pre-funded warrants, or Pre-Funded Warrants, together with the Common Warrants to purchase up to 2,333,333 shares of common stock at a nominal exercise price of $0.001. Each share of common stock and accompanying Common Warrant and each Pre-Funded Warrant and accompanying Common Warrant were sold together at a combined offering price of $6.00.

The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The Pre-Funded Warrants have an expiration date of the earliest of (i) November 15, 2026, (ii) the date the Pre-Funded Warrants are exercised in full and (iii) immediately prior to the consummation of a fundamental transaction. The Common Warrants are exercisable until the earliest of: (a) November 15, 2024, (b) immediately prior to the closing of certain fundamental transactions or (c) five business days after written notice following the earliest of: (i) submission of the Company's NDA for veverimer with the FDA, or (ii) the date that both of the following have occurred: (x) six weeks following the issuance of a press release reporting the results of the primary analysis of the VALOR-CKD trial and (y) one of the following: (aa) the completion of a common stock financing resulting in not less than $75.0 million in gross proceeds at an offering price of not less than $13.50 per share, or (bb) the volume weighted average share price of the Company's common stock is greater than $15.00 per share with certain multiple-day trading volume requirements.

Net proceeds from the Registered Direct Equity Financing were approximately $41.5 million, after deducting offering costs of $0.5 million. An officer of the Company participated in the Registered Direct Equity Financing and purchased 166,667 shares of common stock and 166,667 Common Warrants at the same terms as the other investors.

Common stock reserved for future issuance as of June 30, 2022 and December 31, 2021, consisted of the following.

	June 30, 2022	December 31, 2021
Stock options and restricted stock units issued and outstanding	13,964,799	10,889,603
Stock options, restricted stock units and employee stock purchase plan shares authorized for future issuance	7,704,031	8,308,937
Pre-Funded Warrants authorized for future issuance	2,333,333	2,333,333
Common Warrants authorized for future issuance	7,000,000	7,000,000
Total	31,002,163	28,531,873

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 six months ended June 30, 2022 and 2021.

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except share and per share amounts)	**2022**	**2021**	**2022**	**2021**
Numerator:				
Net loss	$ (28,536)	$ (33,553)	$ (58,175)	$ (86,915)
Denominator:				
Weighted-average common shares outstanding	55,492,303	50,294,787	55,439,269	50,271,373
Weighted-average Pre-Funded Warrants outstanding	2,333,333	—	2,333,333	—
Weighted-average number of shares used in basic and diluted net loss per share	57,825,636	50,294,787	57,772,602	50,271,373
Net loss per share, basic and diluted	$ (0.49)	$ (0.67)	$ (1.01)	$ (1.73)

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.

	June 30,	
	2022	2021
Warrants to purchase common stock (excluding Pre-Funded Warrants, which are included in weighted-average common shares outstanding)	7,031,352	31,352
Assumed conversion of Convertible Senior Notes	6,019,560	6,019,560
Stock options and restricted stock units issued and outstanding	13,964,799	12,075,502
Total potential common shares excluded from the computation of diluted net loss per share	27,015,711	18,126,414

NOTE 8. SUBSEQUENT EVENTS

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 New Drug Application, or 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. On July 29, 2022, the court issued an order granting in part and denying in part the defendants' motion to dismiss. The court granted the defendants' motion with respect to all but one of the alleged misrepresentations on the grounds that the lead plaintiff had failed to meet the required pleading standards for a securities fraud claim, but ruled that those requirements had been satisfied with respect to one alleged misrepresentation from May 7, 2020. The court granted the lead plaintiff leave to file an amended complaint within 21 days of the court's order.

For a summary of the commitments under the Securities Class Action, refer to Note 5. "Commitments and Contingencies."

On July 30, 2022, the Company and Patheon entered into Amendment No. 3, effective as of July 1, 2022, which amends certain terms of the Manufacturing and Commercial Supply Agreement, effective October 4, 2019, as amended by Amendment No. 1 dated March 30, 2021 and Amendment No. 2 dated August 26, 2021, between Tricida and Patheon.

Pursuant to Amendment No. 3, the parties have agreed, among other things, to (i) manufacture veverimer for commercial use using a payment structure that, in addition to payment for delivery of commercial product on a per kilogram basis as established by the Agreement, provides an additional incremental payment to Patheon to cover certain manufacturing costs, (ii) maintain the existing cap on maximum compensation to Patheon for commercial manufacturing during the upcoming campaign, (iii) work on development of a second generation manufacturing process, and (iv) defer payment of certain costs to the fourth quarter of 2023.

For a summary of the commitments under the Manufacturing and Commercial Supply Agreement as amended by Amendment No. 3, refer to Note 5. "Commitments and Contingencies." The Company is currently evaluating the accounting impact associated with Amendment No. 3.

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" in this Quarterly Report on Form 10-Q and Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K 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, through the treatment of metabolic acidosis 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.

In the second quarter of 2022, we stopped our renal outcomes clinical trial, VALOR-CKD (also known as TRCA-303), early for administrative reasons, as permitted by the current protocol. Accrual of primary endpoint events will continue into the third quarter of 2022 and the reporting of top-line results from the VALOR-CKD trial is anticipated to occur in October 2022. The VALOR-CKD trial was designed to determine if veverimer slows CKD progression in patients with metabolic acidosis and CKD. Our VALOR-CKD trial is a randomized, double-blind, placebo-controlled, time-to-event trial. The primary endpoint of the VALOR-CKD trial is the time to first occurrence of any event in the composite of renal death, end-stage renal disease, or ESRD, or a confirmed ≥ 40% reduction in estimated glomerular filtration rate, or eGFR, which is also known as DD40. The VALOR-CKD trial is a multi-national trial conducted at over 200 sites worldwide. Enrollment of patients in the VALOR-CKD trial was completed at the end of 2021 with 1,480 subjects randomized. As of August 8, 2022, the average duration of treatment in the VALOR-CKD trial was approximately 26.5 months and the trial had accrued 281 subjects with positively adjudicated primary endpoint events.

There are currently no therapies approved by the U.S. Food and Drug Administration, or FDA, to slow progression of kidney disease through the treatment of chronic metabolic acidosis in patients with metabolic acidosis and CKD. We estimate that metabolic acidosis affects approximately 4.3 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 eubicarbonatemic acidosis, or latent acidosis, who may also benefit from a therapy that aids in acid removal.

Veverimer is a non-absorbed, 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.

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 2037 in Japan, at least 2035 in Australia, China, Europe, Hong Kong, Israel, Mexico and Russia, and at least 2034 in South Korea and certain other markets.

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, other than in Ukraine.

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 June 30, 2022, we have primarily funded our operations through the sale of $152.4 million of convertible preferred stock, gross proceeds of $255.6 million ($237.7 million, net) from our initial public offering, or IPO, on July 2, 2018, gross proceeds of $231.8 million ($217.9 million, net) from our underwritten public offering on April 8, 2019, issuance of $200.0 million aggregate principal amount of 3.50% convertible senior notes due 2027, or the Convertible Senior Notes, ($193.3 million, net) on May 22, 2020, gross proceeds of $42.0 million ($41.5 million, net) from our Registered Direct Equity Financing on November 15, 2021 and gross borrowings of $75.0 million ($72.1 million, net) 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 $28.5 million and $33.6 million for the three months ended June 30, 2022 and 2021, respectively, and $58.2 million and $86.9 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $856.2 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.

Our business operations and those of our business partners, vendors, government regulators and other third parties may be affected by global or regional events, such as the on-going COVID-19 outbreak and the Russian invasion of Ukraine. At this time, COVID-19 has not materially impacted our current financial resources or our outlook. Our VALOR-CKD trial has sixteen sites located in Ukraine, which include approximately 15% of the patients randomized in the trial. Actions taken by the Russian Federation, beginning in February 2022, in Ukraine have disrupted normal VALOR-CKD clinical trial procedures in that area, including compliance with the trial protocol due to the inability of some study sites to conduct normal business, the prioritization of local hospital resources away from clinical trials, the relocation or evacuation of site staff, study monitors and subjects, and government-imposed curfews, warfare and violence. These disruptions could have a material adverse effect on the results of the VALOR-CKD trial.

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 termination of our VALOR-CKD trial;
- continue to optimize the manufacturing processes and manufacture drug substance and drug product to support future clinical and nonclinical trials and 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 New Drug Application, or 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 and, if approved, commercialize veverimer. We believe that our existing cash, cash equivalents and investments are not likely to be sufficient to fund our operations through the second quarter of 2023.

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 clinical research organizations, or 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 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 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.

Results of Operations

The following table presents our results of operations for the three and six months ended June 30, 2022 and 2021.

(in thousands)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Change $	Change %	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021	Change $	Change %
Operating expenses:								
Research and development	$ 16,859	$ 19,781	$ (2,922)	(15) %	$ 35,363	$ 51,956	$ (16,593)	(32) %
General and administrative	9,824	9,550	274	3 %	18,994	19,445	(451)	(2) %
Total operating expenses	26,683	29,331	(2,648)	(9) %	54,357	71,401	(17,044)	(24) %
Loss from operations	(26,683)	(29,331)	2,648	(9) %	(54,357)	(71,401)	17,044	(24) %
Other income (expense), net	123	(296)	419	*N/M*	131	149	(18)	(12) %
Interest expense	(1,976)	(3,926)	1,950	(50) %	(3,949)	(9,539)	5,590	(59) %
Loss on early extinguishment of Term Loan	—	—	—	*N/M*	—	(6,124)	6,124	(100) %
Net loss	$ (28,536)	$ (33,553)	$ 5,017	(15) %	$ (58,175)	$ (86,915)	$ 28,740	(33) %

N/M = Not meaningful

Research and Development Expense

The following table presents our research and development expense for the three months ended June 30, 2022 and 2021.

(in thousands)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Change $	Change %
Clinical development costs	$ 9,935	$ 13,120	$ (3,185)	(24) %
Personnel and related costs	2,996	3,107	(111)	(4) %
Stock-based compensation expense	3,008	2,723	285	10 %
Other research and development costs	920	831	89	11 %
Total research and development expense	$ 16,859	$ 19,781	$ (2,922)	(15) %

Research and development expense was $16.9 million and $19.8 million for the three months ended June 30, 2022 and 2021, respectively. The decrease of $2.9 million was primarily due to decreased activities in connection with our veverimer clinical development program, resulting in a decrease of clinical development costs of $3.2 million related to drug substance manufacturing costs and clinical trial costs related to our VALOR-CKD trial following the administrative stop announced in May 2022 and decreased personnel and related costs of $0.1 million, partially offset by an increase in stock-based compensation expense of $0.3 million primarily related to annual awards granted in February 2022.

The following table presents our research and development expense for the six months ended June 30, 2022 and 2021.

(in thousands)	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021	Change $	Change %
Clinical development costs	$ 21,915	$ 38,795	$ (16,880)	(44) %
Personnel and related costs	5,826	6,280	(454)	(7) %
Stock-based compensation expense	5,793	5,129	664	13 %
Other research and development costs	1,829	1,752	77	4 %
Total research and development expense	$ 35,363	$ 51,956	$ (16,593)	(32) %

Research and development expense was $35.4 million and $52.0 million for the six months ended June 30, 2022 and 2021, respectively. The decrease of $16.6 million was primarily due to decreased activities in connection with our veverimer clinical development program, resulting in a decrease of clinical development costs of $16.9 million related to drug substance manufacturing costs and other clinical trial costs related to our VALOR-CKD trial following the administrative stop announced in May 2022 and a decrease in personnel and related costs of $0.5 million primarily related to higher bonus expense in 2021; partially offset by an increase in stock-based compensation expense of $0.7 million reflecting annual awards granted in February 2022 and performance awards granted in September 2020, partially offset by awards fully vested in 2021.

General and Administrative Expense

The following table presents our general and administrative expense for the three months ended June 30, 2022 and 2021.

	Three Months Ended June 30,		Change	
(in thousands)	**2022**	**2021**	**$**	**%**
Personnel and related costs	$ 2,341	$ 2,282	$ 59	3 %
Stock-based compensation expense	4,063	3,886	177	5 %
Other general and administrative costs	3,420	3,382	38	1 %
Total general and administrative expense	$ 9,824	$ 9,550	$ 274	3 %

General and administrative expense was $9.8 million and $9.6 million for the three months ended June 30, 2022 and 2021, respectively. The increase of $0.3 million was primarily due to an increase in stock-based compensation expense of $0.2 million primarily related to annual awards granted in February 2022.

The following table presents our general and administrative expense for the six months ended June 30, 2022 and 2021.

	Six Months Ended June 30,		Change	
(in thousands)	**2022**	**2021**	**$**	**%**
Personnel and related costs	$ 4,677	$ 4,842	$ (165)	(3)%
Stock-based compensation expense	7,802	7,522	280	4 %
Other general and administrative costs	6,515	7,081	(566)	(8)%
Total general and administrative expense	$ 18,994	$ 19,445	$ (451)	(2)%

General and administrative expense was $19.0 million and $19.4 million for the six months ended June 30, 2022 and 2021, respectively. The decrease of $0.5 million was due to a decrease in personnel and related costs of $0.2 million reflecting lower headcount; an increase in stock-compensation expense of $0.3 million primarily related to annual awards granted in February 2022; and a decrease in other general and administrative costs of $0.6 million, primarily related to a reduction in legal and finance costs.

Non-Operating Income (Expense)

The following table presents our non-operating income (expense) for the three months ended June 30, 2022 and 2021.

	Three Months Ended June 30,		Change	
(in thousands)	**2022**	**2021**	**$**	**%**
Other income (expense), net	$ 123	$ (296)	$ 419	*N/M*
Interest expense	(1,976)	(3,926)	1,950	(50)%

N/M = Not meaningful

Other income (expense), net increased by $0.4 million for the three months ended June 30, 2022, due foreign exchange losses on payments made in 2021 and higher interest income from investments. Interest expense decreased $2.0 million for the three months ended June 30, 2022, due the effect of the adoption 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, on January 1, 2022, which resulted in reduced non-cash interest expense previously associated with the equity component of the Convertible Senior Notes.

The following table presents our non-operating income (expense) for the six months ended June 30, 2022 and 2021.

	Six Months Ended June 30,		Change	
(in thousands)	**2022**	**2021**	**$**	**%**
Other income (expense), net	$ 131	$ 149	$ (18)	(12)%
Interest expense	(3,949)	(9,539)	5,590	(59)%
Loss on early extinguishment of Term Loan	—	(6,124)	6,124	(100)%

Other income (expense), net decreased by $18 thousand for the six months ended June 30, 2022, due to a decrease in interest income from investments and changes in compound derivative liability, partially offset by foreign exchange losses on payments made in 2021. Interest expense decreased $5.6 million for the six months ended June 30, 2022, due the effect of the adoption ASU No. 2020-06 on January 1, 2022, which resulted in reduced non-cash interest expense previously associated with the equity component of the Convertible Senior Notes and the repayment of the Term Loan in March 2021. The loss on early extinguishment of Term Loan of $6.1 million was recognized in March 2021 on repayment of the Term Loan.

Liquidity and Capital Resources

Sources of Liquidity

From our inception in 2013 through June 30, 2022, we have primarily funded our operations through the sale of $152.4 million of convertible preferred stock, gross proceeds of $255.6 million ($237.7 million, net) from our IPO on July 2, 2018, gross proceeds of $231.8 million ($217.9 million, net) from our underwritten public offering on April 8, 2019, issuance of $200.0 million Convertible Senior Notes ($193.3 million, net) on May 22, 2020, gross proceeds of $42.0 million ($41.5 million, net) from our Registered Direct Equity Financing on November 15, 2021 and gross borrowings of $75.0 million ($72.1 million, net) under the Term Loan with Hercules on February 28, 2018. As of June 30, 2022, we had cash, cash equivalents and investments of $98.7 million.

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. Net proceeds from the offering were $193.3 million after deducting underwriting discounts, 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 provide 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 June 30, 2022, the "if-converted value" did not exceed the remaining principal amount of the Convertible Senior Notes.

Registered Direct Equity Financing

On November 15, 2021, we consummated a registered direct equity financing pursuant to which we sold an aggregate of 4,666,667 shares of our common stock, pre-funded warrants to purchase up to 2,333,333 shares of our common stock and common warrants to purchase up to 7,000,000 shares of our common stock. Each share of common stock and accompanying common warrant and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $6.00. The pre-funded warrants are immediately exercisable at a nominal exercise price of $0.001. The common warrants are exercisable at an exercise price of $11.00 on or after May 15, 2022. Net proceeds were approximately $41.5 million, after deducting offering costs of $0.5 million.

The pre-funded warrants have an expiration date of the earliest of (i) November 15, 2026, (ii) the date the pre-funded warrants are exercised in full and (iii) immediately prior to the consummation of a fundamental transaction. The common warrants are exercisable until the earliest of: (a) November 15, 2024, (b) immediately prior to the closing of certain fundamental transactions or (c) five business days after written notice following the earliest of: (i) submission of the NDA for veverimer with the FDA, or (ii) the date that both of the following have occurred: (x) six weeks following the issuance of a press release reporting the results of the primary analysis of the VALOR-CKD trial and (y) one of the following: (aa) the completion of a common stock financing resulting in not less than $75.0 million in gross proceeds at an offering price of not less than $13.50 per share, or (bb) the volume weighted average share price of our common stock is greater than $15.00 per share with certain multiple-day trading volume requirements.

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 June 30, 2022, we had an accumulated deficit of $856.2 million. Existing cash, cash equivalents and investments are not likely to be sufficient to fund our operations through the second quarter of 2023 as we expect to incur additional losses in the future to conduct research and development and pre-commercialization activities. We recognize that we will need to raise additional capital to fully implement our business plan. We plan to evaluate obtaining additional capital prior to the end of 2022. In addition, we have common warrants outstanding that are eligible for exercise at the discretion of the holders.

Such future capital requirements are difficult to forecast and will depend on many factors, including:

- the progress, outcome and results of our VALOR-CKD trial;
- the impact of termination of our VALOR-CKD trial;
- the costs and timing of resubmission of our NDA and, as necessary, our success in addressing 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 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 we entered into with Patheon on October 4, 2019, as has been and 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.

Cash Flows

The following table presents a summary of the net cash flow activity for the six months ended June 30, 2022 and 2021.

	Six Months Ended June 30,	
(in thousands)	**2022**	**2021**
Net cash provided by (used in):		
Operating activities	$ (51,984)	$ (73,107)
Investing activities	52,574	40,990
Financing activities	449	(82,875)
Net increase (decrease) in cash and cash equivalents	$ 1,039	$ (114,992)

Cash Used in Operating Activities

During the six months ended June 30, 2022, cash used in operating activities was $52.0 million, which consisted of a net loss of $58.2 million, adjusted by non-cash charges of $14.1 million and changes in cash used in operating assets and liabilities of $7.9 million. Non-cash charges consisted primarily of stock-based compensation of $13.6 million, accretion of Convertible Senior Notes of $0.4 million and depreciation and amortization of $0.2 million. Changes in cash used in our operating assets and liabilities were primarily due to a decrease in accounts payable of $6.3 million and a decrease in accrued expenses and other current liabilities of $3.0 million, partially offset by a decrease in prepaid expenses and other assets of $1.3 million.

During the six months ended June 30, 2021, cash used in operating activities was $73.1 million, which consisted of a net loss of $86.9 million, adjusted by non-cash charges of $24.4 million and changes in cash used in our operating assets and liabilities of $10.6 million. The non-cash charges consisted primarily of stock-based compensation of $12.7 million, loss on early extinguishment of Term Loan of $6.1 million, accretion of Term Loan and Convertible Senior Notes of $4.8 million, non-cash operating lease costs of $0.5 million, net amortization of premiums and discounts on investments of $0.3 million and depreciation and amortization of $0.3 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 current liabilities of $9.1 million, a decrease in accounts payable of $0.8 million and an increase in prepaid expenses and other assets of $0.8 million.

Cash Provided by Investing Activities

Net cash provided by investing activities was $52.6 million and $41.0 million for the six months ended June 30, 2022 and 2021, respectively. Net cash provided by investing activities during the six months ended June 30, 2022 was due to proceeds from maturities of investments of $101.5 million, partially offset by purchases of investments of $48.9 million. Net cash provided by investing activities during the six months ended June 30, 2021 was due to proceeds from maturities of investments of $137.9 million, partially offset by purchases of investments of $96.9 million and purchases of property and equipment of $0.1 million.

Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $0.4 million for the six months ended June 30, 2022 and cash used in financing activities was $82.9 million for the six months ended June 30, 2021. Net cash provided by financing activities during the six months ended June 30, 2022 was primarily due to proceeds from issuance of common stock under equity incentive plans of $0.7 million, partially offset by payments for taxes related to net share settlement of equity awards of $0.2 million. Net cash used in financing activities during the six months ended June 30, 2021 was primarily due to cash paid for early extinguishment of Term Loan of $83.3 million, partially offset by proceeds from the issuance of common stock under equity incentive plans of $0.4 million.

Contractual Obligations and Commitments

We have contractual obligations relating to our manufacturing and service contracts, Convertible Senior Notes, lease obligations and other research and development activities. We also enter into other contracts in the normal course of business with CROs, contract development and manufacturing organizations and other service providers and vendors. These contracts generally provide for termination on short notice and are cancelable contracts.

Our existing cash, cash equivalents and investments as of June 30, 2022 are not likely to be sufficient to meet our contractual obligations through the second quarter of 2023, as we expect to incur additional losses in the future to conduct research and development and pre-commercialization activities and recognize that we will need to raise additional capital to fully implement our business plan.

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 as of 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, 2021.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our market risk during the six months ended June 30, 2022, compared to the year ended December 31, 2021. 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, 2021.

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 June 30, 2022. 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 June 30, 2022.

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 June 30, 2022 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 ones in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021, as well as other information contained elsewhere in this Quarterly Report on Form 10-Q, including Part I, Item 1 “Financial Statements” and Part I, Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as our other filings with the Securities and Exchange Commission, or SEC, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described in our filings with the SEC 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.

We will require substantial additional financing to achieve our goals, including the possible resubmission of the New Drug Application, or NDA, for veverimer and commercialization of veverimer, if approved. 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 June 30, 2022, we had working capital of $82.3 million and cash, cash equivalents and investments of $98.7 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 termination of the VALOR-CKD trial, obtaining data from that trial and resubmission of the NDA for veverimer. 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 $98.7 million as of June 30, 2022, will allow us to continue funding our operations through the first quarter of 2023. However, our existing cash, cash equivalents and investments are not likely to be sufficient to fund our operations through the second quarter of 2023. 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 and our ability to raise additional capital will depend on many factors, including, but not limited to:

- the ability of the VALOR-CKD trial to achieve its primary endpoint and for data from that trial to be sufficient to support NDA resubmission and/or approval;
- 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 traditional approval process or the Accelerated Approval Program;
- the costs associated with the delays in regulatory approval and resubmission of our NDA, and any increased costs associated with raising capital in light of such delays;
- the progress, timing, scope and costs of conducting our nonclinical and clinical studies and trials, including termination of our 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 U.S. Food and Drug Administration, or 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 epidemics and pandemics, including COVID-19, local or regional military actions, including the Russian invasion of Ukraine, or natural disasters on the health care system, financial markets and economy generally and on our business in particular, including the potential impact on the 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 and debt securities and other debt financing, we cannot assure you that we will be able to do so in the future. If 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. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the date of this report.

Stopping the VALOR-CKD trial early increases the risk that the trial will not achieve its primary endpoint. 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 stopped our VALOR-CKD trial early for administrative reasons pursuant to the current protocol in the second quarter of 2022. The VALOR-CKD trial was designed originally to randomize approximately 1,600 subjects and to terminate once the trial reached 511 subjects with positively adjudicated primary endpoint events, which was estimated to be in 2024. In the fourth quarter of 2021, we requested and were granted a Type A meeting with the FDA to discuss approaches to stopping the VALOR-CKD trial early based on lack of financial resources to complete the study as originally planned. Consistent with feedback provided by the FDA in its preliminary comments for the Type A meeting, we decided that, among the alternatives considered, stopping the VALOR-CKD trial early for administrative reasons in 2022 pursuant to the existing protocol was likely to provide the most complete and interpretable data within our financial runway, reduce the risk of missing data required for key efficacy analyses, and maintain the integrity of the trial.

As of August 8, 2022, the VALOR-CKD trial had accrued 281 subjects with positively adjudicated primary endpoint events. For the VALOR-CKD trial to be successful, veverimer will need to demonstrate greater efficacy compared to placebo than if the trial had continued to 511 subjects with primary endpoint events. Stopping the VALOR-CKD trial early thus increases the risk that the VALOR-CKD trial may not meet its primary endpoint and/or that the data obtained from the trial may not be sufficient to support a resubmission and/or approval of the NDA.

In addition, stopping the VALOR-CKD trial early creates additional risks and could affect the results of the trial. The Complete Response Letter issued by the 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 VALOR-CKD trial in the United States, Canada and Western Europe, and subsequently also in other non-Eastern European regions (i.e., Latin America and Asia-Pacific). The proportion of patients randomized in the VALOR-CKD trial in various geographic regions are: Eastern/Central Europe, 72%; US/Canada/Western Europe, 10%; Latin America, 9%; and Asia-Pacific, 9%. The number of endpoint events from subjects in the United States or regions with "U.S.-like" subjects will 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.

Our clinical trial sites, including in Ukraine, may be impacted by local and regional economic, political and social conditions, including war, as well as government policies and actions, any of which could have a material adverse effect on our ability to operate clinical trials in such jurisdictions.

Our VALOR-CKD trial has 16 sites located in Ukraine, which include approximately 15% of the patients randomized in the trial. Actions taken by the Russian Federation, beginning in February 2022, in Ukraine have destabilized the region and have disrupted normal VALOR-CKD clinical trial procedures in that area, including compliance with the trial protocol due to the inability of some study sites to conduct normal business, the prioritization of local hospital resources away from clinical trials, the relocation or evacuation of site staff, study monitors and subjects, and government-imposed curfews, warfare and violence. These disruptions could have a material adverse effect on the results of the VALOR-CKD trial. The ability of the FDA to conduct pre-approval inspections in Ukraine or other disrupted areas could also be adversely affected. In addition, the Russian invasion of Ukraine has caused the adoption of comprehensive sanctions by, among others, the European Union, the United States, and the United Kingdom, which restrict a wide range of trade and financial dealings with Russia and Russian persons, as well as certain regions in Ukraine, including by imposing stricter export controls, prohibiting dealings with major Russian banks and credit institutions. These sanctions could also extend to Russian allies, such as Belarus, that also contain sites for VALOR-CKD. If we are unable to overcome the challenges we encounter with

respect to these risks and other factors affecting companies operating in the affected region, our business operations and future prospects could be materially adversely affected.

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
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	Filed herewith		
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed herewith		
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith		
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith		
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document	Filed herewith		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith		
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	Filed herewith		

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 8, 2022

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
Senior Vice President of Finance and Chief Accounting Officer
(Principal Accounting Officer)

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: August 8, 2022

/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: August 8, 2022

/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 Annual Report of Tricida, Inc. (the "Company"), on Form 10-K for the fiscal year ended June 30, 2022, 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: August 8, 2022

/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 Annual Report of Tricida, Inc. (the "Company"), on Form 10-K for the fiscal year ended June 30, 2022, 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: August 8, 2022

/s/ Geoffrey M. Parker
Geoffrey M. Parker

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